Women's intentions to Human Papillomavirus self-sample: development of an intervention to increase self-sampling intentions.

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Summary

Testing for Human Papillomavirus (HPV) is being incorporated into the cervical screening programme, with the probable future introduction of HPV as a primary test and a possibility of HPV self-sampling. In anticipation of this development, it is imperative to identify potential barriers to HPV self-sampling. The work presented in this thesis identified women's attitudes and intentions regarding the possible introduction of primary HPV self-sampling, and developed a preliminary intervention designed to address barriers and increase intentions to HPV self-sample. A mixed-methods approach was used to explore women's attitudes and intentions regarding HPV self-sampling through a cross-sectional questionnaire survey, in-depth qualitative interviews and intervention user testing.

A questionnaire based on the extended Health Belief Model was developed and validated using content validity assessment and cognitive interviews. A survey of 194 women recruited through Cervical Screening Wales and in community settings identified that perceiving more barriers than benefits to HPV self-sampling, reporting lower self-efficacy in relation to self-sampling, and lower HPV knowledge were associated with lower hypothetical intention to HPV self-sample. Qualitative interviews with a sub-sample of 19 survey participants revealed further barriers including lack of confidence in ability to self-sample correctly, lack of confidence in self-sampling results, concerns about sample contamination and identity theft, and low confidence in the rationale for the introduction of a new screening programme. Content designed to address these barriers was incorporated into a leaflet designed to increase intentions to HPV self-sample. The leaflet was well received in user testing.

Overall, findings suggest that if HPV self-sampling is incorporated into the cervical screening programme, personal and system barriers as well as concerns about operational factors will need to be addressed. The pilot HPV self-sampling intervention may be a mechanism for increasing intention to HPV self-sample by

improving women's HPV knowledge, confidence in their ability to self-sample properly, and confidence in operational factors. It is anticipated that this may alleviate women's concerns about a new method of cervical screening, ultimately leading to increased uptake.

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List of abbreviations used in this thesis

Content Validity Analysis	CVA
Cervical Screening Wales	CSW
Fecal occult blood test	FOBT
General Practitioner	GP
Health Belief Model	HBM
Human Papillomavirus	HPV
Papanicolaou test	Pap
Principal Components Analysis	PCA
Protection Motivation Theory	PMT
Randomised Controlled Trial	RCT
Social Cognitive Theory	SCT
Theory of Reasoned action	TRA
Theory of Planned Behaviour	TPB
Trans-theoretical model of behaviour change	TTM

Chapter 1

Introduction and thesis overview

1.1 Chapter Overview

The present chapter will provide an overview of the clinical background to cervical cancer, the current cervical screening programme in the United Kingdom, incorporation of Human Papillomavirus (HPV) testing, and the possibility of HPV self-sampling as a primary screening modality. In the absence of an organised HPV self-sampling programme in the UK, evidence regarding barriers to the use of another self-sampling method for cancer screening (colorectal cancer) will be examined. Psychological determinants of primary HPV self-sampling uptake including knowledge, attitudes towards HPV self-sampling and HPV self-sampling intentions will be presented. The need for an intervention that addresses barriers to HPV self-sampling will be outlined, followed by description of the aims, objectives and the rationale of the PhD. Finally, an outline of the PhD research phases and methods will be presented.

1.2 Clinical Background

1.2.1 Cervical cancer incidence

Cervical cancer is the second most common cancer in women with 527,000 cases diagnosed worldwide (Ferlay J. et al. 2013). Cervical cancer rates are highest in Eastern Africa and lowest in Western Asia. In Europe, it is the sixth most common cancer for females with around 58,400 new cases diagnosed in 2012. European age standardised rates of cervical cancer were identified as the highest in Romania and the lowest in Switzerland (2012) (Ferlay J. et al. 2013). In the UK cervical cancer is the third most common gynaecological cancer after ovarian and uterine cancer (Cancer Research UK 2015). Variation between countries may reflect differences in

provision of cervical screening such as age of screening onset, perceived risk factors and diagnostic methods.

1.2.2 Cervical abnormalities

Cervical cancer occurs following the development of invasive cervical intraepithelial neoplasia (cervical abnormalities). Cervical intraepithelial neoplasia (CIN) is graded in severity between CIN1 which constitutes low grade cervical lesion precursors, through to CIN2 and CIN3 which constitute high grade lesion precursors of invasive cervical cancer. Treatment of screen detected lesions (particularly CIN2 and CIN3) by ablative or excisional procedures is necessary to stop the natural progression of CIN into invasive cervical cancer and to reduce the incidence of mortality from the disease.

1.3 Current cervical screening method

1.3.1 Cervical screening through cervical smear test

Cervical screening can detect cervical abnormalities at an early stage when the initiation of treatment has a high probability of preventing the abnormalities developing into cervical cancer, or in curing an existing cervical cancer. Cervical screening tests such as the Papanicolaou (Pap) test, or cervical smear test, have been the backbone of one of the most successful cancer reduction programmes in the public health system (Petignat and Vassilakos 2012). The cervical smear test is able to detect precancerous lesions (CIN), therefore identifying cervical cancer before it becomes advanced. In countries with high-quality and broad-coverage use of this test, invasive cervical cancer incidence has declined significantly (National Cancer Institute 2014). The national cervical screening call/recall programme was implemented in the UK in 1988 and involves the collection of a sample of cervical cells by a healthcare professional during a smear test. The sample is passed to a pathology laboratory for slide preparation and screening by a cytologist under a microscope, and women are notified of their results in writing.

Although the cervical smear test has proven to be useful in the detection and reduction of cervical cancer, it has several limitations. False negative screening test results are possible due to the subjective nature of cytological assessment or inadequate sampling. For example, 22% of women with a fully invasive cervical cancer have had a negative smear test result within three years of diagnosis (Sasieni et al. 1996). False positives may also occur because cytological inspection cannot distinguish identified low grade abnormalities which may resolve without treatment, from those which will develop into invasive cervical cancer. It has been estimated that 60% of identified low grade abnormalities will spontaneously regress to normal cervical healthy state (Largo-Janssen and Schijf 2005). As a result, many women may undergo unnecessary procedures and experience elevated levels of anxiety. Furthermore, cervical screening participation has an impact on the development of invasive cervical cancer with 60% of cervical cancer cases being associated with inadequate uptake of screening (National Institutes of Health Consensus Development Panel 1996).

1.3.2 The UK Cervical Screening programme.

Cervical screening in the UK is routinely offered to all eligible women, with the aim of detecting cervical abnormalities which if left untreated will develop into cervical cancer. Currently, cervical screening is offered to women between the ages of 25-64 years in England, Wales and Northern Ireland and 20-60 years in Scotland. Women under 50 years of age are invited for screening every three years, whilst women over 50 years of age are invited for screening every five years. Cervical screening is free and offered by regional National Health Service (NHS) Cervical Screening programmes. At the beginning of the current PhD research, cervical screening policy in Wales differed to the rest of the UK countries, with screening initiated in women from the age of 20 years until 64 years every three years. In 2013, the Welsh cervical screening programme was brought in line with English guidelines: first screening invitation at 25 years with three yearly screening until age 50, and five yearly screening for women aged 50-64. Most women invited to

cervical screening have their initial screening test at their GP surgery or at an NHS community clinic such as a family planning clinic.

1.3.3 Cervical screening uptake

Over the past decade, cervical screening coverage has been steadily declining throughout the UK (Health and Social Care Information Centre 2013-2014; Cervical Screening Wales 2013-2014), and is now below the NHS cervical screening target of 80% needed to ensure cost-effectiveness and to significantly reduce cervical cancer incidence (Baker and Middleton 2003). Cervical screening coverage is defined as the proportion of eligible women in a population who were screened adequately within a specified time point. Current cervical screening rates are 78.6% in Wales and 78.3% in England (Cervical Screening Wales 2013-2014; Health and Social Care Information Centre 2013-2014). Attendance in women aged 25-29 years has been particularly negatively affected (Cervical Sceening Programme: England 2006; Willoughby et al. 2006; Lancuck et al. 2008; Cervical Screening Wales 2013-2014; Health and Social Care Information Centre 2013-2014).

1.3.4 Barriers to cervical screening

Cervical screening barriers have been identified in the literature. It has been found that women from certain sociodemographic groups are less likely to participate in cervical screening, including younger women (Lancuck et al. 2008; Cervical Screening Wales 2013-2014), women in the most socioeconomically deprivation quintiles, and those from ethnic minority backgrounds (Moser et al. 2009; Marlow et al. 2015). Inconvenient appointment times (Waller et al. 2009), the gender of the medical practitioner (Oscarsson and Wijma 2008), embarrassment (Sutton and Rutherford 2005), a lack of trust (Blomberg et al. 2008) and concerns about discomfort have often been cited as barriers to cervical screening uptake (Chiu 2003). Research suggests that practical barriers such as difficulties with taking time off work to attend appointments may be more influential in determining cervical screening uptake than emotional barriers such as embarrassment and fear of

discomfort during the test (Cervical Sceening Programme: England 2006; Szarewski et al. 2009; Wilson 2009). Sociodemographic differences in reasons for non-attendance have been found. In particular, it has been found that older women attribute cervical screening non-attendance to a lower perceived risk of cervical cancer, whilst younger women are more likely to attribute non-attendance to competing time demands (Szarewski et al. 2011). Furthermore, a recent study by (Cadman et al. 2014) found that women from an ethnic minority background were more likely to report emotional barriers, such as embarrassment and shame associated with a diagnosis of cervical cancer (Marlow et al. 2015). Non-attenders are at higher risk of developing cervical cancer and encouraging women to attend cervical screening can save lives and reduce costs associated with invasive cancer treatment (Szarewski et al. 2011).

1.4 Advances in cervical cancer aetiology

1.4.1 Human Papillomavirus

The main aetiological agent in the development of cervical cancer has now been recognised as being a sexually transmitted infection of a viral nature called Human Papillomavirus (HPV) (Bosch et al. 2002). HPV infections are common and most sexually active men and women will become infected with HPV at some point in their lives (Cervical Screening Wales: HPV Facts). Although in most cases the infection will clear on its own, persistent low-risk types of HPV (non-oncogenic) are associated with genital warts, and high risk types of HPV (oncogenic) are associated with cancers of the cervix, vulva, vagina, penis, anus and rectum. There are 14 strains of HPV that are identified as “high risk” and can cause cancer. The high risk types of HPV 16 and 18 are known to be responsible for around 70% of all cervical cancer cases. High risk infections usually self-resolve and do not cause any health problems (Rodriguez et al. 2008). Of the minority of infections that do persist, some will cause precancerous changes to the cervical cells, which if left untreated may become invasive cervical cancer. The identification of oncogenic types of HPV has

provided an opportunity to prevent cervical cancer on two fronts: by immunisation with HPV vaccines and by screening using HPV DNA assays (Almonte et al. 2011).

1.4.2 HPV vaccination

The HPV vaccination programme was introduced in the UK in 2008 for girls aged 12-13 years (Henderson et al. 2011), alongside a catch-up programme for girls aged 14-17 years (Almonte et al. 2011). The vaccine does not offer complete protection against all cervical cancers, but among the most common high-risk types of 16 and 18. The vaccines used in the UK are the Cervarix® vaccine and the quadrivalent Guardasil® vaccine. The national average for HPV vaccination uptake in the UK is high and currently stands at 86.7% (Public Health England 2014)

The implementation of universal HPV vaccination for all young girls is the best prospect for controlling cervical cancer; however, this benefit is unlikely to be observed for several decades due to the latency between HPV infection and the development of cervical cancer (Almonte et al. 2011). Therefore, the NHS cervical screening programme continues to play an important role in cervical screening despite the introduction of HPV vaccination, and protects women who have not received the HPV vaccine. Cervical screening also helps protect HPV vaccinated girls from cervical cancers that are caused by high-risk types of HPV that are not included in the vaccine, and helps prevent cervical cancer in those already infected with HPV prior to being vaccinated. Despite vaccination advances, it is therefore imperative that cervical screening uptake remains high.

It has been suggested that as vaccinated cohorts reach the age of cervical screening, the rate of cervical cytology screen-detected disease will decrease, leading to a reduction of between 40-60% of current colposcopy referral rates (Ault 2007). Such reductions are likely to translate to savings for the healthcare system; however, vaccine-induced disease in cervical lesions may lead to a degradation of cytological performance. It has been suggested that the positive predictive value of cytology will decrease as lesions become less common (Cuzick et al. 2008).

Therefore, the screening performance characteristics of HPV testing such as its high positive predictive value and long-term negative predictive value make it an attractive alternative to cervical cytology (Almonte et al. 2011).

1.4.3 Primary HPV testing for cervical screening

The use of HPV testing in cervical cancer screening has gained momentum, firstly with the issue of the 2012 guidelines by professional societies (Saslow et al. 2012) and the approval of high risk (HPV) testing for the use of first-line cervical screening, and most recently with the publication of interim clinical guidance on the use of primary HPV screening instead of cervical cytology in women aged 25-29 (Huh et al. 2015). This is a significant advance, as it has been shown that around 30% of women with grade III cervical intraepithelial neoplasia (CIN3) are between the ages of 25-29 years (Baker 2015). This is a lower age threshold compared to the 2012 guidelines which recommended HPV testing in addition to cervical smear testing for women aged 30-65.

Sensitive and cost effective tests for high-risk types of HPV have been developed (Kim et al. 2002) and are widely advocated as a means of conducting HPV testing. Trials have shown that HPV testing has a higher sensitivity for cervical intraepithelial neoplasia grade 2 or worse and that high risk HPV testing on clinician taken cervical scrapes provides better protection against cervical cancer than cytology (Rijkaart et al. 2012). In particular, the ATHENA trial (Wright et al. 2015) involving 47,000 women demonstrated that cervical screening via cytology performed poorly in its ability to detect CIN3+ disease. Overall, the trial identified that compared to cervical cytology, HPV primary screening provided a 28.3% increase in sensitivity for CIN3+ in women over 25 years of age. Furthermore, the trial identified that the negative predictive value of primary HPV testing was more significant than cervical screening via cytology. The trial identified that the cumulative incidence rate of high-grade pre-cancer (CIN3) and cancer (CIN3+) in women over 25 years of age who were HPV negative at enrolment was approximately half of those women who were cytologically negative at enrolment.

Although HPV testing can lack some specificity (Miller 2001), it offers a number of advantages compared to conventional cervical screening. These include a higher sensitivity to high grade precancerous disease (Wright et al, 2015), the potential to extend screening intervals for women who have tested negative for HPV, and the reduction of unnecessary colposcopy examinations in women with borderline abnormal smears (Solomon et al. 2001). Consequently, there is growing interest in the use of HPV testing as a primary screening tool in the UK, (Petignat and Vassilakos 2012). however, issues remain about how it may be widely implemented (Almonte et al. 2011).

1.4.4 Implementation of HPV testing within the U.K cervical screening programme

Cervical screening programmes in the UK are changing to facilitate a new era of cervical screening. HPV testing for high risk HPV is currently being incorporated throughout the UK, although it is not yet used as a primary screening modality. The evaluation of how to incorporate HPV testing into the cervical screening programme began in 2008 in England with the Sentinel Sites project. HPV testing as triage for women with borderline and low-grade dyskaryosis results has become routine practice in Northern Ireland and England. Wales and Scotland have introduced HPV testing as a test of cure following colposcopy. Recommendations are being made to the Welsh Assembly Government on potential plans to also adopt HPV triage alongside test of cure in Wales (British Society for Colposcopy and Cervical Pathology 2015).

Due to growing evidence of superior sensitivity and negative predictive value compared to cervical cytology, as well as the considerations discussed previously regarding the new post-HPV vaccination era (Isidean and Franco 2014), it seems likely that future cervical cancer screening in high resource settings such as the UK will evolve to include primary HPV testing. Broad implementation of primary HPV testing and the possibility of lengthening of screening intervals due to the superior negative predictive value of primary HPV testing, may result in a new cervical screening system that is more cost-effective and provides greater safety than

cervical cytology (Isidean and Franco 2014). However, implementation of HPV screening requires consideration of important logistical challenges such as ascertaining appropriate screening intervals, defining triage and management policies for HPV positive women, ensuring quality and adherence to revised policies, and most importantly the type of HPV screening test to be used and its acceptability to women.

1.4.5 Human Papillomavirus Self-sampling

Primary HPV self-sampling for cervical screening may be possible using self-sampling methods (Petignat and Vassilakos 2012). Samples for HPV testing can be conducted similarly to cervical smear tests, using a swab taken by a healthcare professional or by the individual themselves through self-sampling. Self-sampling methods are increasingly advocated in tests for sexually transmitted infections (Waller et al. 2006) as well as for cancer screening such as faecal occult blood (FOB) testing in colorectal cancer screening (Hardcastle et al. 1996).

Similarly to cervical screening, HPV self-sampling is a preventative health behaviour undertaken by a seemingly healthy individual for the sole purpose of preventing or detecting disease before symptoms occur (Tanner-Smith and Brown 2010). Self-sampling for cervical screening is a method where a woman can collect a sample of her own cells for HPV DNA testing. To carry out HPV self-sampling, a woman will need to insert a soft swab into the vagina and follow simple instructions for collection of cells. She will then need to put the swab into a safe transportation device, such as a sealed tube containing preserving liquid, and post it to a laboratory using a pre-addressed envelope through the standard mail service. The sample will then be tested in a laboratory for the presence of high risk HPV. Women will be notified of their result through a letter in the post explaining whether any further action such as colposcopy examination needs to be conducted.

1.4.6 HPV self-sampling sensitivity

As discussed previously, it is now well recognised that HPV testing on cervical samples provides better protection against cervical cancer than cytology (Snijders et al. 2013; Bosgraaf et al. 2014). HPV self-sampling using a clinically validated self-sampling device and HPV test, has been found to have a sensitivity for detecting high grade CIN similar to that of HPV DNA testing on clinician collected material (Schmeink et al. 2011; Arbyn et al. 2014; Galbraith et al. 2014). Furthermore, a UK randomised trial study of HPV self-sampling found that 99% of returned self-sampling kits had an adequate sample for analysis, versus 91.2% of clinician obtained smear test samples for cervical cytology (Szarewski et al. 2011). This has supported the concept of introducing HPV self-sampling as an alternative means for cervical cancer screening (Petignat and Vassilakos 2012). If self-sampling proves to be an acceptable cervical screening method to women it may be possible to make it widely available. Laboratories around the UK are in a state of change, and have been adapted or are currently being adapted to facilitate the recent introduction of HPV testing on abnormal cervical samples and as a test of cure. Furthermore, as the sample is sent to a laboratory through the post, the service does not need to be available in every hospital/laboratory but can be concentrated at sites of expertise and capacity.

1.5 Current self-sampling methods for cancer screening: the UK colorectal cancer screening programme

The first UK population screening programme to use a self-sampling method is colorectal cancer screening (CRC). Secondary prevention of CRC through regular screening is important because CRC can have a long period during which the disease is detectable but asymptomatic, much like cervical cancer (Winawer et al. 1993). CRC can be diagnosed through various means, including faecal occult blood testing (FOBT) that is conducted through self-sampling. Annual or biannual screening using FOBT has been found to reduce colorectal cancer mortality by 27% in those who use the test (Scholefield et al. 2002).

The FOBT test can be conducted with a self-sampling kit which is sent through the post, so that individuals collect their own stool samples over a period of days for FOBT. A national screening programme was initiated in England in 2006, offering FOBT for adults aged 60-69 years. The eligible population is re-invited every two years until age 69 years. Individuals are instructed to post their FOBT test kit in a hygienically sealed free-post envelope to a laboratory for sample analysis, with a test result received within two weeks. If the result is positive, the person concerned may be asked to repeat the test or invited to have a colonoscopy. The bowel screening programme has been shown to be feasible and is now routinely implemented in the UK (Weller et al. 2003). However, uptake is currently around 60% (Weller et al. 2006) and demonstrates a socioeconomic gradient, ranging from 35% uptake in the most deprived areas to 61% uptake in the least deprived areas (von Wagner et al. 2011). It has also been found that FOBT uptake is lower in the most ethnically diverse areas independent of socioeconomic group, age and gender (von Wagner et al. 2011).

Reasons for low uptake of FOBT include practical objections such as a perceived hygiene risk in handling, storing and sending faecal matter through the post, as well as the perception of complex or unfeasible instructions and processes (von Wagner et al. 2011; Hall et al. 2013; Palmer et al. 2014). Perceived risks and taboo associated with handling faeces have been identified, and include the belief that conducting the test might physically pollute the individual or their environment, and that individuals would need to take extreme measures to manage the possibility of such pollution (Palmer et al. 2014). Another reported reason for non-uptake of FOBT is the lack of familiarity with FOBT and habituation to screening tests being conducted by healthcare professionals (Palmer et al. 2014).

The FOB test programme has demonstrated that a self-sampling screening method for cancer is a feasible and cost-effective alternative to conventional outpatient screening, as long as the relevant population engages in the screening process. The introduction of FOBT self-sampling into the UK setting has also identified that although the FOBT test avoids many of the commonly reported barriers to cancer

screening such as embarrassment and attending healthcare appointments, it is not acceptable to a large proportion of the population and presents different barriers. This needs to be considered in future self-sampling programmes such as HPV self-sampling. Indeed, the perception that conducting HPV self-sampling is "dirty" or taboo has been reported in a UK study investigating HPV self-sampling perceptions in Hindu women (Cadman *et al,* 2014).

1.6 Uptake of HPV self-sampling

HPV self-sampling is a promising means of increasing cervical screening coverage, potentially enabling the programme to reach women in their own homes and reducing the need for surgery appointments, as well as the financial and labour costs associated with repeat smear taking. Self-sampling may also be useful in reaching women from lower socioeconomic groups, ethnic minority groups (Webb et al. 2004; Sutton and Rutherford 2005; Marlow et al. 2015) and younger age groups, who are less likely to attend cervical screening. Participation rate is a fundamental factor determining the acceptability, cost effectiveness and reach of a potential HPV self-sampling screening programme, therefore careful consideration of any influences that may affect its successful implementation is crucial (Verdoodt et al. 2015).

The majority of research into acceptability of HPV self-sampling has been conducted in women who are cervical screening non-responders or those who are under-screened. The rationale behind this research is evident: for a cervical screening programme to function well, uptake must remain high and therefore efforts are often concentrated on women who do not participate as they are known to be at higher risk of developing cervical cancer. A recent systematic review and meta-analysis of HPV self-sampling versus usual care in cervical screening non-attenders identified an increased participation in self-sampling when kits were mailed directly to women (Verdoodt et al. 2015). The meta-analysis included sixteen trials, two of which were conducted in the UK (Szarewski et al. 2011;

Cadman et al. 2015), and concluded that HPV self-sampling may provide an alternative cervical screening method that is acceptable to non-responders.

Results from meta-analysis should be interpreted with caution however, since they provide a very general overview of uptake and differences between studies need to be considered. The UK study conducted by Szarewski *et al* (2011) reported a significantly lower uptake rate of HPV self-sampling compared to studies in the Netherlands and Sweden which identified uptake rates of 34% (Bais et al. 2007), 39% (Sanner et al. 2009b) and 27% (Gok et al. 2010). Szarewski *et al* (2011) found that when persistent non-responders (defined as women who have not responded to at least two invitations for cervical screening) were sent a self-sampling kit, a total uptake of 10.2% was achieved, of which 6.4% utilised the kit and 3.8% attended cytological screening. Of those who utilised self-sampling and underwent colposcopy, high-grade disease (CIN) was found in 43% of women. This relatively high yield of abnormalities is consistent with that expected among a hard to reach and relatively high-risk group of non-responders. The different uptake rates observed between different countries may therefore be attributed to characteristics of the populations sampled. However, methodological differences between studies may also explain this phenomenon, for example non-responders in Sweden and the Netherlands were contacted more than once to encourage them to participate. A further limitation of the Szarewski *et al* (2011) study is that only 10% of participants were under 35 years old. This is an important limitation as research has identified that women from younger age groups are less likely to participate in cervical screening. Further work is needed to ascertain women's attitudes towards HPV self-sampling in women from different groups (Szarewski et al. 2011), such as different sociodemographic backgrounds and cervical screening histories.

Studies have shown that although HPV self-sampling can increase cervical screening acceptance in some non-responders, the majority of non-responders do not participate in HPV self-sampling. This is important when considering that it is a method which addresses many of the commonly identified barriers to cervical smear, testing such as test-related issues including pain, discomfort or

embarrassment and doctor-related issues including access, difficulty obtaining appointments or time constraints. This poses the question of whether HPV self-sampling may be better suited as a primary cervical screening method and if it would be acceptable to cervical screening responders, when compared to cervical smear tests. A study by Waller et al. (2006) found HPV self-sampling to be more acceptable than a clinician-administered test in women attending for a cervical smear screen. Participants were able to compare the two different modes of screening because they were asked to conduct HPV self-sampling at the clinic they were attending, followed by their standard cervical smear test. The study highlighted women's lack of confidence in conducting self-sampling. A limitation of the study is that women conducted self-sampling in a health care setting. This might have avoided perceived barriers associated with suitability of environment for self-sampling (as identified in FOBT literature) which may have been present if women were performing the self-sampling procedure at home. Therefore, the observed lack of confidence in conducting self-sampling properly, may have been even higher if participants were conducting the test at home. Furthermore, because women were aware that they were also receiving a clinician test as well as HPV self-sampling, it is possible that anxiety levels might have been lower, because participants might have perceived the clinician cervical screening tests as a safeguard should self-sampling be conducted incorrectly. Therefore, further research investigating acceptability of HPV self-sampling in cervical screening responders is needed.

1.6.2 Psychological determinants of HPV self-sampling uptake

1.6.2.1 Attitudes towards HPV self-sampling

A mixture of positive and negative attitudes towards HPV self-sampling have been identified in studies exploring women's attitudes towards HPV self-sampling in different countries. Although the majority of studies have been conducted in women who are classified as non-responders to cervical screening, they provide important insight into attitudes towards HPV self-sampling. Whilst some studies have found HPV self-sampling to be an acceptable form of cervical screening

(Harper et al. 2002; Waller et al. 2006; Galbraith et al. 2014; Broquet et al. 2015; Hanley et al. 2015; Sultana et al. 2015),others have identified that HPV self-sampling would raise significant concerns and might not be an acceptable form of screening (Cadman et al. 2014; Fargnoli et al. 2015). A reduction in time commitment needed compared to attending a clinic for a cervical smear test and the reduction of discomfort and embarrassment by avoiding gynaecological examinations, (Barata et al. 2008; Bosgraaf et al. 2014; Fargnoli et al. 2015; Llangovan et al. 2016), as well as the perception that women feel more relaxed conducting self-sampling (Hanley et al. 2015) have been identified as benefits. However, the belief that self-sampling is not safe (Barata et al. 2008; Hanley et al. 2015), concerns over performing self-sampling properly (Forrest et al. 2004; Cadman et al. 2014; Hanley et al. 2015) and a subsequent lack of trust in the results (Sultana et al. 2015) have been identified as barriers.

Sociodemographic differences have been reported in women's concern over performing self-sampling correctly. A UK study found that women from Indian and African-Caribbean backgrounds were significantly more likely to be worried about doing the test properly (66% and 70% respectively) compared to White or Pakistani women (Forrest et al. 2004). In contrast, a preference for HPV self-sampling has been identified in a study of women from lower socioeconomic groups (Galbraith et al. 2014), who found that most women (92%) trusted that a HPV self-sampling test would be able to detect cervical cancer if it is present (sensitivity). However, only 26% of women trusted that a positive test result correctly identified those who had cervical cancer (positive predictive value).

Later studies have reported preferences for cervical smear tests over HPV self-sampling (Szarewski et al. 2009; Cadman et al. 2014; Fargnoli et al. 2015). For example, a mixed methods study by Cadman et al (2014) in Hindu women from London identified that preferences for smear testing were underpinned by higher confidence in clinician collected samples, and the perception that a positive HPV test may cause relationship problems. This study also noted generational differences in attitudes, represented in the belief that younger women would be more comfortable with conducting self-sampling compared to older women. The

study included cervical screening responders and provided an insight into the views of women who attend cervical screening; however, it involved a highly selected sample of educated Hindu women, resulting in limited generalisability of findings. Fargnoli et al. (2015) also highlighted generational differences in women's attitudes towards HPV self-sampling in Switzerland. It was found that younger women who were more used to regular gynaecological appointments were less in favour of a new screening test, compared to older women who were less used to regular gynaecological appointments and those who had a bad experience with pelvic examinations in the past. However, the cervical screening in Switzerland is opportunistic and primarily conducted by gynaecologists, whilst in the U.K cervical screening is conducted primarily by nurses and is facilitated by a cervical screening recall system. The differences in the way cervical screening is organised in the U.K. and Switzerland might explain the different views reported.

A recent study by Llangovan et al. (2016) investigated the acceptability of HPV self-sampling in uninsured Haitian and Latino women in the U.S. It was reported that acceptability of HPV self-sampling was high overall, most (over 90%) of women reported that HPV self-sampling was easy to perform and that they felt they conducted the test correctly. However, it was found that when provided with a choice between HPV self-sampling and cervical cytology, Haitian women were less likely to choose self-sampling (60% vs 87%) compared with Latino women. Although the difference in cervical screening method might be due to ethnic differences, it might also be because the majority of Haitian women have less experience with cervical cytology than Latino women (Seay et al. 2015). It has been identified that preference for cervical smear over HPV self-sampling has been associated with adherence to cervical screening (Winer et al. 2016). Consequently, the Haitian women might have been more amenable to a different form of screening. Furthermore, the study was conducted in two safety-net clinics that provide accessible healthcare to individuals who do not have health insurance. The healthcare centre that provided service to the Haitian women required an extra fee for conducting a cervical smear test, whilst the cost of obtaining a cervical smear was included when conducted as part of a visit. Therefore, financial considerations might have also influenced Haitian women's preference for HPV self-sampling.

Financial considerations have been identified by Fargnoli et al. (2015) who reported that migrant women perceived HPV self-sampling as less expensive than cervical smear tests. Although, healthcare in the U.K. is free and provided by the National Health Service (NHS), women might have specific perceptions about the financial impact of HPV self-sampling on the NHS.
Further studies exploring women's attitudes to HPV self-sampling from different screening histories, cultural backgrounds, age ranges and socioeconomic backgrounds need to be conducted.

1.6.2.2 HPV knowledge

Despite the recent introduction of HPV testing and the introduction of the HPV vaccine, women's HPV-related knowledge has remained low (Marlow et al. 2013; Galbraith et al. 2014). Mixed results have been reported relating to knowledge that HPV can cause cervical cancer. A U.S. study reported that the majority of participants (63%) could identify HPV as a cause of cervical cancer (Galbraith et al. 2014). However, other studies have reported lower HPV-related knowledge, with the majority of women being unaware that cervical cancer is caused by a sexually transmitted infection (STI) (Marlow et al. 2007). An international survey conducted in the UK, US and Australia found that 39% of participants had not heard of HPV before taking part in the research (Dodd et al. 2014). International variation in HPV knowledge levels may be partly attributable to differential implementation of HPV testing between countries, and variable HPV coverage by public health campaigns and news stories. HPV knowledge has also been associated with educational level, with more educated individuals often being more aware of HPV and HPV testing (Marlow et al. 2013; Dodd et al. 2014). Variation of HPV knowledge by ethnicity has also been found, with women from ethnic minority backgrounds reporting a lower level of HPV knowledge (Galbraith et al. 2014).

As well as a general lack of knowledge about HPV, low understanding of HPV test results and their emotional consequences have been observed (Daley et al. 2015). Women have reported negative emotional reactions to positive HPV test results

including anxiety, distress, embarrassment and concern about sexual relationships (McCaffery et al 2006). Women with normal cytology undergoing a follow-up HPV test 12 months after an initial positive HPV test reported disappointment that the virus had not cleared up, fear and concerns about fertility (Waller et al. 2007). In addition, it has been found that women may not understand the implications of a negative HPV result (e.g. the knowledge that a negative HPV test means that a woman's cervical cancer risk is low at that point in time) (Dodd et al. 2014). HPV testing may therefore raise some difficult issues for women. Although HPV is extremely common amongst the sexually active population, awareness of the role of this virus and its interaction with cervical cancer may raise concerns about stigma surrounding a potential diagnosis (Forrest et al. 2004). Improving knowledge that HPV causes the majority of cervical cancer cases and understanding of the implications of HPV results may help to increase HPV testing acceptability and minimise negative psychological consequences associated with HPV results (Dodd et al. 2014; Crofts et al. 2015).

1.6.2.3 HPV self-sampling intentions

Some studies have focused on investigating HPV self-sampling intentions because HPV self-sampling is not routinely available. Studies have reported mixed findings regarding women's intentions to HPV self-sample. One study found that 56% of women would use HPV self-sampling if it was available (Forrest et al. 2004). However, it was found that intention was affected by ethnic background and HPV knowledge, with intention rate varying between 71% in White British women to 46% in women from Indian and Pakistani backgrounds. This finding might reflect the differences in attitudes towards HPV self-sampling that have been described earlier in women from different sociodemographic groups. A recent study by Smith et al. (2014) that investigated women's intentions to conduct HPV self-sampling compared to having a cervical smear test, has reported HPV self-sampling intentions of 45.6%. This study also reported socioeconomic differences in intention, with women from a higher educational background were more likely to intend to HPV self-sample.

Although research on intention to self-sample suggests that HPV self-sampling might be an acceptable form of screening in certain populations, intentions can vary from actual behaviour. A recent systematic review and meta-analysis of sixteen randomised controlled trials (Verdoodt et al. 2015) identified an average HPV self-sampling participation rate of 23% (range from 6.4% -34%) in cervical screening non-attenders who were mailed a HPV self-sampling kit. The wide range of reported participation highlights the heterogeneity observed in the included studies, in terms of study characteristics such as the use of reminders as well as the contextual differences in studies which were conducted in different countries.

Although evidence regarding women's intentions to HPV self-sample is invaluable in facilitating understanding of their potential behaviour. Should HPV self-sampling become available, it must be interpreted with caution. Reported intentions to HPV self-sample do not automatically result in uptake of HPV self-sampling. Intention formation is influenced by beliefs about the value of engaging in HPV self-sampling, in terms of benefits and barriers, as well as an individual's perceived ability to perform the behaviour in question (e.g. collecting a sample for HPV testing). Although intentions are necessary, they are not sufficient for behaviour change (Fishbein and Ajzen 1975). Behavioural intentions are defined as "instructions that people give to themselves to behave in certain ways" (Triandis 1980). Therefore, a behavioural intention represents an individual's motivation to perform a certain behaviour, such as HPV self-sampling. It has been found that more than half of individuals who form an intention fail to put that intention into practice (Orbell and Sheeran 1998). This is known as the intention-behaviour gap and should be considered when interpreting findings presented, especially when correlations as low as 0.03 between intentions and behaviour for cancer screening have been found (Montano and Taplin 1991). Furthermore, the intention-behaviour gap may be larger in research that uses hypothetical scenarios compared to research investigating attitudes towards services available. The intention-behaviour gap could be bridged by the use of post-intentional constructs focusing on how people pursue goals after an intention has been formed. It has been suggested that as well

as setting specific implementation-intention tasks (Gollwitzer and Sheeran 2006), an increase in self-efficacy, particularly 'coping self-efficacy' (Schwarzer 2008) which refers to the ability to cope with impediments to the desired behaviour, can help translate intentions into behaviour.

1.7 Interventions designed to increase screening uptake

As previously discussed the success of any cancer screening programme is dependent on its uptake, and uptake of HPV self-sampling could be potentially be increased by an intervention. To date, only one intervention designed to increase HPV self-sampling uptake has been identified in the literature. Sossauer et al. (2014) reported that a video, which included culturally tailored messages, was able to increase knowledge about cervical cancer and HPV, as well as increase the acceptability of HPV self-sampling. However, this study was conducted in Cameroon, a low income country without an organised cervical screening programme, therefore the results may not be generalizable to the UK setting.

In light of the limited evidence regarding interventions designed to increase HPV self-sampling uptake, evidence from other types of screening interventions will be discussed. Although inferences will be drawn from studies reporting the effectiveness of interventions to increase uptake of cervical and colorectal cancer screening, a detailed review is outside of the scope of this thesis. Evidence from the current cervical and colorectal screening programmes will be presented due to similarities with HPV self-sampling (screening for cervical cancer and self-sampling).

The most recent Cochrane review of interventions targeted to encourage cervical screening has suggested that interventions which provide educational materials and those that have been developed with involvement of a lay person (e.g. showing mastery of a certain behaviour) are effective in increasing cervical screening participation (Everett et al. 2011). Interventions have attempted to increase participation in colorectal cancer screening, for example it has been found that a mailed psychoeducational intervention in a community setting was able to increase

screening attendance by modifying individual's attitudes (Wardle et al. 2003). Interventions designed to increase FOBT colorectal cancer screening may be particularly useful, as the screening mode is similar to that of HPV self-sampling. Studies have shown promising results in increasing colorectal cancer screening rates using interventions designed to increase FOBT utilisation (Davis et al. 2014). Interventions have included patient directed interventions such as written materials and reminders (Lee et al. 2009). A recent UK study has identified that interventions which focus on reducing delay in completion of FOBT kit and facilitating preparation to conduct the procedure may be useful in increasing intention to FOBT self-sample (Lo et al. 2015). These findings suggest that there is potential for the development of a HPV self-sampling intervention with the aim of increasing future uptake.

1.8 The need to develop a HPV self-sampling intervention

Interventions have been designed to increase uptake of screening in cervical and other forms of cancer. However, to date, interventions to increase women's intentions to HPV self-sample have not been developed in the UK setting. Should HPV self-sampling be incorporated into the U.K cervical screening programme as a primary cervical screening modality, the development of an intervention will be needed to help increase potential uptake of HPV self-sampling. The Medical Research Council (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008) states that development phase research must be conducted to enable the development of suitable key messages to be included in an intervention, and that interventions must be based on the best available evidence for the target population (which for this PhD research is women from the general population).

Studies to date have mainly involved cervical screening non-responder samples, or have been conducted in countries with different healthcare systems. The characteristics of women who are cervical screening non-responders may be different to those of women who adhere to current cervical screening guidelines. Population based surveys have found that women who are non-responders are

more likely to be from an ethnic minority background, single, younger in age and to have fewer educational qualifications (Sutton and Rutherford 2005; Lancuck et al. 2008; Marlow et al. 2008; Moser et al. 2009). Some non-responders are disengaged with the cervical screening programme (Marlow et al. 2015), which might reflect different barriers to potential HPV self-sampling uptake. Where the views of cervical screening responders have been sought in the UK, research has mainly focused on the views of women from ethnic minority backgrounds. Whilst research into women from ethnic minority backgrounds is crucial for understanding potential uptake of HPV self-sampling, in women who may present specific cultural barriers, findings may not be representative of the population as a whole. If HPV self-sampling is to be used as a primary screening tool for the whole population, rather than targeted at cervical screening non-responders, then it will be important to understand the barriers and facilitators to HPV self-sampling in women from a range of demographic backgrounds.

1.9 Summary and research gap

Testing for Human Papillomavirus (HPV) is currently being incorporated into the cervical screening programme, with the probable future introduction of HPV as a primary test and the possibility of HPV self-sampling. In anticipation of this development, research into the psychological factors associated with acceptance/rejection of HPV self-sampling in a general population sample is needed to explore the acceptability of this method. The majority of studies examining women's attitudes towards HPV self-sampling have focused on cervical screening non-responders, therefore the views of women who are currently engaged in the cervical screening system are underrepresented.

The identification of constructs associated with intention to engage in HPV self-sampling in a general population sample will facilitate the exploration of women's views on the possible future introduction of primary HPV self-sampling. Insights into women's attitudes towards HPV self-sampling could be used in the development of policy and practice regarding the possible incorporation of HPV

self-sampling into the cervical screening programme, as well as the development of an intervention to increase acceptability. The development of an intervention will help ensure that cervical screening uptake does not decline, should HPV self-sampling be incorporated into the cervical screening system in the future. Psychological theory will be applied in the investigation of women's hypothetical attitudes and intentions to HPV self-sampling and the development of an intervention designed to increase self-sampling uptake (Craig et al. 2008).

1.10 Aims and objectives

The overarching aims of the PhD research are to examine women's attitudes towards HPV self-sampling, with a particular focus on self-efficacy, and to develop and pilot an intervention designed to increase the acceptability of HPV self-sampling.

Specific objectives are: to gain a rich understanding of women's attitudes, knowledge and intentions regarding HPV self-sampling using relevant health psychology theory; to explore the influence of self-efficacy on intentions to self-sample using a mixed-methods approach; to produce messages to be used in an intervention designed to increase the acceptability of HPV self- sampling, to develop a HPV self-sampling intervention, and to conduct preliminary user testing with women and service providers to explore acceptability of intervention as well as barriers and facilitators to implementation.

1.11 Study design

The investigation of complex health behaviours such as HPV self-sampling, requires the use of a multi-level investigative approach. Mixed methods research combines qualitative methods, such as in-depth interviews to understand individual experiences and barriers and facilitators to action, with quantitative methods such as surveys of attitudes and beliefs (Plano Clark 2010). For the purpose of this PhD research, the mixed methods approach will be defined as an approach that (Creswell et al. 2011):

- focuses on research questions that call for real-life contextual understandings and multi-level perspectives
- employs quantitative research assessing magnitude and frequency of constructs with qualitative research to explain the meaning and understanding of the constructs
- employs multiple methods such as surveys and interviews
- combines the methods to draw on the strengths of each respective method
- frames the investigation within a theoretical position.

1.12 Research Phases

The PhD research is presented in five phases:

Phase one identified and evaluated health behaviour theories that can be used to help understand women's attitudes towards HPV self-sampling. A suitable theory was be selected to structure subsequent mixed-methods research stages.

Phase two presented the development of a structured survey based on health behaviour theory, designed to examine women's attitudes towards HPV self-sampling. The questionnaire was developed using content validity analysis and cognitive interviewing.

Phase three utilised the survey developed in Phase two to survey attitudes towards primary HPV self-sampling and to quantify HPV self-sampling intentions in a cross-sectional sample of women from South-East Wales. The influence of HPV knowledge, attitudes, self-efficacy, and clinical and demographic background characteristics including previous cervical screening history on HPV self-sampling intentions was examined.

Phase four explored in depth women's attitudes towards primary HPV self-sampling, using semi-structured interviews with women purposively sampled from

the Phase three questionnaire survey who reported low intentions to HPV self-sample.

Phase five utilised the information gathered in previous phases to develop an intervention designed to increase HPV self-sampling intention, followed by a preliminary user testing of the draft intervention using pre and post-questionnaire and semi-structured interviews with a small sample of potential users and providers.

Chapter 2

Review of health behaviour models and theories relevant to HPV self-sampling.

2.1 Chapter Overview

This chapter will explore the theoretical background to the PhD, in order to facilitate an understanding of the likely influences on women's intentions to HPV self-sample. The use of theory is an important recommendation from the MRC intervention development guidelines (Craig et al 2008) for the successful development of complex behaviour change interventions.

A range of theoretical approaches will be described in order to highlight the effect of health beliefs on intention and behaviour in relation to cervical screening, and to identify relevant theories that can be used to investigate HPV self-sampling intention. A justification for the use of the extended Health Belief Model (HBM) with its focus on self-efficacy to inform the current research will be presented. Finally, an outline of how the extended HBM will be utilised in the subsequent PhD phases will be presented.

2.2 Introduction

The aim of the NHS cervical screening programme is to ensure that at least 80% of eligible women in the UK receive a cervical screen. Health beliefs have been shown to be influential in determining uptake of screening such as cervical smear tests, FOBT tests and HPV self-sampling (see Chapter 1). These studies have helped to form an understanding of why certain population groups may not engage in screening. However, the possible introduction of an alternative method of cervical screening, may raise different barriers and facilitators to engaging in screening that have not been previously reported. Since HPV self-sampling has not yet been incorporated into the cervical screening programme, theories that have been found useful for exploring barriers to other forms of cancer screening need to be reviewed regarding their relevance and usefulness in context of HPV self-sampling.

As recommended by the MRC guidelines (Craig et al. 2008), a theoretical underpinning to any intervention is crucial to help explain the mechanisms of behaviour change. The MRC complex intervention guidelines specify that a clear description of how intervention components interact to achieve a desired outcome, such as an increase in intention to HPV self-sample, is required.

Therefore, the incorporation of theory in the design of this PhD research and the development of the HPV self-sampling intervention was important for a number of reasons. Firstly, the use of theory to inform the study of women's attitudes towards HPV self-sampling can facilitate the development of study materials such as surveys and interview schedules. Secondly, theory can provide a framework for the intervention designer to consider which beliefs need to be modified, thereby identifying motivational processes relating to HPV self-sampling intention (Michie et al. 2011). Thirdly, theorising about the mechanisms that may influence intention to HPV self-sample promotes the assessment of appropriate mediators for intervention inclusion. This enables the determination of whether the intervention has influenced the hypothesised mediator and subsequently whether that mediator has an effect on intention to self-sample. Therefore the use of theory can facilitate the identification of 'active ingredients' present in behaviour change interventions (Michie and Abraham 2004). Finally, designing an intervention based on a specific theory also enables the theory to be evaluated in terms of its ability to explain a particular behaviour, such as women's intentions to HPV self-sample.

Although many theories have been proposed to explain the adoption of health protective behaviours, the aim of this chapter is to discuss health behaviour theories that are considered to be most relevant to HPV self-sampling. Health behaviour theories can be used to explain determinants of a behaviour in a specific context. Therefore, when considering which theories might be most suitable for the exploration of women's attitudes towards HPV self-sampling, it was important that theories that have previously been used to explain engaging in preventative health behaviours, such as cervical screening, were considered. Furthermore, because the

emphasis is placed on the individual to conduct HPV self-sampling, theories that incorporated the concept of self-efficacy were also explored.
The theories that will be presented in this chapter are: the Trans-Theoretical Model of Health Behaviour Change (TTM), Protection Motivation Theory (PMT), the Theory of Reasoned Action (TRA) and Theory of Planned Behaviour (TPB), Social Cognitive Theory (SCT) and the Health Belief Model (HBM). The theories and their relevance to HPV self-sampling will be described, and their strengths and weaknesses will be critically appraised.

A focus on the use of theory in understanding intention to engage in primary HPV self-sampling will be presented. As well as research relating to HPV self-sampling, studies of cervical, breast and FOBT cancer screening will also be outlined. Cervical, breast and FOBT screening studies will also be presented because they are the main organised cancer screening campaigns in the UK that are comparable to a future primary HPV self-sampling programme.
A wide range of psychological theories and models have been used to understand and identify reasons for low rates of participation in cancer screening (Austin et al. 2002). Due to the voluntary, infrequent and non-habitual nature of cervical screening through smear tests, or HPV self-sampling in the future, it is possible that individuals make a decision whether to engage in cervical screening each time they are invited to participate (Bish et al. 2000). Therefore, uptake of cervical screening, such as HPV self-sampling, may be a behaviour that is particularly suited to study with social cognition models.

However, some previous research has identified social cognition models as poor predictors of screening behaviour (Godin and Kok 1996). Although it is possible that some cognition models might have a limited utility in predicting certain behaviour, this finding should be interpreted with caution. The categories of health behaviour used by the above study were broad and included early detection behaviour such as self-examination and seeking medical care for symptoms, as well as screening behaviours such as participating in mammography. Early detection behaviours require awareness of symptoms and are thus different to preventative screening

behaviour which is asymptomatic. Therefore, the lack of predictive ability of health cognition models reported by Godin and Kok (1996) might be due to the type of screening behaviour studied and the specific models chosen, different models might be better suited to different types of behaviour. In fact, it has been found that participation in different forms of screening is predicted by specific beliefs about the different types of screening (Marteau 1993), as well as previous experiences. For example, private breast self-examination (BSE) may be a more acceptable form of screening for a woman who may be anxious at the prospect of a cervical smear screen that involves participation of a health care professional.

2.3 Trans-Theoretical Model of Behaviour Change (TTM)

The fundamental concept of the TTM (Prochaska 1993; Prochaska and Velicer 1997) is that behaviour change is most successful when behavioural strategies called processes of change are applied at the correct time (Prochaska et al. 1992). The model was initially developed as an approach to psychotherapy, but was then applied to health and lifestyle behaviours such as tobacco cessation and cancer screening behaviour (Prochaska et al. 1992). The TTM proposes that a behaviour change occurs in five different stages from precontemplation (not planning to change within the next six months), contemplation (thinking about changing), preparation (taking steps to change), action (attempting the change) and maintenance (having changed for at least six months). Although the stages are presented in a linear fashion, in reality individuals may pass back and forth through different stages. It is proposed that individuals in the early stages of change use cognitive or experiential strategies, such as self-re-evaluation, to progress forward through the stages of change. Individuals in the later stages use behavioural processes such as helping relationships or stimulus control more frequently. As the individual progresses further through the processes of change, the cons relating to a particular health behaviour should decrease whilst the pros should increase.

The TTM processes as applied to HPV self-sampling will be outlined below. The first stage (precontemplation) involves increasing awareness about HPV self-sampling

and improving accuracy of information about HPV self-sampling and the self (consciousness raising), experiencing and releasing feelings about HPV self-sampling and engaging in HPV self-sampling (dramatic relief), and thinking that engaging in HPV self-sampling would impact on the social environment (environmental re-evaluation). The second stage (contemplation) refers to the cognitive and affective assessments of how engaging in HPV self-sampling may impact on the individual's self-image. The third stage (preparation) refers to an individual's belief that they are able to overcome previous barriers related to HPV self-sampling and their commitment to act on the belief (self-liberation). The fourth stage is the action stage and refers to the utility and availability of helping relationships, counter-conditioning, reinforcement management and stimulus control. The final stage is maintenance and involves social liberation, social, policy or environmental changes that support healthy behaviour.

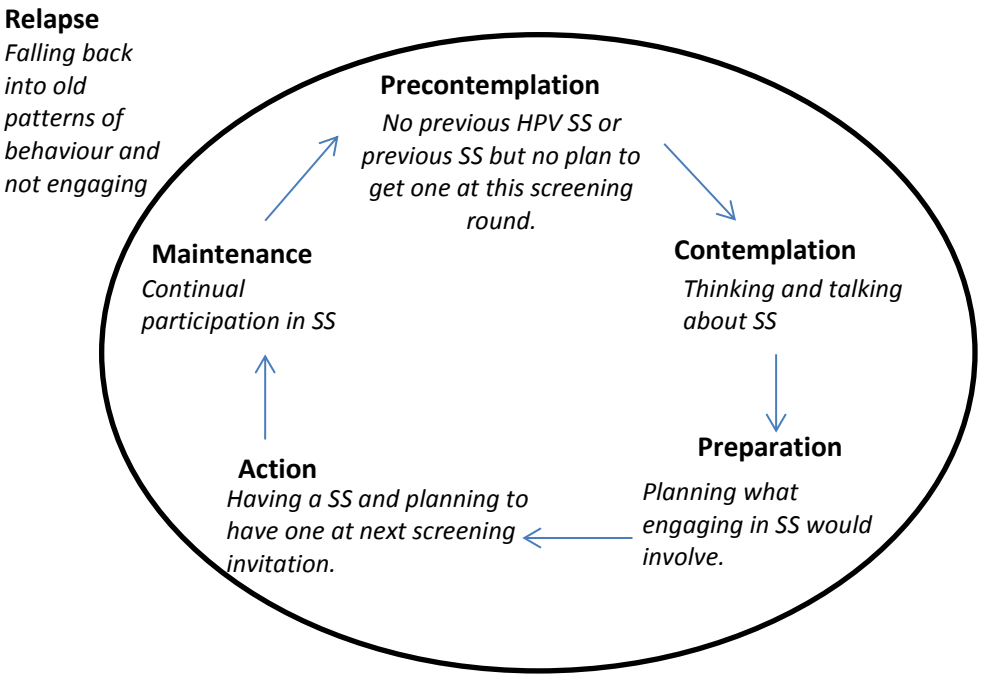

Figure 2.1: The TTM applied to HPV self-sampling (SS), adapted from (Prochaska and DiClemente 1982)

A further two intervening variables are proposed to influence movement from stage to stage: decisional balance and self-efficacy. Decisional balance refers to the perceived benefits and barriers associated with engaging in health behaviour such

as self-sampling. When more benefits are perceived, a change is more likely. Self-efficacy is defined as a person's beliefs about their ability to carry out behaviour in any given situation (Michie et al. 2014). Self-efficacy refers to both behaviour change and to temptations to carry out the problem behaviour (or in the case of self-sampling to avoid the healthy behaviour). Self-efficacy influences the processes of change throughout the different stages. Self-efficacy level increases and temptation levels decrease over time (Michie et al. 2014).

The TTM has been utilised as a theoretical framework in a number of studies investigating cervical screening and mammography attendance (Rimer et al. 1996; Kelaher et al. 1999; Abdullah and Su 2013). Studies have identified that cervical smear test screening and mammography behaviour were largely influenced by women's decisional balance of pros and cons. Cons included advanced age, lack of education and misconceptions about the screening method (Rimer et al. 1996). Abdullah and Su (2013) identified that women who were in the pre-contemplation stage were most likely to be at an action stage following exposure to an intervention designed to increase cervical screening, such as the introduction of a call/recall system.

Although the TTM has been used to investigate women's intentions to engage in cervical smear test screening attendance, staging as proposed by the TTM may be problematic in the cervical screening context, in which the behaviour occurs once every three or five years. The TTM has been criticised for the concept of staging and the proposition that discreet and categorical stages exist for any given behaviour (Sutton 2000). It has been argued that individuals do not progress through discreet stages but that they progress along a continuum of change (Sutton 2000). Staging for cervical screening behaviour, such as HPV self-sampling, can be difficult because of variations in screening recommendations based on previous cervical screening history and policy variations between different countries. Cervical screening recommendations in terms of age of onset of cervical screening, frequency of screening and the introduction of HPV testing, have been modified as further advances in cervical screening have been made. Furthermore, cervical screening is

stratified based on women's previous cervical screening history (e.g. women who have had a previous cervical abnormality are under increased surveillance and screened more frequently, whilst in some areas in the UK older women are screened at longer intervals). Therefore, if staging for cervical screening occurs every three years, depending on which cervical screening strata (e.g. standard screening vs increase surveillance) a woman is in, she could be classified as being in an action stage or a relapse stage (Spencer et al. 2005).

The TTM is better used to account for frequent behaviour, especially operationalising the issue of resisting temptation (as in smoking cessation) as well as the stages from action to maintenance. A cancer detection behaviour that might be better suited to this model is breast self-examination (BSE) behaviour, which can be conducted and maintained at regular time points. Although it may be argued that cervical screening may be seen as a habitual behaviour (as women may have up to twelve routine cervical screens in their lifetime), it still requires re-engagement with the programme, booking of an appointment and having the cervical smear conducted. This would also be applicable to the potential routine introduction of HPV self-sampling as a primary screening method at infrequent intervals, similarly to the UK cervical smear and the FOBT screening programmes. Therefore, a theory that does not delineate specific staging of habitual behaviour would be better suited to understanding women's attitudes towards HPV self-sampling.

2.4 Protection Motivation Theory (PMT)

Protection motivation theory (Rogers 1975, 1983) is a model of cognitive appraisal that occurs in reaction to a health threat. The theory was originally developed to explain the effect of fear appeals on health related attitudes and behaviours and later revised to include self-efficacy and reward components. PMT proposes that cognitive appraisal is initiated by sources of information that can be environmental (e.g. verbal persuasion) or intrapersonal (e.g. prior experience). The theory stipulates that behaviour is a result of decision making processes based on the

expected consequences of engaging in behaviour and the value of those consequences. Threat appraisal in the context of HPV self-sampling can include perceived susceptibility to HPV infection and perceived severity of HPV infection. During threat appraisal, factors that increase or decrease the likelihood of a maladaptive response are appraised. Intrinsic (e.g. avoiding effort required to conduct HPV self-sampling) and extrinsic rewards (e.g. not having to wait for an appointment in G.P. surgery) are proposed as factors that facilitate maladaptive responses, whilst severity of threat and perceptions of vulnerability to threat decrease the probability of maladaptive behaviour. Factors that influence an individual's ability to cope with a threat are described as being response efficacy (beliefs about how effective a coping response would be) and self-efficacy (beliefs about whether one is capable of performing the coping response). Factors that decrease the likelihood of a coping response are costs associated with coping (e.g. embarrassment of conducting HPV self-sampling).

As shown in Figure 2.2 protection motivation for engaging in HPV self-sampling may arise as a product of high perceived severity of HPV, vulnerability to developing cervical abnormalities, response efficacy such as the belief that the HPV self-sampling test would be able to identify a problem, high self-efficacy referring to the belief that the individual is able to conduct the HPV self-sampling procedure properly, low perceptions of intrinsic/extrinsic rewards and costs such as scheduling a time to conduct HPV self-sampling.

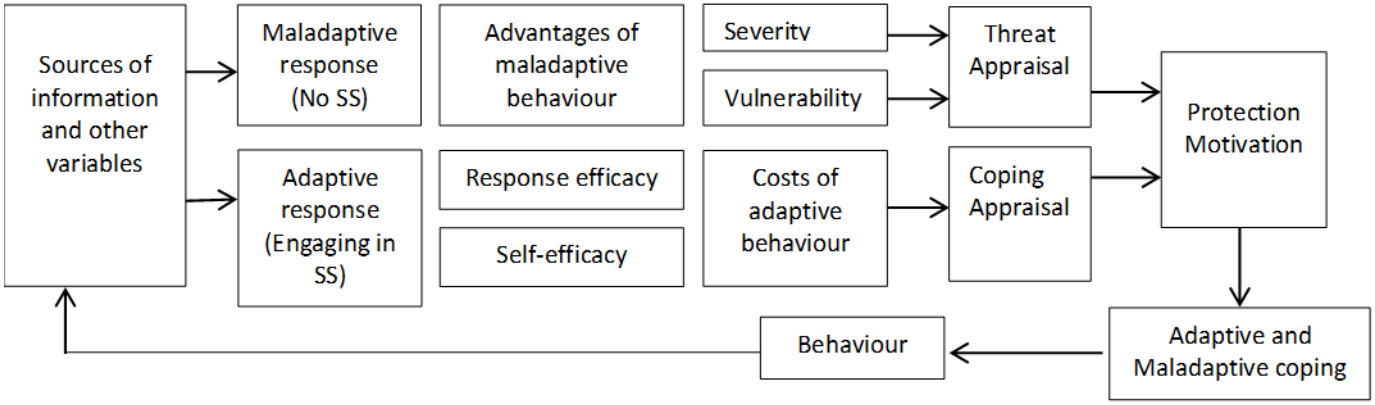

Figure 2.2 A schematic representation of PMT, applied to HPV self-sampling (SS), adapted from Boer and Sydel (1996).

A number of studies have adopted the PMT to explore uptake of cervical screening and mammography, with mixed results. A study by Orbell and Sheeran (1998) of non-responders to cervical smear tests identified perceived vulnerability, self-efficacy and response efficacy costs of adaptive behaviour as determinants of intention to engage in future cervical screening. A meta-analysis by Milne et al. (2000) of studies focusing on the effect of PMT on the prediction of health related behaviours identified that self-efficacy had the largest effect size in predicting intention. However, other studies have identified weak predictive ability for a large number of the PMT variables (Plotnikoff and Higginbotham 1998; Murgraff et al. 1999).

The PMT theory has often been criticised for its assumption of rational appraisal, although the most recent adaptation of the theory states that action may not always be determined by protection motivation and can be irrational. Action is determined by protection motivation and may not be rational as appraisals can also be biased by heuristic judgements (Michie et al. 2014). Nevertheless, the assumption behind protection motivation is a rational weighing up of threat and the costs of adaptive behaviour. Furthermore, beliefs that health-impairing behaviour is rewarding but that giving it up is costly are not fully applicable in the current context. It is difficult to describe non-uptake of cervical screening through HPV self-sampling as a rewarding behaviour, in contrast to smoking which can be described as providing a physical reward of nicotine. It is therefore likely that the PMT theory may be better able to explain addictive behaviours such as cigarette smoking and over-eating. Furthermore, the subdivision of response efficacy and self-efficacy is questionable and it has been suggested that an individual would not consider themselves as capable of performing an action if they did not have the means by which to engage in the action (Bandura 1997). Therefore, a model that accounts for the benefits and barriers of engaging in HPV self-sampling, as well as the influence of self-efficacy without differentiating response efficacy, is needed.

2.5 Social Cognitive Theory (SCT)

SCT proposes a multi-faceted causal structure for explaining health behaviour (Bandura 1997). The theory proposes that self-efficacy beliefs operate alongside goals, outcome expectations, perceived environmental impediments and facilitators in the regulation of human health behaviour (Figure 2.3). The model proposes that knowledge about health risks and benefits help create a desire for health behaviour change, but that the construct of self-efficacy is crucial in facilitating the change in behaviour. The SCT assumes that people with higher self-efficacy are better able to initiate new health behaviours and are able to place more effort into initiating and maintaining these behaviours. It has been suggested that efficacy may be influenced by previous behaviour, vicarious experience, physiological signs and receiving strong verbal persuasion (Bandura 1997). SCT also proposes that health behaviour is affected by the outcome expectations of individuals. Physical outcomes can be pleasurable or aversive effects that accompany an action (e.g. material loss), as well as social outcomes such as social approval and self-evaluative reactions.

Self-efficacy has been identified as the most influential construct on health behaviour within the SCT (Armitage and Conner 2000). Self-efficacy is highly relevant to HPV self-sampling due to the emphasis placed on the individual to conduct self-sampling independently. However, the SCT assumes that environmental changes will automatically result in changes in the individual, when this may not always be the case. Although environmental changes may help alleviate some of the barriers associated with engaging in HPV self-sampling, it may not be enough to individually modify behaviour. Furthermore, the theory does not seem to specify the nature of the dynamic between the individual, behaviour and environment, and which elements may be more influential than others. Although SCT highlights the relevance of self-efficacy to engaging in HPV self-sampling, the lack of guidance in assessing the importance and interaction between the environmental and individual factors in affecting behaviour makes it unsuitable for the study of attitudes towards HPV self-sampling. A theory that incorporates the construct of self-efficacy and provides

specific guidance regarding the way in which theoretical constructs might influence intention to HPV self-sample is needed.

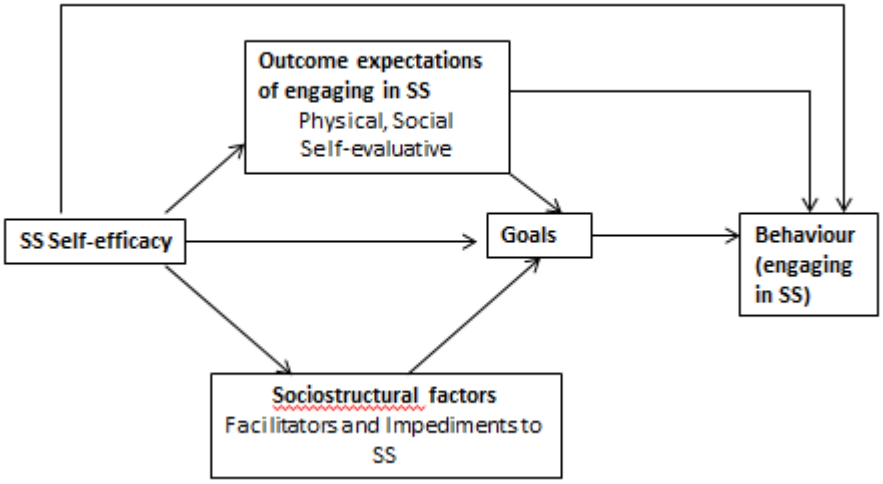

Figure 2.3: A schematic representation of the Social Cognitive Theory, applied to HPV self-sampling (SS), adopted from Bandura (2004).

2.6 The extended Health Belief Model (HBM)

The extended HBM (Rosenstock et al. 1988) was developed to predict the likelihood of an individual adopting a health behaviour and has served as one of the most widely used frameworks for examining and explaining health behaviour (Burak and Myer 1997). The extended HBM posits is that health behaviour is determined by personal beliefs about a disease and the strategies that can be adopted to protect oneself from its occurrence. The extended HBM views health behaviour change as an appraisal of the balance between the benefits and barriers attributed to engaging in health behaviour, as well as the susceptibility and severity of a health threat. The original constructs of the model were: perceived benefits, perceived barriers, perceived susceptibility and perceived severity. Each construct can be used to explain health behaviour individually or collectively. Becker and Maiman (1975) refined the extended HBM by incorporating modifying factors such as knowledge about the disease, sex and age. The extended HBM was later extended to include the concept of

self-efficacy as well as cues to action (Rosenstock et al. 1988). Applied to HPV self-sampling, self-efficacy refers to a person's beliefs about whether or not they are capable of properly conducting HPV self-sampling (Michie et al. 2014), whilst cues to action refer to any external stimuli that can motivate an individual to engage in HPV self-sampling. High perceived severity and susceptibility to HPV, low perceived barriers and high perceived benefits to HPV self-sampling increase the likelihood of engaging in HPV self-sampling. Most of the model's components are regarded as independent predictors, please refer to Figure 2.4.

Studies have generally found that the extended HBM is able to predict women's intentions to have a cervical smear test and in many cases the use of the extended HBM framework has resulted in the extraction of important information regarding participant beliefs (Burak and Myer 1997). The extended HBM has been found to predict 32% of the variance in intentions to have a cervical smear test in a sample of women aged 18-70 years (Hill et al. 1985). Other studies have reported lower prediction rates of around 27% (Henning and Knowles 1990; Burak and Myer 1997). Perceived benefits of conducting cancer screening behaviours have been identified as highly influential in predicting bowel screening uptake (Frank et al. 2004) and BSE. Other studies have identified perceived susceptibility as one of the more powerful extended HBM constructs in promoting people to engage in healthy behaviours. High perceived susceptibility has been identified as motivating individuals to engage in preventative health behaviours such as vaccination programmes (Chen et al. 2007), whilst low perceived susceptibility has been identified as a risk factor for not participating in FOBT testing (Moattar et al. 2014). As previously described (in SCT), the construct of self-efficacy has also been identified as an important predictor of engaging in health behaviour. An individual is unlikely to engage in a behaviour if they do not believe that they would be able to conduct that behaviour correctly, even if they believe they are at risk (high perceived susceptibility) and that engaging in a health behaviour is useful (high perceived benefit). For example, it has been found that women who believe that they are unable to conduct BSE are less likely to engage in the behaviour (Umeh and

Rogan-Gibson 2001). The studies described above suggest that self-efficacy, perceived susceptibility and benefits and barriers are influential in the adoption of health behaviours, and indicate that the extended HBM may be particularly suited to the investigation of HPV self-sampling intentions.

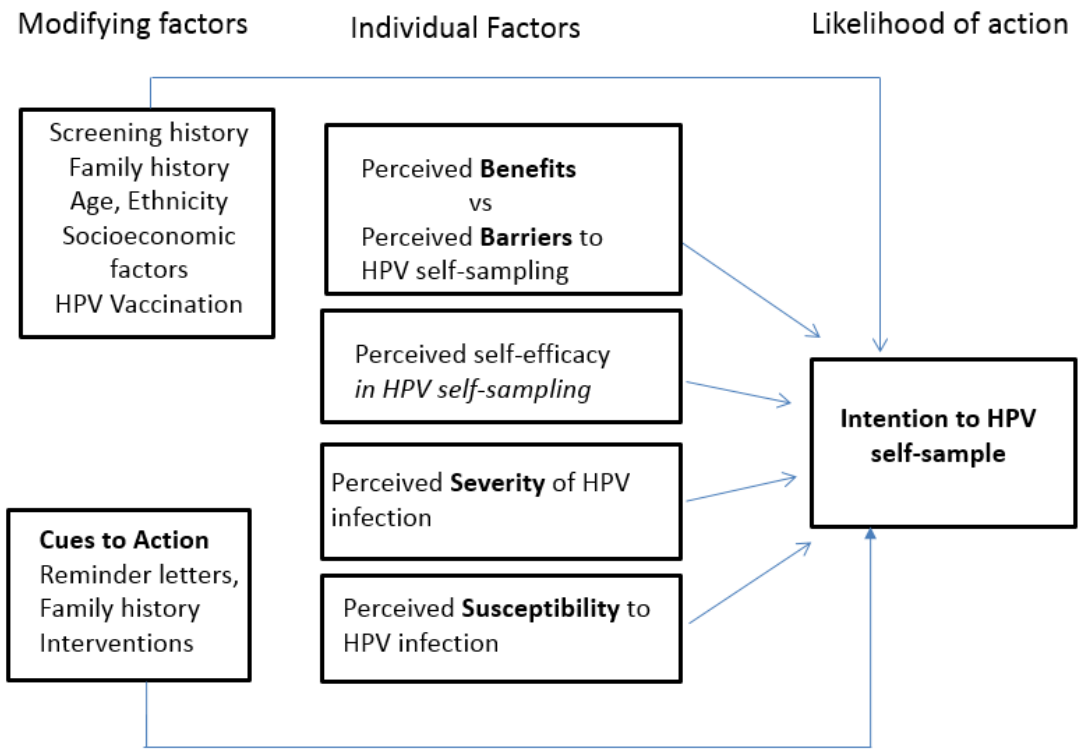

Figure 2.4: The extended HBM (Rosenstock et al. 1988) applied to HPV self-sampling.

2.7 The Theory of Reasoned Action (TRA) and Theory of Planned Behaviour (TPB)

The TPB (Ajzen 1985) is one of the most widely applied behaviour theories. The TPB is an extended version of the TRA (Fishbein and Ajzen 1975) (Figure 2.5). The TPB evolved from the TRA which proposed intention to act as the best predictor of behaviour. The TPB is differentiated from the TRA by the addition of perceived behavioural control. The TPB assumes that the immediate cognitive precursors to behaviour are not an individual's attitudes towards a particular behaviour but their behavioural intentions. Behavioural intentions are proposed to be a complex mix of prior beliefs that form attitudes towards a behaviour. According to the TPB intentions are determined by three constructs: attitudes towards a certain behaviour, perceived behavioural control and subjective norms. Attitudes refer to an individual's positive or negative evaluation of behaviour such as engaging in cervical screening. Subjective norms involve perceptions of how other people think the individual should behave, for example whether they perceive that significant others would endorse participation in HPV self-sampling. Perceived behavioural control refers to the perceptions of personal control over carrying out the particular behaviour, for example having the physical and mental capacity to collect a sample using a HPV self-sampling kit. The TPB has been used to explain both health-related and non-health related behaviours (Godin and Kok 1996).

The TPB is a value-expectancy theory and lacks the perceived benefits and barriers and susceptibility and severity constructs seen in the extended HBM, although it may be argued that the attitudinal component of the TPB partly reflects these constructs (Taylor et al. 2007). The TPB was developed to promote understanding of volitional behaviours, rather than behaviours determined by situational factors outside the individual's control, although the addition of the perceived behavioural control construct to the TPB has gone some way in counteracting this. For example, perceived behavioural control might be influenced by social positioning as well as external factors such as economic and environmental barriers to service access. PBC refers to both

internal and external constraints on control (Ajzen 1991). However, it is possible that external and internal constraints are not the same (Terry and O'Leary 1995) and therefore it is difficult to group them into one variable of PBC. Internal constraints may be classified as being close to the concept of self-efficacy (Bandura 1977), whereas external constraints are beyond the individual's control (Bish et al. 2000). A benefit to the TBP is that it provides explicit rules regarding how to combine constructs, which is not observed in other theories such as the extended HBM. Consequently, a model that can differentiate between external constraints and internal constraints on intention to engage in HPV self-sampling is needed.

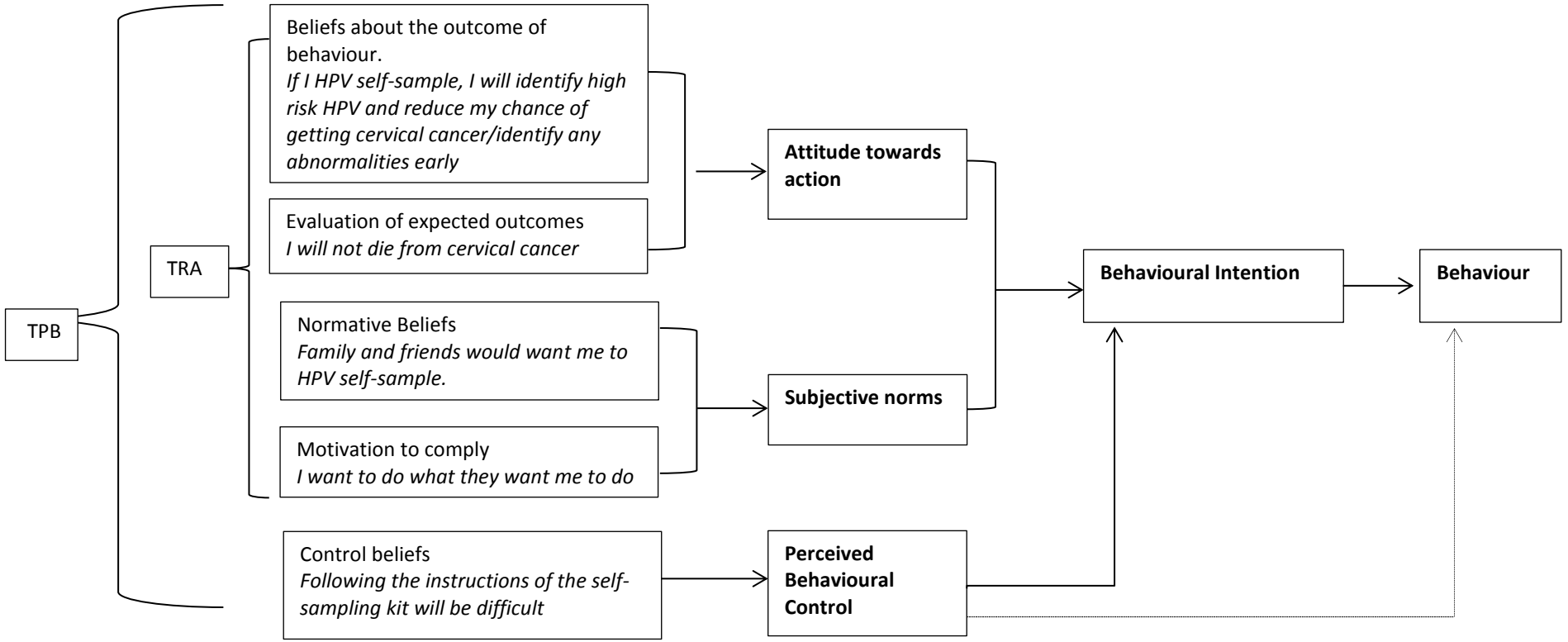

Figure 2.5: A schematic representation of the TRA and TPB applied to HPV self-sampling, adapted from Taylor et al. (2007).

2.8 Chosen theoretical approach to understanding HPV self-sampling

The theories and models of health-related behaviour described in this chapter postulate that health beliefs play a major role in explaining and determining intention to HPV self-sample. To aid the understanding of women's attitudes towards HPV self-sampling, a theoretical approach that incorporates the concept of self-efficacy without differentiating response efficacy, includes individual perceptions of benefits and barriers to HPV self-sampling, and that differentiates between internal and external constraints is needed. The model that is able to incorporate these factors is the extended Health Belief Model (HBM) (Rosenstock et al. 1988). The extended HBM was also chosen over other theoretical frameworks because of its proven relevance to preventative health behaviour, such as participation in screening programmes (Brewer and Fazekas 2007). With the foundations of the extended HBM in value-expectancy theories, it is primarily a cognitive approach which posits that individuals will engage in preventive health behaviour if they believe themselves to be threatened by an illness and if they believe that the benefits of taking action will outweigh the barriers or costs of that action (Rosenstock 1974). More recently, the extended HBM has also been used to understand health service utilisation and engaging in health behaviour such as cervical and FOBT screening. The extended HBM has been criticised for a lack of clear definition of individual constructs and a lack of clear combinational guidance of extended HBM constructs (Armitage and Conner 2000). Therefore, the extended HBM can be regarded as a descriptive model that is suitable for exploring new health behaviours such as HPV self-sampling. The constructs underlying the extended HBM and their relevance to HPV self-sampling will be discussed in further detail below.

2.8.1 Perceived susceptibility and perceived severity

Although perceived severity might often be attributed to medical knowledge, it may also be formed from beliefs that an individual has about the difficulties a disease may cause to their life, as well as past experiences formed from significant others or media portrayal. For example, women with a family member or relative who has been treated for low grade cervical abnormalities, and who has recovered quickly and well following treatment, may perceive cervical abnormalities as a health threat that is easily treated with minimum disruption to their life. Conversely, an individual with a family member who has been diagnosed with high grade cervical abnormalities and has had extensive treatment and has taken a long time to recover and return to normal daily function might have a different perception of the severity of the illness. The belief that screening could reduce 'susceptibility' and 'severity' of bowel cancer has been found to be influential in uptake of FOBT self-sampling (Brouse et al, 2003). However, it has also been suggested that perceived severity might not be as important as perceived susceptibility in influencing the adoption of health protective behaviour (Bandura 1997).

Perceived susceptibility has been described as a powerful influence in promoting the adoption of healthy behaviour. Higher perceived susceptibility has been significantly associated with increased uptake of screening behaviours such as cervical smear tests (Nadarzynski et al. 2012) and preventative health behaviours such as hepatitis B vaccination (deWit et al. 2005), and the use of condoms to decrease HIV infection (Belcher et al. 2005). Perceived susceptibility has also been shown to motivate individuals to engage in health behaviours such as influenza vaccination (Chen et al. 2007), sunscreen use for the prevention of cancer, and teeth flossing for prevention of gum disease (Hayden 2014). Conversely, it has been reported that older women who might perceive themselves as less susceptible to cervical cancer are less likely to engage in cervical smear testing (Cervical Screening Wales 2013-2014). Although the

perception of increased susceptibility has often been associated with healthier behaviour and decreased susceptibility with unhealthy behaviour, this is not always the case, especially in young individuals. It has been found that the perception of susceptibility has rarely been associated with health behaviour such as sun exposure in university students even when perception of susceptibility is high (Lamanna 2004). Similar findings have been reported in research in unsafe sex behaviour (Belcher et al. 2005). For example, it has been found that students who report a high perceived susceptibility to HIV infection are not more likely to practice safe sex behaviour, than those who report a lower perceived susceptibility (Lewis and Malow 1997). These findings should be considered as HPV self-sampling would involve women from a wide age range.

2.8.2 Perceived Barriers and Benefits

According to the extended HBM, likelihood of action can be influenced by an individual's perceptions of benefits and barriers associated with HPV self-sampling. In fact, one of the most recent and comprehensive meta-analyses (Carpenter 2010) of the extended HBM's effectiveness in predicting behaviour concluded that perceived barriers and perceived benefits were consistently the strongest predictors of screening behaviour. Perceived benefits are particularly important in the adoption of secondary prevention behaviours such as engaging in cervical screening (Glanz et al. 2008). Perceived barriers refer to an individual's own interpretation of the challenges associated in adopting a healthy behaviour. In order for a healthy behaviour to be adopted, the individual has to believe that the benefits of the new behaviour outweigh the benefits of continuing old behaviour and the barriers associated with the new behaviour. When applied to FOBT, Moattar et al. (2014) found that cost and motivation in terms of perceived barriers to screening, such as lack of time and symptoms of colorectal cancer in FOBT screening, and perceived benefits to screening are key predictors of participation in FOBT. Furthermore, Davis et al (2014) identified that

complex health literacy interventions designed to overcome key FOBT related barriers, such as access to tests, lack of recommendation, negative beliefs, poor self-efficacy and complexity of independently completing the test, are useful in increasing FOBT uptake.

2.8.3 Cues to action

Cues to action are any environmental or personal cues that may facilitate an individual to engage in health protective behaviour such as HPV self-sampling. Cues to action may be system-related such as reminder letters, social such as normative pressures from significant others to engage in screening or they could be specific interventions designed to promote uptake of screening. Cues to action that have utilised the extended HBM in the form of interventions for increasing uptake of FOBT self-sampling will be discussed later in this chapter. The extended HBM model has been used to guide development of health interventions, which can act as cues to action (Rosenstock et al. 1988). For example, interventions based on the extended HBM have been used as cues to action in enhancing uptake of colorectal cancer screening (Davis et al. 2014; Moattar et al. 2014).

2.8.4 Self-efficacy

Expectations of self-efficacy are self-regulatory cognitions that determine whether instrumental actions will be initiated, how much effort will be expended and how long it will be sustained in the face of obstacles (Bandura 1977, 1997). Self-efficacy beliefs are considered to be one of the most powerful predictors of health behaviour (Rosenstock et al. 1988; Schwarzer and Fuchs 1996) and have been shown to predict uptake of FOBT self-sampling (Brouse et al. 2003), cervical smear screening (Fernandez et al. 2009) and breast self-examination (Chalmers and Luker 1996; Norman and Brain 2005). It has been argued that a conceptual distinction can be made between feelings of confidence in one's ability to perform a behaviour (self-efficacy) and the perception

of barriers towards that behaviour (Rosentstock et al. 1988). Perceived self-efficacy is highly relevant to HPV self-sampling because of the emphasis placed on women's ability to carry out the succession of actions involved in self-sampling.

Individuals with high self-efficacy beliefs about a task call on these beliefs and abilities to engage in the behaviour (Bandura and Adams 1977; Manne et al. 2006). For example, individuals who believe that they will be able to perform a task and that the behaviour will lead to a favourable outcome, are considered likely to be more strongly motivated, set themselves higher goals and to have the strength to carry out the act than those with low self-efficacy beliefs (Bandura 1997). Self-efficacy has been shown to be highly influential in influencing engagement in preventative health behaviours, such as cervical smear testing (Fernandez et al. 2009), breast self-examination (BSE) (Chalmers and Luker 1996) and FOBT (Brouse et al. 2003).

2.8.5 Trait and state self-efficacy

It has been suggested that self-efficacy can exist as both as a transient state and a generalised trait. Self-efficacy as a state can be defined as the individual's belief that they can achieve required performance for a specific task e.g. HPV self-sampling. When considered as a trait, self-efficacy can be defined as one's belief in their overall competence to achieve required performance across different situations. Generalised trait self-efficacy can affect the susceptibility of external influences on specific state self-efficacy, for example an individual with high trait self-efficacy may be less worried about conducting HPV self-sampling incorrectly than someone who holds low trait self-efficacy. However, trait self-efficacy alone has been found to poor at predict behaviour (Bandura 1997). Therefore, a relationship between generalised traits and task specific self-efficacy has been suggested (Chen et al. 2000).

It seems likely that self-efficacy encompasses a general state-like self-efficacy belief accompanied with a task-specific self-efficacy belief. Bandura (1997) claimed that trait

self-efficacy measures *"bear little or no relation either to efficacy beliefs related to particular activity domains or behaviour"* (p.42). Bandura's original self-efficacy concept referred to one's belief that one can perform a behaviour-specific task. Therefore, for the purposes of this PhD research, self-efficacy will be regarded as a specific state and not a generalised trait.

Investigating the way in which state self-efficacy influences an individual's intentions to HPV self-sample will help further our understanding of the contributory factors associated with HPV self-sampling, and inform the development of key messages to be used in a future HPV self-sampling intervention. As a psychological state, it is likely that there are many components to perceived self-efficacy when relating to HPV self-sampling. These may include previous experience with other self-sampling technologies, previous experience with cervical screening, a general sense of ability to carry out the procedure, and motivation for accomplishment of the self-sampling task. Due to the behaviour specific nature of perceived self-efficacy, specific questions need to be developed to investigate it (Bandura 1977). Furthermore, specific techniques such as vicarious experience and social persuasion (Bandura 1998) can be devised and incorporated into a HPV self-sampling intervention to facilitate and improve perceived self-efficacy if it is identified as a barrier.

2.9 Summary

This chapter has presented a rationale for the use of theory in this PhD research study. Different health behaviour models and theories have been outlined and critiqued. The utility of the extended HBM in exploring women's attitudes towards HPV self-sampling has been highlighted and a justification for the use of the extended HBM has been presented. The extended HBM has been found particularly useful when studying screening behaviour such as cervical screening (Barata et al. 2008) and FOBT self-sampling (Moattar et al. 2014). The extended HBM has also been able to account for a

relatively high amount of variance in attitudes towards cervical screening (Burak and Myer 1997), although it has been criticised for a lack of combinational rules (Armitage and Conner 2000). The extended HBM has traditionally been used as an exploratory model to assess why people do not use preventive health services (e.g. cervical screening) and eventually to understand why people use or fail to use other health services in general (Becker 1974). The extended HBM has provided the theoretical framework for many studies examining a variety of health behaviours such as breast self-examination (Sensiba and Stewart 1995; Norman and Brain 2010), condom use (Hiltabiddle 1996), diabetes self-care (Pham et al. 1996) and needle practices for HIV (Falck et al. 1995), and most importantly cervical smear testing and FOBT self-sampling (Moattar et al. 2014).

The extended HBM will be used throughout the study to help inform and structure both quantitative and qualitative methods, which will be used to quantify and explore women's attitudes towards primary HPV self-sampling. The extended HBM and the results from the mixed methods used throughout the phases of this PhD research will be used to inform the content of a HPV self-sampling intervention.

2.10 PhD study phases and the use of the extended HBM

Phase one of the research utilised survey data. The extended HBM will be used to structure the survey to explore potential barriers and facilitators to HPV self-sampling. The survey will facilitate the collection of large amounts of data in a short period of time, as well as the identification and quantification of key determinants of HPV self-sampling intention. Furthermore, results obtained from the survey will facilitate testing of the utility of the extended HBM. Traditionally, survey methods limit respondents to pre-set responses and although useful for the quantification of key determinants of HPV self-sampling intention, they cannot explore the way identified determinants affect intention.

The second phase of the research will facilitate the further exploration of the extended HBM constructs and the opportunity for the identification of new influences through the use of semi-structured interviews. Interviews will be conducted according to an interview schedule that will explore the HBM determinants identified in the survey phase, and provide the opportunity for the extrapolation of new unidentified determinants. Interviews are particularly useful for the study of complex and sensitive data, and enable the study of a small number of participants in depth. The use of mixed-methods in phase 1 and 2 will combine the strengths of quantitative and qualitative methods to help understand women's intentions to HPV self-sample.

Phase three will involve the synthesis of findings generated from phase one and phase two to inform the content of an intervention designed to increase intention to HPV self-sample by addressing identified determinants of self-sampling. Phase three will also involve the pilot testing of the intervention. The intervention will be based on the extended HBM and will consist of the 'active ingredients' identified through the mixed methods approach (Craig et al. 2008). The theoretical basis will also be useful in informing and measuring the effects of the intervention during user testing (Craig et al. 2008). The user testing will utilise a mixed methodology: short pre and post intervention surveys and interviews. The surveys will be used to identify a potential change in knowledge and intention to self-sample following intervention exposure. Qualitative interviews will be used to explore perceptions of the intervention, to understand what part/s of the intervention had the most effect on intention to self-sample, and to identify areas for improvement.

The following chapter will describe the development and preliminary validity testing of the theoretically based phase one quantitative survey.

CHAPTER 3

Development and preliminary validation of a survey to investigate women's intentions to HPV self-sample.

3.1 Chapter overview

The current chapter describes the development of survey measures used to investigate women's attitudes and intentions to HPV self-sample. Methods used to develop survey measures that included a literature search, development of initial survey items, content validity analysis, and cognitive interviewing will be discussed.

3.2 Introduction

The lack of evidence regarding women's intentions to engage in primary HPV self-sampling, and the limited information about the HPV self-sampling perceptions of women from the general population, was presented in Chapter 1. It was important that intentions to HPV self-sample in women from a general population were investigated because of the possibility of primary HPV self-sampling in the future. To aid understanding of HPV self-sampling intentions, the constructs of the extended Health Belief Model (HBM) were operationalised in the development of a survey.

The constructs of interest in the survey were the core HBM constructs: perceived severity, perceived susceptibility, perceived benefits and barriers to HPV self-sampling and cervical screening, and the concept of self-efficacy. Measurement of the extended HBM constructs and intention to HPV self-sample is complex because constructs are ambiguous in nature and open to differential interpretation. Nevertheless, surveys form an important method of data collection for the social sciences and have been extensively used (Grant and Davis 1997). Preliminary validity and reliability of the

survey were explored. Validity refers to whether the survey items actually measure the constructs that they are intended to measure (Kline 2005). Reliability refers to the extent to which scores are free from random error, therefore the extent to which scores are precise, consistent and repeatable (Kline 2005). The adequacy of construct definition and measurement in the survey is critical because there is no overall agreement on what is meant by HBM constructs (Kline 2005). Poor construct definition and measurement may elicit responses that are not representative of the construct. Furthermore, if the construct definitions and measures used in the survey are not clearly defined, the survey results will be less likely to detect the hypothesised relationships between extended HBM constructs and intention to HPV self-sample. Data from an invalid instrument can over-represent, underrepresent or even omit notions of the construct in question (Haynes et al. 1995). Exploration of the survey validity is presented in this chapter, whilst validity assessment is presented in Chapter 4. The development of the survey measures as well as the methods used to investigate construct validity and face validity will be presented below.

3.3 Content validity

It was imperative that the extended HBM constructs were represented as clearly and fully as possible, because survey responses were to be subsequently used in structuring the phase two interview schedule and shaping the HPV self-sampling intervention. Content validity is a form of construct validity that refers to the degree to which survey items represent the intended constructs, in this context the extended HBM and intention constructs, as well as HPV knowledge (Pallant 2007). This was examined using content validity analysis. Content validity analysis is a consensus estimate (Stemler 2004) that examines the extent to which experts share a common interpretation of a construct, and are able to agree on how to apply the rating scale to the items (Polit et al. 2007). In the current context, the aim of content validity analysis was to establish the extent to which the components of the survey were relevant to and representative

of core HBM constructs: perceived benefits, perceived barriers, perceived susceptibility, perceived severity and perceived self-efficacy. Knowledge and intention constructs were also validated through content validity analysis. Specific objectives were to assess the relevance of survey items to the construct specified and function of the survey, and to examine the representativeness of survey items in reflecting and measuring all facets of a construct.

3.4 Face validity

Following content validation, the face validity of survey items was assessed using cognitive interviewing techniques to investigate whether participants interpreted the items as intended, and whether the items were easily understood and accessible (Davis and DeMaio 1993). The use of cognitive interviewing as a means of investigating face validity in surveys has become increasingly popular (Willis 1999). The cognitive interview can be used to evaluate sources of response error in a participant's understanding of items and/or response categories, to facilitate understanding of how participants interpret survey items and what mental processes they engage in to answer each item. It was anticipated that the use of cognitive interviewing in survey modification would improve uptake and completion of the subsequent HPV self-sampling survey.

Although there are various cognitive theory models (Jobe and Herrmann 1996), Tourangeau (1984) model is most commonly used in cognitive interviewing and was used in the current study. The model consists of four processes:

1. Question comprehension: what the participants believe the question is asking and what certain phrases may mean to different participants.
2. Information retrieval: the types of information that participants need to recall and the strategies that they use to elicit that information.

3. Decisional processes: the amount of effort devoted by the participants so that they can answer particular questions and whether social desirability may have an effect on their answers.
4. Response processes: whether the participants are able to match their internally generated answer to the response categories provided by the survey.

Think aloud and verbal probing methods are traditionally used in cognitive interviewing. The think aloud method explicitly instructs participants to articulate their thoughts and feelings as they answer each question and map their answer onto the response categories provided (Fonteyn et al. 1993; Charters 2003). Verbal probing involves asking specific 'probes' for each item to assess each of the four processes as described above by Tourangeau (1984).

3.5 Aims and objectives

The aims of the current phase of research were to develop a psychometrically sound tool to examine the effects of extended HBM constructs on women's intentions to HPV self-sample, and to inform the content of the subsequent interview topics. Specific objectives were: 1) to examine previous literature in order to identify whether a survey based on the extended HBM has been developed to investigate HPV self-sampling intention, 2) to develop theoretically based survey items to identify determinants of women's intentions to HPV self-sample, and 3) to perform preliminary validation of the developed survey items.

The methods and results of the literature search, development of initial survey items, content validity analysis, and cognitive interviewing are presented below.

3.6 Literature search: Identifying previous HBM based HPV self-sampling surveys

Two literature searches were conducted to identify whether any previous studies had utilised the extended HBM in understanding women's intentions to HPV self-sample,

and whether a survey had been used to do this. An initial literature search was conducted in October 2010 prior to survey development, and a supplementary replica search in 2012 to identify any new studies.

3.7 Methods

Search Strategy and Inclusion Criteria

Six electronic databases were searched: PsychInfo, PubMed, Web of Knowledge, CINAHL, EMBASE and SCOPUS. No date restrictions were imposed, however it was specified that the articles must be presented in English. Search strategies combined the following free text search terms and were specifically limited to article title and abstract: Health Belief Model, HBM, Human Papillomavirus, HPV, self-sampling, home testing. Follow-up searching by hand was conducted by scanning the reference lists of identified papers. Key inclusion criteria were: (i) participants were female, (ii) the study focus was on HPV self-sampling, (iii) the study utilised the extended HBM in its material development, (iv) the study investigated attitudes or behaviour. Studies which involved male participants, that were laboratory based or that focused on HPV vaccination were excluded.

Study Identification

Identified study titles and abstracts were screened for relevance. Study bibliographies were also searched. Full texts of potentially relevant studies were evaluated. Data were extracted regarding study design and context, participant characteristics, theoretical framework used, and study findings.

3.8 Results

Electronic searches in 2010 yielded eighteen studies. Following removal of duplicate studies, four studies were identified (Burak and Myer 1997; Barata et al. 2008; Marlow et al. 2009; Reiter et al. 2009). These four studies underwent data extraction to aid identification of relevant studies (please refer to Appendix 3.2). One study (Barata et al. 2008) out of the four met inclusion criteria. The studies that did not meet inclusion criteria focused on HPV vaccination (Marlow et al. 2009) and cytology (Burak and Myer 1997; Reiter et al. 2009). The supplementary search in 2012 yielded 108 studies. Following removal of duplicate references (n=78), 30 studies were identified and underwent data extraction. One out of the thirty studies met the inclusion criteria, and was the study originally identified in 2010 (Barata et al. 2008).

The qualitative study by Barata et al (2008) used HBM constructs to develop an interview topic guide for discussions with women about HPV self-sampling. The study identified barriers such as low HPV knowledge, the belief that HPV self-sampling is unsafe, and the perception that HPV self-sampling is not as accurate as cervical smear testing. Benefits identified included convenience and a reduction of cultural taboos associated with cervical smear testing. It was found that themes identified were able to map onto the HBM. However, the population sampled were women from Canada, where the health system and cervical screening recommendations are different to those in Wales: at the time the literature search was conducted, onset of screening age was 20 years in Wales as opposed to 25 years in Canada. These differences may have affected the way the way in which the HBM based topic guide was developed and executed in the focus groups, and may have influenced the perceptions of women regarding HPV self-sampling and cervical screening in general.

The literature search results and identification of only one qualitative study confirmed the need to develop a new scale based on the extended HBM constructs in order to investigate women's intentions to HPV self-sample.

3.9 Development of initial survey items

Hypothetical HPV self-sampling intention, the constructs of the extended HBM, HPV knowledge and cervical screening history were operationalised for the development of *a priori* survey items. Items reflecting benefits and barriers were constructed by identifying benefits and barriers to HPV self-sampling and cervical screening reported in previous studies (Chapter 1). Conceptual definitions of the extended HBM constructs were developed. Items were developed to assess each construct and response categories were created. The number of items needed to investigate each construct was determined by whether the construct was defined as being unitary or multiple. A multiple construct required a number of different items to assess each multiple aspect. It was crucial that the constructs were clearly operationalised, because imperfections within a construct definition can result in deficiency or contamination of survey items and/or response formats during development.

Women's intentions to HPV self-sample are influenced by their attitudes towards HPV self-sampling. Attitudes are by nature continuous tendencies defined as "a psychological tendency that is expressed by evaluating a particular entity with some degree of favour or disfavour" (Eagly and Chaiken 1993). Therefore, a continuous response measurement scale was needed to measure women's attitudes to HPV self-sampling. The process of filling out a survey has been shown to be 'reactive' (French and Sutton 2010b). Reactive refers to the notion that survey items often pose opportunity for personal reflection of past experiences and actions, which in turn can affect thoughts about self-sampling and predicted behaviour. Therefore, it was important that issues such as measurement reactivity (French and Sutton 2010b) and question framing were considered during the development of the initial HBM-HPV survey because they can affect responses. For example, positively framed questions

are more likely to elicit positive attitudes, whilst negatively framed questions are more likely to elicit negative attitudes (French and Sutton 2010a). Items were framed neutrally to try and avoid effects of item framing on reported intentions to self-sample. Likert scales ranging from 1 (not at all likely) to 5 (very likely) were used in line with Likert scale development guidelines (Kline, 2005). This was done to encourage the participants to 'lean' towards either a positive or negative attitude, without pre-defining an 'undecided' response. Survey items examining past screening history and sociodemographic details were explored through categorical items and response formats (Streiner and Norman 2008).

A free text box was included in the HPV self-sampling section to encourage comments from participants, with the aim of discovering any new considerations/issues regarding HPV self-sampling. The items pertaining to cervical screening history and attitudes towards cervical screening were included to enable categorisation of participants according to their previous screening history and attitudes towards cervical screening. This facilitated the comparison of women's attitudes and intention towards HPV self-sampling and their attitudes towards and past utilisation of cervical screening.

Table 3.1 displays construct definitions which were used to develop *a priori* survey items designed to measure HPV self-sampling intention and extended HBM constructs applied to HPV and cervical cancer. The initial survey is shown in Appendix 3.3. The first page provided information about HPV self-sampling and instructed women on how self-sampling would need to be conducted. Subsequent pages contained items divided into four sections: intentions and attitudes towards HPV self-sampling, HPV knowledge, thoughts about cervical cancer, experiences of cervical screening and cervical cancer, demographic details. Intention to HPV self-sample was the first item on the survey in order to minimise measurement reactivity and order effects. Measurement reactivity and order effects have been shown to influence emotional responses to questions concerning the prospect of future disease (e.g. HPV infection or cervical cancer) (Schwarz 1999), which might alter intention to HPV self-sample.

Construct	Definition	Unitary or Multiple	Number of items	Initial Item/s
Intention to HPV self-sample	The overall predicted intention to HPV self-sample (hypothetical)	Unitary: hypothetical intention to HPV self-sample	1	Overall, how likely do you think that you would be to use a home testing kit?
Perceived severity	Perception of severity of HPV infection or cervical cancer	Unitary: severity of HPV	1	How serious of an infection do you think HPV is?
Self-efficacy	A belief regarding one's ability to exert effective control over behaviours associated with self-sampling.	Multiple: succession of actions needed to carry out self-sampling	6	How sure are you that doing the test yourself will provide accurate results? How sure are you that you will be able to understand the instructions provided in the home test kit? How sure are you that you will be able to carry out the sampling procedure (placing swab in vagina)? How sure are you that you will be able to place the swab into the tube containing the special liquid without touching or dropping the swab? How sure are you that you will be able to send off the completed test within the time allowed (2 weeks)? How sure are you that your completed test kit will be good enough for testing?

Perceived susceptibility	Perception of comparative personal susceptibility of HPV infection.	Unitary: likelihood of infection with HPV	1	How likely do you think you are to be infected with HPV?
Perceived benefits	Beliefs about the benefits associated with self-sampling.	Multiple: benefits identified from previous studies (Barata et al. 2008a; Szarewski et al. 2009b)	4	Using a home kit is convenient, as it can be done at home I would not have to take time off work/arrange childcare. Using a home kit can help make sure no-one will know that I am being screened for cervical cancer. Using a home kit is less embarrassing than having a GP or nurse carrying out a smear test. Using a home kit seems less painful than a smear test.
Perceived barriers	Beliefs about the barriers associated with self-sampling.	Multiple: multiple barriers identified from previous studies (Barata et al. 2008a) (Szarewski et al. 2009b)	2	I wouldn't trust the results of the home kit. I am worried that I may hurt myself using the home kit.
Cues to action	External event that prompts a desire to make a health decision: whether to attend smear testing.	Unitary: a reminder to attend screening is sent automatically through Cervical Screening Wales. This was used as a reference point.	1	The three yearly reminders I get help me remember to attend my cervical screening appointments.

Table 3.1: HBM construct definitions and *a priori* items

3.10 Content validity analysis

The content validity of individual survey items was examined in order to establish the extent to which each item measured the intended construct (Hyrkas et al. 2003). Experts were asked to review item content, with the purpose of eliminating irrelevant items (Chaiyawat and Brown 2000), re-phrasing or supplying new wording for the items representing relevant constructs (Hughes 1998; Aminzadeh et al. 1999).

3.10.1 Methods

Content validity analysis materials

A content validity analysis (CVA) protocol was developed and was sent to expert participants (see Appendix 3.4). The protocol was divided into various sections: an explanation of the purpose of the survey, a definition of CVA and the steps that the method entailed, a description of participant eligibility and definition of the survey constructs that needed to be evaluated. Instructions on how to carry out CVA and a CVA score card were also included (Appendix 3.4).

Recruitment of content experts

Experts were purposively recruited based on their expertise in health behaviour measurement. Some participants were directly e-mailed asking if they would serve as a content expert, whilst others were recruited through a general mailshot to all researchers in the Institute of Primary Care and Public at Cardiff University. Further input from an individual with clinical expertise in HPV and cervical screening was sought.

3.10.2 Rating

A priori items were rated by the content experts in relation to their relevance to and representativeness of operationalised constructs. Each rater independently scored each of the items in the HPV self-sampling survey (items QV1 to QV27, with the exception of Q9 which was a free text question). Items 28-31 were excluded from the content validity analysis because they were items about demographic details. Scoring took place according to the following criteria:

> **Relevance**: the appropriateness of the items in relation to both the construct and the function of the survey
>
> **Representativeness**: whether the items covered a representative sample of the construct.

Raters were instructed to score each item on a scale of 1 to 4 for relevance and representativeness, respectively (where 1 = poor relevance/representativeness and 4 = very good relevance/representativeness). Raters were also asked to provide free text comments, particularly if they gave a score of less than 3 to any item.

3.10.3 Analysis

The content validity index for each item was calculated as the percentage of raters who gave a high score in terms of relevance and representativeness. For each item, the number of raters giving a rating of 3 or 4 for relevance or representativeness was calculated. This was then divided by the total number of raters to give a content validity index for relevance and representativeness, respectively. As there is no universally agreed threshold for defining adequate content validity, content validity was considered to be adequate if the index was greater than 78% (Schwarzer and Fuchs 1996). This is a level at which chance agreement is unlikely to explain a high score (Schwarzer and Fuchs 1996).

If the content validity was less than 78% for any of the items on any dimension, the following were considered: 1) whether the item was not sufficiently comprehensive to collect data on the construct, 2) whether the item measured constructs other than the one of interest, 3) whether the item should be removed, 4) whether further items were needed, 5) free text data provided by the experts. Free text data were used to help re-phrase items that scored under 78%. Additionally, items that scored over 78% but received substantial critique in the free text comments section were also re-evaluated.

3.10.4 Results

A total of nine experts were recruited: eight with expertise in health psychology and healthcare research, and one with clinical expertise on HPV and cervical screening.

Nine out of thirty four items had scores of 78% or less on either the representativeness or relevance dimensions (see Appendix 3.5 for individual item scores and Appendix 3.6 for all rater comments). As summarised in Table 3.2, three items were removed and eight items were added. The usefulness of the item *'Do you think that HPV can clear up by itself'* was questioned by reviewers. However, it was decided that this item would be retained and examined in the cognitive interview phase of validation. Table 3.2 presents the main item modifications.

Items removed	Items added	Item retained for further cognitive testing
1. How sure are you that you will be able to understand the instructions provided in the home test kit? *(Self-efficacy)* 2. How sure are you that your completed test kit will be good enough for testing? *(Self-efficacy)* 3. Using a home kit seems less painful than a smear test. *(Perceived benefits to SS)*	1. I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory. *(Perceived barrier to SS)* 2. Having a smear test is painful. *(Perceived barrier to smear test)* 3. Going for smear tests can be difficult because I have to make arrangements (e.g. time off work, childcare). *(Perceived barrier to smear test)* 4. Going for smear tests provides me with reassurance. *(Perceived benefit to smear test)* 5. I trust the GP/nurse to take an adequate sample. *(Trust)* 6. I worry about my sample getting lost. *(Perceived barrier to smear test)* 7. I don't trust the results of the smear test. *(Perceived barrier)* 8. I worry that others (e.g. family members, friends, people at the GP surgery) will know that I am being screened for cervical cancer. *(Perceived barrier to smear test)*	1. Do you think that HPV can clear up by itself? *(Perceived severity of HPV infection)*

N.B. The construct each item was intended to measure is shown in brackets and italics

Table 3.2: Modifications made to the survey following CVA

3.11 Cognitive interviewing

Establishing the face validity of the survey was an essential step following content validity analysis. It was imperative that face validity was investigated to help ensure that items were easily and correctly understood by participants and that the format was accessible. The number of cognitive processes investigated in each item depended on the complexity of that item (Tourangeau, 1984). Trivial questions such as *'Have you ever had a smear test'* necessitated the investigation of fewer processes, whilst non-trivial questions such *as 'I expect that I would use a self-sampling kit for HPV?'* required investigation of multiple processes.

3.11.1 Methods

Prior to recruitment for cognitive interviewing during 2012, approvals were obtained from the South East Wales Research Ethics Committee and Public Health Wales Risk Review Committee for Research and Development.

Participant recruitment

Women resident in Cardiff or Newport were targeted for recruitment because it was considered important that the women participating in the cognitive interviews were from the same geographical area as the women who were to receive the survey.

Three recruitment strategies were utilised:
1. An e-mail campaign was targeted at female administrative staff at the School of Medicine in Cardiff University in order to reduce the likelihood of prior exposure to cognitive interviewing or survey development. Potential participants were sent a recruitment e-mail asking if they would be interested in taking part in an interview study looking at the usability of a recently developed survey. Women who were interested in taking part in the cognitive interviews contacted the researcher directly

via e-mail. Women who expressed interest were e-mailed a participant information sheet and consent form. If participants were happy to take part in the study, a suitable time and location was arranged. All interviews were conducted at Cardiff University.
2. Female administrative staff at Cardiff City Football Club. Women were alerted to the study by their line manager a day before the researcher visited the Club. Potential participants were provided with an information sheet and consent form. The researcher visited the club and explained the study in further detail to potential participants. Participants who were happy to participate were interviewed individually at the football club.
3. Snowball sampling of participants identified through participants from Cardiff City Football Club as well as researcher contacts.

Consent process

Potential participants who expressed an interest in the cognitive interviewing study were given a participant information sheet and consent form (see Appendix 3.8). Women read the information sheet in their own time and had opportunity to ask questions. Women were reassured that participation was voluntary, that they could withdraw from the interview at any point without providing a reason, and that their participation would have no effect on their future healthcare.

Cognitive interview process

A structured pre-interview phase was conducted to ensure that participants were aware that 'think aloud' and verbal probing cognitive interviewing techniques were going to be applied throughout the interview, and to minimise bias in the way that participants examined and reported on items. The interviewer explained how the interview was going to be conducted and outlined the reasons why participants were being asked to 'think aloud', using a standard operating procedures document (SOP)

for each interview. The SOP outlined a series of steps that were to be conducted (Appendix 3.8). The think aloud and verbal probing techniques were discussed during the SOP with participants. Participants were encouraged to report out loud their thoughts when answering survey items. The interviewer then provided an example of how someone may 'think aloud'. Participants were made to feel as comfortable as possible during the cognitive interview, in order to encourage open and honest discussion of the survey items.

The main phase of cognitive interviewing was structured according to a pre-defined interview schedule (Appendix 3.10). Interviews lasted between 20 minutes and 1 hour. A concurrent probing technique was applied and the interview schedule was developed following guidance on cognitive interviewing (Willis 1999). The interview schedule explored the participants' cognitive processes relating to item comprehension and how participants reached their answers. Participants were provided with the survey and were instructed to read each item individually and answer it by mapping their answer onto the response categories provided. Participants were encouraged to think aloud at the time of reading and answering the item. Once the item was answered, participants' responses were explored using the probes. Specific probe questions (Appendix 3.10) were used throughout the interview schedule to assess how participants interpreted the questions and what mental processes were engaged to answer them (Davis and DeMaio 1993).

Informal discussions with Cervical Screening Wales were conducted during the cognitive interview phase and suggested revisions to survey items were also incorporated.

3.11.2 Analysis

A thematic analysis approach was applied (Braun and Clarke 2006) which focused on characterising the reasons why participants had identified items or response categories as problematic to answer. The term 'problematic' refers to a difficulty in understanding an item, difficulty in answering an item in general, or difficulty in mapping response to the response scale/categories provided. Following coding of all transcripts, codes were grouped together into overarching themes.

3.11.3 Results

Sample characteristics

Of a total ten participants recruited for cognitive interviewing, two were from the School of Medicine in Cardiff University, five from Cardiff City Football Club, and three from snowball sampling. Please refer to Table 3.3 for participant characteristics.

Participant no	Age	Highest Educational Level	Own home	Ethnicity	Recruitment Source
1	39	A level or equivalent	Yes	Welsh	Cardiff University
2	26	Degree	No	Welsh	Cardiff University
3	29	GCSE or O level	Yes	Welsh	Football Club
4	26	GCSE or 0 level	No	Welsh	Football Club
5	20	A level or equivalent	No	Welsh	Football Club
6	24	A level or equivalent	No	English	Football Club
7	27	GCSE or equivalent	No	Welsh	Football Club
8	63	Left school at or before age of 15	Yes	British	Snowball Sampling
9	51	Degree	Yes	Welsh	Snowball Sampling
10	58	Left school at or before 15	Yes	Welsh	Snowball Sampling

Table 3.3: Participant demographic details and recruitment source.

3.11.3.1 Interview themes

Overall, the survey was received positively and all women found its content and layout user friendly. Two broad themes for improvement of survey items were identified: mismatch and irrelevance.

Mismatch

The majority of identified issues with the survey related to a perceived mismatch between the terminologies used in survey items and answer scales, causing difficulty in

mapping answers. Two items were identified as being mismatched with their response categories. For example, the item "*How much of a risk factor do you think HPV is in developing cervical cancer" (1- Not important at all- 5 Very important)*. Participants understood what the term risk factor was pertaining to, however they described being unable to relate their answers to the response options. Participants seemed to identify the term as 'risk factor' as synonymous with the term 'important'.

> *P- it's really difficult because where it's on a scale of not at all likely or very likely and it's I want to use, to me that should be yes, no or unsure…*
> *I- so you are saying that the question kind of does not transfer to the responses*
> *P- yeah (P2)*

> *P- […]so I don't really understand it straightaway…so like I want to use one…I am likely to use one or I am not likely to use one*
> *I-[…] so would you like me to put would you like to use*
> *P- yeah how likely am I to use or how likely are you to use and then obviously not at all likely and very likely (P5)*

> *P- um, I don't really know where to go on the scale as it says how much of a risk factor do you think, but then it says not important or very important (P1)*

Irrelevance

The item "*Have you made any lifestyle choices to try and reduce your risk of cervical cancer?"* was consistently misunderstood and perceived as irrelevant by most participants. Participants perceived it to be asking about general lifestyle choices, as opposed to choices that participants have actively made to try and reduce their risk of cervical cancer. Participants used the item to reflect their current lifestyle choices.

However, when participants were alerted to the fact that this item was specifically designed to identify any conscious efforts made to reduce risk of cervical cancer or HPV, they stated that their responses did not relate to a conscious effort to reduce cervical cancer risk. This theme was prevalent throughout transcripts. For example:

> *P- I don't know how to answer that one, practicing safe sex, I practice safe sex to avoid pregnancy not to avoid catching STI's or STD's because I know that my partner and myself don't carry anything ... it is a choice I am choosing to practice safe sex,*
> *which I am (P2)*
> *I- would it have been something that you would have thought of to reduce your risk of cervical cancer (Interviewer)*
> *P- no (P2)*
>
> *P- yeah well I don't smoke (P5)*
> *I- but you haven't given up smoking to stop cervical cancer (Interviewer)*
> *P- no (P5)*

Following participant comments, the utility of the item was re-addressed. The aim of the item was to establish whether participants have consciously made lifestyle changes to reduce their risk of cervical cancer. However, following cognitive interviewing it was established that the choices presented were lifestyle choices in general and not choices that were specifically adopted to reduce the risk of cervical cancer. The utility of the item was re-evaluated and it was decided that the item should be removed

3.12 Survey modification

In addition to changes to survey items, the survey front cover was modified following participant uncertainty about the current availability of HPV self-sampling (whether it

is currently available through the NHS). Guidance was sought from Cervical Screening Wales. The information was modified to make it clear to women that the HPV self-sampling kit was not routinely available through the NHS and that it was important that women attend their cervical smear appointments. The final survey was can be seen in Appendix 3.11. Ten appropriate revisions to address the themes of mismatch and irrelevance, as well as changes suggested following review by Cervical Screening Wales, were made (Table 3.4). An item investigating whether participants have had the HPV vaccine was added, as this was considered potentially important as a moderating factor for intention to HPV self-sample.

Survey Modification type	**Original Question**	**Question following Cognitive Interviewing**
Re-wording of item	*6 items were **reworded**:* 1. I want to use a self-sampling kit for HPV. 2. If made available to me **I intend** to use the self-sampling kit for HPV. 3. How much of **a risk factor** do you think HPV is in developing cervical cancer? 4. Going for regular smear tests means that **cervical cancer** can be found early on. 5. The **three yearly** reminders I get help me remember to attend my smear test appointments.	*The items were further modified:* 1. I would be likely to use a self-sampling kit for HPV. 2. If made available to me, **I would** use the self-sampling kit for HPV. 3. How **important** do you think HPV is in developing cervical cancer? 4. Going for regular smear tests means that **cervical abnormalities** would be found early on. 5. The reminders I get help me remember to attend my smear test appointments. 6. I trust the **nurse/doctor** to take a good sample.

<table>
<tr><td></td><td>6. I trust the nurse/GP to take an adequate sample.</td><td></td></tr>
<tr><td>Response category modification</td><td>A response category on 1 item was modified:
How confident, are you that you would notice a symptom of cervical cancer?
<table><tr><td>Not at all confident</td><td>Slightly confident</td><td>About the same</td><td>Fairly confident</td><td>Very confident</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table>
A response category was deleted from 1 item:
What is the highest level of education you have?
<table><tr><td>Left school at or before age 15</td><td></td></tr><tr><td>GCSE or O level or equivalent</td><td></td></tr><tr><td>A level or equivalent</td><td></td></tr><tr><td>Further education but not a degree</td><td></td></tr><tr><td>Degree or higher (e.g. Masters, PhD)</td><td></td></tr><tr><td>None of the above</td><td></td></tr></table></td><td>The response category was further modified:
How confident are you that you would notice a symptom of cervical cancer?
<table><tr><td>Not at all confident</td><td>Slightly confident</td><td>Unsure</td><td>Fairly confident</td><td>Very confident</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table>
The response category was deleted respectively:
What is the highest level of education you have?
<table><tr><td>Left school at or before age 15</td><td></td></tr><tr><td>GCSE or O level or equivalent</td><td></td></tr><tr><td>A level or equivalent</td><td></td></tr><tr><td>Further education but not a degree</td><td></td></tr><tr><td>Degree or higher (e.g. Masters, PhD)</td><td></td></tr></table></td></tr>
</table>

<table>
<tr>
<td>Removal of Question</td>
<td>The following item was removed:

Have you made any lifestyle choices to try and reduce your risk of cervical cancer?

<table>
<tr><td>Attending smear appointments</td><td></td></tr>
<tr><td>Practicing safe sex</td><td></td></tr>
<tr><td>Limiting number of sexual partners</td><td></td></tr>
<tr><td>Not smoking</td><td></td></tr>
<tr><td>Getting immunized against HPV</td><td></td></tr>
<tr><td>Other (please describe)</td><td></td></tr>
<tr><td>I have not made any specific lifestyle choices to reduce my risk of cervical cancer</td><td></td></tr>
</table>
</td>
<td>Removal of item in the ‘Your thoughts about cervical cancer’ section of the survey.</td>
</tr>
<tr>
<td>Addition of Question</td>
<td>The following item was added:

Have you had the HPV vaccine?

<table>
<tr><td>Yes</td><td></td></tr>
<tr><td>No</td><td></td></tr>
</table>
</td>
<td>Inclusion of additional item in the ‘Your views on HPV’ section of the survey</td>
</tr>
</table>

Table 3.4: Modifications made to the survey following cognitive interviewing.

3.13 Discussion

A preliminary questionnaire was developed to measure women's attitudes and intentions regarding HPV self-sampling, in order to examine the determinants of anticipated uptake should HPV self-sampling become routinely available. A search of the empirical literature on intentions to HPV self-sample highlighted the need to develop appropriate survey measures of extended HBM constructs.

The use of content validity analysis provided preliminary validation that some *a priori* survey items adequately reflected the constructs of interest. The content validity analysis facilitated the development of the survey by highlighting the need for item refinement or removal, and the development of additional items. The findings of cognitive interviews helped to ensure that the format of the survey was accessible, and that individual items were easily and correctly understood. Overall, the survey was very well received by participants with two themes identified for improvement (mismatch and irrelevance).

Strengths and Limitations

The use of content validity analysis helped to ensure that the survey did not over-represent, omit or under-represent facets of the extended HBM constructs, and that variables which were not part of the construct definition were not reflected in the survey items (Haynes et al. 1995)

The recruitment of nine experts to perform CVA (Lynn 1986) and the threshold of 78% for positive agreement (Hobbs and Vignoles 2007) reduced the probability of drawing incorrect conclusions about items that needed to be modified due to chance agreement. Although the survey validation through content validity analysis did not establish test integrity, it helped determine the degree of confidence that can be placed on conclusions made (Streiner and Norman 2008) about the way that the HBM constructs may affect women's intentions to self-sample.

However, content validity indices are specific to the particular function of the survey and the particular population, in this case the assessment of women's intentions to HPV self-sample and the factors that may affect these intentions. The content validity of the survey is only valid within this particular context and population, therefore limiting wider generalisability of construct validity. Furthermore, because the definition of many constructs can evolve over time, the relevance and representativeness of the survey is likely to degrade over time (Haynes et al. 1995). Therefore, conditional validity was established for the items of the survey. Conditional validity refers to the notion that indices of validity are relevant for one function of a survey (e.g. postal survey examining HPV self-sampling attitudes) and also the target population (Mitchell 1986).

The use of the cognitive interview to help pre-test the survey following content validity analysis facilitated the further evaluation of possible sources of response error. The in-depth exploratory features of the cognitive interview made it particularly suitable for further validation of the survey through examining both overt and covert responses. Although some variability of participant characteristics was observed such as educational level, the sample was largely homogenous. Little variability was achieved in terms of age and ethnicity as the majority of respondents were relatively young and either White Welsh or British/English. Younger respondents might represent different understanding of items compared with women from an older generation. Furthermore, the lack of representation of women from different ethnic backgrounds further limits the generalisability of findings, as women from other ethnic groups and those whose first language is not English, might hold different interpretations. It was not feasible to specifically target older women and women from different ethnic backgrounds due to time constrains, however it is acknowledged that the homogenous nature of the sample may serve as a barrier for determining the general validity of the survey outside the sample population.

Both concurrent verbal probing and think aloud techniques were adopted in the cognitive interviews. The initial instruction for participants to 'think aloud' when

processing items helped support an open-ended format throughout the interview. This ensured that the participants had the opportunity to provide information that might have been unanticipated by the interviewer and helped establish the notion that personal reflection by the participant was highly beneficial for the interview. However, the use of the think aloud techniques has been criticised for placing too much burden on the participants to verbalise cognitive processes and a bias in the individuals' information processing. Thinking aloud encourages individuals to invest considerable amount of mental effort into processing the questions compared to the amount of mental effort used when individuals are simply answering questions. This may therefore lead to over-processing of information and a different interpretation of the items in hand as opposed to when answering items in a real-life survey setting. Furthermore, the majority of participants provided simplistic answers, expressing that the question is 'ok' or 'clear'. Consequently, the majority of participants' verbalisation relied heavily on the probes used throughout the interview. Probes were targeted to guide the participants' focus on the items and the response formats presented. Throughout the course of the interview, the use of probes actually facilitated participants to think aloud and offer their own spontaneous thoughts and critiques, because participants seemed to expect the use of probes and pre-empted responses in some cases. The use of concurrent probing enabled the exploration of information that was still fresh in the participant's mind, resulting in it being easier to access and discuss. Verbal probing has been criticised for its potential to bias participant responses by the probes selected and the way that they are phrased. The possibility of bias was minimised in this study by only using non-leading probes.

Cognitive validity analysis and cognitive interviewing served as preliminary forms of construct validation. Alternative forms of validation can be applied to further assess the validity of the survey items, such as convergent validity and further types of construct validity. Construct validity examines how well survey items represent underlying extended HBM constructs. The construct validity of survey items was further examined using principal components analysis, presented in Chapter 4. Convergent validity can be established by correlating a measure with other

established measures that have proven validity. For example, the HPV knowledge measure used in the survey can be compared against a measure of HPV knowledge such as that developed by Waller et al. (2013). However the HPV knowledge measure was not available at the time of this research (2012). Internal reliability of factor-derived scales was also investigated, and is presented in Chapter 4 using inter-item correlations and Cronbach's alpha to determine whether constituent items were measuring the same underlying construct.

3.14 Conclusion

The use of the content validity analysis and cognitive interviews resulted in item modifications that helped to increase the content and face validity of questionnaire items, prior to their use in identifying women's attitudes and intentions to HPV self-sample. The internal consistency of measures and the fit of underlying components with the proposed extended HBM constructs will be reported in the next chapter.

Chapter 4

Identifying factors associated with women's intentions to HPV self-sample using survey methods.

4.1 Chapter Overview

Previous literature on women's intentions and beliefs regarding HPV self-sampling has mainly focused on women who are non-responders to cervical screening. Few studies have been conducted involving women from the general population, the majority of whom attend cervical screening and might present different barriers to HPV self-sampling compared to women who do not participate in cervical screening. A cross-sectional study is presented, in which the ability of the extended HBM (Rosenstock, 1988) to explain women's intentions to HPV self-sample was tested. The findings will be used to guide the development of a qualitative interview schedule (Chapter 5) to explore women's intentions to HPV self-sample in greater depth, as well as to inform the content of an intervention designed to increase intentions to HPV self-sample.

4.2 Introduction

Understanding women's intentions to engage in primary HPV self-sampling will provide insight into the possible impact of introducing primary HPV self-sampling on cervical screening attendance. The extended HBM (Rosenstock et al. 1988) proposes that individuals are more likely to HPV self-sample if they believe themselves to be highly susceptible to HPV, they perceive HPV infection as serious, they believe that the benefits of taking action outweigh the barriers or costs of conducting in HPV self-sampling, and they believe that they are able to conduct HPV self-sampling properly (high self-efficacy). Please refer to Chapter 2 for a detailed discussion of the extended HBM constructs.

Due to the reliance on the individual to perform the sampling procedure in HPV self-sampling independently, it is possible that perceived HPV related self-efficacy may have a significant impact on women's intentions to self-sample. Although a

lack of confidence in conducting HPV self-sampling properly has been identified (Waller et al. 2006; Cadman et al. 2014), the way in which self-efficacy may affect intention to self-sample has not been investigated. It was therefore important to examine associations between intention to HPV self-sample and self-efficacy, as well as to identify which aspects of the HPV self-sampling procedure may be particularly associated with lower self-efficacy.

In addition to extended HBM constructs, modifying factors that will be investigated include HPV knowledge, clinical details such as cervical screening history, HPV vaccination history and family history of cervical cancer, and sociodemographic characteristics such as age, socioeconomic group and ethnicity. Cues to action can also be seen as modifying factors that can increase intention to engage in a health behaviour. However, cues to action were investigated in relation to actual cervical screening testing rather than hypothetical HPV self-sampling intention. Cues to action were investigated in relation to cervical screening because a HPV self-sampling programme is not available. It was felt that exploring the influence of the standard cue to action (receiving a call/recall letter for a cervical smear) would provide information about its effectiveness in promoting women to attend cervical screening and could be extrapolated for HPV self-sampling programme recommendations.

4.2.1 Aim of the present study

The extended HBM was used to identify correlates of HPV self-sampling intention in women drawn from the general population. The primary study hypothesis was that higher self-efficacy would be associated with higher intention to HPV self-sample.

Secondary hypotheses were that higher intention would be associated with higher perceived severity of HPV and/or cervical cancer, higher perceived susceptibility to HPV and/or cervical cancer, greater perceived benefits of HPV self-sampling and fewer perceived barriers to HPV self-sampling and greater perceived barriers to cervical smear tests.

4.3 Materials and Methods

A questionnaire-based survey (described in Chapter 3) was used to investigate women's intentions to HPV self-sample using opportunistic sampling methods. In order to increase the sample size and the heterogeneity of the participants, the research was conducted in two waves of recruitment: primary recruitment through Cervical Screening Wales (Cervical Screening Wales), followed by supplementary recruitment through healthcare practices and community groups. The survey was conducted between April-August 2013.

Ethical Approval

Ethical approval was obtained from the South East Wales Research Ethics Committee Panel C and Public Health Wales Risk Review Committee for Research and Development.

4.3.1 Primary recruitment via Cervical Screening Wales

For the primary recruitment, recruitment cards were sent alongside women's cervical screening call/recall letter from Cervical Screening Wales (Appendix 4.1). The recruitment card was designed to look colourful and attractive with a bold statement *"Cervical Screening- Your opinion counts!"* to try and engage the reader. The study information outlined the sampling criteria (women need to be 20-64 years), and provided basic information about the research question and HPV self-sampling. The study information stated that HPV self-sampling was not currently available and that women should therefore attend their cervical smear appointment. The section entitled *"What would you need to do"* provided simple instructions on how women could get involved with the study and what to expect if they expressed interest. The reverse side of the card provided researcher details and a section to be completed by the potential participant. The card content was

approved by Cervical Screening Wales and assessed for accuracy of information provided.

Inclusion/Exclusion Criteria

Inclusion criteria stipulated that women were aged 20-64 years, were living in South East Wales and had given written consent to participate. Women were excluded if they were outside the recommended cervical screening age at the time of the survey (20-64 years) or were unable to speak English. Only women who were in the age bracket for cervical screening were targeted because they would be the potential individuals who would receive a HPV self-sampling kit.

4.3.1.1 Procedures

Recruitment materials were sent to 11,961 women with their cervical screening invitation/recall letter from Cervical Screening Wales. Women were due to be invited for their cervical screening via invite/reminder letter in the Bro Taf Health Authority Area during March 2013. Women who were interested in participating were instructed to fill in their details on the reverse of the recruitment card (Appendix 4.1) and to return it using the supplied pre-paid envelope. Women who returned the completed recruitment card were then sent the full participant pack and survey.

Sample Size Calculation

Sample size was calculated with the advice of a statistician and based on previous studies that have found uptake of HPV self-sampling to be around 30% (Gok et al. 2012). Assuming that 30% of individuals likely to participate in self-sampling have a high self-efficacy level, it was proposed that intention to self-sample would be approximately 15% in respondents who are at the mid-way point on a perceived self-efficacy scale. Informed by an article describing the relationship between self-

efficacy and cervical screening (Fernandez et al. 2009) which reported a 2.69 effect size of self-efficacy on cervical screening, it was decided to consider an odds ratio effect size of 2 (adjusted for the influence of sociodemographic variables such as age). The effect size of 2 was somewhat less than the 2.69 odds ratio reported by Fernandez et al. (2009) to facilitate a more conservative sample size calculation. A two-sided test at the 5% significance level was chosen, which enabled bi-directional study of the effect of self-efficacy on intentions to self-sample. Using these figures, and the formula described by Hsieh, Bloch and Larsen (Hsieh et al. 1998), it was calculated that a sample size of 172 would achieve 90% power to detect the effect of self-efficacy on intention to HPV self-sample.

A predicted response rate of 7% for the recruitment card was informed by a reported response rate of 7% from a study that used a postal questionnaire to examine women's attitudes towards cervical screening (Szarewski et al. 2011). Therefore, it was predicted that the number of recruitment leaflets that needed to be sent through Cervical Screening Wales was approximately 12,000, based on an estimated 7% (n=840) response rate to the recruitment card, and a conservative estimated 25% response rate to the questionnaire packs (210/840).

4.3.2 Supplementary recruitment

In order to reach the target sample size and to increase sample variation in terms of sociodemographic factors, alternative recruitment was initiated at sites including a sexual health clinic, community groups and GP practices.

4.3.2.1 Procedures

The same inclusion/exclusion criteria applied to primary recruitment were applied to the supplementary recruitment. Participants recruited through the sexual health clinic were provided with a study recruitment card from the receptionist at the clinic. The receptionist briefly outlined the study and asked women if they would be happy to be provided with more information about the study. Potential participants

were provided with a study pack containing an information sheet, consent form, questionnaire and a pre-paid return envelope. The majority of participants completed their questionnaire whilst waiting for their appointment.

Community leaders were initially approached and asked if they would be happy for the researcher to attend a group meeting and provide information about the study. If community leaders expressed interest in the study, the researcher attended the group to present the study to group members and distributed recruitment cards. The researcher returned during the subsequent meeting to distribute questionnaires to the individuals who had expressed an interest in participating in the study. The researcher left the study information packs and surveys with the potential participants and returned after the 'session' had ended and collected any completed surveys. Subsequent return and collection of the surveys ensured that potential participants did not feel obliged to participate due to researcher presence.

Recruitment through GP practices involved practice nurses distributing study recruitment card and pre-paid return envelopes to women aged 20-64 in their clinic appointments. Women who returned a completed recruitment card were sent the study pack.

4.4 Measures

The development of items used to investigate women's intentions to HPV self-sample was presented in detail in Chapter 3. Please refer to Table 4.1 for an outline of items used to investigate HBM *a priori* survey constructs and women's intentions to HPV self-sample. All HBM and intention items were scored on a Likert scale ranging from one to five. Three items were used to measure perceived benefits and three items were used to measure perceived barriers to self-sampling, whilst five items were used to measure barriers to cervical smear tests and three items were used to measure benefits to cervical smear tests. Five items were used to measure perceived self-efficacy in conducting HPV self-sampling. Perceived susceptibility to

and perceived severity of HPV and cervical cancer were investigated with one item each (four items in total). One item was used to measure the effect of cues to action in relation to cervical smear screening.

HPV knowledge, clinical variables such as cervical screening history and variables such as age, socioeconomic status (determined by postcode deprivation level), home ownership, ethnicity and educational level were measured using categorical response formats. Women were asked for consent for re-contact by the inclusion of an item asking women to indicate whether they would be happy to participate in a follow-up interview study.

Variable	**Item/s in questionnaire and response scale range.**
Intention to HPV self-sample	I would be likely to use a self-sampling kit for HPV. *1= Not at all likely, 5= Very likely* How likely would you be to use the self-sampling kit instead of going for a smear test? *1= Not at all likely, 5= Very likely* I expect that I would use a self-sampling kit for HPV. *1= Not at all likely, 5= Very likely* If made available to me, I would use the self-sampling kit for HPV. *1= Not at all likely, 5= Very likely*
Self-efficacy	How certain are you that you would do the test well enough? *1=Not certain, 5= Very certain* How certain are you that you would be able to carry out the sampling procedure (placing swab in vagina)? *1= Not certain, 5= Very certain* How certain are you that you would be able to place the swab into the tube containing the special liquid without touching or dropping the swab? *1=Not certain, 5= Very certain* How certain are you that you would be able to carry out the self-sampling procedure despite other commitments (e.g. work/children)? *1= Not certain, 5= Very certain* How certain are you that you would be able to send off the completed test within the time allowed (2 weeks)? *1= Not certain, 5= Very certain*
Benefits to HPV self-sampling.	Using a self-sample kit is convenient because it can be done at home and means that I would not have to make arrangements (e.g. going to a GP surgery/taking time off work /arranging childcare.) *1= Strongly disagree, 5= Strongly agree* Using a self-sample kit would mean that no-one will know that I am having cervical screening. *1= Strongly disagree, 5= Strongly agree* Using a self-sample kit would be less embarrassing than having a GP or nurse do a smear test. *1= Strongly disagree, 5= Strongly agree*

Barriers to HPV self-sampling.	I am worried that I would hurt myself using the self-sample kit. *1= Strongly disagree, 5= Strongly agree* I wouldn't trust the results of the self-sample kit. *1= Strongly disagree, 5= Strongly agree* I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory. *1= Strongly disagree, 5= Strongly agree*
Perceived susceptibility to HPV	Compared to most women your age, how likely do you think it is that you will come into contact with HPV? *1= Much less likely, 5= Much more likely*
Perceived severity of HPV	How serious an infection do you think HPV is? *1= Not at all serious, 5= Extremely serious*
Benefits to cervical smear screening	Going for cervical smear tests means that cervical abnormalities would be found early on. *1= Strongly disagree, 5= Strongly agree* Going for smear tests provides me with reassurance. *1= Strongly disagree, 5= Strongly agree* I trust the nurse/doctor to take a good sample. 1= Strongly disagree, 5= Strongly agree
Barriers to cervical smear testing	Having a smear test is painful. *1= Strongly disagree, 5= Strongly agree* Going for smear tests can be difficult because I have to make arrangements (e.g. time off work, childcare). *1= Strongly disagree, 5= Strongly agree* I worry about my sample getting lost. *1= Strongly disagree, 5= Strongly agree* Having a cervical smear test is embarrassing. 1= Strongly disagree, 5= Strongly agree I worry that others (e.g. family members, friends, people at the GP surgery) will know that I am having cervical screening. *1= Strongly disagree, 5= Strongly agree*
Perceived susceptibility	Compared to other women your age, how likely do you think it is that you would get cervical cancer at some time in your life? Would you say you are…? *1= Much less likely, 5= Much more likely*

to cervical cancer	
Perceived severity of cervical cancer	If I got cervical cancer, it would be more serious than other cancers. *1= Strongly disagree, 5= Strongly agree*
Cues to action	The reminders I get help me remember to attend my smear test appointments. *1= Strongly disagree, 5= Strongly* agree

Table 4.1: Items used to measure intention to HPV self-sample and variables associated with HBM *a priori* constructs in relation to HPV self-sampling and cervical smear testing.

4.5 Statistical analysis plan

Survey data were analysed using SPSS for Windows V20. Descriptive statistics were used to characterise the sample. Missing data were excluded from analysis and normality of data was examined using skewness and kurtosis statistics.

Principal components analysis (PCA) with Varimax rotation (Tabachnick and Fidell 2007) was conducted on HBM *a priori* items in order to construct HBM scales relating to HPV self-sampling. The adequacy of sampling for principal components analysis was first investigated through the Kaiser-Myer-Olkin (Kaiser 1970, 1974) statistic and Bartlett's test of sphericity (Bartlett 1954). Initial unrotated and final rotated factor solutions were calculated for factor derived scales. Based on Keiser's criterion it was decided that factors with eigenvalues over 1 would be retained. Research has shown that Keiser's criterion is accurate when the number of variables is less than 30 and the average communality of the variables is greater than 0.6 (Jolliffe 1972, 1986). Items strongly loading above 0.364 (Field 2005) were retained. Internal reliability of multi-item scales was examined using Cronbach's alpha with a minimum accepted value of 0.70 (Kline 1999). Inter-item correlation was investigated with an accepted range between 0.2 and 0.4 (Briggs and Cheek 1986).

Intention and self-efficacy scales were transformed into binary scales. The intention scale was transformed to measure lower and higher intention to self-sample, whilst the self-efficacy scale measured lower and higher HPV self-sampling related self-efficacy.

Associations between extended HBM constructs applied to HPV self-sampling were identified using Pearson's correlations and t-tests.

Univariate analyses examined preliminary associations between intention to HPV self-sample and sociodemographic, HBM and clinical variables. The univariate analysis used independent t-tests and chi-square tests, as appropriate for the

different types of independent variables, with a significance level of p≤0.05. The significance level of 0.05 ensured that there is only a 1 in 20 chance of a type 1 error occurring during analysis. A type I error would result in the incorrect rejection of the null hypothesis and the incorrect finding that there is an association between variables, which is actually due to a random occurrence (Coolican 2004). Conversely, a type II error might occur when the null hypothesis is retained when it is false and an association is actually present. The lower the significance level, the higher the probability of a type II error occurring (Coolican 2004). Therefore, the significance level of 0.05 was suitable for this analysis as it was sensitive enough to reject the null hypothesis correctly (with a 1 in 20 chance of type I error) but it also wasn't too low which would have increased the chance of a type II error occurring.

Multilevel modelling of independent variables identified as statistically significantly associated with HPV self-sampling intention was conducted using a stepwise logistic regression analysis. A logistic regression analysis was performed to assess the impact of factors on the likelihood that participants would report being more or less likely to HPV self-sample. A stepwise format was selected to facilitate the identification of variables that contributed most to the prediction of the model. In addition, all extended HBM variables regardless of statistical significance in predicting intention were modelled for conceptual reasons. The logistic regression was used to identify the strongest predictors (p≤0.05) and effect sizes on intention to HPV self-sample, with a binary intention outcome measure (likely vs less likely to self-sample) entered as the dependent variable.

4.6 Results: Principal components analysis and internal consistency of factor derived scales.

4.6.1 Psychometric testing of HBM *a priori* constructs through principal components analysis.

Principal components analysis (PCA) was used for the psychometric testing of *a priori* constructs. PCA is an exploratory technique which identifies the maximum

number and nature of factors. PCA aims to produce a smaller number of linear combinations of original variables (Tabachnick and Fidell 2007). Therefore, PCA was particularly suitable for reducing the number of variables in the survey into a smaller number of components and therefore exploring whether the components reflected *a priori* constructs and their related items.

Examination of the data indicated its suitability for PCA. The sample size was above n=150, the correlation matrix revealed the presence of many coefficients greater than 0.3, and a spot check of variable scatterplots showed linear relationships.

The Kaiser-Meyer-Olkin value of sampling adequacy was 0.774. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy provides an index of the proportion of variance among variables that might be common and therefore signifies that underlying factors might be present. The KMO is scored between 0 and 1, with a minimum accepted value of 0.6 , values closer to 1 signify that an analysis of factors (through PCA) would be suitable (Tabachnick and Fidell 2007). Furthermore, Bartlett's test of Sphericity reached statistical significance at $p<0.001$. Bartlett's test of Sphericity tests for relationships between variables and if no relationships are present, all correlation coefficients would be zero. Therefore, to enable a principal components analysis, Bartlett's test of Sphericity needed to be significant ($p<0.05$) (Field 2005).

Examination of the KMO statistic and Bartlett's test of Sphericity supported the ability to extract factors from the correlation matrix.

4.6.1.1 Initial factor solution

Items relating to the HBM *a priori* constructs were entered into PCA. Five factors with eigenvalues >1.00 were extracted, explaining 33.9%, 13.5%, 11.2%, 8.8% and 8.5% of variance in item scores respectively. Eigenvalues represent the amount of variation that is explained by the factors identified through PCA and it has been recommended that factors with eigenvalues over 1 represent a significant amount of variation (Kaiser 1960). In order to aid interpretation of the factor solution, a Varimax rotation was performed. Varimax rotation was performed to maximise the dispersion of loadings on factors, therefore to maximising high correlations and

minimising low correlations between factors (Tabachnick and Fidell 2007). Varimax rotation loads a smaller number of variables (with a higher loading) on each factor resulting in more interpretable clusters of variables on each factor (Field 2005). As shown in Table 4.2, all *a priori* items loaded in line with theoretical expectations, apart from the item *"Using a self-sample kit is convenient because it can be done at home and means that I would not have to make arrangements (e.g. going to the GP surgery/taking time off work/arranging childcare"*. This item was expected to load onto component III with the interpretative label of perceived benefits to HPV self-sampling, but actually loaded onto component I with the interpretative label of self-efficacy. This item was removed from component I and from the whole analysis on conceptual grounds because it did not significantly load on the benefits scale.
Two *a priori* items loaded >0.36 on two components (Table 4.2). Loading strength and conceptual issues were considered when deciding which *a priori* item should be retained on each component.

Item	Factor	I	II	III	IV	V
How certain are you that you would be able to place the swab into the tube?		**.898**				
How certain are you that you would be able to carry out the self-sampling procedure despite other commitments?		**.892**				
How certain are you that you would be able to carry out the sampling procedure?		**.857**				
How certain are you that you would be able to send off the completed test within the time allowed?		**.857**				
Using a self-sampling kit is convenient because it can be done at home and means I would not have to make arrangements (e.g. going to GP surgery/talking time off work/arranging childcare).		**.798**				
How certain are you that you would do the test well enough?		**.669**			-.407	
I wouldn't trust the results of the self-sampling kit.			**.840**			
I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory.			**.702**			.424
I am worried that I would hurt myself using the self-sample kit.		-.354	**.586**			
Using a self-sampling kit would be less embarrassing than having a GP or nurse do a smear test.				**.816**		
Using a self-sampling kit would mean that no-one will know that I am having cervical screening.				**.716**		
Compared with most women your age, how likely do you think it is that you will come into contact with HPV?					**.829**	
How serious an infection do you think HPV is?						**.909**

Factors were labelled as follows: Factor I perceived self-efficacy, Factor II perceived barriers, Factor III perceived benefits, Factor IV perceived susceptibility, Factor V perceived severity.

Table 4.2: Initial PCA of extended Health Belief Model constructs relating to HPV self-sampling.

4.6.1.2 Final factor solution

The final PCA using Varimax rotation and excluding the item *"Using a self-sample kit is convenient because it can be done at home and means that I would not have to make arrangements (e.g. going to the GP surgery/taking time off work/arranging childcare"* extracted five factors with eigenvalues >1.00, explaining 34.9%, 14.2%, 9.9%, 9.2% and 8.5% of variance in item scores (Table 4.3). Inspection of the scree plot (Figure 4.1) complemented findings based on Kaiser's criterion outlining a break following the first two components and then a further break following the fifth component.

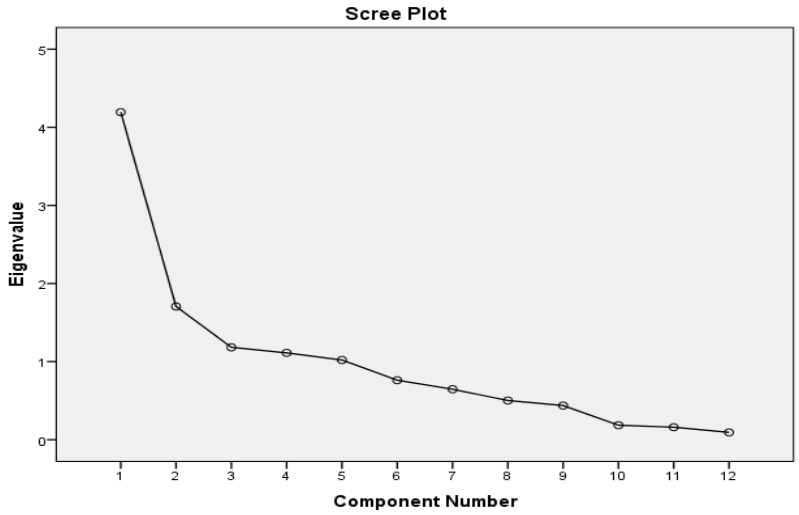

Figure 4.1: Scree plot

Nine items strongly loaded on one component independently. Three items loaded on two components each. Statistical and theoretical considerations were undertaken when deciding which item should be retained on which factor. The item *"I am worried that I would hurt myself using the self-sample kit"* will be used to exemplify this process. It was decided that this item would be incorporated into component II because its factor loading was higher on component II than I, and the remaining variables in component II were theoretically related to the item. The same principles were applied to the other items that loaded onto more than one

component. Overall, the results of the final rotated PCA supported the five *a priori* constructs and their related items. Table 4.4 presents the final factor-derived scales and items.

Item	Factor	I	II	III	IV	V
How certain are you that you would be able to place the swab into the tube?		**.890**				
How certain are you that you would be able to carry out the self-sampling procedure despite other commitments?		**.884**				
How certain are you that you would be able to carry out the sampling procedure?		**.877**				
How certain are you that you would be able to send off the completed test within the time allowed?		**.836**				
How certain are you that you would do the test well enough?		**.703**			-.378	
I wouldn't trust the results of the self-sampling kit.			**.834**			
I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory.			**.710**			.417
I am worried that I would hurt myself using the self-sample kit.		-.376	**.576**			
Using a self-sampling kit would be less embarrassing than having a GP or nurse do a smear test.				**.818**		
Using a self-sampling kit would mean that no-one will know that I am having cervical screening.				**.738**		
Compared with most women your age, how likely do you think it is that you will come into contact with HPV?					**.837**	
How serious an infection do you think HPV is?						**.910**

Factors were labelled as follows: Factor I perceived self-efficacy, Factor II perceived barriers, Factor III perceived benefits, Factor IV perceived susceptibility, Factor V perceived severity.

Table 4.3: Final rotated PCA of Health Belief Model constructs relating to HPV self-sampling.

Component number and corresponding HBM construct	**Item/s loading on component**
Component 1 Perceived Self-Efficacy	How certain are you that you would do the test well enough? How certain are you that you would be able to carry out the sampling procedure (placing swab in vagina)? How certain are you that you would be able to place the swab into the tube containing the special liquid without touching or dropping the swab? How certain are you that you would be able to carry out the self-sampling procedure despite other commitments (e.g. work/children)? How certain are you that you would be able to send off the completed test within the time allowed (2 weeks)?
Component 2 Perceived barriers to HPV self-sampling	I am worried that I would hurt myself using the self-sample kit*. Please circle a number.* I wouldn't trust the results of the self-sample kit. I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory.
Component 3	Using a self-sample kit would mean that no-one will know that I am having cervical screening.

Perceived benefits to HPV self-sampling	Using a self-sample kit would be less embarrassing than having a GP or nurse do a smear test.
Component 4 Perceived susceptibility to HPV infection	Compared to most women your age, how likely do you think it is that you will come into contact with HPV?
Component 5 Perceived severity of HPV infection	How serious an infection do you think HPV is?

Table 4.4: Final factor-derived scales and items

4.6.1.3 Internal consistency of factor-derived scales

Benefits and barriers to HPV self-sampling

Internal consistency of the two perceived benefits items was low (Cronbach's α=0.555). The inter-item correlation was r=.386, within the accepted range of 0.2 and 0.4 (Briggs and Cheek 1986). Items were combined to form a perceived benefits scale, with a score range of 2 to 10 (a higher score indicating more perceived benefits of HPV self-sampling).

Perceived barriers items had a Cronbach's α of 0.582. Inspection of the mean inter-item correlation r=0.315 suggested that the three items exhibited internal consistency and were aggregated into a perceived barriers to HPV self-sampling scale, with a score range of 3 to 15 (a higher score indicating more perceived barriers).

Perceived benefits and perceived barriers to cervical smear tests

Perceived benefits of cervical smear tests scale initially consisted of three items (Table 4.4, component 3). Items had a moderate Cronbach's alpha value of 0.690 with an inter-item correlation of r=0.416. Removing the item *"Going for cervical smear tests means that cervical abnormalities would be found early on"* improved the internal consistency of the scale (α=0.805, r=0.674). Therefore, the scale was formed with two items, with a score range of 2 to 10.

Perceived barriers to cervical smear tests scale consisted of four items (Table 4.4, component 2). Internal consistency of perceived barriers items was low (α=0.448, r=.173). The scale was comprised of four items with a score range of 4 to 20.

Self-efficacy in relation to HPV self-sampling

Perceived self-efficacy consisted of five items (Table 4.4) with high internal consistency (α=0.900, r=.664). Inter-item correlation indicated that Cronbach's α would be slightly higher if item *"How certain are you that you would do the test well enough?"* was removed (0.917). Exploratory cross-tabulation indicated that responses to this item exhibited variation when compared to the other self-efficacy item responses. However, self-efficacy in relation to HPV self-sampling is a combination of both a general belief that one would be able to carry out self-sampling (as measured by this item) as well as the succession of tasks associated with actually carrying out the self-sampling procedure (the other self-efficacy items). It was therefore decided to retain item *"How certain are you that you would do the test well enough?"* in the self-efficacy scale to reflect the complex nature of perceived self-efficacy. The self-efficacy scale therefore consisted of 5 items with a score range of 5 to 25 (a higher score indicating higher self-efficacy).

The self-efficacy scale was recoded into a binary scale to help differentiate between individuals who perceived higher versus lower self-efficacy in their ability to conduct HPV self-sampling. Group one reflected lower self-efficacy (respondents who scored lower 1, 2, or 3 on any of the self-efficacy items), whilst group two reflected higher self-efficacy (individuals who scored consistently 4 or 5 on every self-efficacy item). As shown in Table 4.5, the recoded variables were then grouped to make up the self-efficacy scale (ranging from 5 to 10). Women who scored 10 (therefore were in group two for each question) were defined as having a higher self-efficacy, whilst women scoring between 5-9 were defined has having a lower self-efficacy.

Recoded self-efficacy scale value	Frequency	Valid %	Cumulative %	Higher/Lower self-efficacy
5	17	8.9	8.9	Lower self-efficacy
6	4	2.1	10.9	
7	11	5.7	16.7	
8	29	15.1	31.8	
9	38	19.8	51.6	
10	93	48.4	100.0	Higher self-efficacy

Table 4.5: Development of binary self-efficacy scale.

Intention to HPV self-sample

Intention to HPV self-sample was measured using four items (Table 4.1, component 1).

Internal consistency of the four intentions items was high (Cronbach's α=0.916) with a mean inter-item correlation of r=0.749. Excluding the item *"How likely would you be to use the self-sampling kit instead of going for a smear test?"* would increase the Cronbach's alpha value to α=.939, as well as the mean item correlation r=0.841. Exploratory cross-tabulations identified that responses to this item were not consistent compared with response to the other intention items. Therefore, it was decided to exclude this item. The intention scale was computed from three items, scored from 3 to 15 (a higher score indicating higher intention).

The intention scale was negatively skewed, with the majority of respondents being in favour of HPV self-sampling. A binary intention variable was created: those who had a higher intention to HPV self-sample scored 4 or 5 on all three intention items, and those who were less likely to HPV self-sample scored 3 or under on any intention item. As shown in Table 4.6, a score of 1, 2 or 3 on the 5 point scale was recoded as 1, whilst a score of 4 or 5 was recoded as 2. The recoded variables were then computed to develop a scale (from 3 to 6). Women who scored 6 consistently answered 4 or 5 on all three intention items, whilst women scoring 3-5 scored either inconsistently between the three items or scored lower on all items.

Recoded Intention Scale Value	Frequency	Valid %	Cumulative %	Higher/Lower Intention
3	25	13	13	Lower Intention
4	17	8.9	21.9	
5	17	8.9	30.7	
6	133	69.3	100	Higher Intention

Table 4.6: Development of binary intention variable.

4.6.1.4 Relationships between factor-derived HBM scales

Inter-relationships between extended HBM constructs were investigated in relation to HPV self-sampling (see Appendix 4.2). Statistically significant relationships were found between more perceived benefits to HPV self-sampling and less perceived barriers to HPV self-sampling ($r=-0.28$, $p\leq0.001$), more perceived benefits to HPV self-sampling and higher perceived susceptibility to HPV infection ($r=0.16$, $p\leq0.05$), as well as perceived barriers to HPV self-sampling and perceived self-efficacy $(t188)=4.24$, $p\leq0.001$. No other statistically significant relationships were identified.

4.7 Survey Results

4.7.1 Sample Characteristics

One hundred and thirty seven (16.31%) of 840 women who received a recruitment pack via Cervical Screening Wales completed the survey. A further 57 women were recruited opportunistically to increase sample representation. The final survey sample therefore consisted of a total 194 participants. Table 4.7 demonstrates the number of women recruited from different sites and figure 4.2 shows the response rate of CSW recruitment.

Most participants were of white ethnicity, in the 31-49 year age group, highly educated and were home owners. The majority had attended a cervical screen within the last four years. Nearly half (43.0%) of participants had received an abnormal smear test result and approximately a quarter (18.2%) had received

treatment for cervical abnormalities. A small proportion of women knew a family member/friend diagnosed with cervical cancer (13.5%) and some had known someone die of cervical cancer (5.7%). Table 4.8 illustrates participant characteristics.

	Recruitment Site/s	**Completed Surveys**
Healthcare providers	Cardiff and Vale Sexual Health Clinics	4
	Newport Sexual Health Clinic	27
	GP Practices (Cardiff, Newport and Cwmbran)	2
Community centres	Women's coffee groups	17
	Community BME ladies group	6
Snowball Sampling	Hospital catering department	1
	Sub total	57
Main recruitment	Cervical Screening Wales	137
	Total	194

Table 4.7 Survey recruitment sites

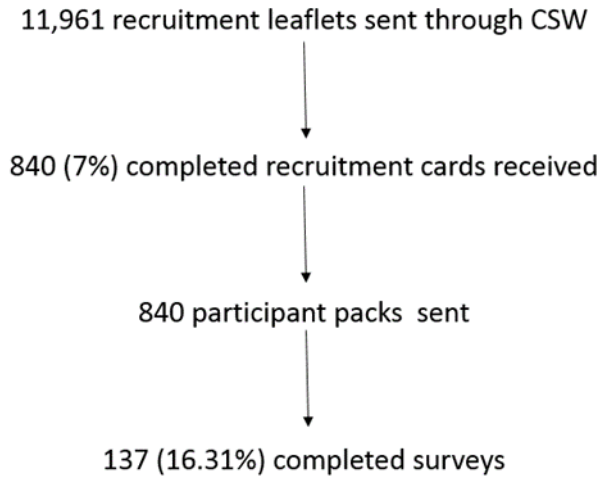

Figure 4.2 Flow chart of response rate through CSW recruitment

Characteristic		N	(%)
Age	Under 30	59	30.6
Min- 20, Max 64			
Range- 44	31-49	78	40.4
IQR- 24*	50+	56	29.0
Educational Level	GCSE	43	22.8
	Further education	69	36.5
	Degree or above	77	40.7
Home ownership	Home owner	125	65.4
	Not a home owner	66	34.6
Ethnicity	White	169	88.5
	Non-white	22	11.5
Previous cervical screening	Yes	185	95.4
	No	9	4.6
Time elapsed since last smear test	Within 4 years	169	90.8
	Over 4 years	6.5	6.5
	Don't know	2.7	2.7
History of abnormal smear test result	Yes	75	43.0
	No	106	57.0
Treatment for cervical abnormalities	Yes	34	18.2
	No	151	80.7
	Don't know	2	1.1
Family/friend diagnosed with cervical cancer	Yes	26	13.5
	No	164	75.1
	Don't know	22	11.4
Family/friend bereavement due to cervical cancer	Yes	11	5.7
	No	164	85.0
	Don't know	18	9.3

*Inter-quartile range

Table 4.8: Participant characteristics

HPV knowledge

As shown in Table 4.9, HPV knowledge was generally low: 31.4% of participants had not heard of HPV before participating in the study, 32.3% of women believed that HPV could be treated with medicines and 51.6% believed that HPV cannot clear up on its own. Most women (85%) had a correct understanding of HPV transmission and believed that HPV can be contracted through sexual contact.

HPV Knowledge Item	Response	Frequency	(%)
Knowledge of HPV prior to study	Yes	127	68.6
	No	58	31.4
HPV transmission			
Correct understanding	Only sexual contact	153	85
Partially correct understanding	Sexual contact and/or dirty toilet seats	11	6.1
	Sexual contact and/or kissing	8	4.4
	Breathing same air and /or sexual contact and/or kissing	1	0.6
	Sexual contact and/or sitting on dirty toilet seats and/or kissing	3	1.7
	All factors	1	0.6
Incorrect understanding	Breathing same air	1	0.6
	Sitting on dirty toilet seats	1	0.6
	Kissing	1	0.6
Belief that HPV can be treated with medicines	Yes	60	32.3
	No	46	24.7
	Don't know	80	43.0
Belief that HPV can clear up on its own	Yes	90	48.4
	No	96	51.6

Table 4.9 HPV knowledge

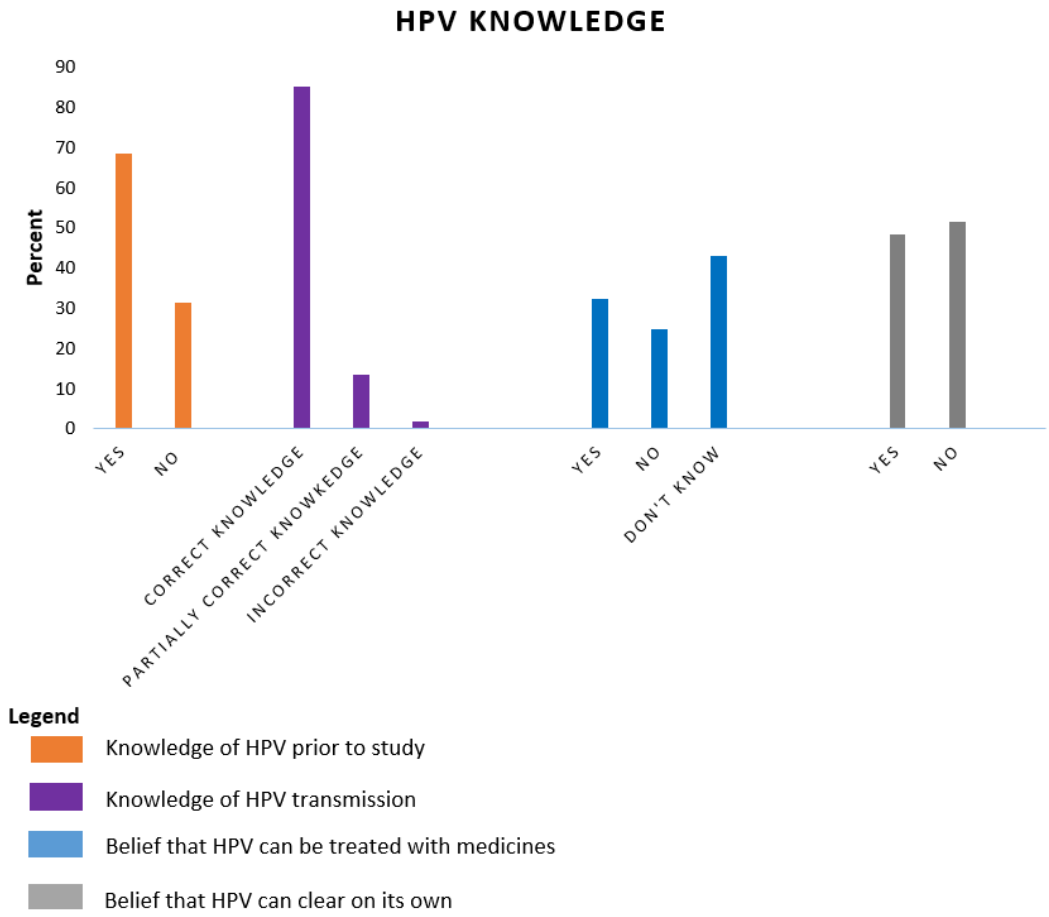

Figure 4.3 HPV knowledge

4.7.2 Preliminary univariate analysis of factors associated with intention to HPV self-sample

A total of 69.3% (n=133) of women were likely to use primary HPV self-sampling if it was available. Preliminary univariate analysis of factors associated with intention to HPV self-sample is shown in Tables 4.10 and 4.11. Women with educational level above GCSE and those educated up to degree level or above were significantly more likely to report a higher intention to HPV self-sample ($p \leq 0.05$) than women who were educated to or below GCSE level. Women who were of a white ethnicity ($p \leq 0.01$) compared to women who were non-white were also more likely to report a higher intention to HPV self-sample. Age ($p=0.13$), socioeconomic group ($p=0.082$) and home ownership ($p=0.33$) were not statistically significantly related to HPV self-sampling intention.

Women who were aware of HPV prior to this study were statistically significantly more likely to report intention to HPV self-sample ($p \leq 0.05$). History of cervical abnormalities ($p=0.63$), treatment for cervical abnormalities ($p=0.70$) and cervical abnormalities of family/friends ($p=0.25$) were not significantly associated with intention to HPV self-sample. There was insufficient sample variation to examine the effects of previous cervical screening, time elapsed since last smear and family/friend bereavement due to cervical cancer on intention to self-sample.

Higher intention to HPV self-sample was statistically significantly associated with higher perceived HPV related self-efficacy ($p \leq 0.001$), more perceived benefits ($p \leq 0.01$) and fewer perceived barriers ($p \leq 0.001$) to HPV self-sampling, as well as higher perceived importance of HPV in cervical cancer ($p \leq 0.01$). Higher perceived susceptibility to HPV infection and higher perceived severity of HPV infection were not statistically significantly related to intention. Greater perceived benefits of cervical smear tests were significantly associated with higher intention to self-sample ($p \leq 0.01$). However, perceived barriers to smear tests, perceived susceptibility to cervical cancer and perceived severity of cervical cancer were not statistically significantly associated with intention to HPV self-sample.

Independent Variables		**Self-Sampling Intention**				**Statistic**
		Low intention		***High intention***		
		N	%	N	%	
Age groups	Under 30 years	24	40.7	35	26.5	X^2(1,191) =4.12, p=0.13,
	31-49 years	19	32.2	58	43.9	
	50-64 years	16	27.1	39	29.5	
Educational Attainment	Up to and including GCSE	18	32.1	24	18.3	X^2(1,187) = 7.50, **p=0.024***
	Further education, no degree	23	41.1	46	35.1	
	Degree or above	15	26.8	61	46.6	
Ethnic background	White	44	77.2	124	93.9	X^2(1,189) =9.672, **p=0.002****
	Non-White	13	22.8	8	6.1	
Socioeconomic status (by postcode deprivation level)	1-most deprived quartile	23	42.6	30	23.6	X^2(1,181) =6.697, p=0.082
	2	7	13.0	25	19.7	
	3	9	16.7	27	21.3	
	4-least deprived quartile	15	27.8	45	35.4	
Home ownership	Home owner	34	59.6	90	68.2	X^2(1,189) = .93, p=0.33
	Not a home owner	23	40.0	42	31.8	
Knowledge of HPV prior to study	Yes	31	53.4	96	72.2	X^2(1,191)= 5.54, **p=0.02***
	No	27	46.6	37	27.8	
Smear test history: history of cervical abnormalities	Yes	20	37.7	54	42.9	X^2(1,172) = .220, p=.639
	No	33	62.3	72	57.1	

Cervical abnormalities: personal history of treatment for cervical abnormalities	Yes	9	16.1	25	19.7	$X^2(1,183) = .139$, p= .709
	No	47	83.9	102	80.3	
History of cervical abnormalities: family/friend history of cervical abnormalities	Yes	24	40.7	62	47.0	$X^2(1,191) = .652$, p=0.722
	No	20	33.9	40	30.3	
	Don't Know	15	25.4	30	22.7	
Cervical Cancer: family/friend history of cervical cancer	Yes	5	8.5	21	15.9	$X^2(1,191) = 2.721$, p=0.258
	No	45	76.3	98	74.2	
	Don't Know	9	15.3	13	9.8	
Previous cervical screening	Yes	56	94.9	127	95.5	^
	No	3	5.1	6	4.5	
Time elapsed since last smear	On time (under 4 years)	53	94.6	114	89.1	^
	Overdue (over 4 years)	1	1.8	11	8.6	
Family/friend bereavement due to cervical cancer	Yes	1	1.7	11	8.3	^
	No	51	86.4	111	84.1	
	Don't know	7	11.9	10	7.6	

*p<.05, ** p≤.01,*** p≤.001, ^ sample size not large enough in some cells to conduct statistical tests

Table 4.10: Preliminary analysis of associations between HPV self-sampling intention and sociodemographic/clinical variables and HPV knowledge.

Independent Variables		**HPV self-sampling intention**		**Statistic**
		Lower intention Mean (S.D.)	*Higher intention Mean (S.D.)*	
Perceived benefits to HPV self-sampling		6.88 (2.25)	7.90 (1.99)	*t*(190)=-3.142, **p=0.002****
Perceived barriers to HPV self-sampling		8.6 (2.5)	6.5 (2.3)	*t*(104.27)= 5.368, **p=0.000*****
Perceived susceptibility to HPV infection		3.07 (0.72)	3.02 (0.70)	*t*(189)=0.487, p=0.627
Perceived severity of HPV infection		4.03 (0.91)	3.96 (0.90)	*t*(187)=0.510, p=0.611
Perceived importance of HPV in cervical cancer		4.14 (0.91)	4.47 (0.62)	*t*(189)= -2.75, **p=0.007****
Perceived self-efficacy	Lower	53 (91.4)	46 (34.6)	X^2(1,n=191) =49.927, **p=0.000*****
	Higher	5 (8.6)[+]	87 (65.4)	
Perceived severity of cervical cancer		2.95 (1.05)	2.73 (1.03)	*t*(189)=1.342, p=0.181
Perceived susceptibility to cervical cancer		3.07 (0.722)	3.02 (0.627)	*t*(189)=0.487, p=0.627
Perceived barriers to smear tests		10.31 (3.48)	10.26 (3.00)	*t*(186)= 0.098, p=0.922
Perceived benefits to smear tests		8.15 (2.34)	8.91 (1.58)	*t*(78.85)=-2.237, **p=0.028***

*p<.05, ** p≤.01,*** p≤.001

Table 4.11: Preliminary analysis of associations between HPV self-sampling intention and extended HBM variables.

4.7.3 Multivariate modelling of intention to HPV self-sample.

All extended HBM variables and background variables that were significantly associated with intention to self-sample (ethnicity, educational level and HPV knowledge) were modelled to determine their effects on intention.
The model contained 13 independent variables. Firstly, background and sociodemographic factors were entered into the stepwise regression model. It was found that the model was statistically significant [X^2 (5, N=174)=17.35, p≤.005], explained between 9.5% (Cox and Snell R^2) and 13.5% (Nagelkerke R^2) of variance in intention to self-sample, and correctly classified 70.1% of cases. Subsequently the extended HBM variables (apart from self-efficacy) were added to the model, which was statistically significant [X^2 (12,N=174)=69.98] and explained between 30.4% (Cox and Snell R^2) and 43.1% (Nagelkerke R^2) of variance in intention to self-sample, correctly classifying 77.6% of cases. Self-efficacy was added to the final model which consisted of all 13 variables (see Table 4.12). The full model was statistically significant [X^2 (14, N=174) = 98.12, p≤.0.001], indicating that the model was able to distinguish between respondents who were more/less likely to self-sample. The model as a whole explained between 43.1% (Cox and Snell R^2) and 61.2% (Nagelkerke R^2) of the variance in intention to self-sample, and correctly classified 83.3% of cases.

As shown in Table 4.12, six independent variables made a unique statistically significant contribution to the final model: perceived self-efficacy, educational level, perceived importance of HPV in cervical cancer, perceived benefits of HPV self-sampling, perceived benefits of smear tests, and perceived barriers to HPV self-sampling. Women who reported a higher self-efficacy in relation to HPV self-sampling (OR=24.96, 95% CI 6.34-98.20), had a higher educational level (OR=6.06, 95% CI 1.40-26.14), perceived HPV as more important in cervical cancer (OR=2.32, 95% CI 1.06-5.07), perceived more benefits to smear tests (OR=1.43, 95% CI 1.07-1.91) and HPV self-sampling (OR=1.36, 95% CI 1.07-1.70) and perceived fewer barriers to self-sampling (OR=.663, 95% CI 0.53-0.82) reported higher intentions to HPV self-sample. Ethnicity, perceived barriers to smear tests, HPV knowledge,

perceived susceptibility to HPV and cervical cancer, and perceived severity of HPV and cervical cancer were not statistically significantly associated with intention to self-sample.

A cross-tabulation was conducted to confirm that the relationship between the two most influential variables, self-efficacy and education, acted independently on intention to HPV self-sample (Appendix 4.3). The cross-tabulation exemplified a variation between educational levels and levels of self-efficacy, showing that not all women who were highly educated had a higher self-efficacy level, and that not all women who had a lower educational level had a lower self-efficacy. This demonstrated that the effect of the variables on intention was independent.

	B	S.E.	Wald	*df*	*p*	Odds Ratio	95% C.I. Lower	Upper
Educational level Up to/including GCSE^			6.147	2	.046			
Further education, no degree	0.79	0.69	1.328	1	.249	2.21	.574	8.478
Degree or above	1.80	.75	5.835	2	**.016**	6.06	1.405	26.144
Ethnicity	1.228	.789	2.423	1	.120	3.414	.727	16.028
HPV knowledge prior to study	-.191	.583	.107	1	.743	.826	.263	2.591
Perceived self-efficacy 0=lower, 1=higher self-efficacy	3.22	.69	21.198	1	**.000**	24.96	6.346	98.201
Perceived importance of HPV in causing cervical cancer 1=not important, 5=very important	.84	.39	4.502	1	**.034**	2.32	1.067	5.070
Perceived benefits of HPV self-sampling. 2=less benefits, 10=most benefits	.31	.12	6.306	1	**.012**	1.36	1.070	1.735
Perceived barriers to HPV self-sampling 3=less barriers, 15=most barriers	-.41	.11	14.136	1	**.000**	.66	0.535	0.821
Perceived susceptibility to HPV infection 1=less susceptible, 5=more susceptible	.091	.318	.082	1	.774	1.095	.587	2.044
Perceived severity of HPV infection 1=not severe, 5=very severe	-.538	.323	2.775	1	0.96	.584	.310	1.100
Perceived barriers to cervical smear tests 4=less barriers, 20=most barriers	.178	.096	3.421	1	0.64	1.195	.989	1.444
Perceived benefits of smear tests *2=less benefits,10=most benefits*	.36	.145	5.830	1	**.016**	1.43	1.070	1.913
Perceived susceptibility to cervical cancer 1=low susceptibility, 5=high susceptibility	-.528	.434	1.476	1	.224	.590	.252	1.382
Perceived severity of cervical cancer 1=not severe, 2=very severe	-.098	.252	.151	1	.698	.907	.554	1.485

^ used as a baseline group for regression analysis.

Table 4.12: Logistic regression predicting lower/higher intention to self-sample.

4.8 Discussion

The current study examined the effect of HBM constructs on women's intentions to HPV self-sample. The survey used in this study was able to assess the impact of HBM constructs on women's intentions to HPV self-sample. The use of principal components analysis facilitated the validation of the survey for the extended HBM items, by detecting the underlying structure of items and classifying them into five separate components relating to extended HBM constructs. The final logistic regression model provided evidence that the constructs proposed by the extended HBM were important in influencing HPV self-sampling intentions, and that the model was able to correctly account for over 80% of intentions to self-sample.

Similarly to Snijders et al. (2013), women's intentions to self-sample were high, with 69% of women reporting that they would be likely to HPV self-sample. Factors associated with lower intention included lower self-efficacy, lower educational level, lower perceived importance of HPV in cervical cancer development, fewer perceived benefits of HPV self-sampling and smear testing, and more perceived barriers to HPV self-sampling. Self-efficacy in relation to HPV self-sampling had the strongest association with intention to self-sample. A high odds ratio of 24 was observed, meaning that a woman who has a higher self-efficacy is 24 times more likely to self-sample compared to someone who has a lower level of self-efficacy. However, this result should be interpreted with caution as wide confidence intervals were also observed for self-efficacy, which might be a result of sampling error. The stepwise regression identified that the addition of self-efficacy to the regression model increased the amount of variance explained by the model. This suggests that women's perceived self-efficacy is highly important in influencing women's intentions to HPV self-sample. Previous studies have identified low self-efficacy as a barrier to HPV self-sampling (Stewart et al. 2007; Huynh et al. 2010; Igidbashian et al. 2011). The effect of self-efficacy on intention to HPV self-sample was highly statistically significant and further exploration is needed to understand how self-efficacy influences intentions.

Barriers to self-sampling included worry about hurting oneself whilst carrying out the procedure, worry about the self-sampling kit being lost in the post and not reaching the laboratory, and a lack of trust in the results. The lack of trust in the self-sampling kit may be a result of women doubting their ability in being able to carry out the self-sampling procedure adequately. Facilitators of HPV self-sampling included perceived self-efficacy in personal ability to carry out the self-sampling procedure adequately as well as the belief that: self-sampling would be less embarrassing than cervical smear testing, no-one would be aware that the women would be having cervical screening, smear tests would pick up any cervical abnormalities early on and having smear tests provides reassurance. These findings reflect the findings of other studies, which have identified barriers to self-sampling (Barata et al. 2008). Concerns regarding personal ability to perform the self-sampling procedure and a subsequent lack of trust in the results, have also been previously identified (Szarewski et al. 2009). The current study suggests that women who perceive fewer benefits of cervical smear tests (typically non-responders), are not necessarily more likely to HPV self-sample.

Perceived susceptibility to HPV and severity of HPV infection were found not to be statistically significantly associated with intention to HPV self-sample. Furthermore, no association between HPV intention and perceived susceptibility and severity to cervical cancer was observed. It is interesting that perceived susceptibility was not associated with HPV self-sampling intention, as it has previously been associated with cervical smear test screening uptake (Nadarzynski et al. 2012). This finding might have occurred because perceived susceptibility to a virus such as HPV, which has been described in participant materials as prevalent and transient, might not be as influential as a perceived susceptibility to cervical cancer in influencing intention to uptake screening. The finding that perceived severity was not associated with HPV self-sampling intention might have been due to a lack of knowledge about HPV and cervical cancer interaction and treatments. Perceived susceptibility and perceived severity constructs could have been combined to form a perceived threat construct (Stretcher and Rosenstock, 1997). However, combination of the two constructs would not differentiate their independent influence on intention to HPV

self-sample. It was important that independent influences were investigated to help determine intervention content (Chapter 6).

Finally, associations between extended HBM constructs relating to HPV self-sampling were examined. Statistically significant relationships were identified between perceived: benefits and barriers to HPV self-sampling, benefits to HPV self-sampling and susceptibility to HPV infection, barriers to HPV self-sampling and perceived self-efficacy. It is interesting to note that although perceived susceptibility was not statistically significantly associated with intention to HPV self-sample, it was associated with perceived benefits to HPV self-sampling. This suggests that perceived susceptibility to HPV self-sampling might influence women's perceived benefits to HPV self-sampling but that it was not significant enough to independently influence HPV self-sampling intentions.

During univariate analysis, women from an ethnic minority background were significantly less likely to HPV self-sample; however, this relationship was not present following statistical modelling. The diminishing effect of ethnicity following statistical modelling suggested that although ethnicity may influence women's intentions to self-sample, its effect was not strong enough to remain significant when other influencing variables were accounted for. Furthermore, the small sample size of women from ethnic minority backgrounds might also explain the diminished effect. Previous studies have identified that women from ethnic minority backgrounds are less likely to engage in cervical screening (Chapter 1).

Educational level was related to intention to HPV self-sample with women from a lower educational level reporting lower intentions. Lower socioeconomic status has been reported as a risk factor for lower smear test attendance (Moser et al. 2009). Lower screening intention in women from a lower socioeconomic status may be due to a lack of knowledge. The current survey also found that women who perceived HPV as less important in causing cervical cancer were also less likely to intend to self-sample. This belief may be due to poor health education and lack of awareness of the aetiology of cervical cancer. This seems highly likely considering

that a third of respondents had not heard of HPV prior to this study and believed that HPV could be treated with medicines and half believed that HPV cannot clear up without medical intervention. Previous studies have reported low public knowledge regarding HPV (Waller et al. 2013). It is surprising that despite widespread HPV vaccination in the UK since 2008 and related advertising campaigns, HPV knowledge still remains low.

4.8.1 Study strengths and limitations

The survey enabled the identification of key variables for subsequent in-depth exploration in interviews, and facilitated focus on key issues for consideration during intervention development. Individual survey items were combined to form scales based on the HBM constructs. Some of the items exhibited a low Cronbach's alpha, particularly items relating to perceived benefits to HPV self-sampling and perceived barriers to cervical smear. The low Cronbach's alpha exhibited in these scales might be due to the breadth, such as the possible benefits associated with self-sampling or barriers associated with cervical screening, or number of items present in the scale (Briggs and Cheek 1986). Consequent examination of mean inter-item correlations revealed correlations within the accepted range of 0.2 and 0.4 (Briggs and Cheek 1986). It has been reported that the accepted range of 0.2 to 0.4 mean inter-item correlation is optimal to ensure that the complexity of items is represented and that the construct measured is not too narrow (Briggs and Cheek 1986). Therefore, it was decided to combine the items into scales. Although the items exhibited optimal mean intra-item correlations, they had low Cronbach's alpha values therefore suggesting that there is a possibility that the scales might not be reliable. Alternative methods to scale formation could have been applied such as retention of single items for analysis.

The self-efficacy and intention scales were recoded into binary scales to help differentiate between women who consistently reported higher self-efficacy and intention, from women who have a lower intention or self-efficacy by consistently scoring lower or scoring inconsistently between items. This method of creating a

dichotomous variable was particularly suitable as it was able to identify women who were consistently reporting higher intention or self-efficacy, as opposed to using an alternative method such as a median split to dichotomise the data. A median split dichotomises data based on a single threshold, the median of a particular sample and does not account for consistency which is important when trying to ascertain an overall high level of intention or self-efficacy.
Although the method used in this analysis seems particularly suitable, it only classified individuals who have consistently scored highly on all items relating to intention or self-efficacy as higher intention/self-efficacy. Therefore, this method classified all individuals who did not score consistently high on every item, as having low intention or low self-efficacy. Therefore, a limitation of this form of analysis is that it could incorrectly classify women who score low on one item related to intention or self-efficacy but who might actually have a high level of self-efficacy or intention but have a particular concern in relation to an item.

Although the cross-sectional nature of the survey was useful for identifying the prevalence of hypothetical intention to self-sample for the population within a given time (Levin 2006), it could not prove causality but could only indicate associations between different factors (Mann 2003). Furthermore, the measurement of variables at one time might have led to inflated associations between health beliefs and intention than might not have been found if they had been measured prospectively.

Target sample size was not achieved through the primary recruitment source of Cervical Screening Wales, therefore supplementary recruitment was initiated to achieve sample size. Women from community centres, sexual health clinics and GP practices were targeted to try and account for non-response bias that is traditionally evident in postal surveys (MacDonald et al. 2009). Alternative recruitment helped to achieve target sample size. However, the response rate of supplementary recruitment was unknown because it was not possible to record number of potential participants that were approached and those who declined to

participate. Furthermore, because participants recruited from the main recruitment source and supplementary recruitment sources were combined for analysis, the effect of recruitment source is unknown.

The very low response rate observed from the CSW recruitment and the self-selected nature of the sample limits the generalisability of the study's findings. Although recruitment was initiated through CSW to try and obtain a population based sample, the fact that recruitment cards were sent alongside cervical screening call/recall letters might have impacted the types of women who participated in the study. The recruitment card did not contain CSW or NHS logos, but it might have been perceived as coming from the cervical screening programme. This could have resulted in a sample of women who were particularly engaged with the cervical screening programme. Although supplementary recruitment was initiated to help reach sample size, the final sample of participants were primarily White, highly educated cervical screening responders, many of who had experienced cervical abnormalities.

A more representative sample could have been achieved through alternative approaches to recruitment such as distribution of the survey through agencies that recruit population representative samples, such as the National Survey for Wales, previously known as the Welsh Health Survey, (http://gov.wales/statistics-and-research/national-survey/?tab=current&lang=en). Furthermore, the survey could potentially be incorporated into a large scale online study such as the new HealthWise Wales study (https://www.healthwisewales.gov.wales/homepage/). Alternatively, purposive recruitment strategies through different recruitment sources, for example community groups and social media, could be adopted to achieve a representative sample.

Cervical screening status of the survey participants was not representative of the population as a whole, with 95% of respondents previously attending a smear test appointment. In Wales, approximately 20% of women do not attend cervical smear tests (Wales 2012-2013). The majority of research into attitudes towards HPV self-sampling has been conducted in women who do not attend cervical screening (Gok

et al. 2010; Szarewski et al. 2011), hence it was considered important to identify HPV self-sampling intentions in screening attenders, due to the lack of routine HPV self-sampling. Exploration of the views of screening attenders was considered crucial to identify whether this would be an acceptable alternative method of screening.

The majority of participants were from a white background, with 1 in 10 women being classified as non-white. Focusing on women who are non-responders to cervical screening might have increased the number of women from ethnic minority backgrounds who have been shown to be more likely to be cervical screening non-responders (Chapter 1). Therefore, if this study had focused more on recruiting non-responders, more women from an ethnic minority background might have been recruited. However, the views of cervical screening non-responders have been investigated in previous studies and were therefore not the focus of the current research.

The majority of respondents from ethnic minority backgrounds were recruited through Asian community groups. It might be possible that the individuals who attended the community groups were more integrated into the community and the healthcare system. Furthermore, all the women who attended these groups were fluent English speakers. Women who are non-English speakers might have different attitudes towards HPV self-sampling and would have to rely on family members or friends to translate the HPV self-sampling procedure and subsequent result. Anticipated anxiety about the impact of a HPV positive result on marital relationships has been reported in women from ethnic minority backgrounds, and the fact that someone else would be aware of the result may have an effect on family relations. Further work is needed to assess women's intentions to primary HPV self-sample within ethnic minority groups where English language acquisition is low.

The majority of survey respondents were educated above a degree level; however, representation was also present from women who were educated to below degree

and those who were educated to GCSE level. The proportion of women in each educational category was representative of the population in South-East Wales (ELLS 2013). It was important that a broad range of ages were represented in this survey, because it has been shown that younger (under 30) and older women (over 50) are less likely to attend cervical screening (Wales 2012-2013). It was therefore important to ascertain whether self-sampling would be an acceptable alternative to smear testing in these women. It might be expected that women who are older and more likely to have habituated to attending cervical smears might be less likely to intend to primary HPV self-sample. However, analyses suggested that age was not a significant influential factor in intention to self-sample. The effect of age on intention to HPV self-sample will be further explored during the qualitative phase of this research.

4.9 Next steps

In-depth qualitative interviews were conducted to explore influences on women's intentions to HPV self-sample. The interviews explored the role of self-efficacy, benefits and barriers to HPV self-sampling as well as HPV and cervical cancer knowledge on women's intentions to HPV self-sample. Women's informational needs regarding HPV and self-sampling and their preferred intervention content, format and style were also be explored.

Chapter 5: Gaining further insight into women's attitudes towards HPV self-sampling.

5.1 Overview

The previous chapter demonstrated that women's intentions to HPV self-sample in the context of cervical screening are complex, and involve a wide range of cognitive factors (Chapter 4). Factors associated with lower intention included perceived HPV self-efficacy, women's belief that HPV is not very important in cervical cancer development, and barriers such as the perception that they may hurt themselves whilst carrying out self-sampling, their worry that the self-sampling kit may be lost in the post and a lack of confidence in the results. This chapter will describe the qualitative methods used to gain further insight into these findings, the rationale for the research design, recruitment, analysis, discussion of the results and strengths and limitations of the analysis.

5.2 Introduction

The previous chapter discussed the quantification of extended HBM variables associated with intention to self-sample. This chapter aims to gain further insight into relationships between factors that were previously identified as influencing HPV self-sampling intentions. For example, a lack of confidence in HPV self-sampling results among women might be due to their low perceived self-efficacy or it may be due to other unidentified factors. Unidentified factors refer to factors that are not part of the extended HBM, which was used to inform the development of the survey (Chapter 3 and 4). Accordingly, an in-depth understanding of how factors might affect intention to self-sample will be fundamental to understanding the processes involved in forming intentions to self-sample. This is an essential step towards developing intervention messages specifically aimed at alleviating women's concerns about self-sampling and increasing women's intentions to HPV self-sample.

A change of cervical screening method may require that women not only consider barriers to self-sampling identified in the survey (Chapter 4), but that they also shift

from habitual and normative behaviours to a new method of cervical screening. Habits in health behaviour can be defined as actions that are triggered automatically in response to contextual cues that have been associated with their performance (Neala et al. 2012). Therefore, it can be argued that because of frequent performance in similar situations in the past, mental representations and the resulting action can be automatically activated by environmental cues (Aarts et al. 1998). For example, breast self-examination may be classed as a habitual behaviour because it must be carried out frequently (at least once a month) and automatic cues may be the action of changing of clothes. Social norms may also be important in understanding screening behaviour. It has been suggested that due to its infrequent nature engaging in cervical screening is not a habitual behaviour but one that requires a decision to be formed each time of whether to be screened or not (Bish et al. 2000). However, older women who have attended numerous cervical screens may have habituated smear testing as a habitual behaviour, while younger women who are close to screening age may expect to engage in routine smear testing due to modelling the behaviour of female family members who have engaged in screening over many years. Women's perceptions regarding this potential shift need to be further investigated as they are likely to be influential in women's intentions to self-sample.

The aims of this part of the research are: (i) to gain a deeper understanding of the influence of self-efficacy on women's intentions to self-sample; (ii) to provide further insight into women's perceptions of benefits and barriers to self-sampling, and the ways in which these factors affect intention to self-sample; and (iii) to reveal influences on self-sampling intentions that were not identified in the existing literature or previous survey chapter. The results presented will be used to inform the content of an HPV self-sampling intervention by addressing women's specific concerns regarding self-sampling.

Women with low intention to self-sample were of significant interest. Women with a lower intention to self-sample were specifically targeted for interviews because

they would be the target audience for any intervention designed to increase self-sampling intention. Perceptions regarding smear tests were sought to inform the feasibility of HPV self-sampling, should it become available for women who are cervical screening attenders.

5.3 Methods

Qualitative analysis was used as part of a mixed methodology. Mixed methods, in which both quantitative and qualitative methods are combined, were considered valuable because they capitalise on the respective strengths of each method (Jick 1979). A mixed methods approach is able to enrich survey findings and to discover factors not identified in a survey by also utilising qualitative methods. The qualitative methods would be able to provide more insight and depth into understanding the influences on women's intention to self-sample (Ritchie and Spencer 2002).

During the quantitative phase of the study, explanations for HPV self-sampling intentions were initially derived from the HBM and literature to design questionnaire measures. The survey facilitated the identification of significant factors that influenced women's HPV self-sampling intentions. Qualitative methods were then used to gain richer insights into individual experiences, beliefs and practices in relation to the relationships identified during the quantitative phase regarding cervical screening and HPV self-sampling. Relationships that were of particular interest were the way in which self-efficacy influenced intention to HPV self-sample, as well as the effect of HPV knowledge on intention.

Semi-structured qualitative interviews were therefore used to focus on specific factors associated with intention to self-sample. Although the survey and HBM were used to structure the exploration of women's intentions to HPV self-sample, it was important to acknowledge that the researcher conducting the interviews was implicated in the construction of knowledge. It was acknowledged that the researcher was an active participant in the knowledge production and is not a

neutral bystander. The background of the researcher as well as their pre-conceived beliefs, biases and knowledge about HPV self-sampling, can influence the methods chosen for enquiry as well as the way data were analysed and the findings considered most relevant (Malterud 2001). During the interview stage of the research, the researcher wrote reflective statements following interviews to reflect on the general atmosphere of the interview as well as researcher perceptions.

This study received approval from the South-East Wales Local Research Ethics Committee C (REC: 11/WA/0213) (Appendix 5.1) and Public Health Wales Research and Development approval (REF:2012PHW0023) (Appendix 5.2).

Inclusion criteria

Women who had previously consented in the survey phase were purposively sampled for lower intention to HPV self-sample. Inclusion criteria stipulated that participants were between the ages of 20-64 years and had consented to be contacted for an interview.

Interview participant recruitment

Women who were classified by the survey as having a lower intention to self-sample and who had indicated that they would be happy to be contacted by the researcher for an interview were sampled. Women were contacted directly by the researcher through the post and sent an information sheet and consent form (Appendix 5.3). Non-responders were not re-contacted. All participants who returned a signed consent form were contacted by telephone to arrange a convenient time and location for interview. During the telephone conversation, the researcher explained the purpose, format and duration (30-60 minutes) of the interview. Participants were also reminded that they were not obliged to participate in the study and were free to withdraw from the study at any point without providing a reason. Further consent to participate and permission to audio-record interviews were taken at the point of interview.

Interviews were conducted in participants' homes (N=16) or in a seminar room at Cardiff University (N=3), depending on participant preference. Interviews were conducted between January and February 2014.

Interview schedule

A semi-structured interview schedule (Appendix 5.4) was developed based on the extended Health Belief Model constructs previously identified as being significantly associated with HPV self-sampling intention (Chapter 4). A mixed methods approach was applied when developing the interview schedule. This involved drawing on basic principles of survey development guidelines to try and minimise potential bias associated with question order effects (French and Sutton 2010a). Furthermore, it is also assumed that participants would have some prior knowledge of the field especially as they were previously involved in the completion of a survey about their attitudes towards HPV self-sampling (Chapter 4). Intention to self-sample was the first topic for discussion, followed by potential influential factors such as HPV knowledge. By ascertaining women's intentions to self-sample from the outset of the interview, the researcher was able to see how reflection upon further questions influenced their stated intention. Although the ordering of the questions was pre-determined, there was opportunity to diverge from the schedule by exploring further issues as they arose.

The interview schedule was then divided into two sections: the first section identified perceptions relating to HPV self-sampling and HPV in general, whilst the second section focused on the current form of cervical screening (cervical smear tests). The interview guide invited discussion on the following topics:

(i) intention to self-sample
(ii) perceptions of self-efficacy in relation to carrying out the self-sampling procedure, the operational factors involved in self-sampling, and subsequent confidence in the self-sampling results
(iii) benefits and barriers to HPV self-sampling
(iv) experiences of using a different self-sampling kit (e.g. pregnancy test)
(v) HPV perceptions

(vi) cervical cancer perceptions and smear test perceptions (benefits and barriers)

At the end of the interview, participants were asked whether they would like to take part in the user testing of a potential HPV self-sampling intervention.

Data management

All interviews were audio-recorded with the participants' consent and were subsequently transcribed verbatim for analysis. Verbatim transcription focused on the word-for-word reproduction of verbal data, with the written words forming an exact replication of the audiotaped conversation (Poland 1995). The interview data were entered into the qualitative analysis software programme NVivo 10 (QSR International Ltd, 2012) for storage, coding and indexing purposes.

5.4 Analysis

Framework analysis

The interviews conducted in this study sought to organise the data according to a framework which was initially developed largely from *a priori* constructs but that was later expanded, making it particularly suitable for exploration through framework analysis. There was a specific interest in gaining further insight into *a priori* constructs and framework analysis enables the process to be primarily focused on the aims and objectives of the research. Furthermore, framework analysis does not aim to build a theory but focuses on the investigation of relationships between concepts that are of interest. Consequently, analysis of these data initially required a more deductive approach such as framework analysis (Ritchie and Spencer 2002).

Framework analysis was developed with the purpose of generating practice-oriented findings, and addresses specific information needs by using *a priori* constructs to produce actionable outcomes (Green and Thorogood 2011). Whilst

allowing for *a priori* construct investigation, framework analysis is driven by the original accounts of the participants and is open to change, addition and amendment throughout the analytic process, whilst also remaining systematic in enabling the methodological treatment of all similar units of analysis (such as paragraphs) that were judged relevant to the question as defined by the aims and objectives of the qualitative phase, and therefore incorporating them into a framework (Ritchie and Spencer 2002).

Framework approach involves a systematic, interconnected five-stage process of analysis. Although depicted as a linear progression, the process is overlapping and iterative (Figure 5.1). Analysis takes form as a rigorous and iterative process of moving back and forth through the five stages. This process leads to modification of the framework in order to best represent the views of participants and the interpretation of the researcher/s. During the analytical process, the approached developed over time from a theory driven framework analysis to a more inductive thematic analysis. A more inductive thematic analysis approach was developed due to the new themes emerging from the data and the subsequent multiple re-iterations and re-evaluations of previously analysed interviews.

The following sections provide an account of how data were analysed through framework analysis and how the analysis became increasingly inductive and thematic. The framework analysis steps used were suggested by Richie & Spencer (2002) (Ritchie et al. 2003). NVivo 10 was used for the development of the framework, coding and indexing of transcripts. The use of NVivo particularly facilitated the iterative re-development of the framework and the subsequent re-coding of data.

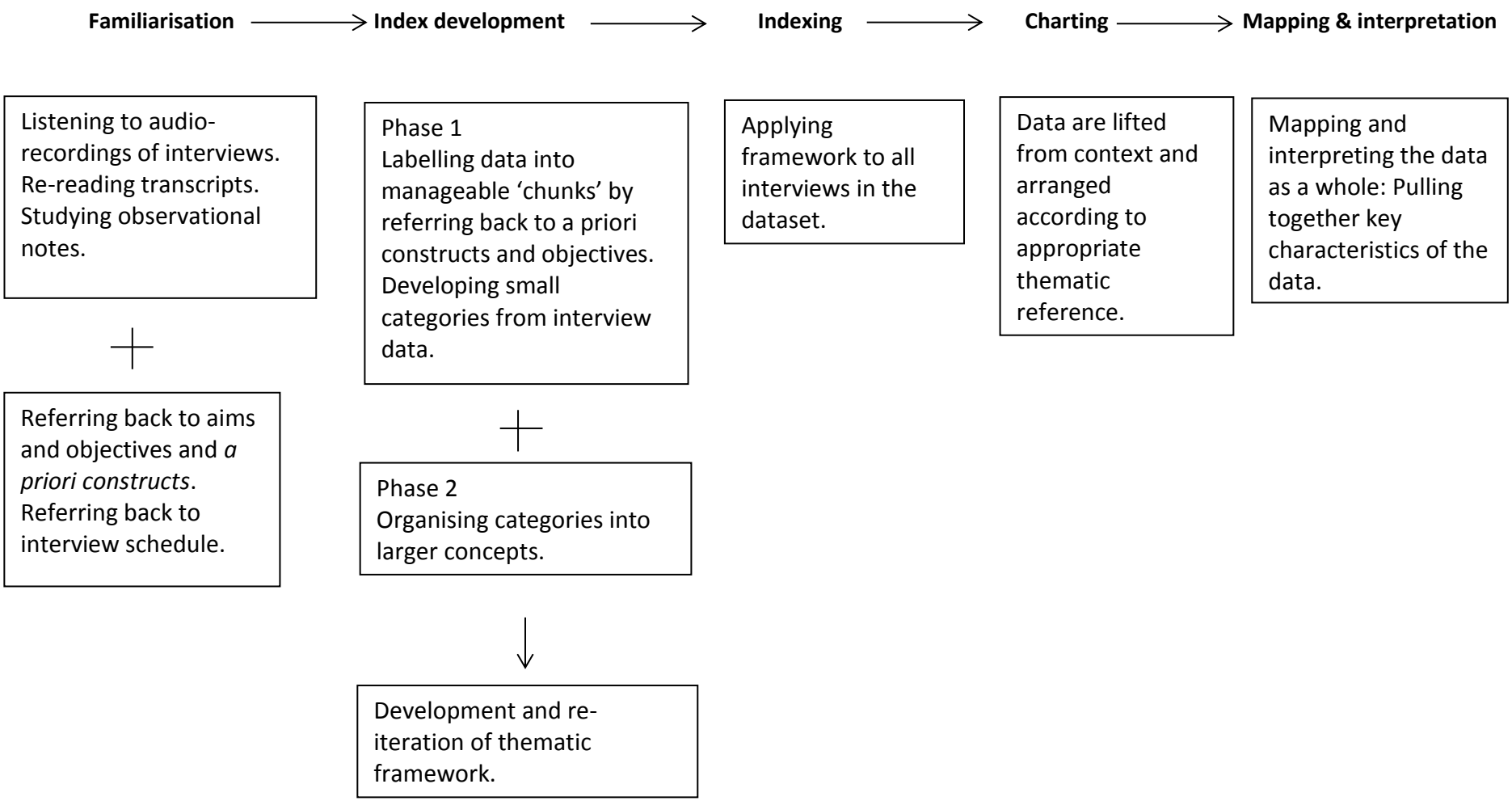

Figure 5.1: Framework Analysis Approach (adapted from Richie & Spencer, 2002)

Familiarisation

Familiarisation refers to the researcher's immersion in the raw data with the aim of maintaining the integrity of respondents' narratives, whilst also focusing on the pre-defined research questions. The familiarisation stage of analysis was crucial to the analysis process as it helped build the foundation of the conceptual framework (Ritchie et al. 2003) used to understand participants intentions to self-sample. Familiarisation was achieved by listening to audio recordings of interviews, reading transcripts, reading the interview schedule and reflecting on interview notes. During this process, key ideas and recurrent themes were listed and the general atmosphere of the interviews and the ease or difficulty of exploring certain subjects during interviews was considered. The familiarisation process continued until it was felt that the diversity of responses within the data was understood.

Index development: Identifying a thematic framework

The aim of this stage was to develop a thematic framework. Following familiarisation with the data, data coding was initiated to sections of the transcript which were relevant to the research question (Ritchie and Spencer 1994). These sections were assigned a 'code' to categorise and summarise them. Coding was carried out in two phases: initial coding involved identification of numerous small categories (codes) from the interview data. The categories can be broadly described as reflections, attitudes, beliefs, personal experiences and contextual issues. Although questions were determined *by a priori* idea, the second phase of coding was inductive, reflexive and increasingly thematic. The second phase involved the organisation of categories into concepts. Secondary coding was developed by drawing on the initial phase codes as well as the *a priori* HBM constructs, interview schedule, and aims and objectives of the study. The relationships between the initial categories were considered in order to develop secondary categories. The index development stage of the analysis process facilitated the development of a clear initial coding structure that facilitated the exploration of women's beliefs about and attitudes towards HPV self-sampling

Figure 5.2 outlines the development of the thematic framework. Some of these were identical to the specified areas of questioning (e.g. potential for physical harm), whilst others were newly defined from emerging themes during the interview (e.g. confidence in self-sampling programme).

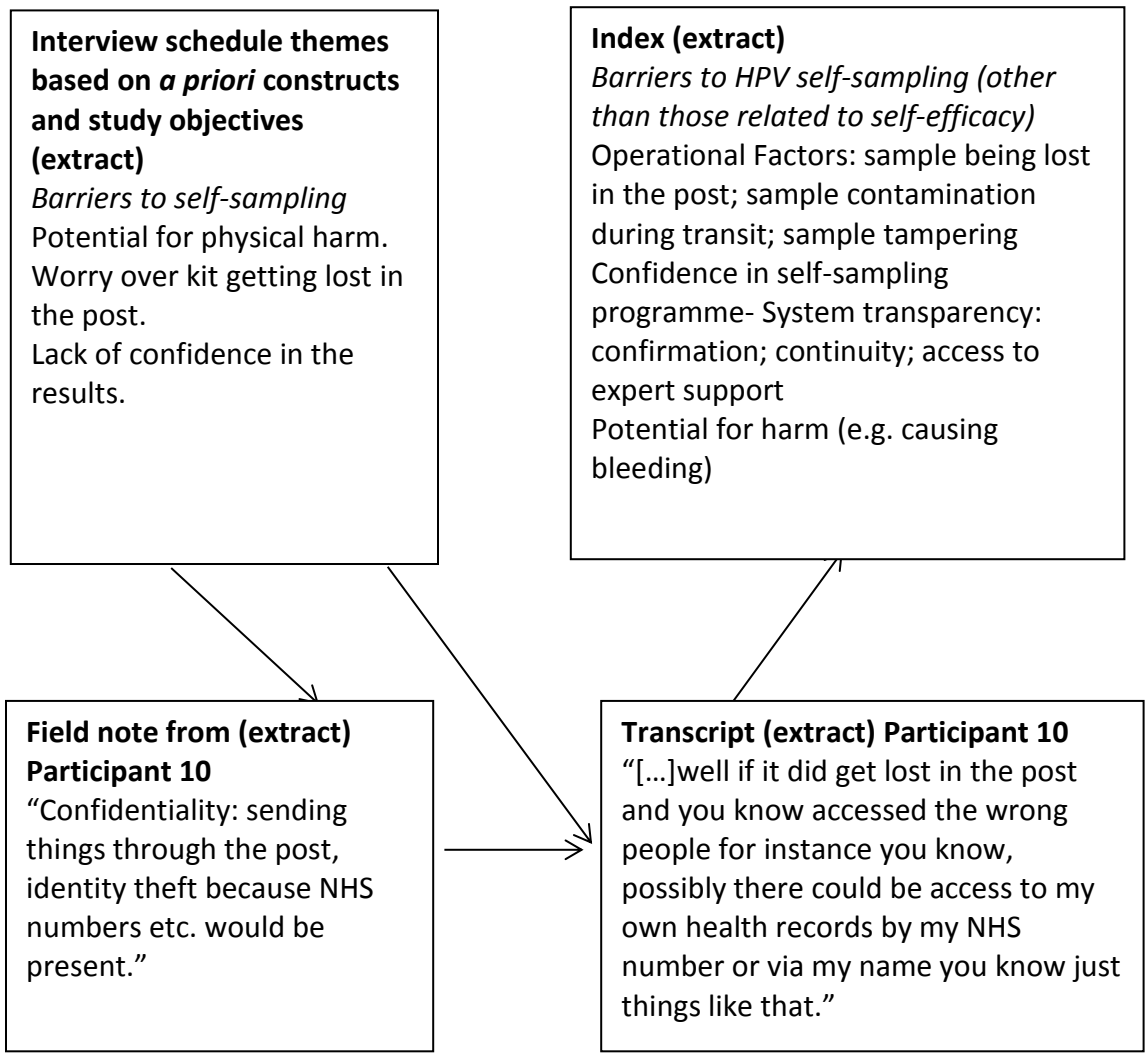

Figure 5.2 Development of the thematic framework

Development of the conceptual framework

The thematic framework was developed by referring back to *a priori* constructs based on the HBM, research questions, study aims and objectives, and was modified throughout by the analytical themes that arose from the patterning of participant views. Once the recurring themes were identified, an initial conceptual framework ('index') was developed. Themes within the index were then grouped together under a smaller number of 'main themes' and used to structure the overall framework. Numbers were assigned to differentiate levels of the individual themes, with low numbers relating to the macro level (main) themes and higher numbers relating to micro level themes.

The first version of the index was largely descriptive and heavily reliant on the *a priori* constructs derived from the extended HBM and the interview schedule. An iterative and reflexive process followed to facilitate further development of the framework. The analytical process became more inductive and thematic as interview analysis progressed. Therefore, although the first framework version was applied to a number of transcripts and was subsequently refined, it became more thematic and responsive to new themes, ensuring that they were encompassed in the framework. For example, the theme of barriers to self-sampling was expanded to include the second level theme of operational factors, and then further expanded to include the third level theme of identity theft, for example *"if it did get lost in the post and you know accessed the wrong people…possibly there could be access to my own health records by my NHS number or via name…" (P10)*. Judgements were made relating to the meaning, relevance and importance of the issues presented in relation to self-sampling intention and how well they could be classified within the developing framework. This iterative and thematic process of framework application to transcripts and subsequent modification continued until the framework was able to account for all relevant classifications.

The framework was applied to all interview transcripts. Chunks of data (at sentence or paragraph level) that were relevant to the research questions were indexed according to the framework. All transcripts were read and annotated according to the thematic framework. This became an increasingly iterative and thematic process, with the framework adapting and changing throughout the analysis. The meaning conveyed for each passage of text was inferred, with consideration of its relevance within the passage as well as the whole interview and subsequently mapped it onto the framework. Indexing references were recorded by a descriptive textual system. It was often found that individual passages contained a number of different themes, leading to multiple referencing within a section of text. Multi-referencing facilitated the exploration of associations within the data (Ritchie et al. 2003). Indexing text to the framework facilitated an analytical process that was clearly visible and accessible to others ensuring transparency in how data were identified and organised.

A proportion of the transcripts (N=5) were double coded by a qualitative researcher with expertise in framework analysis (MD). Transcripts were double coded to test the utility of the framework and to ensure a shared understanding and interpretation of the data being coded into the framework (Weston et al. 2001)

Inter-rater agreement during double coding was 85% (690/826 codes). Although no base percentage of agreement has been defined, it is generally accepted that inter-rater agreement over 85% is satisfactory (Saldana 2009). Discrepancies were resolved through discussion.

Thematic Charting

Following the development and application of the thematic framework to all transcripts, the process of charting was initiated. Richie and Spencer (1994) suggest that charts are developed for each key subject area and that entries are made for each respondent in the same order in every chart (Ritchie and Spencer 1994). However, the comprehensive framework developed for the present study would produce highly complex and large charts which would be difficult to cross-reference and compare. In

order to facilitate a clear chart development, it was therefore decided to chart illustrative quotations that were considered to best summarise the themes within the framework for all theme levels reflecting the increasingly inductive and thematic nature of the analysis. For example, the following quote was used to illustrate the main theme relating to confidence in the self-sampling programme *"yeah it the whole, not just the test itself, but the whole process associated with the test, I would just be sort of like, then I might worry about whether or not it was any good…"* (P5).

Mapping and Interpretation

The final stage of analysis involved in-depth thematic interpretation of the data by pulling together key characteristics and interpreting the data as a whole. During this process, the thematic framework and research notes were used to compare and contrast the perceptions and experiences of the participants, whilst searching for patterns and connections within the data. Mapping and interpretation involved the identification of expected and emerging influences on attitudes to self-sampling, and consideration of their relationship and relative importance. This process helped to further define the concepts in the framework. For example, the processes facilitated the identification of system as well as individual barriers to self-sampling. Some of the system barriers related to operational factors in the set-up of the self-sampling system which included sub-themes such as identity theft. Individual barriers such as low self-efficacy were also multi-faceted and included sub-themes such lack of professional expertise, lack of practice and lack of confidence in result.

5.5 Results

Thirty seven potential participants who had indicated on their survey that they would be happy to receive information about a follow-up interview and were classified as less likely to HPV self-sample were sent an interview recruitment pack. Twenty two women returned a consent form and indicated that they would be happy to participate in the

interview study. Women were contacted via telephone to arrange a suitable interview date and venue. A total of nineteen participants were recruited.

5.5.1 Sample Characteristics

Participants were aged between 23 and 63 years (Table 5.1). The majority were from a white ethnic background (n=17) and educated to degree level (n=10). Participants were purposively sampled for low intention to HPV self-sample. Most participants reported having experienced an abnormal cervical smear test result in the past (n=12) and had heard of HPV prior to the study (n=14).

Participant number	Age	Educational level	Ethnicity	Heard of HPV	Previous abnormal cervical screen
1	23	Degree	White	Yes	No
2	27	Degree	White	Yes	No
3	40	Degree	White	No	Yes
4	24	Left school at 15	White	Yes	Yes
5	30	Degree	White	Yes	Yes
6	53	GCSE/O Level	Other	Yes	Yes
7	35	Degree	White	Yes	Yes
8	31	Degree	Other	Yes	Yes
9	53	Further education	White	No	No
10	57	Further education	White	Yes	No
11	27	Degree	White	Yes	Yes
12	28	Degree	White	No	No
13	63	GCSE/O Level	White	No	Yes
14	52	Further education	White	Yes	No
15	23	Degree	White	Yes	No
16	56	GCSE/O Level	White	Yes	Yes
17	44	Degree	White	Yes	Yes
18	23	GCSE/O Level	White	No	Yes
19	63	GCSE/O Level	White	Yes	Yes

Table 5.1 Interview participant characteristics

5.5.2 Themes identified

The full thematic framework contained nine 1st level categories (themes) (Table 6.2) and 109 2nd level categories (themes) (Appendix 5.5).

The nine themes were: general cancer perceptions, HPV and cervical cancer perceptions, women's understanding of HPV self-sampling, women's intentions to HPV self-sample, perceived intentions of other women to engage in HPV self-sampling, women's confidence in their ability to perform HPV self-sampling properly, barriers to HPV self-sampling and facilitators to HPV self-sampling.

Major theme	**Description**
Own intention to self-sample	Explicit reference to own intention to self-sample.
Other's perceived intention to self-sample	Explicit reference to perception of other's intention to self-sample.
Understanding of self-sampling	Placing self-sampling in the context of other screening methods
Perceived self-efficacy	Components of self-efficacy and its effect on intention to self-sample.
Barriers to self-sampling	Perceived barriers associated with self-sampling, other than those related to self-efficacy.
Facilitators to self-sampling	Perceived advantages of self-sampling
Cervical cancer perceptions	Attitudes to causality, prevalence and impact of cervical cancer.
General cancer perceptions	Attitudes towards cancer.
HPV perceptions	Attitudes towards HPV and self-sampling.

Table 5.2 Major themes identified in qualitative analysis.

Nine charts were developed based on the nine main themes identified in the framework. Appendix 5.6 presents one of the charts used to provide more insight into the perceived benefits to self-sampling. Each theme will be discussed below in detail.

5.5.3 General cancer perceptions

Participants often felt that the causes of cancer in general were still unidentified, but they had positive views of cancer screening and felt that the earlier a cancer is caught the better the chance of survival.

> *sooner you catch cancers and they're dealt with then it's so much better you have a better chance. (P9)*

General cancer beliefs regarding fatalism and cancer prevalence were also discussed by women. Fatalistic beliefs were influenced by a belief that the availability of screening and its ability to detect cancer at an earlier stage would result in it being more treatable.

> *I think that cancer obviously is a deadly thing um but most people do survive if it's found early enough (P18)*

However, one participant (P4) had a strong sense of severity of the disease, which may have been influenced by the death of her mother from cervical cancer when the participant was a teenager:

> *I was listening to the radio this morning, and he was saying that on the radio the UK is the biggest place for cancer in the world...loads of sufferers of it, it's a killing disease (P4)*

5.5.4 HPV and cervical cancer perceptions

Cervical cancer causality

Most women did not know what caused cervical cancer. Some attributed cervical cancer to lifestyle factors, genetic factors or something that just happens.

> *I think it's more a genetic thing and passed down […] (P18)*
>
> *lifestyle and your diet and um stress I guess, all sorts of things […] (P17)*

General HPV knowledge

One participant, who had completed a microbiology degree and had worked with HPV, had prior knowledge of HPV and understood its link with cervical cancer. All others had a lack of HPV awareness despite stating that they had heard of HPV prior to the study. Twelve women had minimal knowledge of HPV: when asked what they knew about HPV, they often referred to the HPV vaccine or said that they had *"heard of it" (P12)* without having an understanding of what the virus is and that it causes cervical cancer. The remaining six participants stated that they had no prior knowledge of HPV:

> *I don't know nothing at all about it (P4)*

The women who were unaware of the link between HPV and cervical cancer often felt embarrassed by their lack of knowledge, and perceived HPV infection to be very serious. They were also shocked to learn that HPV is highly prevalent.

> *I know it's very serious and that's why I'm a bit embarrassed that I don't know more about it (P11)*

Other women talked about the sex education they had received at school and stated that they had not been taught about HPV or its link with cervical cancer. Some women acknowledged that they had been regular cervical smear attenders from a young age, but that the role of HPV in cervical cancer was never explained to them. Consequently, women felt that more education about cervical cancer and HPV was needed.

> *…basically my generation was never educated in anything like that, you know especially with school with sex education … so I think for me I'm a missed generation to understand what it is fully (P10)*

Missed opportunities for education included sex education classes during school, as well as abnormal cervical screening results and appointments. Some women referred to their experience of having an abnormal screening result and subsequent treatment,

and expressed surprise that they were not informed about HPV during these appointments.

> *I had abnormal cells back from a smear test um once I had to go and have some treatment, but they never mentioned HPV to me, you know, that was never something that they mentioned…(P11)*

HPV transmission

Women's knowledge about HPV was reflected in their differing beliefs about HPV transmission, some of which were congruent with scientific understanding, whilst others were not congruent. Most women were unsure about how HPV is transmitted and often cited a number of different ways. However, the majority of participants believed that HPV is transmitted during sexual activity.

> *…well I assume it's sexually transmitted then… that sounds most logical (P14)*

The majority of participants believed that multiple sexual partners increased the risk of HPV transmission, with one participant stating that younger women would be at a higher risk of transmitting and catching HPV because they engage in more short–term relationships. This participant believed that the issue of HPV transmission would be irrelevant for her because she was in a long-term monogamous relationship, suggesting that she saw herself at a lower risk of HPV infection than younger or promiscuous women.

> *I would think certainly for younger people it would be more relevant, or for unmarried people or something, but you know I'm in a stable relationship sort of thing now… I would imagine if people are single, or maybe if they're sleeping around, or they've got a few different partners, or something like that then it would probably be more relevant… (P19)*

Some participants also stated that HPV may be transmitted during unprotected sex with someone who was previously infected.

> *…someone that's carrying it, and you have unprotected sex with and then contract it… (P11)*

Participants also rationalised that because HPV was a virus its transmission may be air borne, similar to a common cold.

> *…catching it off someone else, air bound (P4)*

Participants also said that HPV may be something that is already in the individual's body, remaining dormant and being activated by a certain trigger.

> *Whether it's just something that is you know like they say it's just in your body, and sometimes you have it, sometimes you don't maybe like a hormone imbalance will trigger something then you get it!" (P1)*

Another participant thought that HPV may be transmitted by insertion of foreign bodies (such as tampons) into the vaginal area.

> *…other than things like tampons or something I don't…how would you get a virus in that area (P1)*

Finally, another participant also believed that HPV may be transmitted by contact with contaminated objects such as toilet seats or bodily fluids from infected individuals.

> *Obviously innit if someone's bleeding or something and you touch that blood you try to help them and then you touch that blood, maybe you can catch it like that, or through I don't know toilet seats coming out of peoples' bodies (P4)*

Incongruity

Incongruity was also a common feature when discussing cervical cancer and HPV, especially when participants realised that HPV is a sexually transmitted virus. One participant whose mother had died from cervical cancer refused to believe that cervical cancer is caused by HPV and rationalised this belief by stating that her mother did not have multiple sexual partners, and that she was in a monogamous marriage. The participant became upset by the proposition that her mother had somehow been infected with HPV and stated that she did not believe that HPV was the only cause of cervical cancer.

> *…well my mum had cervical cancer and she never had a lot, multiple partners she had one husband from the age of 16 and till she died which was 2 years ago… and I'm not sure whether it does and that's the only reason, my mum didn't have multiple partners (P6)*

When discussing the link between HPV and cervical cancer, some women believed cervical cancer to be less threatening than previously thought because it was caused by a virus which they thought might be treatable.

> *…because it a virus [HPV] I would think is something that can be treated…if you said to somebody oh you've got this virus, which we can treat, or if you said...they'd be going "that's great thank you very much" but if you said to someone "right you've got cervical cancer which we can treat" you'd be like...cancer, cancer! That's how I would look at it, I'd think oh virus yeah people have viruses all the time (P1)*

5.5.5 Women's understanding of HPV self-sampling

Women had a basic understanding of HPV self-sampling, which was attributed to the description of what HPV self-sampling would involve that was included in their participant information packs. Women clearly comprehended that self-sampling would involve a three step procedure of (1) sample collection, (2) placing the sample in a transport medium and (3) posting the completed kit to the laboratory.

> *um well I imagine that it's got some kind of brush […]that you'd insert and you know you'd move it around a bit and then you'd put it in a pot and then stick it in the post (P2)*

However, even though women understood the three steps of self-sampling, they rationalised their understanding in the context of cervical smear tests. They often compared the two screening methods and perceived similarities between them. Most women believed that the self-sampling kit would involve collection of material from the cervix and some also believed that a speculum might need to be used.

> *My only concern would be am I putting it in far enough, because obviously when they do a smear test they open up your sort of cervix type thing and then they take, it's in quite deep to take the sample and it would be "am I inserting it high enough?" (P17)*

> *Um uh and I sort of perhaps can't quite imagine how using the contraptions the stuff they do how you can do a self-sample? (P9)*

The majority of women did not relate HPV self-sampling to other widely available self-sampling tests, such as faecal occult blood test (FOBT) or pregnancy tests, with only one participant relating the FOBT self-sampling test for bowel cancer to HPV self-sampling. Women did not see similarities between HPV self-sampling and pregnancy testing, and felt that the two tests were not comparable.

…to me a pregnancy test isn't the same as that [HPV self-sampling], you're just weeing on a stick, anybody could do that […] I wouldn't even class that as the same… (P11)

Confidence in HPV self-sampling results

When questioned early in the interview about their confidence in the results obtained from self-sampling, women stated that they would have the same level of confidence for results produced from self-sampling as cervical smear tests.

"yeah, yeah I would yes absolutely I mean just like my smear test I don't know the ins and outs of that, but I just get a letter back saying your smear is abnormal or normal and then you take that as read you know I would never question it"(P11)

5.5.6 Women's own intention to HPV self-sample

Women directly discussed their own intention to self-sample and contextualised intention according to a number of factors. Although women were sampled for a lower intention to HPV self-sample as determined by the survey, the majority now stated that they would be willing to try self-sampling if it was available.

yeah, I would have a go yeah (P 17)

Most women perceived benefits to self-sampling.

I think it's a really good idea (P15)

Women often viewed self-sampling as a positive step in the advancement of cervical screening. One participant contextualised her intention to self-sample as helping the future screening availability for her children.

I would love it for my children um in the years to come if they could just do it and could be hassle free then I'd be all up for it (P7)

Some women referred to their previous experience of cervical abnormalities as a direct factor in determining their positive intention to self-sample, and held particularly favourable attitudes towards screening.

> *yeah I think it's brilliant I would definitely embrace it, especially as I've had problems in the past with… potential cervical cancer I think it's brilliant and if it's, if it's another way of screening people and I welcome all screening*, (P11)

Availability of cervical smear test

Availability of a cervical smear was an important influence on intention to self-sample. Women stated that their intention would be highly influenced by the availability of an alternative, and often saw self-sampling as an inferior method of cervical screening compared to cervical smears.

> *if it was the only option that I had then I would do it… but if I had an option of having a smear test with the nurse, or doing it myself then I'd go with the nurse. (P1)*

Women's preference for cervical smear tests appeared to be linked to their confidence in the current form of cervical screening, and concerns about losing access to professional expertise.

> *you know if you were to use, use the self-sampling would you still be able to go then to your GP… (P3)*

The habitual nature of cervical screening behaviour influenced women's intentions to self-sample, with women who expressed a preference for the habitual behaviour reporting a lower intention to self-sample.

> *I don't know....I think I'd stay with my GP because it's what I'm used to. (P3)*

Women felt that they would be more likely to engage in self-sampling once it had been established as routine cervical screening.

> *…when it becomes more open and discussed with people to say oh look it's quite natural now we just self-sample… (P3)*

Ease of self-sampling kit

Intentions were also formed on the basis that the self-sampling kit would be easy to use and/or the instructions supplied with the self-sampling kit would be simple. Perceptions that the instructions provided were going to be simple could be attributed to women's confidence in carrying out self-sampling (discussed later in this chapter).

> *…no as long as I've got idiot proof instructions I would give it a go. (P13)*

One participant found it difficult to fully form an intention to self-sample because the kit and the programme discussed were hypothetical. She wanted to have more information about the self-sampling kit and the proposed set-up of the programme. The effect of operational factors on perceived barriers to self-sampling is discussed later in this chapter.

> *I would have to have all the details about the actual kit itself before I'd want to do something like that, especially with something that is to do with something kind of a very serious topic and illness I think (P15)*

The participant wanted to have more information before receiving the HPV self-sampling kit which she felt would result in her not needing to seek extra information from experts.

> *If I knew more about it before the kit landed on my doorstep I would be less inclined to call someone just to verify it if I knew more about it (P15)*

5.5.7 Perceived intentions of other women engaging in HPV self-sampling

Women often referred to the perceived intentions of others to engage in self-sampling when questioned about their own intention. Primarily, women thought that cervical screening non-attenders would be particularly in favour of self-sampling. Women often cited barriers to cervical screening, such as embarrassment, and perceived benefits to self-sampling, such as carrying out the procedure at their own convenience in the comfort of their home.

> *I think it would be a fantastic idea because a lot of women are nervous and a bit apprehensive about going to the surgeries to have smear tests and different, you know just to be looked at down that area… (P10)*

> *I think to do it from the comfort of your own home would make sure that more women would do it (P8)*

Age

Women identified age as an influential factor on other women's intentions to self-sample. Women perceived self-sampling as being less intrusive than cervical smear tests, and believed that it might be particularly favoured by younger women who had not yet engaged in sexual activity. Conversely, some participants thought that older women might be more inclined to prefer a cervical screening procedure that was carried out by a health professional.

> *I think it might be a generational thing, but I think maybe people of an older age maybe less inclined to do it because of um that, that kind of authoritarian voice saying "you need to come to the doctors, doctors and nurses are the only ones that are going to be able to give you the decision about it" I think that might be an issue (P15)*

5.5.8 Women's confidence in their ability to perform HPV self-sampling properly

Women generally felt that their lack of confidence in performing self-sampling adequately would affect their intention to self-sample, for example, by delaying completing the kit. While self-efficacy appeared to have been an additional barrier for some, it was found among others that low-self efficacy directly influenced intention. Low self-efficacy beliefs influenced intention by outweighing any possible benefits to self-sampling that women perceived. This reflected the significant impact of women's lack of confidence in their ability to carry out self-sampling properly.

Lack of confidence (low-self-efficacy)

Most women in the sample were worried that they would not be able to carry out self-sampling properly.

> *I'd carry it out by all means, but then I would also be worried in the back of my mind that I hadn't done it properly (P10)*

Underlying this concern was a perceived lack of personal expertise to be able to carry out self-sampling properly. Women referred back to cervical smears and said that they lacked the professional training needed to carry out a screening test.

> *I guess my concern would be if a medical person had been doing this for all this time, would your sample be um good enough… (P9)*

Lack of skills was also a factor that was prominent in women's discussions about their worry that they would not be able to carry out self-sampling properly. Women associated their lack of confidence with the novelty of the procedure.

> *I think perhaps I would question if I had done it correctly the first time (P11)*

Women's belief that they might not carry out the self-sampling properly influenced their confidence in the self-sampling results. Some women expressed concern that if

they received a 'negative' result stating that no high risk HPV was found within their sample, they would worry whether they had actually carried out the self-sampling procedure correctly, and had "missed" something due to not having sampled from an area in their vagina that might have contained the high risk HPV.

> *I think if it was negative I'd be worrying whether I'd done it right […] because if there's nothing there then there's a chance that you might've missed it (P2)*

These women felt that they would have low confidence in the results obtained from self-sampling and would seek expert support.

> *I can see the potential for people rushing to the GP who wouldn't like myself included, who wouldn't go if they'd had the procedure done by a professional but would go because they were like I've done it, I might've done it wrong (P5)*

Women often talked about the consequences of not performing self-sampling correctly. Women were worried that an incorrect 'healthy' diagnosis might be made if they had not performed self-sampling properly. Women felt that if they had carried out the test incorrectly and were given a wrong diagnosis, that it would be a further three years before they would be able to repeat the test and receive a correct diagnosis. One participant referred to carrying out self-sampling incorrectly and receiving a wrong diagnosis as a catastrophic event.

> *if you don't do it right and there is a problem, you're talking of maybe a life and death situation (P1)*

High confidence (high perceived self-efficacy)

Although the majority of women felt that they may not be able to carry out self-sampling properly, two participants expressed high confidence in their ability to carry out self-sampling properly.

I would be happy to carry that out myself I wouldn't feel you know anxious to do it myself, or nervous or anything like that I think I'd be more confident to carry it out myself rather than somebody doing it for me you know (P10)

I think the only person you can trust is yourself so do it all yourself innit? (P4)

Participant four in particular was highly confident in her ability to carry out self-sampling properly throughout the interview. Participant four was a 24 year old woman who had left school before obtaining any formal qualifications. The participant stated that her mother had died due to cervical cancer and lived with her grandparents and her young daughter. She distrusted health professionals (this is discussed later in this chapter in the barriers to self-sampling section) and felt that she would be the best person to carry out the sampling; however it must be noted that most of the sample did not share her view. She felt that she would make every effort to ensure that the self-sampling had been done correctly, whilst alluding to the belief that an individual who was not carrying out the procedure on themselves (e.g. health professional) might take less care.

When discussing confidence in self-sampling results, participant four was the only one to state that she would have more confidence in the self-sampling test result than a cervical smear test result, because she felt that she would ensure that the three step procedure was followed correctly.

yeah I would, I'd trust them more because I, I don't know, I don't want to die like, I'd make sure it was the right thing to go in the right bottle, or whatever like… (P4)

Other women who reported higher confidence in their ability to carry out self-sampling referred to their experience with using other feminine technologies such as tampons.

> *I do use tampons so I'd be like fine, maybe if I didn't use tampons I might be a bit more worried… (P5)*

Increasing confidence in ability to self-sample (increasing self-efficacy)

Women stated that they would be more confident in carrying out self-sampling if they felt that they were provided with clear information outlining how to carry out self-sampling and what the sampling was actually looking for.

> *it's just filling that information gap and sort of you know saying it's okay because you know if the virus is there, it's everywhere so you're bound to find it (P7)*

Women also talked about practice and felt that if they had carried out self-sampling a number of previous times and received a result, they would feel more confident engaging in self-sampling. Women also talked about habituation to self-sampling as the usual method of cervical screening through repeated sampling exposure.

> *I think it's around practice if it became the norm and you knew it was part of your lifestyle um I suppose you'd get used to it… (P3)*

The issue of receiving a result was highly salient to women's perceptions of how their confidence might be increased. Some women reported that receiving a result would provide reassurance that they had self-sampled correctly, whilst others stated that they would be particularly reassured if the result had led to the identification of any abnormalities.

> *if it was positive you know if it was a...if it had detected some cellular abnormalities then I'd probably be reassured that I'd done it right…(P2)*

5.5.9 Barriers to HPV self-sampling

Women often felt apprehensive about the potential introduction of HPV self-sampling. They were worried about the efficacy of a new screening method and felt that there might be a "grey area" (P14) of whether self-sampling would be an efficient method of cervical screening. Some women also struggled with the hypothetical nature of the questions and felt that they could not accurately predict whether they would wish to engage in self-sampling until the method was actually available to them. Two main constructs were identified as reflecting women's salient concerns: operational factors and confidence in the self-sampling programme.

Operational factors

When women were discussing operational factors associated with HPV self-sampling, they referred to the logistical issues involved with the self-sampling programme and the way in which they might affect their intention to self-sample. The majority of women were concerned with the postal nature of the self-sampling kits, especially that the completed kit would have to be sent to the laboratory through the Royal Mail as opposed to hospital services. Women were primarily concerned that their kit might get lost during transit or not reach the designated laboratory.

> *…the sending it off would worry me hoping it reached where it was reaching and not got lost in the post…(P10)*

> *just putting it in the post it's just relying on the postman to pick it up…but I know in big companies…letters have places to go and sections and there's a TNT in everything it's had its correct place (P11)*

Participant 11 referred to a well-established and organised postal system used in her workplace and compared that to the generic postal system, which she believed to be basic. There was an overall preference for the use of expert systems:

I think I would prefer to take it to like a doctors and they can send it to the hospital, or send it wherever it needs to go (P1)

Other women thought that the self-sampling kits might not reach the laboratory because postal workers might not wish to handle them, or that their sample might become spoilt if their kit took a long time to reach the laboratory.

…if I was a post lady I wouldn't want to handle someone's thing that has been in places… "I'm not taking that to get delivered, I'll leave that one in the box" like they'd put it in the box and pretend they'd never seen it (P4)

The women were also concerned about any potential contamination or damage caused during postage leading to inaccurate results.

I've had mail sometimes come through and it's soaking wet and opened you know it's that not just the packaging damaged is the sample itself gonna be damaged? Or contaminated maybe? (P3)

Some women felt that individuals might seek to tamper with their kit during transit, whilst others were worried about the possibility of identity theft. Women felt that identity theft might be an issue, because the self-sampling kits would contain DNA, as well as women's personal details such as their name, address, date of birth and/or hospital number.

that would be a big thing for me because something so personal has gone missing so you've got my DNA, you've got probably all my personal details…that would be an issue (P1)

Confidence in the programme

Women's confidence in the self-sampling programme was also a potential barrier to self-sampling. Women were concerned about the quality and reasoning behind the new programme, not just the self-sampling kit itself. One of the most salient barriers to

self-sampling was a perceived lack of confirmation of receipt of the self-sampling kit from the laboratory. All women wanted reassurance (in the form of a text message/e-mail/letter) that the sample had arrived safely to its destination. One woman in particular had very strong feelings about the availability of such provision and felt that if it was not in place, her confidence in the self-sampling programme would be low.

> *If there's nothing about acknowledgment of samples, I might be concerned about the fact that there was nothing in place, you know not specifically "oh my sample is definitely going to get lost" but more like "this is a bit stupid, why isn't there something like this in place?" um and it would definitely make me perceive things more negatively if I felt like it wasn't being rolled out in an organised manner, you know it would make me have entirely less confidence in the whole process…" (P5)*

Women had a lack of confidence in the reasons for offering self-sampling. The women thought that any 'glitch' in the organisation of self-sampling might result in a lack of confidence in the programme as a whole. Women thought that self-sampling might be a method that is *"politically motivated"* or simply *"rushed through" (P5)*. A lack of confidence in the reasons for offering self-sampling was primarily shaped by the perception that self-sampling was simply going to be offered to help cut NHS costs, rather than as a benefit to health. This was reflected in women questioning why research was being carried out into this form of cervical screening.

> *Um I'm not sure, if the benefit to doing self-sampling as in a benefit to health because more people would do it more often, or is it a benefit because it was reduce costs within the NHS or is it a mixture of both? I don't know quite what was driving, driving um research (P9)*

The notion of cost-cutting was related to women's perceived lack of confidence in the motivating factors behind self-sampling provision. If it was perceived that the transition to self-sampling was motivated by cost, confidence in the programme would

be low. However, women felt that if self-sampling was optional, they would be happy to participate and help save funds for the NHS as well as staff time.

> *Very happy with it if it's optional, um less happy if it's forced… (P5)*

Two participants (P5 and P13) voiced concerns about a withdrawal of service if self-sampling replaced cervical smears as an initial screening test, and even felt that they would be denied a right to have a cervical smear.

> *Are they taking away my rights to have a smear test…(P13)*

Service continuity was also an influential factor in women's confidence in the new HPV self-sampling system. Women thought that they would be more confident in the self-sampling programme if the same individuals were involved as those currently involved in cervical cytology.

> *Are they going to the same person, I mean so I get my sample and I've sent it off, would it go to the same place as when I have a smear test? (P1)*

Apprehension concerning a lack of access to expert support was also a barrier to self-sampling. Women wanted to have the opportunity to talk to an expert should they come into difficulty whilst doing the self-sampling or to ask any questions. Other women wanted to have access to expert support following self-sampling, especially if they felt that they might not have carried out the sampling properly and they wanted to have the option to access their GP.

> *I think that it would be a good idea…try and give it a go, knowing that you've got the option of still going to your GP… (P3)*

Confidence in cervical smear tests

Women saw cervical smear tests as beneficial to their health. They often mentioned that that although they might be difficult to schedule and they can be embarrassing, they were in general happy to attend. Attending for a cervical smear test was often represented as habitual behaviour.

> *But I'm so used to going every 3 years. Every 3 years that you know it's become normal now routine… (P10)*

Women who had a previous history of cervical abnormalities particularly felt that the cervical smear test was a tried-and-tested method of cervical screening, and questioned the motivation for developing a new system. These women were confident that smear tests were able to identify cervical abnormalities and often referred to cervical smear tests as being able *"to pick up a problem".* Women also felt reassured that a cervical smear test was carried out by an expert. They felt that the individual taking the sample was trained to carry out the sampling and would have expertise in this form of screening method. In addition to the perceived benefit of having an expert take the cervical smear sample, women perceived the smear test as a general gynaecological health check, with an all seeing expert carrying out the procedure.

> *…there might be problems you know infections, or um well anything really that they could see, like I've got the coil fitted, so they could check that that's in place… (P1)*

Contamination of sample during self-sampling

Women were concerned about the potential for contamination when carrying out the self-sampling procedure. Women were concerned that they might drop the self-sampling kit or that the environment they were to carry out self-sampling would not be as clean as a GP surgery.

> *…there would be things around hygiene…cos you know you wash your hands, it's cross contamination its things like that again, in surgeries you wonder sometimes how clean they are, but you automatically assume I'm in a surgery, health environment, everything is fine. (P3)*

Women were also concerned about a potential delay in completing the self-sampling kit, which was often attributed to everyday tasks taking priority over completion of the kit, as well as a potential lack of privacy within the home to carry out the procedure.

> *You know you need to have privacy in your own home, you've got the children you are rushing when you are doing it (P3)*

New method of cervical screening

The fact that self-sampling would be a new method of cervical screening and women's lack of knowledge about the test were also identified as potential barriers. Women felt that the method would need to be well publicised and evidence that it was safe and efficient would need to be widely distributed. Women were particularly concerned with the efficacy of the test being able identify any abnormalities and its efficacy compared with cervical smear tests. Women wanted reassurance that self-sampling would not be an inferior cervical screening compared to cervical smears.

> *…because it's new I think long-term with evidence demonstrating that it's just the same as on a par, I'd have no problem with that, with evidence (P3)*

As a result, women were worried about having to exert double the effort if engaging in self-sampling. This refers to women's belief that if carrying out self-sampling the first time was not effective, for example if an insufficient sample was taken, they would then have to repeat the procedure.

If they say "sorry you need to do it again" or whatever, un then you might think, oh actually no I'd rather go to the doctor's, at least know that it's done and I haven't got to have it re-done (P12)

5.5.10 Facilitators to self-sampling

Advantages compared with attending for cervical smear

Women perceived facilitators to self-sampling in terms of the advantages that self-sampling might have over attending a cervical smear test. Negative perceptions of smear tests acted as facilitators to HPV self-sampling. Participants who felt that cervical smear tests were inconvenient, embarrassing or painful were more likely to report intentions to self-sample. The inconvenience of arranging a cervical screening appointment was discussed by all participants.

…yeah inconvenient would be the best word particularly now with the little boy who there's always something that needs to be organised" (P12)

Women highlighted convenience as the most salient facilitator to self-sampling. Women particularly liked the idea that self-sampling would be a time-efficient method of cervical screening because the sampling could be conducted whenever they had a chance, meaning that no planning would be required.

I think is the most beneficial bit because it doesn't kind of eat into your working day or eat into whatever else, you can kind of fit it in into your lifestyle and fit it in around you (P8)

A general dislike for the cervical smear procedure in terms of embarrassment and discomfort was discussed. Women believed that self-sampling would be a more comfortable and less embarrassing form of cervical screening by being less invasive and home-based.

> *…well if it's slightly less invasive [than a smear test] I very occasionally have a little bit of bleeding [following smear test], I wouldn't have that, that would be nice… (P5)*

The physiological and psychological effect of having children was referred to by women when discussing cervical smear testing. In general, most women felt that they were psychologically better prepared for having a smear test following childbirth. However, one participant (P3) felt that the physical trauma endured during childbirth and the resulting scar tissue, actually made having cervical screening physically more difficult.

> *…as I said after having 2 children I've got a lot of scar (tissue)… you know your body changes and it's a case that they need to be a bit more sensitive…(P3)*

Facilitating practitioner availability and funds for the NHS

Women believed that participating in self-sampling could release medical practitioners' time which could be reallocated to individuals with urgent medical conditions. The altruistic nature of women's beliefs was conditional on the availability of practitioners' extra time to see others, as opposed to taking some workload from doctors/nurses to help them.

> *…and not just for me, but also for the fact that I wouldn't then be taking up time of a nurse who might need to see somebody (who may) actually got a problem, you know it would free up appointments for other people (P5)*

Women also talked about how self-sampling might save money for the NHS and benefit others. This altruistic notion was conditional on the saved money being invested into a worthwhile cause such as treating women who have cervical cancer, and not for profit for the NHS as an institution.

> *…in the ideal world it would be nice to think that yes okay we'll go through this learning process and it's worthwhile because the funds would then go to maybe you know actually treating people with cervical cancer and then getting….better care (P5)*

Lack of confidence in health professionals

A lack of confidence in health professionals was identified by one participant. This was in contrast to all of the other participants who felt that a health professional was someone whom they could trust to perform a cervical screen. Participant four was a twenty four year old woman whose mother had died from cervical cancer when she was a teenager. She had an inherent lack of trust of health professionals and felt that they might not exert effort in obtaining a correct cervical sample because they were not performing the screening test for their own benefit. Participant four explained her lack of confidence in health professionals by referring to high staff turn-over and the limited rapport/poor communication with staff whose native language might not be English:

> *they're different every day you know, some of them can't even speak my language and I don't got to get my kecks down in front of that person, not only have I got to get my kecks down in front of them, I've got to trust them and I can't understand what they are saying, you know I'd rather do it myself. (P4)*

The participant's lack of confidence in health professionals may have been due to psychosexual issues. The participant referred to health professionals conducting cervical screening as an intimate procedure. This is exemplified by the following extract:

I don't want my kid I don't want any old man touching her, I know they're a doctor or whatever but there are still a man, or you've got a lady there she, she no, no-one can be trusted these days… (P4)

A lack of confidence and psychosexual factors seem to have been extremely salient influences on participant four's perceived self-sampling intention. These issues were especially evident when she reflected that the only person who could be trusted to carry out a cervical screening procedure properly and with care would be the individual themselves.

I think the only person you can trust is yourself so do it all yourself innit? (P4)

Confidence in system

Positive views of the operational factors associated with self-sampling were also facilitators to favourable self-sampling intentions. Some women were confident that a system would be in place to alert women if they had not sampled correctly, providing reassurance.

I presume somebody would come back and say "you didn't do it right we haven't got what we need" then that would be fine. (P12)

Women who believed that self-sampling would be managed by the same organisation as cervical smear screening had a higher confidence in the new system.

…knowing that the sample would go to the same, basically the same sort of people the same sort of qualified lab staff I'd have equal confidence in them… (P5)

Confidence in the postal services also facilitated positive intention to self-sample, with six out of nineteen women stating that they would not worry about sending their self-

sampling kit in the post. One participant expressed the belief that Royal Mail are *"quite good these days" (P6)*, whilst other participants referred to the use of postal services in other screening methods:

> *"I know they do it with the bowel don't they, with the bowel screening, so I don't think I would worry unduly" (P14)*

The availability of research data was also an influential facilitator to positive self-sampling intentions. Women said that they would feel reassured if data were available regarding the effectiveness of HPV self-sampling.

> *…reassurance in that you know it's been, it's been tried and tested and you know trying to instil confidence… (P8)*

5.6 Discussion

The present chapter enabled further insight into the factors associated with women's hypothetical intention to HPV self-sample, and provided further insight into how the HBM constructs influence women's intentions to self-sample. The chapter also revealed new factors that were highly salient in forming women's perceptions of self-sampling and that had not been previously reported in the literature. The new factors were operational factors and confidence in the system set-up, reflecting the need for transparency of any new screening programme, preferences for the availability of professional expertise, and a lack of confidence in the postal system.

As previously identified in the literature (Pitts and Clarke 2002; Waller et al. 2003; Marlow et al. 2013), interviews highlighted a lack of HPV knowledge. Most women believed that that there was no specific cause of cervical cancer, whilst some proposed genetic or lifestyle factors. This finding is similar to other studies which have also reported that women were not aware that cervical cancer is caused by HPV (Low et al. 2012). Low awareness that HPV causes cervical cancer is even more striking in the present study because this was not the first point of contact with participants in

relation to HPV and cervical cancer. That the majority of participants still did not identify HPV as the exclusive cause of cervical cancer could be attributed to three factors: women might not have read the provided information about HPV during the previous study stage; they might have forgotten the information they were given, or they might not have believed that HPV was the only cause for cervical cancer. The latter participants may have been expressing a form of cognitive dissonance, which refers to a state of psychological discomfort that arises from conflicting attitudes or beliefs (Festinger 1957).

In common with Marlow et al. (2013) women reported that they had heard of HPV prior to engaging in the study and the majority were aware that HPV is sexually transmitted. However, most participants did not perceive HPV as the sole cause of cervical cancer and believed that HPV might be transmitted in other ways. It was also interesting to note that although the majority of women thought that HPV was sexually transmitted, consistent with other studies (Bowyer et al. 2013), a number also believed that it might be transmitted through the air, similarly to the common cold virus or through contaminated bodily fluids.

Although participants were sampled for a lower intention to self-sample (as determined by the survey in Chapter 4), similarly to other studies (Forrest et al. 2004; Crofts et al. 2015; Llangovan et al. 2016) the majority of participants reported acceptability of HPV self-sampling in general. However, conversely to Crofts et al (2015) and Llangovan et al. (2016), participants had reservations regarding conducting the test properly as well as test efficacy, system set-up and confidence in results. This might be due to the different sample populations and setting of the other studies. The Llangovan et al (2016) study investigated the acceptability of HPV self-sampling in Latina and Haitian women in the U.S., many of which had not ever participated in cervical screening and therefore were unable to compare HPV self-sampling and cervical smear tests. The participants in the current study were all cervical screening

responders and some had experience with cervical abnormalities and were therefore engaged within the current cervical screening system. The Crofts et al (2015) study was conducted in Cameroon which is a country that does not have an organised cervical screening programme and participants were involved in a lecture explaining cervical cancer, HPV and self-sampling with an opportunity for questions. Therefore the women had more knowledge of HPV self-sampling and had any questions answered before conducting actually conducting the procedure. In the current study, women's hypothetical intentions were explored and they were not provided with thorough information explaining cervical cancer, HPV and self-sampling, therefore any concerns would not have been addressed as they were in the Crofts et al (2015) study. Furthermore, the intention-behaviour gap must be considered as women may behave differently to their reported intentions if HPV self-sampling is available (Chapter 1). Similarly, Forrest et al. (2004) also found that intention to self-sample was high when asking women about their hypothetical self-sampling intentions. Although the present study and that of Forest et al both report a hypothetical HPV self-sampling intention, they utilised different methodologies and populations. Forest et al used a quantitative approach only and excluded women who had previous cervical abnormalities. However, the current study explored women's intentions to HPV self-sample in depth through qualitative methods and provided insight into the attitudes of women who have previously had cervical abnormalities.

Women's belief that they would not be able to carry out the self-sampling procedure properly was highly important in determining their self-sampling intentions and their level of confidence in the results. Although women's concerns about their ability to conduct self-sampling properly have been identified in previous research (Barata et al. 2008; Szarewski et al. 2009; Fargnoli et al. 2015), others have identified the ability for women to conduct HPV self-sampling themselves as a facilitator to conducting self-sampling (Bosgraaf et al. 2014). However, this was the first study to provide insight into how self-efficacy influenced women's intentions to self-sample. Low self-efficacy was

exhibited by women's concern that they would not be able to carry out self-sampling properly. Lack of confidence in self-sampling result was attributed to a lack of personal expertise, lack of practice, age, lack of information and lack of expert support. It is interesting to note that, very early in the interview, women disclosed a higher level of confidence when discussing their understanding of HPV self-sampling. As the interviews progressed however, many stated that they might not be confident in the results of HPV self-sampling, due to a fear of carrying out the procedure incorrectly. It is therefore plausible to infer that when discussing confidence in the self-sampling results in the context of understanding self-sampling, women might not have thought about how confident they would be in their ability to carry out the sampling correctly and the impact that belief might have on their confidence in the results obtained.

The effect of self-efficacy as a direct influencing factor, as well as part of a multitude of perceived barriers to self-sampling, was also identified (Zumbo and Wu 2008). When self-efficacy was part of multiple barriers that would be weighed up against perceived benefits in determining self-sampling intention, it appeared to be an additional barrier. Conversely, when women stated that worry about not carrying out self-sampling properly (low self-efficacy) would be the most influential factor in determining intention to self-sample, despite all other barriers and benefits, self-efficacy acted as a direct influence.

Waller et al (2006) found that women reported higher self-efficacy in their ability to carry out self-sampling compared to that observed in the current study. Waller et al. (2006) examined the acceptability of HPV self-sampling among British women who actually carried out self-sampling and also received a health professional cervical screen as part of the study. Their survey found that over 90% of women felt 'fairly' or 'very' confident that they had carried out self-sampling properly, with 44% of women not being more confident that the clinician administered test had been done properly. The discrepant study findings may reflect the different methods used. The current study asked women about hypothetical intention to self-sample and to discuss factors

that might impact their intention, whilst Waller et al (2006) involved women self-sampling in a clinic environment. Although women were left on their own in the clinic to carry out the self-sampling (therefore potentially replicating a scenario at home), they were nevertheless in a health care setting which may have reassured them that the environment was suitably clean for them to self-sample (a barrier identified in the present study). They also had contact with a healthcare provider or researcher who would have explained the study, providing an opportunity for questions and immediate access to expert advice. Furthermore, women would have been aware that they were carrying out self-sampling for the purpose of a study and were also receiving a clinician administered test. This might have reassured them that even if they had not conducted the self-sampling properly, any abnormalities would have been identified by the clinical test. In the current study, women were asked to discuss self-sampling without the availability of an alternative clinical test. This could have led women to identify self-efficacy as a more salient factor in forming their intention to self-sample as they felt that it would be the only opportunity for a cervical screen. This might have caused them to reflect on the factors that might impact their decision to self-sample in more depth, with further insight being facilitated by the use of qualitative methodology adopted.

Barriers to HPV self-sampling that emerged in the present study reflected women's concerns about safety and, similar to previous studies, included perception of physical harm to self, lack of confidence in the results, and worry about sending the kit through the post. However, this study is the first to provide insight into the potential influence of operational and system-related barriers to HPV self-sampling. Women were worried about the self-sampling kit getting lost or contaminated and the possibility of identity theft, and wanted to receive an acknowledgment that their kit had arrived at the laboratory safely.

Confidence in the self-sampling programme was also identified as very important in determining women's self-sampling intention, with some women even being sceptical as to why the present research was being conducted. Similarly to Sultana et al. (2015) women wanted information about the organisation that would be responsible for HPV self-sampling. Furthermore, participants wanted to understand the motives behind a new cervical system set-up and expressed concerns that it will be motivated by cost cutting for the NHS and compromise patient safety.

Barriers such as worry about potential kit contamination due to dropping the kit swab or sampling in an 'unclean' environment and a perceived delay in completing the kit due to privacy issues and distractions within the home were also identified. Whilst some of these barriers are similar to those previously identified by research into attitudes towards FOBT sampling, such as worry about sending kit through the post (Palmer et al. 2014), others were different. When discussing FOBT individuals reported concerns that their bathroom may become contaminated with faecal matter and therefore become dirty (Palmer et al. 2014). In contrast for HPV self-sampling women were concerned that their home environment may not be clean enough to carry out self-sampling. Perceived benefits of and reassurance associated with cervical smear tests were also identified as barriers to self-sampling, particularly the perception that the health professional conducting the smear test would also carry out a general gynaecological health check, which would not be possible if women were engaging in self-sampling.

The current study revealed a number of HPV self-sampling enablers, including convenience, time efficiency and the perception that self-sampling would be less embarrassing, uncomfortable and invasive than having a cervical smear. These are similar to the findings of previous studies (Harper et al. 2002; Barata et al. 2008; Bosgraaf et al. 2014; Sultana et al. 2015). However, the present study also identified conditional altruism, psychosexual issues and devolved responsibility as facilitator to

self-sampling. Some women felt that participating in self-sampling might result in more health practitioner appointment availability for the benefit of individuals who need access to health care. Women thought that by participating in self-sampling they would be contributing to reduced costs for the NHS, which could be redistributed to enhance available treatments. Altruistic beliefs were conditional because women were only happy to contribute to cost and time-saving as long as it benefited patients and not the NHS as an institution. For one participant, fear and mistrust of health professionals taking cervical smears were highly salient motivators for engaging in HPV self-sampling. Psychosexual issues in women who have been sexually abused have been identified as barriers to cervical smear testing (Cadman et al. 2012). Finally, devolved responsibility was also evident as a facilitator to self-sampling. This was a facilitator in women who felt reassured that a system would be in place to alert them if they had not sampled correctly.

5.6.1 Strengths and limitations of the current study

In this study, sampling continued until 'data saturation' was achieved. However, it is important to acknowledge that true data saturation would be something that is very difficult to achieve as every individual will have a slightly different perception relating to HPV self-sampling. Therefore, data saturation in this context refers to the identification of no new significant or relevant themes of interest to the study objectives. The type of information that is obtained from qualitative studies is very rich in detail, necessitating relatively small sample sizes so that the data can be analysed in depth (Ritchie et al. 2006). Furthermore, because participants were purposively recruited based on low intention to self-sample as measured by the survey (Chapter 4), different themes might have been identified if other women had been recruited. The potential for sampling bias is acknowledged as the sample was not representative of the population as a whole. The sample was not representative as it included a high number of highly educated white women and women who had all previously attended

a smear test appointment, and many of whom had previously received abnormal smear test results.

The majority of research into attitudes towards HPV self-sampling has been carried out in women who do not attend cervical screening, and is helpful if self-sampling is to be offered as an additional method for cervical screening in non-attenders. However, it was considered important to understand the attitudes of cervical screening attenders if self-sampling is to potentially replace routine cervical smear screening or be used as a method of triage. It was also important to ascertain the self-sampling intentions of women who have had an abnormal smear test result because many of them would eventually be returned to the screening programme and may have to utilise HPV self-sampling. However, this study investigated women's attitudes towards HPV self-sampling in a hypothetical scenario where women were asked to predict their intention to self-sample should it become incorporated into the cervical screening programme. Therefore, it may be argued that women's intentions may be different if they were physically presented with a HPV self-sampling kit for cervical screening.

Although all women interviewed had been classified as less likely to self-sample by the survey, some reported that they would engage in HPV self-sampling. This discrepancy might have been observed because the survey stated that the women were less likely to self-sample as opposed to not intending to self-sample at all. It therefore might have identified women who had more questions about self-sampling and were more apprehensive about this screening method. Furthermore, the survey utilised quantitative methods to ascertain women's intentions to self-sample, whilst the interviews provided further insight and depth on how intentions were formed. The high level of self-sampling intention observed is contrary to that observed in some other studies (Bais et al. 2007; Sanner et al. 2009a; Gok et al. 2010), where only around a third of women reported that they would be likely to self-sample. It is important to note that the majority of these studies involved women who were cervical screening non-responders and were therefore a difficult group of women to engage in screening.

In contrast, all of the participants in the current study had attended a cervical smear screen and were already engaged in the cervical screening programme, which might explain the high intention rate. The qualitative approach was able to provide more insight and depth in understanding the way in which intentions to self-sample were formed by acknowledging the world view of the participants (Ritchie and Spencer 2002). Interviews were an appropriate data collection method as they facilitated the in-depth exploration of interactions between factors previously identified (Chapter 4) as being associated with intentions to self-sample (Smith 1995). The semi-structured interview schedule consisted of open ended questions, probes and follow up questions, ensuring that the topics covered in each interview were standardised. This ensured that all participants responded to the same questions, representing a range of views (Bourgeault et al. 2010). However, due to the flexible and reflexive nature of interviews, deviations from the interview schedule were often observed, and therefore interviews allowed new themes to emerge (Green and Thorogood 2011).

Verbatim transcription was conducted and was a useful method in bringing the researcher closer to the data than selective transcription (Halcomb and Davidson 2006). Verbatim transcription was beneficial for facilitating the development of the conceptual framework by enabling the researcher to check the relevant primary data. It also provided an audit trail (Halcomb and Davidson 2006) for the data analysis and framework modification process. Nevertheless, the process of transcription is prone to human error and interpretation of phrases might have been altered if the intonation of words transcribed were also noted. To minimise this risk, the researcher listened to all the interview recordings before the transcript analysis and was familiar with the tone of the interview.

Framework analysis was particularly suitable for the present study, because findings will be used to inform the content of a behavioural intervention and to help inform policy and practice (Green and Thorogood 2011). A detailed framework analysis was conducted which was highly time consuming but was able to provide a rich, clear and

structured representation of women's attitudes towards HPV self-sampling. Although the framework originally started deductively from pre-set categories relating to the HBM and findings from the survey, it was modified extensively throughout the analytical process which became more thematic and therefore became a highly complex multi-level framework. The structured nature of the framework facilitated the viewing and assessment of the data analysis process by people other than the primary analyst (Pope et al. 2000).

5.6.2 Conclusion

The present chapter facilitated a rich understanding of potential facilitators and barriers to primary HPV self-sampling. This is the first study to highlight the potentially important influence of system factors on intentions to self-sample. To encourage uptake of HPV self-sampling, an intervention is needed that aims to increase women's HPV knowledge, confidence in their ability to carry out HPV self-sampling and confidence in the set-up of a potential self-sampling programme.

The following chapter will describe how factors identified in this PhD research were synthesised to form the content of a theoretically-based intervention designed to increase engagement with HPV self-sampling.

Chapter 6

Intervention development and user testing

6.1 Chapter Overview

This chapter will present the development, preliminary user testing and subsequent modification of an intervention to enhance uptake of HPV self-sampling.

6.2 Introduction

Findings from the previous phases of work were used to develop a draft intervention to enhance uptake of HPV self-sampling. Barriers and enablers to HPV self-sampling identified in Chapters 4 and 6 were synthesised in the draft intervention, which was designed to increase women's HPV related knowledge, address identified barriers, highlight benefits of self-sampling and to increase self-efficacy. Self-efficacy refers to the users' confidence in their ability to carry out self-sampling correctly. Increasing self-efficacy beliefs was highly important because self-efficacy was shown to be the strongest predictor of intention to self-sample (Chapter 4) and influenced women's confidence in HPV self-sampling results.

Interventions to promote health protective behaviour can be developed at an individual level, community level and organizational level or societal level (Westmaas et al. 2007). Interventions designed to promote healthy behaviour can be targeted directly at the individual, by attempting to alter attitudes and beliefs through an intervention directly distributed to the individual such as a leaflet. Interventions that attempt to alter societal or community attitudes attempt to influence whole communities. Such interventions can include media campaigns such as posters and social organisations to promote healthy behaviours. The population based interventions are wide spread interventions designed to portray simple messages and include laws such as wearing seat belts whilst in cars and the prohibition of smoking in social spaces. The Behaviour Change Wheel (BCW) (Michie et al. 2011) can be used to

design interventions that capture different sources of behaviour, such as individual perceptions regarding capability, motivation and opportunity, as well policy considerations. Therefore, the BCW could have been used to develop an intervention designed to address both individual, as well as social and policy level considerations associated with HPV self-sampling intention. However, as a HPV self-sampling programme is currently not available, policy considerations are still to be debated. Therefore, it was decided that although the BCW would be a useful model for intervention development that can account for individual, societal and policy considerations, an intervention that focused on the individual level would be preferable in this context. It was decided that the intervention would be based on the extended Health Belief Model (Rosenstock, 1988), which focused the investigation and exploration of women's intentions to HPV self-sample throughout this research. Therefore, the intervention was developed to address the identified barriers and facilitators to HPV self-sampling and was structured around the HBM constructs. Guidance for developing quality health-related information (Charnock 1998) was also used to structure the draft intervention. In line with MRC guidance for developing complex interventions, key empirical findings and theoretical concepts were linked to each section of the draft tool. The DISCERN handbook (Charnock 1998) was used to guide intervention development. DISCERN determines the quality criteria for consumer health information on treatment choices. Although the HPV self-sampling intervention does not provide information about treatment choices, the principles of the DISCERN handbook were transferrable in terms of helping to ensure the clear presentation of information. A small sample of potential intervention users and providers were recruited to explore the usability of the draft intervention to help ensure that it is user-friendly and reflective of a potential future HPV self-sampling system.

This chapter aims to (1) describe the creation of the first draft HPV self-sampling intervention, (2) outline usability and acceptability testing of the draft intervention during a small pilot study, and (3) present modifications to the intervention based on the findings of preliminary user testing.

6.3 Development of the HPV self-sampling intervention

6.3.1 Intervention format and content preferences

Women who participated in the interview study (Chapter 5) were asked to provide hypothetical suggestions for preferred intervention content and format at the end of their interviews. A framework analysis approach was applied (Ritchie and Spencer 2002). The framework analysis approach is described in Chapter 5.

Participants made suggestions relating to the design and layout of a hypothetical HPV self-sampling intervention. Participants felt that a simple layout stating the facts about HPV self-sampling with a question and answer format would be the most appropriate, for example in the form of *"frequently asked questions" (P7).*

Participants felt that their confidence in the credibility of the information presented would be increased if the hypothetical intervention appeared to look official:

> *I'd like colours for sure…I think that for my confidence if it felt like a proper, proper document that would feel good (P5)*

There was also a preference for visual representations.

> *I want it to have like a sort of, I want it to have pictures, quite a lot of pictures, because I think that when I'm nervous I find it hard to take in too much text (P5)*

Two of the participants felt that as well as a paper-based intervention, they would also hypothetically like to have access to a video (on-line). They felt that a video with a health professional explaining what self-sampling is and demonstrating the way self-sampling should be conducted would provide them with more confidence. Although the provision of a video in addition to a paper-based intervention was suggested by some participants, they felt that this form of intervention would potentially act as supplementary to a paper-based intervention. Therefore, the development of a paper-

based intervention was prioritised because the development of both paper and video interventions was beyond the scope of this study. Future research should develop an on-line educational and instructional HPV self-sampling video to compliment the paper-based intervention developed.

6.3.2 Information quality

Based on DISCERN guidelines the draft intervention was designed to include:

(1) a clear statement of aims at the beginning of the publication.
(2) a clear format of the intervention to help achieve the aim of increasing self-sampling intentions
(3) explanation of the relevance of the information to the individual
(4) clear reference to sources of information
(5) production date of sources of information and version number of intervention
(6) a balance of information
(7) provision of additional sources of support and information

Evidence for the fulfilment of these requirements will be shown in the description of the intervention.

To ensure that the content of the draft intervention was user friendly, the Plain English Campaign guidelines (http://www.plainenglish.co.uk/free-guides.html) were followed. Sans serif type font was chosen because serif fonts can be confusing for readers, headings were made bigger than the text size and emphasis was shown in bold type and not italics or underlining. Sentences were kept to a maximum of around 20 words. A preference for active verbs was applied throughout the text, following a subject, verb and object pattern as much as possible. This facilitated the content to sound more active, less confusing and more engaging. A question and answer format was adopted throughout most of the intervention to enable the reader to easily navigate through the text.

To help ensure that the intervention was accessible to the majority of the target population, a Flesch reading ease score of 87.1 was obtained, which is equivalent to the reading ability of an eight to nine year old.

6.4 Content of draft HPV self-sampling intervention

Content development is presented below, with each section of the intervention linked to empirical findings and theoretical concerns. A graphic design company (Jessica Draws) was commissioned to design the characters and diagrams included in the intervention. The intervention only included information relating to HPV and cervical cancer and did not include information about other HPV related cancers and conditions, such as genital warts and cancer of the vulva, vagina, anus and oropharynx (Parkin and Bray 2006). It was thought that provision of such information might have resulted in too much information for participants to meaningfully interpret and might also have resulted in unnecessary elevation of anxiety relating to a potential HPV positive status.

Front page

Following guidance from DISCERN point 1 (Charnock 1998), the front cover of the intervention included a clear statement of its aims: *"This guide will help you understand what HPV self-sampling is and how easy it is for you to do".* Self-efficacy in relation to HPV self-sampling was addressed in the form of a statement highlighting that self-sampling is *"easy... for you to do".*

The second section of text explained what the intervention does not do (explain how to conduct HPV self-sampling) and directed individuals to an information source where they could access that information: *"The instructions in your self-sampling kit will show you how to do HPV self-sampling."*

Figure 6.1: Front page

System continuity and confidence in a new screening method were previously identified as barriers to self-sampling. The Cervical Screening Wales logo was therefore located at the bottom of the front page to signify a form of system continuation and confidence in the self-sampling method by referring to an agency that women were already familiar with.

The first section of the leaflet entitled **"What is it all about**" provided information to help increase HPV knowledge and perceived susceptibility to HPV infection and provide reassurance about perceived severity. The section was comprised of five question and answer sub-sections that are discussed below.

"Who is organising self-sampling?"

As identified in Chapter 5, women had more confidence in HPV self-sampling if they perceived continuity with the existing cervical screening programme. Low confidence was identified as a barrier to self-sampling intention; therefore alleviating this barrier should help users to form a more positive intention. The information within this section was designed to increase confidence by identifying the professional organisations involved in self-sampling. This sub-section explicitly identified two familiar organisations: the National Health Service (NHS) and Cervical Screening Wales.

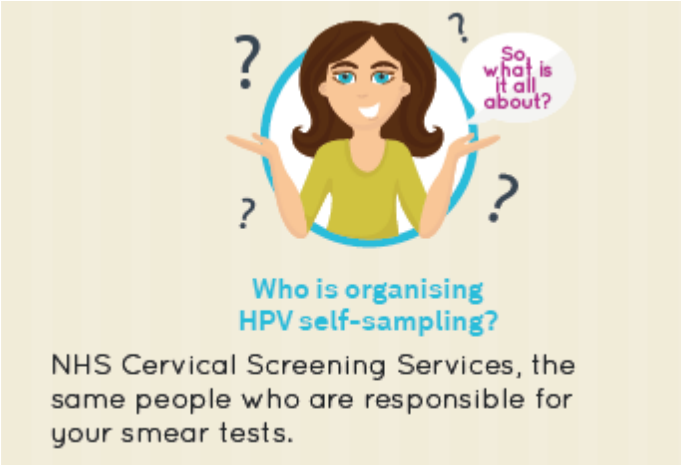

Figure 6.2: Design and content of *Who is organising HPV self-sampling?*

"What is HPV self-sampling?"

The qualitative interview phase (Chapter 5) identified that when first presented with the idea of HPV self-sampling, most women had misconceptions regarding what HPV self-sampling would involve and perceived that self-sampling was the same as cervical smear testing. This resulted in concerns regarding the complexity of self-sampling and acted as a potential barrier. An initial statement pertaining to speed and ease of self-sampling was included to help address this misconception. The second sentence in the sub-section section related to women's concerns that HPV self-sampling is a new method that has not been tried and tested, as identified in the qualitative phase

(Chapter 4). The sentence aimed to reassure the user that research has been conducted into self-sampling and that it is a good method of cervical screening. The third sentence explained the purpose of HPV self-sampling, in order to help increase understanding of the test.

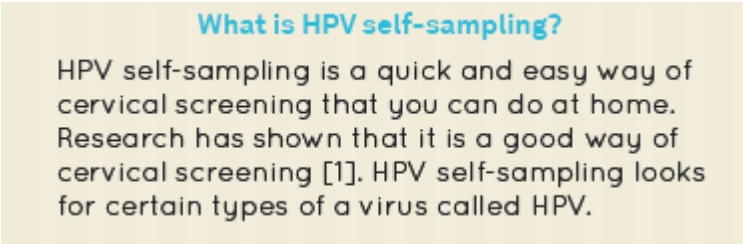

Figure 6.3: Design and layout of *What is HPV self-sampling?*

What is HPV? How can I get HPV? Can HPV be treated?

The following three sub-sections were primarily designed to increase women's HPV related knowledge. Both the survey (Chapter 4), the interviews (Chapter 5) and other studies (Marlow et al. 2013) have highlighted women's low knowledge in relation to HPV and cervical cancer.

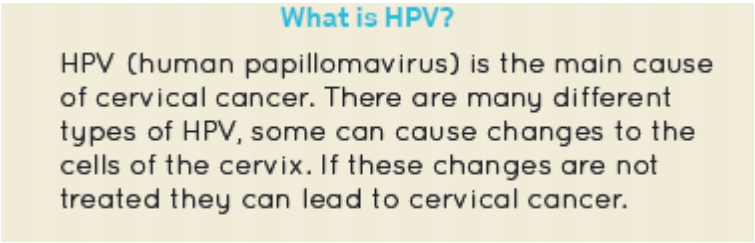

Figure 6.4: Design and layout of *What is HPV?*

The first sub-section *"What is HPV?"* aimed to increase the users' HPV knowledge by explaining that the cause of cervical cancer is HPV. It was considered important that a simple and bold statement about the causal agent of cervical cancer was included because many of the interview participants did not perceive HPV as the sole cause of cervical cancer and cited other factors. Belief that HPV is the main cause of cervical

cancer was shown to be significantly associated with intention to self-sample (Chapter 4).

As well as addressing knowledge, the sub-sections *"How can I get HPV?"* and *"Can HPV be treated?"* addressed the issues of perceived susceptibility to HPV and perceived severity of HPV infection. The sub-section *"How can I get HPV?"* aimed to increase women's perceived susceptibility to HPV by highlighting its high prevalence rate and addressing the misconception that having a small number of sexual partners would be protective against HPV, therefore making the publication relevant to the user (as required by point 3 in the DISCERN checklist). These misconceptions were identified in the previous phases of work (Chapter 5).

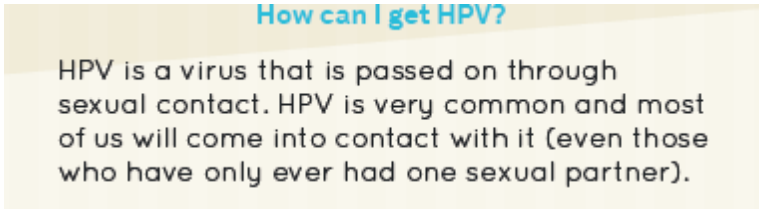

Figure 6.5: Design and layout of *How can I get HPV?*

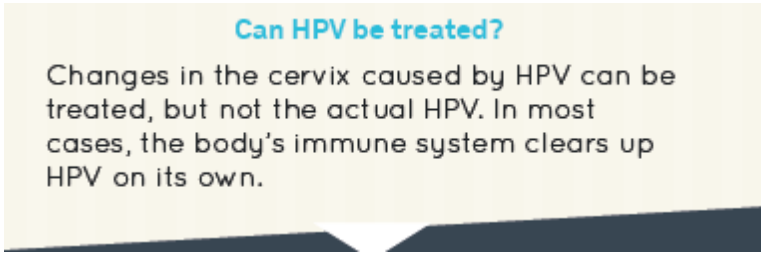

Figure 6.6: Design and layout of *Can HPV be treated?*

The sub-section *"Can HPV be treated?"* aimed to increase users' knowledge by providing information about the treatment of abnormal cells but not HPV. The section also addressed women's perceived severity to HPV infection by stating that the infection cannot be treated with medicines and that the infection is usually cleared away by the immune system. This section had to be balanced to ensure that it would not elevate women's anxiety at the prospect of HPV infection, but would encourage

the infection to be perceived as something that would warrant monitoring through self-sampling.

The second section of the intervention entitled *"Tell me more"* aimed to minimise perceived barriers and maximise perceived benefits of self-sampling, as well as increase HPV related self-efficacy. According to the HBM, maximising benefits, minimising barriers and increasing self-efficacy beliefs about self-sampling would result in an increase in intention to self-sample. This section also aimed to increase the users' confidence that they would not be receiving an inferior test compared to a cervical smear. This section was comprised of six question and answer sub-sections as well as a graphical representation of the female genital tract. These are discussed below.

"Is HPV self-sampling as good as a smear test?"

Confidence in the reasons for the introduction of HPV self-sampling was identified as a salient barrier to HPV self-sampling during the qualitative aspect of this study (Chapter 5). The purpose of this sub-section was to reassure the user that self-sampling was an effective and credible method of cervical screening. Research findings indicating that HPV self-sampling is a good method of cervical screening were used to highlight this. During the qualitative phase and when asked for suggestions for intervention content women expressed a strong desire for information based on research.

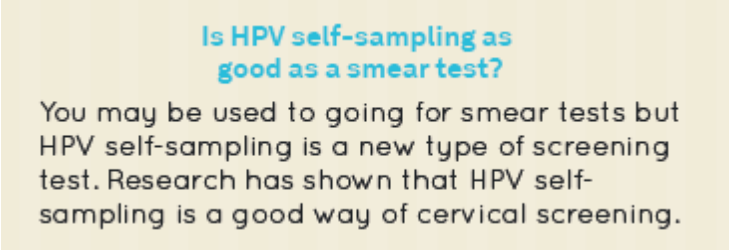

Figure 6.7: Design and layout of *Is HPV self-sampling as good as a smear test?*

"What is good about HPV self-sampling?"

The benefits of self-sampling were highlighted in this sub-section. The benefits that were most commonly reported by women during the previous survey (Chapter 4) and interview (Chapter 5) phases related to perceived convenience of HPV self-sampling. Although conditional altruism was also identified as a benefit during the qualitative phase, it was not included in the intervention because it was not one of the most salient benefits, was very difficult to summarise and would have made the sub-section too long.

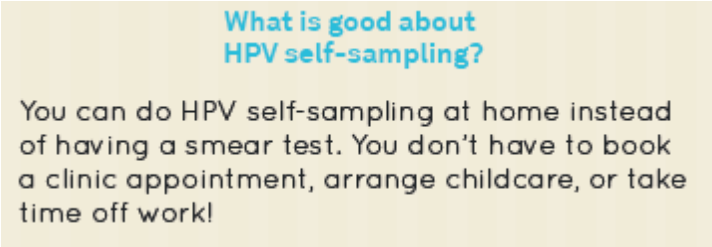

Figure 6.8: Design and layout of *What is good about HPV self-sampling?*

"I am not a doctor/nurse, can I do HPV self-sampling?"

The focus of this sub-section was to increase the users' confidence that they could carry out HPV self-sampling correctly, therefore increasing their perceived self-efficacy. Consequently, a statement outlining that most women can carry out self-sampling correctly was first in this sub-section. Women reported being worried that they were not health professionals and held no expertise in conducting self-sampling, thus a statement was included to explain that the user does not need to be a health professional. The last sentence addressed women's concerns that the self-sampling test would be complicated and that instructions provided with the kit would be easy to understand, therefore not necessitating practice. The combination of the information provided in the three sentences of this sub-section was designed to address common self-efficacy concerns.

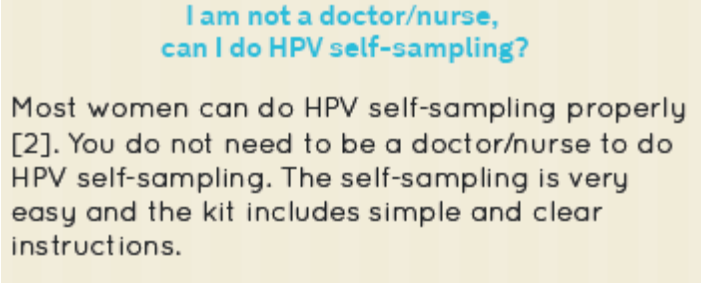

Figure 6.9: Design and layout of *I am not a doctor/nurse, can I do self-sampling?*

"*Will someone tell me if I haven't done the HPV self-sampling right?*" and ***"What if I don't reach far enough inside or miss something?"***

During the interviews, women were concerned that they might sample incorrectly and that the laboratory staff would be unaware of this. As a result, women felt that they might be provided with false negative results due to their improper sampling technique. When referring to inaccurate results, women were concerned that they might have failed to collect a sample from a HPV infected area within their vagina. This lack of confidence was seen as a highly salient barrier to self-sampling and is a crucial factor within the HBM in determining intentions to engage in behaviour. A statement and diagram were therefore developed to highlight that if HPV was present, it would be in the whole genital tract. The diagram was a simple way to show the location of HPV, and to demonstrate that HPV would not be solely present in a small differentiated area which could be 'missed'.

It was considered important that a statement differentiating the HPV self-sampling procedure from cervical smear testing was incorporated in this sub-section, because the previous phases of research identified that many women believed that self-sampling would involve collection of cells from the cervix. Evidence suggests that visual representations of clinical information can be beneficial to aiding understanding (Edwards et al. 2002).

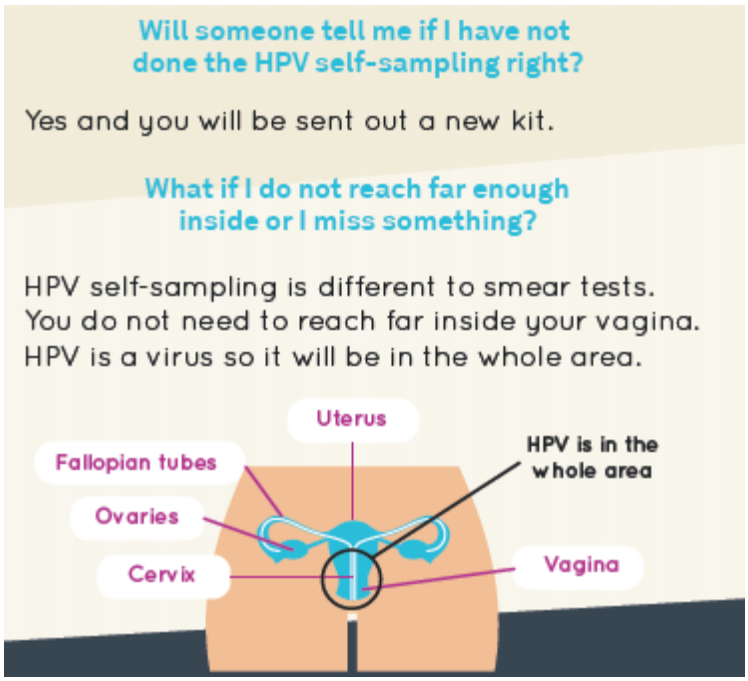

Figure 6.10: Design and layout of *Will someone tell me if I have not done the HPV self-sampling right?* and *What if I do not reach far enough inside or I miss something?*

Diagram of operational aspects of HPV self-sampling

Concern regarding the operational factors associated with self-sampling was identified as an important influence on women's intentions to self-sample (Chapter 5). The intervention therefore included a visual representation of the operational factors associated with self-sampling. The operational factors are textually explained in the preceding question and answer section.

Figure 6.11: Design and layout of diagram of operational aspects

"Do I have to send my completed kit through the post", "How will I know if my kit has been lost?" and "How will I receive my results?"

Women wanted to have as much information as possible about how a new HPV self-sampling programme would function. Specific barriers associated with operational factors, such as concerns that their self-sampling kit might get lost, damaged or contaminated in the post, contributed to low confidence in self-sampling results. It was considered important that the effect of any barriers to self-sampling was minimised to help promote positive beliefs about self-sampling.

The first two question and answer sub-sections: *"Do I have to send my completed kit through the post?"* and *"How will I know if my kit has been lost?"* aimed to address women's concerns about sending their completed self-sampling kit through the post. It was important to reassure women that they would be alerted if their sample was not received, and that they would be provided with an opportunity to re-sample. The lack of an acknowledgment that a sample has reached a testing laboratory safely was a significant barrier to intention. However, because the self-sampling programme is not yet developed, the procedures applied to the Bowel Screening Programme in regards to sample loss/contamination or damage were stated: that another self-sampling kit would be sent to women for re-sampling.

The final question and answer sub-section related to the receipt of self-sampling results. The aim of this sub-section was to increase women's self-efficacy beliefs in being able to carry out self-sampling by suppressing negative emotional arousal. Emotional arousal has been cited as a source of influence on perceived self-efficacy (Bandura 1997). In this context, emotional arousal referred to women's apprehension about not carrying out self-sampling properly, which may make them feel less capable of mastering self-sampling. Therefore, a clear statement was included with the aim of reassuring women that if they were provided with a result, then they had self-sampled correctly.

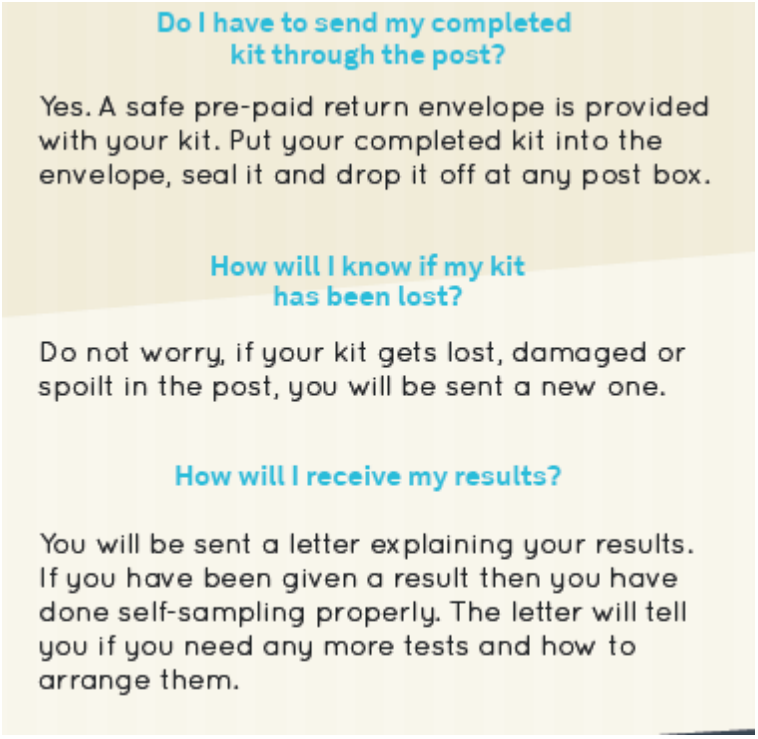

Figure 6.12: Design and layout of *Sending your kit and receiving your results*

Visual representation of 99/100 women

Due to the significant effect of women's perceived ability to conduct self-sampling correctly on intention to self-sample (as identified in Chapters 4 and 6), it was considered necessary to include a visual aid to represent the high proportion of women who have been shown to carry out self-sampling properly (Szarewski et al. 2011).

Icon array diagrams can help aid accurate understanding of probabilities (Trevana et al. 2012), by reducing biases such as denominator neglect and framing effects. Icon array diagrams can be particularly useful in individuals who have high graphical literacy and those who have problems with understanding and applying numerical data (Trevana et al. 2012).

The icon array diagram used in the intervention was designed to represent 99 women (portrayed by female icons) who had conducted self-sampling properly, along with a positive character representation of one woman who had not conducted self-sampling properly. The positive framing of the text and the smiling character aim to decrease any apprehension in women, which has been shown to be important in increasing perceived self-efficacy (Bandura 1997).

Figure 6.13: Icon array of *99/100*

Vignette: "Miriam's worry: Doing HPV self-sampling properly"

Figure 6.14: Vignette

A vignette was included to help balance out the benefits versus barriers equation within the HBM and to increase self-efficacy. The benefits, barriers and self-efficacy concerns used within the vignette were the most prominent ones identified in the previous phases of work.

The vignette was designed to represent a real-life situation and required a degree of contextualisation (West 1982). It was used within the intervention to help emulate a source of vicarious experience. Through social comparison processes, vicarious experience was used to increase perceived benefits and self-efficacy beliefs when a model person that is similar to the individual is shown to have mastered a specific behaviour (Bandura 1997).

The character 'Miriam' in the vignette represents the most salient barrier to self-sampling: self-efficacy. The character on the left presented self-efficacy as a barrier to self-sampling in stating that she would be concerned about carrying out self-sampling properly, and whether she may have failed to obtain a sample from a HPV infected area. The character subsequently presents a further barrier that was identified as highly salient: lack of trust in self-sampling results. The character on the right represents a model person. The model person exhibits mastery of self-sampling by stating that she had conducted self-sampling and reassures 'Miriam' that the procedure was easy. The model person also highlights one of the most salient benefits of self-sampling as identified by this study (convenience) and other studies, for example Barata *et al.* (2008). The model person further reassures 'Miriam' by stating that she would be informed if she had conducted self-sampling incorrectly and that it would be difficult for her to miss a HPV infected spot if she followed the instructions. The aims of this last statement were to increase confidence in the programme and self-efficacy. An explanation of the concerns presented in the vignette was included to provide a rationale for its inclusion and to reiterate that most women are able to self-sample correctly.

"Do you have any more questions about self-sampling?" and logos, further support and sources of information

This section provides the reader opportunity to contact a relevant body relating to self-sampling should they have any further questions. The study identified the need to provide a telephone number that women could contact should they need to discuss self-sampling. It was identified previously (Chapter 5) that women felt that the opportunity to speak to a health professional might result in them being more likely to conduct self-sampling.

This relates to point 4 of the DISCERN handbook regarding information. Sources of research evidence quoted in the intervention were also included. The section outlines

the developers of the intervention and states that women from South Wales were involved with development, helping women to identify with the content.

The logos presented identify the institutions involved in the development of the leaflet (Cardiff University, HealthCare Communication and Quality group), and the service providers (The NHS and Cervical Screening Wales). It was important that logos were presented in the intervention to help highlight that the same agencies responsible for the current cervical screening programme would be involved in HPV self-sampling.

Figure 6.15: Further information

6.5 User testing study

The usability of the HPV self-sampling intervention was investigated with the aim of incorporating any suggested improvements into a further draft of the intervention. This phase involved a small pilot study to examine the acceptability of the draft intervention.

Specific objectives were to:

1. To explore whether the self-sampling intervention is acceptable to women by exploring ease of understanding, whether it adequately addresses the most salient barriers to self-sampling, and whether it sufficiently engaged users in terms of language and graphical representations.
2. To discuss perceived barriers and facilitators to implementation with potential providers.
3. To pilot test the feasibility of using a before and after questionnaire that can be used to examine whether the intervention is able to increase intention to self-sample by addressing identified barriers and facilitators to self-sampling.

6.5.1 Study design

Semi-structured qualitative interviews were carried out with a small sample of potential intervention users and providers. In addition, intervention users completed questionnaires before and after exposure to the intervention, in order to examine the impact of the intervention on key outcomes. The aim of the questionnaires was to identify participant HPV knowledge and HPV self-sampling intentions and beliefs to enable a basic comparison of before intervention exposure and after intervention exposure effects. The purpose of the semi-structured interviews was to explore the usability of the intervention and to seek feedback regarding intervention improvement.

Objective 1 was addressed by a pre-and post-intervention questionnaire, as well as discussion during semi-structured interviews. Objective 2 was explored during the

interview stage; however participants were also encouraged to complete a free-text box during the questionnaire which also addressed this objective. Objective 3 was explored during interviews with Cervical Screening providers.

6.5.2 Materials and Measures

Intervention users

Women completed pre- and post-intervention questionnaires (Appendix 6.1) and semi-structured interviews (Appendix 6.2) to assess the face validity of the intervention.

Questionnaire measures included HPV self-sampling intention, HPV knowledge and health beliefs based on the extended HBM and process measures. HPV knowledge was investigated by a free text item at the beginning of the questionnaire *"What do you think causes cervical cancer?"* as well as items adapted from a validated HPV measure (Waller et al. 2013), which were scored using true or false response options.
Intention to HPV self-sample was measured using three items previously developed during this research (Chapters 3 and 4). Intention was scored on a Likert scale that ranged from 3 (lowest intention) to 15 (highest intention).

Items relating to health beliefs as measured by the extended HBM were HPV self-sampling self-efficacy, severity of HPV, susceptibility to HPV and benefits and barriers to HPV self-sampling. These items were developed during an earlier phase of this research (Chapters 3 and 4) and were all scored on a Likert scale. The self-efficacy scale ranged from 4 (lowest intention) to 20 (highest intention); the severity scale ranged from 1 (not at all serious) to 5 (very serious); the benefits scale ranged from 2 (least benefits) to 10 (most benefits); the barriers scale ranged from 3 (least barriers) to 15 (most barriers).

Knowledge and health belief items were identical in the pre- and post-intervention questionnaires. The pre-intervention questionnaire contained additional basic information about what conducting HPV self-sampling would entail. The post-intervention questionnaire included process measures to ascertain what women thought about the HPV self-sampling leaflet. Process measures included items to identify if intervention users found the leaflet *"useful"*, *"easy to understand",* if they thought the information included was *"too much", "too little"*, or *"just right"* and if they though that the vignette was *"helpful"*. Response options included tick boxes as well as space for free text comments. Further items investigated whether there was anything that intervention users wanted to *"know more about"*, if they "*found any sections less useful"* and if they had any suggestions for improvement. Response format for these items was space for free text comments.

A semi-structured interview schedule (Appendix 6.2) was designed to explore the general acceptability of the HPV self-sampling intervention in terms of content and graphical representations. The interview schedule also explored women's views on their whether their hypothetical intention to HPV self-sample, perceived benefits and barriers to self-sampling and self-efficacy were affected by the intervention. The interview schedule also invited suggestions for improvements to the intervention.

Intervention providers

The interview schedule for potential providers (Appendix 6.3) explored opinions relating to ease of understanding of the intervention, as well as its layout, accuracy of content and potential implementation. Implementation issues related to the feasibility of implementing the intervention within the cervical screening programme should primary HPV self-sampling be incorporated, as well as best point of implementation (e.g. alongside HPV self-sampling kit or prior to receipt of HPV self-sampling kit).

6.5.3 Participants

Cervical Screening Wales service users and service providers were recruited.

Inclusion criteria (not applicable to providers): ability to converse in English, aged between 20 and 64 years, and able to provide written informed consent.

6.5.4 Recruitment

The study received ethical approval from the Cardiff University School of Medicine Research Ethics committee (SMREC number: 14/63) (Appendix 6.4)

Users were opportunistically recruited using snowball sampling (e.g. afterschool clubs) and health professionals were recruited via e-mail invitation through established links with Cervical Screening Wales (please refer to Chapter 4).

All participants were provided with a participant pack containing an information sheet (Appendix 6.5 and 6.6), consent form (Appendix 6.7) and pre-addressed envelope. All participants who consented to take part in the study were contacted to arrange a suitable time and date for interview. Interviews were audio recoded. The same process was used as in the main qualitative study (Chapter 5).

6.5.5 Methods

Service users completed a four step process: (1) completion of a pre-intervention questionnaire, (2) exposure to the intervention, (3) completion of the post-intervention questionnaire, (4) participation in a semi-structured interview (face-to-face interviews with women and telephone interviews with health professionals). The service providers only participated in step 4.

For intervention users, steps one to three involved the following procedure: participants were provided with two sealed, numbered envelopes and instructed to firstly open envelope one and complete the pre-intervention questionnaire enclosed

and to return it back in the envelope. Participants were then instructed to open envelope number two and take time to read the enclosed intervention and to complete the post-intervention questionnaire enclosed and return it in the envelope. At the end of the study participants were instructed to return both envelopes to the researcher but to retain the HPV self-sampling intervention. All participant instructions were stated on the questionnaires and envelopes.

Participants were informed that they were free to withdraw from the study at any point without giving a reason and were fully debriefed at the end of the study. Participants were offered £10 to reimburse their time.

6.5.6 Analysis

Statistical analysis

Baseline questionnaire data were summarised in terms of age, HPV knowledge and HPV self-sampling health beliefs. Descriptive statistics were used to assess potential influences of the intervention on outcomes including knowledge and health beliefs. Frequencies of scores were compared pre and post intervention.

Qualitative analysis

Interviews were transcribed and analysed using thematic analysis. Thematic analysis involved familiarisation with the data by reading transcripts and listening to interview recordings, generating initial codes, searching for broader themes among codes and reviewing and re-defining themes (Braun and Clarke 2006).

6.5.7 Results

Participant characteristics

Six women aged between 27 and 52 years were recruited.

Participant number	Age	Education
1	42	A level
2	27	GCSE
3	52	GCSE
4	40	A level
5	39	GCSE
6	39	A level

Table 6.1 Characteristics of users

Health Professionals

Two female health professionals were recruited from the Screening Division in Public Health Wales. The Screening Division in Public Health Wales is responsible for cervical screening within Wales.

Questionnaire results

HPV knowledge

An increase in HPV related knowledge following intervention exposure was evident in the following: free-text identification of HPV as cause of cervical cancer, belief that HPV is common, belief that most sexually active individuals would get HPV at some point in their lives, belief that HPV can transmitted sexually and that men can also get HPV. Please refer to Figure 16. No changes in HPV knowledge following intervention exposure were observed in the following items: HPV does not need treatment, HPV has many different types, HPV cannot be cured with antibiotics, and HPV is an extremely serious infection.

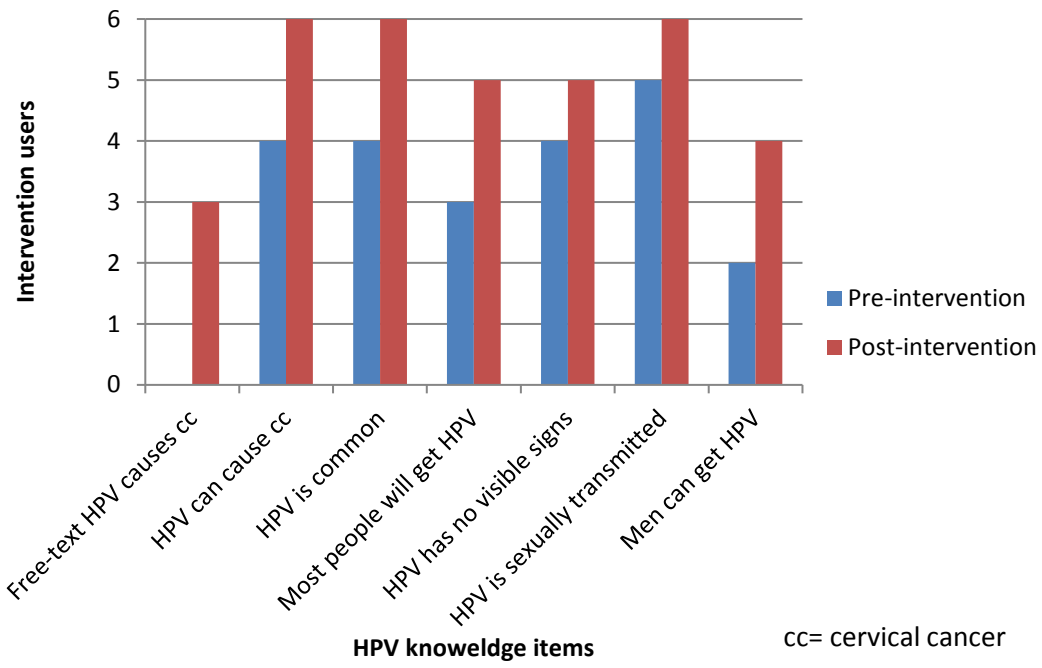

Figure 6.16: Increase in intervention users correctly identifying HPV knowledge items post intervention.

Intention to HPV self-sample, HPV self-sampling related self-efficacy, barriers and benefits to self-sampling.

Table 6.2 provides summary statistics for HPV self-sampling intention, self-efficacy and perceived benefits and barriers to self-sampling before and after exposure to the intervention. A ceiling effect was observed for self-sampling intention, with four participants reporting the highest possible score for intention both at baseline and follow-up. A small increase in intention score (from 12 to 15) was observed for one participant, whilst intention score remained low for one participant. Self-efficacy scores were high overall at both time points level, and remained unchanged in three participants. A slight increase in self-efficacy was observed in two participants, and a slight decrease in one participant. One participant reported a small increase in perceived benefits of self-sampling, whilst the rest remained unchanged. Two participants reported a decrease in perceived barriers to self-sampling, two reported an increase in barriers, and two remained unchanged.

Participant number	Pre/post intervention	Intention to self-sample (range 3-15) ^	Self-efficacy (range 4-20) ^	Benefits (range 2-10) ^	Barriers (range 3-15) ^
1	Pre	15	18	9	4
	Post	15	20*	9	3*
2	Pre	15	20	10	7
	Post	15	20	10	9*
3	Pre	15	20	8	12
	Post	15	19*	9	14*
4	Pre	3	16	10	9
	Post	3	16	10	7*
5	Pre	15	20	10	3
	Post	15	20	10	3
6	Pre	12	15	7	3
	Post	15*	20*	7	3

* Change observed following intervention.

^ Higher scores denote a higher intention to self-sample, higher self-efficacy and more perceived beliefs and barriers to HPV self-sampling.

Table 6.2 Pre- and- post questionnaire responses

Process measures

All women stated that the intervention was useful and five users stated that it made them feel more confident in their ability to carry out self-sampling correctly (Table 6.3).

Process measure	Responses (N=6)
Overall, did you find the leaflet useful?	
Yes	6
No	0
Did you find the leaflet easy to understand?	
Yes	6
No	0
Did you think the amount of information in the leaflet was:	
Too much	0
Too little	0
Just right	6
Did the leaflet make you feel more confident in doing HPV self-sampling?	
Yes	5
No	1
Did you think Miriam's story was helpful?	
Yes	6
No	0

Table 6.3: Process measures

Interview Results

All participants reported that they understood that the intervention was not a HPV self-sampling instructional leaflet. All participants understood that additional material would be supplied alongside the HPV self-sampling kit which would demonstrate how self-sampling should be conducted.

Three main themes were identified from the interviews: positive aspects of the intervention, negative feedback and recommendations.

Quotes presented in this section exemplify identified themes. Quotes are presented in italics, insertions to clarify content topic are presented in square brackets "[…]" and sections of irrelevant text are presented as "…". Participants will be denoted as follows:

health professionals will be denoted as HP7 or HP8 and users will be denoted as P1 to P6.

6.5.7.1 Positive aspects of intervention

The intervention was generally viewed very favourably. Positive comments were made regarding aspects of design and content that were viewed by participants as promoting HPV knowledge, self-efficacy and perceived benefits of HPV self-sampling.

Purpose of intervention

Participants reported that they clearly understood the purpose of the intervention, which was described as encouraging women to participate in HPV self-sampling and to make them feel confident enough to engage in self-sampling:

> *to get people to do self-sampling and to tell them about the HPV virus (P2)*

> *not to be afraid really to have a go yourself, that's what comes across to me (P4)*

> *um I guess explaining what HPV self-sampling is (HP7)*

Format of intervention

Participants reported that they liked the format of the intervention and found it simple and easy to understand:

> *very plain and simple, it is easy to understand (P4)*

The layout was positively perceived and facilitated participant understanding:

> *easy to read […] it's nice and spaced out so it's not just one big block and it's fine, good (P2)*

Content of intervention

The content of the intervention was well-received. Participants reported that the information provided was adequate.

> *the content was great. It told you everything you needed to know (P2)*

Participants also commented that the intervention was *"very easy"* to understand *(P1)* and that they believed that it would be understood by a range of different women.

> *it's simple isn't it, I don't think you could get it much simpler than that … so everybody would understand it I suppose, it doesn't matter what your background … it's clear (P4)*

The information content was positively described as *"straightforward really" (P5)* and *"pretty informative" (P6),* whilst one participant reported that the content was engaging *"you can get through it very quickly and it's not boring me" (P4).*

Participants also reported that they identified with the vignette presented. Participants felt that it represented a real life situation that they could relate to, and referred to themselves as the character that might have been unsure about engaging in self-sampling.

> *it is good because I think it's probably the conversations lots of women would have with their friends anyway (P6)*
>
> *I liked the conversation bits, I thought that was quite nice" (HP8)*
>
> *I really like seeing on the back there was a real example of real women talking about it (HP7)*

The vignette was also described by one participant as helping to ensure that the intervention was reassuring and potentially helped to avoid increased anxiety in women regarding HPV and cervical cancer.

the conversation bit on the back is good , it's a bit more light hearted almost, a little bit, so people don't worry too much because you don't want to sort of go "oooh my god and panic I've got HPV" …it's reassuring as well (P1)

HPV knowledge

HPV information was viewed as clear and useful. Participants reported that their HPV related knowledge had increased due to the question and answer sections.

I think it's really clear, like I said I didn't know anything about it really before I read that (P6)

it told you everything you needed to know really, yeah (P5)

[when questioned about the content of the intervention] well I didn't know that HPV clears up on its own in most cases (P2)

Self-efficacy

Participants reported feeling more confident about their ability to undertake self-sampling effectively following the intervention. Participants stated that the intervention made them feel that self-sampling would be simple to perform. Women felt reassured that they would not have to replicate a cervical smear procedure or to sample from a specific area within the vagina or the cervix.

I didn't think I'd be able to do it at first, but reading it and it explain in detail and I think I'd be able to do it, yeah (P3)

it makes me feel really confident, like I say I didn't think it would be as simple as it is, this sounds really simple as it's not like a smear where you've got to go so far internally (P6)

pretty confident because you don't have to get a specific spot (P2)

When referring to feeling confident about being able to carry out self-sampling correctly, participants often referred to the diagram of the female anatomy. Participants liked how the diagram exemplified that HPV would be present in the whole of the inside vaginal area and found this reassuring.

"I think the diagram of the anatomy, I think it's a really useful thing to have (HP7)

" …the diagram you know it just reassures you I suppose (P1)

Participants reported that the diagram helped them to specifically understand how far the swab would have to be inserted into the vagina and that the cervix would not need to be directly sampled.

where um obviously the swab can go and how far … and obviously with the cervix and yeah it's more detailed that's what I like (P3)

it's not like a smear where you have to do so far internally (P6)

Although the icon array diagram was not favourably viewed (discussed below), most participants found the information stating that 99 out of 100 women are able to carry out self-sampling correctly reassuring.

Benefits and barriers to HPV self-sampling

Participants reported an increase in benefits of self-sampling and a decrease in barriers to self-sampling following the intervention. Participants often referred to *"not having to go to the doctor and finding childcare"* (P2) as benefits of self-sampling. Participants

also reported that the intervention helped them perceive self-sampling as a simple and easy procedure that would be difficult to conduct incorrectly.

> *"I don't think I thought self-sampling would be as easy as that so yeah I think it's a benefit for me…" (P6)*

> *"it explains and reassures me that it would be quite difficult to do it wrong" (P1)*

> *"to me it's simple in actually showing you how to do it, I mean it's got the diagrams everything, it's simple" (P4)*

Most participants felt reassured that there would be a system by which they would be informed if they had carried out self-sampling incorrectly. The provision of this system was perceived as a benefit to self-sampling.

> *even if you make a mistake they'd send you another kit, so you don't think you've got to get it right that time, cos even if it's not right, or it gets lost you'll get another kit! (P6)*

Barriers to self-sampling were not thoroughly discussed by participants. The barriers referenced by one participant during the interviews were the potential to conduct self-sampling incorrectly and not trusting the self-sampling result because the participant was used to having cervical screening conducted by a healthcare professional.

> *I don't know if I would be happy in doing it myself, purely because I'd be, I'm used to having it done professionally…even though it says that you can't go wrong in my mind, Oh my God, you know I don't think I did that right (P4)*

Although participant 4 reported that the vignette was useful, it had evidently not addressed her concerns as presented in the above quote. The participant may have been referring to perceived usefulness of the vignette for other people.

6.5.7.2 Negative aspects of intervention

When probed about aspects of the intervention that were perceived as negative or required further clarification, most participants referred to the icon array diagram exemplifying 99 out of 100 women being able to conduct self-sampling correctly.

Some participants described the icon array diagram as having no impact on their intention to self-sample and therefore being superfluous.

> *[when questioned if the icon array diagram made any impression on the participant] um no, I just passed over it (P1)*
>
> *um, I didn't really take much notice of that [referring to icon array diagram] to be honest, I just read all that [referring to the text stating 99/100] (P3)*

Other participants described the icon array diagram as confusing and potentially misleading.

> *I think that was a little bit confusing actually you know, I didn't quite understand that then I had to look at it a bit more, it's only a little bit of information you know 99 out of 100 but it looks quite hang on, what are they on about here … I don't suppose you need to see all the pictures really (P5)*
>
> *when I looked at that first reading down, that my first impression was 99 out of 100 women don't have HPV and 1 does or something like that (HP7)*
>
> *[referring to the icon array] I wouldn't, I don't think that adds very much (HP8)*

One of the health professionals suggested that a modification be made to the vignette depicting a conversation between two women, because it referenced an incorrect appointment type.

> *Cervical screening isn't a doctor's appointment it's a nurse appointment (HP8)*

The icon array image depicting 99 out of 100 women being able to conduct self-sampling correctly was not liked by most participants, and viewed by some as superfluous:

> *I don't suppose you needed to see all the pictures really, yeah, um but I suppose you're filling the leaflet's page up (P5)*

> *I'm not sure I would have put a whole side on that (HP7)*

6.5.7.3 Recommendations

Design issues

Although participants stated that the intervention was easy to read and generally liked the layout and contents, one participant commented that the font of the main text of the 'Answer' sections was slightly difficult to read and suggested that it was made a darker colour. Health professionals also highlighted that the font size was slightly small and recommended that it was increased to help promote ease of readability.

> *the writing with the black needs to be … a bit bolder, but I think it's my eyesight, which is not 100% so if you're trying to read it and sometimes it sort of … blends back (P2)*

> *I wonder whether the text is maybe a bit small … [referring to the font size] my guess is that it might be 10 because we've recently done some*

stuff with RNIB recently and they said minimum 12 and 14 if you can (HP7)

The health professionals commented that the intervention colour scheme and characters seemed more suited to a younger audience. They suggested that the colour scheme was modified to make the intervention also appealing to an older audience.

It struck me as being quite young … I think it's the colours … the lady as well, I mean what we have on some of our things … the newer stuff we are trying to develop it's a couple of people on it you know like you've got younger women and an older woman (HP7)

I don't think the font and colours really work. I like the cartoony bits on it, but that actually makes it quite young (HP8)

Additional information

The health professionals suggested that it was crucial that the NHS be presented on the front page of the intervention. They felt that it needed to be obvious from the outset that HPV self-sampling would be provided by the NHS. This would ensure that women took notice of the intervention and would reassure them that self-sampling was a method that was routinely offered.

I guess on the front cover it wasn't obvious it was a NHS thing … it's something at feedback we've had about our leaflets like with the bowel screening kit … people didn't take notice of things if it wasn't obvious (HP7)

okay so if we were hypothetically in a situation where we were doing HPV self-sampling then actually it would be important to have our logo on it, yeah so actually have the NHS (HP8)

The addition of a website on the back page of the intervention was suggested.

on the contact bit on the back you've put "please ring" whether you could put a website address or something like that as well (HP7)

The inclusion of clarification of the purpose of cervical screening as well as clarification of how women would obtain a self-sampling kit was suggested by one of the health professionals.

cos in smear letters we kind've say the point of doing a smear test is to reduce your risk of cervical cancer, whereas I am not sure that comes across all that clearly…I think you could do with a bit on saying…maybe right aim of HPV self-sampling is… (HP7)

it doesn't clearly say what will actually happen, so there isn't a section that says you will get sent a kit (HP7)

Further clarification was also sought about whether men could also get HPV and the time-frames involved in sending the sample and receiving results and what would happen after receiving a self-sampling result.

one question whether the HPV whether men could contract it (P2)

when it's posted off and stuff would it get there …if I did do it, obviously it's getting the results or whatever. (P3)

it's the bit what happens next isn't it, if you get a positive you know what happens next (HP8)

One health professional felt that more in-depth information was required about cervical cancer.

Implementation

Some discordance was observed when women were asked when they would like to receive the HPV self-sampling intervention, with some stating that they would prefer to receive it before receiving the HPV self-sampling kit, whilst others felt that it would

be useful to receive the intervention alongside the kit. The health professionals felt that the intervention would be best presented before receipt of the HPV self-sampling kit and at community engagement events.

6.5.8 Amendments

Amendments that were made to the intervention following usability testing are outlined in Table 6.4. The final version can be seen in Appendix 6.8. The readability of the final intervention was assessed using two readability formulas, Flesch-Kincaid and SMOG (Friedman and Hoffman-Goetz 2006). The Flesch-Kincaid Grade score was grade five (10-11 year olds) and the SMOG score was grade six (11-12 year olds).

Intervention main sections	**Modifications made**
All sections	Pale blue font colour changed to navy blue and black font changed to be a darker more bold black. Increase in font size to 12 point. Removal of 'female' signs in main sections to facilitate increase in font size and addition of extra sections.
Front cover	Addition of NHS logo. Modification of characters: addition of older character and a character from an ethnic minority background.
What is it all about?	Addition of *"Why is it important to take part in cervical screening*" sub-section. Addition of sentence *"You will be sent a free self-sampling kit through the post by Cervical Screening Wales"* and removal of sentence *"Research has shown that it is a good way of cervical screening [1]" i*n *"What is HPV self-sampling?"* subsection. Modification of sub-section *"How can I get HPV?"* from *"HPV is very common and most of us will come into contact with it"* to "*HPV is very common and most men and women will come into contact with it".*
Tell me more	*"Can HPV be treated?"* sub-section has been moved to this main section from "*What is it all about?"* main section due to a lack of space. Addition of *"I have had the HPV vaccine, do I need to do HPV self-sampling?"* sub-section. Addition of sentence *"Self-sampling is less uncomfortable than smear tests."* in *"What is good about HPV self-sampling*?" sub-section. Image of female anatomy has been deleted and a new version has been included in the new *"99 out of 100 women can do HPV self-sampling properly"* section.
Sending your kit and receiving your results	This main section has been replaced with a main section titled *"99 out of 100 women can do HPV self-sampling properly"* The sub-sections of this main section have been moved to the back page of the intervention and replaced the vignette which has been moved.
New section: 99 out of 100 women can do HPV self-sampling properly.	*"I am not a doctor/nurse can I do HPV self-sampling?"* and *"What if I do not reach far enough inside or I miss something?"* sub-sections have been moved to this section. Images of self-sampling kit and female anatomy have been included.
Original section: 99 out of 100 women	Icon array has been deleted. Section no longer exists in original form. Section now contains the vignette conversation between two women which was originally at the back of the intervention.

can do HPV self-sampling properly.	
Vignette	Modification of characters, removal of original characters and addition of new characters to represent a range of ages and ethnicities. Removal of *"or finding someone to watch the kids"*. Removal of *"The people testing the kit would tell you if you did it wrong, and I don't think you could miss anything if you follow the instructions."* which was replaced with "*Just follow the instructions, they are simple. You will be sent another kit if you do it wrong*." Removal of sentence *"Most women worry that they will not be able to do HPV self-sampling properly or that they will miss something."* Addition of *"Will someone tell me if I have not done the HPV self-sampling right?"* sub-section. This sub-section was initially in the *"Sending your kit and receiving results"* main section.
Back page	The vignette has been moved and replaced with sub-sections originally found in the *"Sending your kit and receiving results"* main section. The further questions, logos and sources of information sub-sections have remained on this page. Jo's cervical cancer trust logo has been removed. A website address and contact details for Jo's cervical cancer trust have been added to the *"Do you have any more questions about HPV self-sampling?"* sub-section.

Table 6.4: Modifications made to the HPV self-sampling intervention

6.5.9 Discussion

The aim of this stage of the research was to test the acceptability of the HPV self-sampling intervention. It was important that the intervention was engaging, clear and easy to understand. The HPV self-sampling intervention was well received overall by participants. All participants understood the purpose of the intervention, which was to encourage women to HPV self-sample.

Most participants reported high pre-existing intention to engage in HPV self-sampling. Participants reported low HPV knowledge: all failed to identify HPV as a cause of cervical cancer prior to receiving the intervention. As expected, an increase in HPV knowledge was observed following intervention exposure. The pattern of findings

observed for self-efficacy and perceived barriers was unexpected and did not reflect the findings of the qualitative interviews. Although most women reported during interviews that the intervention made them feel more well-disposed towards HPV self-sampling and more confident in their ability to carry out self-sampling, this was not reflected in their post-intervention questionnaire scores. This may be because their intention scores were already high at pre-intervention or because a very small and unrepresentative sample of women were recruited for user testing, suggesting that qualitative methods are more useful and informative in small samples. Self-efficacy scores increased in only two participants and decreased in one participant following intervention exposure. Furthermore, an increase in perceived barriers was observed in some participants. These counterintuitive findings might be attributed to the extra time spent by participants reflecting on the self-sampling method and their ability to carry out the procedure correctly, by the time they completed the post-intervention questionnaire. It is possible that the pre-intervention questionnaire captured participants' automatic reaction to self-sampling before they were presented with the intervention which provided more detailed information. This might have encouraged participants to deliberate and therefore score more cautiously on the post-intervention measures.

Interviews identified that the intervention was perceived to be engaging, easy to understand and of an appropriate length. The characters, layout and balance of text to graphics in the intervention were positively viewed. The vignette *'Miriam's worry'* was included to help increase women's self-efficacy by referring to the notion of vicarious experience, a method proposed to increase self-efficacy. The vignette was particularly praised and women reported that it was easily identifiable and exemplified a real life situation.

Participants reported that the intervention increased their HPV knowledge and made them feel better able to carry out self-sampling successfully. The inclusion of the female anatomy diagram was well received, and alleviated worries about sampling

directly from the cervix. Participants described an increase in perceived benefits to self-sampling, particularly the belief that self-sampling was an easy procedure, a belief that they often attributed to the female anatomy diagram as well as the statement: *You do not have to reach far inside the vagina*. *HPV is a virus so it will be in the whole area inside your vagina.*

Implementation of the HPV self-sampling intervention was discussed. Healthcare professionals and most participants felt that the intervention would be particularly suited for promoting positive health beliefs about HPV self-sampling prior to receiving the kit. However, some participants felt that the intervention would be best included alongside the HPV self-sampling kit as they feared that they may not engage with the intervention if it arrived prior. Further research is needed to determine the best point of implementation.

The 99 out of 100 icon array diagram was the least favourably viewed component of the intervention, and was described as confusing, unnecessary and potentially misleading. Visual displays have been shown to reduce biases such as framing effects (Garcia-Retamero and Cokely 2011) and have been proposed as an aid for accurate understanding of probabilities (Charnock 1998). However, individuals vary in their ability to extract meaningful data from visual arrays and it has been shown that people who have low graphic literacy may be better presented with numbers (Gaissmaier et al. 2012). This may have been observed with the participants in this study. Alternatively, it is possible that the icon array diagram did not significantly help the participants' understanding.

The modification to the female anatomy diagram was made following suggestions from health professionals. The diagram was modified to outline a basic representation of the self-sampling procedure. The aim of the diagram was not to provide instruction on how to perform self-sampling, as that would be presented with the actual self-sampling kit, but to provide a simple idea of what self-sampling would involve once women received the kit.

Although the vignette was very positively received by all participants, the health professionals suggested modifications to some of the phrasing. The health professionals felt that some of the phrasing which was meant to reassure participants that they would not carry out self-sampling incorrectly was over-emphasised and could be misleading. The DISCERN handbook explicitly states that author opinion is not a credible source of information that would help readers discriminate between good and poor quality interventions and warns authors to pay particular attention to field testing (Charnock 1998). Therefore, this section was modified and the potentially misleading text was removed.

It was decided not to include additional in-depth information about cervical cancer because it was important that the aims of the tool were clearly reflected in its content. The previous chapter (Chapter 5) highlighted participants' difficulty in differentiating HPV self-sampling and cervical smear tests. The aim of the tool was not to provide thorough and in-depth information about the development of cellular abnormalities and their progression to cervical cancer but to increase women's intentions to HPV self-sample by increasing HPV knowledge and promoting positive beliefs about self-sampling. Providing further information about cervical cancer would have deviated from the aims of the intervention and may prove confusing for the reader. It was therefore considered important to maintain the intervention's focus on HPV (Charnock 1998).

6.5.9.1 Study limitations

Although eight participants were considered sufficient for the purposes of the interview study, only six completed the survey. This number was too small to allow meaningful statistical comparisons of changes in outcome measures before and after intervention exposure. The process measure items were positively framed which might explain the uniformly positive response of participants. Nevertheless, the questionnaire data provided an indication of potential intervention acceptability and effects which were further explored during interviews.

Ultimately, the survey was not able to meaningfully identify the effect of the intervention on women's intentions to self-sample, perceived self-efficacy level, HPV knowledge or the associated benefits and barriers of HPV self-sampling. The use of the survey was useful as a pilot to determine whether its use would be acceptable to the participants, whether the participants were able to understand the sequential nature of the pre and post intervention survey and to establish whether using the pre and post intervention surveys was feasible.

The sample recruited was biased as it did not include any participants from ethnic minority backgrounds, who have been shown to be less receptive to cervical screening (Marlow et al. 2015) and may subsequently present lower intention to HPV self-sample. Furthermore, most of the participants recruited into this study had a high intention to self-sample at baseline and therefore may have interpreted the intervention more favourably than a group with low self-sampling intentions. It would be useful to explore the effect of the intervention on women who have low self-sampling intentions.

Data collection was carried out using different methods: face to face interviews with women and telephone interviews with health professionals. Some research suggests that interview modes may yield different results (Sturges and Hanrahan 2004), primarily because of the absence of non-verbal signals during telephone interviews. However, because the health professionals were a distinctively different group than the women interviewed and their feedback did not need to be directly compared, the use of different interview methods was deemed suitable.

The use of interviews could be criticised for potential of bias (Willis 2005). The selected variety of questions used may have influenced participants' answers. Nevertheless, the aim of this study was to identify and understand the positive aspects of the intervention as well as the sections that needed further clarification/addition/removal. The interview technique facilitated investigative focus to particular areas that may have needed modification by actively searching for problems. However, focus groups

have been shown to be useful in developing patient information materials (Franics et al. 2008) as they facilitate dialogue between individuals and could have been and alternative method for exploring participant's views about the intervention.

The intervention could be criticised for not being primarily designed according to a scientific evidence-base for intervention development. The intervention was primarily developed based on what women said they would like to see in an intervention designed to address barriers associated with intention to HPV self-sample. However, the intervention did follow guidelines for the development of clear patient information, such as the DISCERN guidance, the plain English campaign guidelines, and the inclusion of a vector diagram to represent the probability (Trevana et al. 2012) of conducting HPV self-sampling properly. The intervention was subsequently modified (e.g. the removal of the vector diagram) based on the comments of potential users, who represented a close as possible scenario to women receiving the HPV self-sampling intervention as part of a screening programme. A similar approach was adopted for the development of informed choice information about breast screening for the English breast screening programme (Forbes and Ramirez 2014). The development and presentation of information was based on recommendations from a scientific evidence-base, experts and a citizen's jury. However, subsequent user testing suggested that the information presented was too detailed leading to a hindering of understanding by the users. Similarly to this study, the authors concluded that the views of the individuals who were involved in the user testing overrode that of the experts and the citizen's jury, as they represented a scenario that was as closer to the experience of an individual receiving the information as part of the screening programme.

Finally, the intervention did not address the issue of informed consent and thus did not present any negative aspects of engaging in cervical screening, such as the potential for false positive and false negative results. The focus of the intervention was on

increasing intention to HPV self-sample, therefore it was considered that inclusion of information about the risks and benefits of cervical screening would distract from the aim of the intervention. It was also assumed that such information would be provided by Cervical Screening Wales at the point of kit receipt or within the kit itself.

6.5.9.2 Future research

A HPV self-sampling intervention was developed with the purpose of increasing intention to HPV self-sample. The user testing presented in this chapter has formed an important initial step in the development of the intervention (Craig et al. 2008). The intervention was positively viewed by both women and healthcare professionals and has been amended according to feedback. Further research should seek to identify a larger and more ethnically diverse sample to i) examine best point of implementation, ii) examine whether the intervention is able to increase intention to HPV self-sample, HPV self-sampling self-efficacy and perceived benefits to HPV self-sampling and iii) investigate whether the intervention will increase women's actual HPV self-sampling behaviour

Chapter 7

General Discussion

7.1 Introduction

The research presented in this thesis explored women's attitudes towards primary HPV self-sampling, and developed an evidence and theory based intervention designed to address barriers and promote benefits of primary HPV self-sampling. In the present chapter, the research findings will be summarised and located within the broader field, and methodological strengths and weaknesses will be discussed. Future utility of the primary HPV self-sampling intervention and suggestions for further evaluation and implementation will be presented.

7.2 Summary of study findings

The research presented in this PhD thesis investigated women's attitudes towards cervical screening through primary HPV self-sampling. By exploring views about a new method of screening, it was possible to establish the factors that might lead women not to participate in primary HPV self-sampling, should this new method be introduced. This research was conducted in response to an evolving cervical screening programme in the UK: recent years have seen the incorporation of HPV testing, calls for primary HPV testing and an interest in future primary HPV self-sampling.

The evidence presented in this thesis identified a lack of research into women's attitudes towards primary HPV self-sampling, and the need for a theoretically driven intervention designed to address barriers associated with primary HPV self-sampling uptake. Subsequently, women's hypothetical intentions and attitudes towards primary HPV self-sampling were investigated using a mixed-methods approach involving a cross-sectional survey and qualitative interviews. Findings were used to develop an evidence and theory-based intervention.

Although some of the findings in this PhD research reflect previous findings reported in the literature, novel insights into the determinants of women's attitudes and intentions regarding primary HPV self-sampling were identified. Similarly to previous research (Pitts and Clarke 2002; Waller et al. 2003; Marlow et al. 2007; Barata et al. 2008; Galbraith et al. 2014), it was found that convenience and the perception that HPV self-sampling would be less uncomfortable and embarrassing than cervical smear testing acted as facilitators to HPV self-sampling intentions, whilst a lack of HPV knowledge and low self-efficacy regarding HPV self-sampling were identified as barriers. Operational and system-related barriers to HPV self-sampling identified in the current study included fears about sample contamination, loss, identity theft, concerns about willingness of postal workers to handle samples and the need for confirmation of receipt of completed self-sampling kit from relevant laboratory. Although preference for returning samples directly to healthcare providers rather than through the post has previously been identified (Cadman et al. 2014), this was the first study to highlight specific concerns about identity theft, unwillingness of postal workers to handle samples and the need for a confirmatory receipt of sample from a relevant laboratory. Confidence in the self-sampling programme was also influential because women wanted to understand the motives behind the set-up of a new cervical screening system, and expressed concerns that it might be motivated by political and financial gains.

Habituation and overall preference for screening tests being conducted by healthcare professionals, have previously been identified as barriers to HPV self-sampling (Cadman et al. 2014) and FOBT self-sampling (Palmer et al. 2014). In this study, women reported an overall preference for medical procedures such as collection of material for testing (self-sampling) to be conducted by healthcare professionals, due to an expectation of expertise needed to conduct the procedure.

Although confidence in conducting HPV self-sampling has previously been identified as a barrier (Forrest et al. 2004; Cadman et al. 2014), a deeper understanding of the way in which confidence affects intention and attitudes towards primary HPV self-sampling

was lacking. This PhD study was the first to quantify and explore the way in which women's perceived confidence (self-efficacy) in being able to conduct HPV self-sampling properly, affected their attitudes and intentions to engage in HPV self-sampling. It was found that perceived self-efficacy in relation to HPV self-sampling not only influenced women's confidence in conducting self-sampling properly, but also affected their confidence in the subsequent result. Although trust in HPV self-sampling results has previously been reported as a barrier to HPV self-sampling by Sultana *et al* (2015), this study was able to explain why women might not trust their results.

The lack of trust reported in this study related to women's concerns about not conducting HPV self-sampling properly: women believed that they might fail to take the sample from a HPV infected area within their vagina. Consequently, women were worried that this could lead to a false negative result and that they would not get an opportunity for repeat screening until the next routine screening round. When rationalising their lack of confidence in self-sampling results, women referred to a lack of personal expertise, lack of practice and a lack of knowledge.

Similarly to previous research (Marlow et al. 2007; Dodd et al. 2014; Daley et al. 2015), a low level of HPV knowledge was observed in women. Previous research has reported that a lack of HPV knowledge is associated with low understanding of HPV test results and negative emotional consequences (Daley et al. 2015). However, the current study was the first to identify the influence of women's beliefs about the importance of HPV in the development of cervical cancer, on intentions to engage in HPV self-sampling. The current study found that women who perceived HPV as less important in the development in cervical cancer to be less likely to HPV self-sample.

7.2.1 Summary of novel findings

This was the first study to explore and quantify the effect of self-efficacy on women's intention to HPV self-sample. The study identified the way in which women's lack of confidence in conducting HPV self-sampling properly influenced their intentions,

namely by affecting their trust in self-sampling results, because of the fear that they might have failed to sample from a HPV infected area whilst conducting HPV self-sampling. This was also the first study to explore the influence of operational factors on women's intention to self-sample and to identify concerns about identity theft and unwillingness of postal workers to handle samples. Additionally, this was also the first study to identify the way trust in the set-up of a new programme can be affected by the omission of a simple confirmation of receipt of completed self-sampling kit from relevant laboratory, as well as scepticism about the motives behind the set-up of a new programme. Finally, this study was to first to identify the influence of the belief that HPV in important in the development of cervical cancer (and not just HPV knowledge in general) as an influence on intention to HPV self-sample.

7.3 Policy, practice and research recommendations

This PhD research identified the impact of personal and system barriers on women's attitudes towards primary HPV self-sampling, and their hypothetical intention to self-sample. As well as identifying barriers and benefits associated with HPV self-sampling this study was able to provide important insight into women's perceptions regarding a potential change from a familiar and established healthcare system (cervical smear testing) to a new and different type of cervical screening system. Therefore, public concerns about safety and acceptability should be addressed if primary HPV self-sampling is to become incorporated into the cervical screening programme. As well as addressing identified barriers and facilitators to HPV self-sampling, particular efforts should be focused on communicating the reason for a shift in screening method, by providing evidence that the change is not driven simply by political or financial gain. An effort must also be made to increase women's HPV related knowledge to facilitate the belief that the primary cause of cervical cancer is HPV. Efforts should also be focused on helping increase women's HPV self-sampling self-efficacy, and the belief that if a HPV self-sampling result has been provided, that the HPV self-sampling procedure has been conducted properly. Operational factor concerns such as the possibility of

identity theft and potential reluctance of postal workers to handle samples must also be addressed. As well as feeding into policy and practice recommendations, findings highlighted a need for the development of an information resource that can be used to address identified barriers regarding primary HPV self-sampling. Consequently, a theory and evidence based intervention that could potentially be incorporated into the cervical screening programme was developed.

However, the findings of this research are based on the reported barriers and facilitators to HPV self-sampling from women who were primarily White, well-educated cervical screening responders, many of whom had experienced an abnormal cervical smear. Further research should focus on identifying whether the facilitators and barriers identified in this research are also applicable to women from different sociodemographic and screening backgrounds.

7.4 Research strengths and limitations

7.4.1 The utility of the mixed methods approach

This section will discuss what was gained through the use of mixed methods. Methodological strengths and weaknesses will also be discussed.

7.4.1.1 Quantitative phase

The quantitative phase of this research facilitated the identification of health beliefs, knowledge, sociodemographic and clinical background factors that were associated with women's intentions to HPV self-sample. The survey was able to quantify the influence of extended HBM constructs including perceived barriers and facilitators to self-sampling, perceived susceptibility and severity of HPV infection, and HPV self-sampling related self-efficacy. Although concerns about performing self-sampling correctly have been previously identified, the quantitative survey was the first to quantify the strength of the relationship between self-efficacy and intention to self-sample. Therefore, the survey helped identify key variables for subsequent in-depth

exploration in interviews and facilitated focus on key issues during intervention development.

The development of the survey was informed by the extended HBM as well as identified barriers and benefits to HPV self-sampling in previous literature (Chapter 1). The development of the survey was an iterative process that involved several modifications of questionnaire items based on the validation methods used. Validation methods investigated that items were able to accurately measure the constructs of interest as well as ensuring that they were understood and acceptable to the participants. Statistical measurement of the completed survey provided evidence that the underlying factor structure corresponded to *a priori* HBM constructs, and measurement of internal reliability facilitated the exploration of whether the survey was able to measure constructs consistently. Although content validity analysis, cognitive interviews, PCA and internal reliability analysis were useful methods for testing the internal reliability and validity or the questionnaire items, alternative validation methods could have been applied. For example, prospective administration of the survey would have facilitated the measurement of test-retest reliability. However, the possibility of practice effects that can artificially inflate the estimate of test-retest reliability (Sushil and Verma 2010). Due to time constraints this form of validation was not possible. A further form of validity is that of predictive validity, which would have shown how well the intentions measured by the survey predict future behaviour. However, it was not possible to measure predictive validity of this survey because a HPV self-sampling programme is not currently available.

7.4.1.2 Qualitative phase

The qualitative phase in this PhD research facilitated the exploration of constructs that influence women's intentions to HPV self-sample, which were identified as significant in the quantitative phase. The qualitative phase also facilitated the identification of novel influences. Semi-structured interviews facilitated further exploration of the way in which extended HBM constructs affected women's intentions to self-sample (Emery

et al. 2013). The qualitative findings explained the way perceived barriers and benefits influenced women's intentions to self-sample. Importantly, the qualitative research stage was able to explain the way in which perceived self-efficacy affected intentions to primary HPV self-sample and was also able to identify novel insights into operational and system-related barriers. Interviews were an appropriate data collection method as they complemented the survey findings by facilitating an in-depth exploration of extended HBM constructs and factors identified as being associated with HPV self-sampling intention in the survey (Smith 1995). In particular, the findings from the interviews facilitated a deeper understanding of the relationship between low self-efficacy on women's attitudes towards HPV self-sampling and facilitated the identification of novel findings.

Although the qualitative phase was extremely useful in exploring women's intentions to HPV self-sample further and facilitated the identification of novel influences, the interviews were conducted with a highly selective sample of women who were white, in general well educated, many had experienced cervical abnormalities and some had received treatment for cervical abnormalities. Therefore, the generalisability of findings is limited to the population sampled. Furthermore, although semi-structured interviews were a useful method of exploring facilitators and barriers to HPV self-sampling intentions, it is questionable whether women could accurately reflect on barriers and facilitators to HPV self-sampling in a hypothetical scenario compared to a real life deliberation. This issue is further discussed later in this chapter.

7.4.2 The utility of the extended HBM in understanding women's intentions towards primary HPV self-sampling.

The extended HBM was central to this research and provided guidance for all aspects of the research process from survey development to the interview schedule and intervention development. The use of the extended HBM throughout the research facilitated an understanding of women's attitudes towards primary HPV self-sampling

and how women's intentions were influenced by health beliefs. The theoretical understanding gained through this research facilitated the development of the intervention, in line with MRC guidance (Craig et al. 2008). The use of theory was crucial in the development of the intervention because it not only provided a basis for tool development, but also facilitated the detection of strengths and weaknesses within the intervention through user testing. In addition, the use of theory informed the choice of constructs that should be measured pre and post intervention exposure in order to assess changes brought about by the intervention (Craig et al, 2008).

The use of the extended HBM constructs has highlighted that although providing information about HPV in the cervical screening context is needed to raise awareness of the association of HPV with cervical cancer, information alone is not sufficient to form intentions. Health beliefs such as perceived benefits and barriers to primary HPV self-sampling as well as perceived self-efficacy were found to be important in determining women's intentions to self-sample. The findings of the logistic regression (Chapter 4) supported the inclusion of extended HBM constructs in identifying intention to engage in primary HPV self-sampling. Extended HBM constructs, in addition to educational level and the belief that HPV is important in cervical cancer development, were able to explain between 43.1 and 61.2% of the variance in women's intentions to engage in primary HPV self-sampling, and correctly classified 83.3% of cases. Although the variance explained by the model is of quite a high percentage, it does not explain all cases suggesting that other constructs not measured by the model might have been influencing intentions. Possible explanations will be presented below.

There were a number of limitations regarding the use of the extended HBM in this research. Emotional consequences in the form of "perceived threat" (Stretcher and Rosenstock, 1997) are an important predictor of health behaviour (Jones et al. 2014), but were not measured in the survey. Perceived severity and perceived susceptibility were measured and analysed separately regarding their relationships with HPV self-sampling intention, rather than being combined to form an underlying perceived threat

construct, as conceptualised in Stretcher and Rosenstock's (1997) version of the extended HBM. Further research could investigate the effect of perceived threat on women's intentions to HPV self-sample.

A further limitation is that the role of subjective norms was not investigated in the quantitative analysis of influences on HPV self-sampling intentions. The construct of subjective norms has been the attention of debate because of an overall weak performance in predicting intention (as theorised in the TPB) compared with attitudes and perceived behavioural control (Pasick et al. 2009). However, it has been suggested that subjective norms might have a role in influencing health beliefs (Armitage and Conner 2001). An association between mammography screening uptake and the belief that significant others endorse attending for mammography screening has been observed in women from ethnic minority groups (Stewart et al. 2009). Subjective norms were explored during the qualitative phase of this study when some participants alluded to hypothetical subjective norms in relation to HPV self-sampling, but these did not seem highly influential on women's HPV self-sampling intentions.

7.4.3 Sample limitations

Sample limitations associated with opportunistic recruitment are acknowledged. Non-response bias is an issue commonly identified in postal surveys (MacDonald et al. 2009) and is also a feature in qualitative research. Target sample size was not achieved through the primary recruitment source (CSW), and therefore there was a need for supplementary recruitment. The response rate from CSW recruitment was very low and did not achieve target sample size. Only 137 participants completed a questionnaire out of 12,000 who were initially sent a recruitment leaflet informing them of the study. The low participation rate necessitated supplementary recruitment through community groups, G.P's and sexual health clinics to help achieve sample size as well as to increase heterogeneity of the sample. The response rate of the supplementary recruitment was unknown because it was not possible to record the

number of individuals who were approached to participate and those who subsequently declined. However, although supplementary recruitment helped achieve sample size, it wasn't able to increase substantially increase the heterogeneity between participants with the majority being white, highly educated, cervical screening responders. Women who were cervical screening non-attenders, less educated and from an ethnic minority background were less likely to participate. Although the majority of women were educated to a degree level, representation was also present from women who were educated to GCSE and college level, with the proportion of women in each educational category being representative of the population of South-East Wales (ELLS, 2013). Participants represented a broad range of ages, which was important as previous research (as discussed in Chapter 1) has identified that women who are older (over 50) and younger women (under 30) are less likely to participate in cervical smear testing. Therefore, the broad range of ages facilitated the investigation of whether self-sampling was an acceptable alternative to cervical smear tests in women. Furthermore, many of the participants had experienced cervical abnormalities, which might have influenced their perceptions of the utility of primary HPV self-sampling compared to cervical smear testing. The majority of women were recruited through Cervical Screening Wales and might have been more likely to take part in research because they were already engaged in the cervical screening process. The health beliefs of women who participate in research may be different to those of women who do not participate, and therefore may not represent population views. Furthermore, the majority of participants who were recruited through supplementary recruitment sources were recruited at a sexual health clinic. The health beliefs of women who attend sexual health clinics may be different to the health beliefs of women from the general population. Additionally, although the same study materials (questionnaires/interviews) were used for women from the main and supplementary recruitment samples, temporal differences in the data collection methods for the two samples mean that they may not be entirely comparable.

Although the majority of the sample was drawn from a cohort of women who were resident in South East Wales and were due to receive an invitation for cervical smear test from CSW on a given month, data are not available to verify the screening status or demographic characteristics of the women who received an invitation to participate in the study but chose not to participate. The availability of such data would have enabled comparison of responders and non-responders, facilitating a more accurate characterisation of the women who were less well represented in study findings.

7.4.4 Cross-sectional research design

The use of a cross-sectional research design facilitated the exploration of factors that influenced women's attitudes towards HPV self-sampling and their hypothetical intentions within a given time (Levin 2006). This approach facilitated the identification of factors that can inform policy and practice considerations in public health planning (Levin 2006), should primary HPV self-sampling be introduced into the cervical screening programme. However, a limitation of cross-sectional research is that it does not allow causal relationships to be inferred (Mann 2003), and may have led to the observation of inflated associations between variables because they were all measured at one time. Prospective research is required to test causal effects of perceived barriers and facilitators on women's intentions to HPV self-sample. Unfortunately, the large scale timeframes and associated costs made prospective research unachievable within the scope of this PhD study.

7.4.5 Hypothetical intention

A limitation of this research was that it explored women's hypothetical intention to engage in primary HPV self-sampling. It would have been optimal if a primary HPV self-sampling trial was being conducted at the time of this PhD research, where real time investigation of women's attitudes, intentions and actual utilisation of primary HPV self-sampling would have been possible. However, due to the lack of such research

and because a primary HPV self-sampling programme was not available, the PhD study explored hypothetical intentions with the aim of informing policy and practice recommendations.

Intention was considered to be the proximal determinant of HPV self-sampling behaviour. It has been proposed that intentions reflect an individual's motivation to engage in a certain behaviour as well as how hard they are prepared to try to conduct the specific behaviour (Ajzen 1991). However, intentions do not always translate into behaviour. For example, although public attitudes towards colorectal cancer screening in the U.K. are broadly positive, with more than 80% (Taskila et al. 2009) of respondents indicating that they thought it was a 'good idea' and 95% (Vart 2010) of respondents in another study stating that they would intend to conduct FOBT if available, actual uptake rates are actually much lower (Chapter 1). Lower uptake may be due to failure to translate positive intentions into actions (Lo et al. 2014). Therefore, the findings of this thesis should be interpreted with caution when considering the likely uptake of primary HPV self-sampling because women's intentions might not translate to real life actions if the programme becomes available. Nevertheless, it was important that women's views regarding the possible implementation of a primary HPV self-sampling programme were explored prior to a possible introduction because findings can be used in policy and practice recommendations as well as to guide further research.

7.5 Intervention development and user testing

The processes utilised by this PhD study highlight the continuous process of developing complex health behaviour interventions (Craig et al, 2008). Based on findings from the previous phases of work, a pilot HPV self-sampling intervention was developed and tested. Examples of interventions with a wide variety of formats, design and content were considered when deciding on the format of the HPV self-sampling intervention which was ultimately designed as a leaflet. It was important that information was

embedded within an intervention that can be incorporated into a future primary HPV self-sampling programme by being easily accessible (e.g. sent with or before the self-sampling kit) and low cost (to maximise potential exposure and impact). It was felt that a leaflet would be the best intervention format. Usability and acceptability were investigated through a sample of potential users as well as potential service providers. Through opportunistic sampling, a range of women participated in user testing to ensure that barriers to HPV self-sampling were addressed adequately and to ensure that no salient barriers or benefits were overlooked. Involvement of a variety of people including potential users and providers highlights the iterative and rigorous development process of the intervention. User testing with women ensured that the intervention was user friendly, whilst the testing with healthcare professionals ensured that the factual information was correct and that the hypothetical operational factors included within the intervention would be feasible in the future. However, the user testing was only able to establish preliminary face validity of the HPV self-sampling intervention, and further testing is needed to determine the effect of the intervention of women's intentions and behaviours.

7.5.1 Informed consent

Informed consent is important in any screening programme so that individuals are aware of the benefits and risks associated with participating in screening. Importantly, information suitable for promoting informed consent should also be thorough enough to enable informed dissent. Fully informed dissent refers to having enough information to withdraw from screening by outlining risks and benefits of engaging in HPV self-sampling, as well as the consequences of not engaging in self-sampling (Public Health England 2009).

The intervention developed in this PhD study was not developed to encourage informed consent or dissent because it was envisaged that information relating to informed consent/dissent in primary HPV self-sampling would be developed by the

screening programme providers (Public Health England 2009). The intervention was therefore specifically designed as a health behaviour change intervention with the aim of increasing intention to engage in primary HPV self-sampling. The intervention content did not include detailed information on the possible risks associated with engaging in HPV self-sampling, or what would happen if a positive HPV result was obtained. Previous phases of the research highlighted system barriers associated with HPV self-sampling including lack of trust in reasons for the set-up of a new programme and concerns relating to operational factors, hence it was considered that including information relating to possible risks of taking part in HPV self-sampling would have a detrimental effect on women's trust in primary HPV self-sampling. The omission of risk information highlights that the HPV self-sampling intervention is not in itself a solution to all informational needs relating to HPV self-sampling; rather, the HPV self-sampling intervention is a tool that should help form intention to self-sample by initiating thoughts and discussion about HPV self-sampling. Other materials ensuring that participants are fully informed of risks associated with HPV self-sampling should also be available.

7.5.2 Under-representation of attitudes of women who are in favour of HPV self-sampling

The intervention content was designed to address the concerns of women who were less likely to engage in primary HPV self-sampling classified by the HBM-HPV survey (Chapter 4). The views of women less likely to engage in HPV self-sampling were explored in depth through semi-structured interviews (Chapter 5) and were used to understand barriers and to help inform the content of the intervention. Therefore, the attitudes of women who were in favour of HPV self-sampling as classified by the survey were under-represented. The aim of the intervention was to address concerns of women who were less likely to engage in primary HPV self-sampling should this method become incorporated into the cervical screening programme, therefore

women who were less likely to engage were targeted. However, the views of a small sample of women who reported that they would be likely to self-sample as well as those who reported that they would not be likely to self-sample, were explored during pilot testing (Chapter 6). In general, women reported that the intervention was user friendly, addressed their concerns and highlighted salient benefits.

7.5.3 Intervention format

In order to promote ease of access, the HPV self-sampling intervention was created in the form of a leaflet, which could potentially be sent through the mail via the cervical screening programme before or alongside receipt of a HPV self-sampling kit. This format would also facilitate the inclusion of the intervention alongside reminder letters prompting women to complete a HPV self-sampling kit not yet returned. However, some participants reported that they would also like to have access to electronic content about HPV self-sampling in the form of an educational video or a website that they could access for more detailed information. This should be considered in future research.

Interventions to increase uptake of screening designed in a form of a leaflet have also been developed for the only other self-sampling programme, the FOBT bowel screening programme. The bowel cancer screening programme is the only established self-sampling programme for cancer screening in the U.K. and many similarities can be drawn regarding the operational factors associated with the colorectal cancer screening programme and a potential HPV self-sampling programme. As discussed in Chapter 1, the U.K. colorectal cancer screening programme has seen a relatively low uptake of around 60%, with the lowest uptake reported in populations in the most deprived quartile (Wardle et al. 2016) and this might also be an issue with a HPV self-sampling programme. Research has identified competing time demands, lack of social support and stress as barriers to participation in FOBT self-sampling (von Wagner et al. 2011). Furthermore, literacy might also account for the lower uptake of FOBT self-

sampling, as all information associated with the screening is sent to individuals through the post, including screening invitation letter as well as a leaflet explaining FOBT self-sampling and the risks and benefits of participating. Therefore, individuals are presented with a large amount of information which they need to digest and understand before considering whether to participate in FOBT self-sampling. Similar issues will need consideration if HPV self-sampling is incorporated as a cervical screening method, as it seems highly likely that information about HPV self-sampling and instructions on how to conduct self-sampling would also be sent through the post. A recent randomised controlled trial (Wardle et al. 2016) demonstrated that additional leaflets (gist and narrative based) alongside standard patient information were not able to increase uptake of FOBT in deprived populations, even though the leaflets demonstrated improved comprehension and intention to conduct FOBT in previous studies (McGregor et al. 2015; Smith et al. 2015). The only intervention that increased participation in FOBT was the tailoring of the invitation letter to include individual's own G.P. practice name. A number of factors might have influenced the effectiveness of the leaflets. Firstly, they were sent in addition to the standard information sent to individuals, which might have resulted in an increased information burden. It would be interesting to explore the effect of the leaflets if they were sent independently of the standard information. Health professionals interviewed during the user testing phase of this PhD study suggested that an intervention leaflet might be best sent before the formal information pack and self-sampling kit, to help reduce potential information overload and to help increase intention to self-sample. Furthermore, the leaflets developed for the ASCEND trial did not address one of the most commonly reported barriers to FOBT which is the unpleasantness of the procedure itself. It is possible that uptake might have been increased if that prominent barrier had been addressed. Furthermore, although interventions such as leaflets that are designed to reduce socioeconomic inequalities in cancer screening by being specifically tailored for individuals from more deprived groups, it is difficult to address all barriers associated with screening uptake including competing time demands and life stressors. Therefore,

as suggested by the ASCEND team the availability of direct contact with professionals would be a useful supplement to paper-based interventions.
However, although it is useful to draw inferences from research focusing on FOBT self-sampling, it must also be acknowledged that the HPV self-sampling programme would involve screening for a different cancer. Furthermore, the HPV self-sampling programme will target a different population and will involve a completely different type of self-sampling test that only needs to be conducted once every screening round, unlike FOBT self-sampling.

7.5.4 User and provider involvement

The target audience and the potential providers of the intervention were consulted in phases of the work, allowing key stakeholders to be influential in the intervention development process. The development of the intervention would not have been as thorough without user and provider involvement. The interviews with potential users of the intervention facilitated an in-depth understanding of the usability of the tool, as well as the identification of problems with the tool. This processes enabled issues relating to the intervention to be identified and modified before the development of the final intervention. Importantly, the feedback was gained from different views due to the inherent attitudinal and sociodemographic differences in women sampled, as well as the feedback that was obtained from the service providers. Women provided feedback regarding the usability and the clarity of the information presented in the HPV self-sampling intervention. Service providers were able to comment on the accuracy of the information presented in the intervention as well as the feasibility of the operational factors presented. It was especially crucial that providers of a potential HPV self-sampling programme were involved during the development of the intervention because the operational factors presented in the intervention are largely based on the feedback from Cervical Screening Wales as well as the operational factors of the FOBT self-sampling programme. Therefore, potential provider feedback was important to ensure that the intervention represented a self-sampling programme as

close to a future HPV self-sampling programme as possible. The provider feedback was also useful in informing the best point of implementation of the intervention within a proposed primary HPV self-sampling programme.

7.6 The future of the HPV self-sampling intervention

The current research has demonstrated the need for the development of a primary HPV self-sampling intervention that provides women with information about primary HPV self-sampling and increases their confidence in their ability to self-sample and confidence in the set-up of a primary HPV self-sampling programme. Further research to evaluate the utility of the intervention and its practical application should HPV self-sampling be introduced as a primary screening method will be required.

7.6.1 Feasibility testing

Potential user attitudes towards the HPV self-sampling intervention could be explored by a before and after exposure to the HPV self-sampling intervention questionnaire in a sample of women. This can assess feasibility as well as whether the intervention affects desired outcomes i.e. increase in intention to self-sample through an increase in knowledge, self-efficacy and perceived benefits to self-sampling. Although a before and after questionnaire was used to identify any change in women's knowledge, attitudes and intentions towards HPV self-sampling in this study (Chapter 6), it was only conducted on a very small number of women and therefore was simply a descriptive survey and unable to statistically detect any effect of the intervention on women's intentions to self-sample. Field testing with a larger cohort of providers and potential users can be used to further explore the acceptability of the intervention content and the feasibility of the operational factor information (e.g. time-frame for results) presented in the intervention. The intelligence gained from conducting the field study could be used to help inform further intervention testing studies regarding the feasibility of the measures used, recruitment and retention of participants.

7.6.2 Controlled evaluation

A controlled evaluation of the effect of the HPV self-sampling intervention would be optimal and a randomised controlled trial (RCT) design should be considered because individual outcomes may be dependent on other processes such as screening history and time of invitation. For example, women are currently called in cohorts for cervical screening on a monthly basis and differences in women's intentions to engage in cervical screening may be influenced by the month of their screening invitation, for example women called in traditionally busy months such as December may be less likely to attend at point of invitation due to other commitments. An RCT should account for this by dividing monthly cohorts, with one half of women being randomised to receive an intervention whilst the other half being randomised not to receive an intervention. A similar process could be followed for screening history. A possible RCT could involve participants completing measures pre- and post-intervention exposure to assess the impact of the intervention on HPV self-sampling behaviour. The RCT would also enable an evaluation of the moderating role of self-efficacy, knowledge, benefits and barriers to HPV self-sampling in influencing intention and behaviour. Additionally, if HPV self-sampling is introduced in the future, an RCT could be used as a direct behavioural measure of HPV self-sampling uptake in women who have been exposed to the intervention compared with women who have not. However, because RCTs involve large numbers of participants to detect effect sizes cost and time limitations need to be considered.

7.6.3 Future implementation consideration and challenges

The HPV self-sampling intervention was based on a hypothetical HPV self-sampling programme and potential set-up was informed by the FOBT self-sampling programme. Therefore, it must be noted that the intervention will need to be modified to reflect

primary HPV self-sampling programme characteristics, should a primary HPV self-sampling programme be developed.

The most likely dissemination of the intervention would be alongside HPV self-sampling kits, which could be sent through the post. Further dissemination opportunities include public health events as well as primary healthcare providers, for example displaying leaflets in G.P. surgeries. However, as well as the identification of suitable implementation sites, research has identified the need for 'buy-in' of those involved in the implementation of interventions. In order for leaflets to be hosted and distributed in primary care settings, the distribution preferences of host sites, costs and additional workload need to be considered and presented (Evans et al. 2014). This further supports the need for evaluation of the intervention (as discussed previously) as well as the need for the assessment of implementation practices and costs.

7.7 Conclusion

The incorporation of HPV testing in the changing cervical screening programme in the U.K. has presented an opportunity for future incorporation of primary HPV testing and the possibility of primary HPV self-sampling. Evidence presented in this thesis suggests that personal barriers such as a lack of knowledge and lack of self-efficacy in ability to self-sample correctly and system barriers such as concerns about reasons for establishing a new method for cervical screening and operational factors are influential in determining intention to engage in primary HPV self-sampling. Ultimately, the insights gained from this research can be used to guide further enquiry into the possibility of primary HPV self-sampling and to help inform future policy and practice. The HPV self-sampling intervention can be a mechanism through which intention to engage in primary HPV self-sampling is increased. Further research is needed to evaluate the acceptability of the intervention and its impact on women's attitudes and intentions towards primary HPV self-sampling.

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Appendix 3.1: Literature search to identify previously developed Health Belief Model Based HPV self-sampling surveys.

Two literature searches were conducted (2010 and 2012) to identify any previously identified scales based on the Health Belief Model which investigated women's attitudes towards HPV self-sampling.

Search Strategy and Inclusion Criteria

Search terms limited to:

Title

Abstract

Electronic databases:

PsychInfo

PubMed

Web of Knowledge

CINAHL

EMBASE

SCOPUS

Supplementary search:

Hand search of references in identified papers.

Search terms:

Health Belief Model

HBM

Human Papillomavirus

HPV

Self-sampling

Home testing

Search terms were combined to form the following searches:

Health Belief Model and Human Papillomavirus self-sampling

Health Belief Model and Human Papillomavirus home testing

HBM and HPV self-sampling

HBM and HPV home testing

Inclusion criteria:

Participants were female

The focus of the study was HPV self-sampling

The study utilised the Health Belief Model in its material development

The study investigated attitudes to behaviour

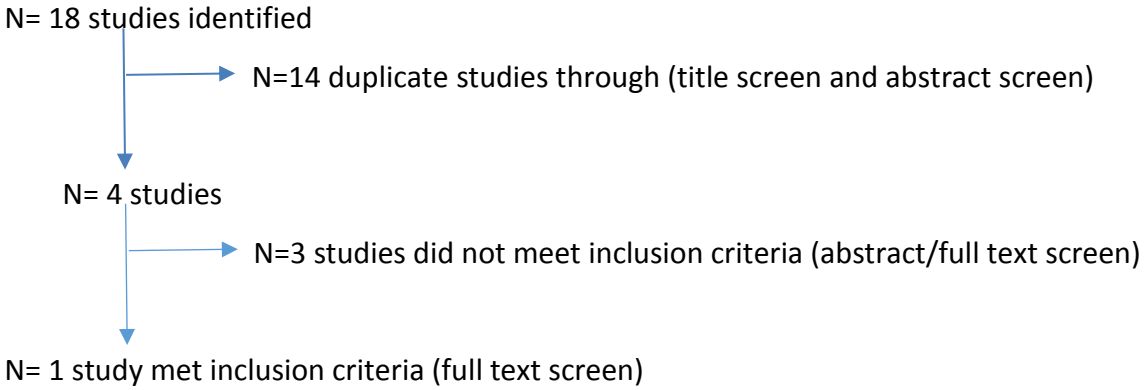
Exclusion criteria:

Male participants

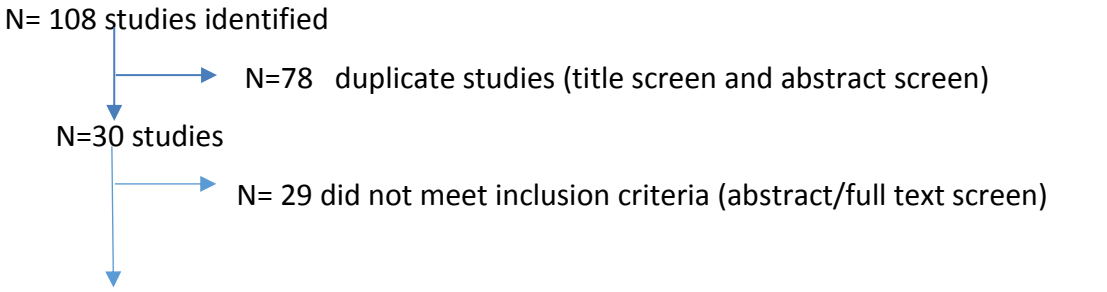
Laboratory based studies

Focus on HPV vaccination

Results of 2010 search



Results of 2012 search



Appendix 3.2: Studies identified from 2010 literature search

Study Title	Authors	Study Focus	Participants	Method	Theoretical Base	Findings	Inclusion criteria met?
Discussions about self-obtained samples for HPV testing as an alternative for cervical cancer prevention	Barata et al (2008)	HPV self-sampling	Women (age range 19-64 yrs)	Focus groups	Health Belief Model (HBM)	Self-sampling provides a different benefits-minus-barriers equation to cytology.	Yes
Using the Health Belief Model to examine and predict college women's cervical cancer screening beliefs and behaviour	Burak et al (2009)	Cervical Screening Cytology	Young women	Survey	HBM	HBM predicted 11-15% of variance in attitudes	No
Predictors of interest in HPV vaccination	Marlow et al (2009)	HPV vaccination	Adolescent girls (16-19yrs)	Survey	HBM	Perceived susceptibility, barriers and benefits were associated with acceptability.	No
Parents' health beliefs and HPV vaccination of their adolescent daughters	Reiter et al (2009)	HPV vaccination	Parents of young girls	Survey	HBM	HBM constructs were associated with HPV vaccine initiation	No

Appendix 3.3: Initial HPV self-sampling survey

Research study: Women's attitudes towards HPV self-sampling

Home screening kits have been made which can allow women to carry out a cervical screening procedure themselves in their own homes. These kits test for Human Papillomavirus (HPV). HPV is a very common infection that most women will have at some point in their lives. Most of the time this infection will not cause any problems and will clear up on its own, but in some cases it can cause cervical cancer.

To carry out the home test a woman will need to put a swab (a cotton bud with a long handle) into the vagina. She will then need to put the swab into a sealed tube with a liquid already inside, and post it to a laboratory using a special pre-addressed envelope.

We would like to ask you a few questions about these kits and your views on cervical cancer and testing. Some of the questions are a little sensitive but it's important for us to know about your views so please try and fill in as much as you can. All of responses will be kept strictly confidential. Your opinions are very important and will help us to plan future health services to reduce cervical cancer.

Please read the instructions for each question carefully. There are questions on both sides of each page. You will mostly need to tick a box or circle a number and the survey shouldn't take too long to complete. This survey is not a test, but we are interested in your views and would like you to answer questions as honestly as possible.

Once you have completed the survey, please return it to us in the PRE-PAID and addressed envelope provided.

We look forward to receiving your survey and would like to thank you for taking the time to help with this study.

If you wish to take part could you firstly fill in your name, address and contact details below:

Full name: ……..

Address:…… ……..

Contact Number:…… E-mail address:……

Your views on home testing

1. Overall, how likely do you think that you would be to use a home testing kit? (please circle) *Please circle a number.*

1	2	3	4	5
Not at all likely				*Very likely*

2. How sure are you that doing the test yourself will provide accurate results? *Please circle a number.*

1	2	3	4	5
Not sure at all				Very sure

3. How sure are you that you will be able to understand the instructions provided in the home test kit? *Please circle a number.*

1	2	3	4	5
Not sure at all				Very sure

4. How sure are you that you will be able to carry out the sampling procedure (placing swab in vagina)? *Please circle a number.*

1	2	3	4	5
Not sure at all				Very sure

5. How sure are you that you will be able to place the swab into the tube containing the special liquid without touching or dropping the swab? *Please circle a number.*

1	2	3	4	5
Not sure at all				Very sure

6. How sure are you that you will be able to send off the completed test within the time allowed (2 weeks)? *Please circle a number.*

1	2	3	4	5
Not sure at all				Very sure

7. How sure are you that your completed test kit will be good enough for testing? *Please circle a number.*

1	2	3	4	5
Not sure at all				Very sure

8. Below are a few comments about doing home testing, please circle how much you agree with them.

a. Using a home kit is convenient, as it can be done at home I would not have to take time off work/arrange childcare. *Please circle a number.*

1	2	3	4	5
Strongly disagree				Strongly agree

b. I am worried that I may hurt myself using the home kit. *Please circle a number.*

1	2	3	4	5
Strongly				Strongly
disagree				agree

c. Using a home kit can help make sure no-one will know that I am being screened for cervical cancer. *Please circle a number.*

1	2	3	4	5
Strongly				Strongly
disagree				agree

d. Using a home kit is less embarrassing than having a GP or nurse carrying out a smear test. *Please circle a number.*

1	2	3	4	5
Strongly				Strongly
disagree				agree

e. I wouldn't trust the results of the home kit. *Please circle a number.*

1	2	3	4	5
Strongly				Strongly
disagree				agree

f. Using a home kit seems less painful than a smear test. *Please circle a number.*

1	2	3	4	5
Strongly				Strongly
disagree				agree

9. If you have any other comments about the home kits, please write them below:

……
……

Your views on HPV

We would like to ask you a few questions about HPV. Please remember that this is not a test and we would just like to get to know a bit more about you and your views.

10. How likely do you think you are to be infected with HPV? *Please circle a number.*

1	2	3	4	5
Not at all likely				*Very likely*

11. Before taking part in this study had you heard of Human Papillomavirus (HPV) before? *Please tick a box*

Yes ☐

No ☐

12. If you had to guess, how do you think HPV spreads from person to person? *Please tick all that apply.*

Through breathing the same air as someone who is infected (like catching a cold) ☐

Through sexual contact ☐

Through sitting on dirty toilet seats ☐

Through kissing ☐

13. How important do you think HPV is in developing cervical cancer? *Please circle a number from 1 (Not at all important) to 5 (Very important)*

1	2	3	4	5
Not important at all				*Very important*

14. Do you think that HPV can be treated with medicines? *Please tick a box.*

Yes ☐

No ☐

15. Do you think that HPV can clear up by itself? *Please tick a box.*

Yes ☐

No ☐

16. How serious of an infection do you think HPV is? *Please circle a number.*

1	2	3	4	5
Not at all severe				*Extremely severe*

Your thoughts about cervical cancer.

17. Compared to most other women your age, how likely do you think it is that you will get cervical cancer at some time in your life? Would you say you are…? *Please circle*

1	2	3	4	5
Much less likely	A little less likely	About the same	A little more likely	Much more likely

18. How confident, are you that you would notice a symptom of cervical cancer?

1	2	3	4	5
Not at all confident	Slightly confident	About the same	Fairly confident	Very confident

19. Please tell us whether you agree or disagree with each of the following statements by circling a number from 1 (strongly disagree) to 5 (strongly agree).

a) Going for regular smear tests means that cervical cancer can be found early on. 1 2 3 4 5

b) The three yearly reminders I get help me remember to attend my cervical screening appointments. 1 2 3 4 5

c) Having a smear test is embarrassing 1 2 3 4 5
and that puts me off attending.

d) If I got cervical cancer, it would be 1 2 3 4 5
more serious than other diseases.

20. Have you made any lifestyle choices to try and reduce your risk of cervical cancer?

Yes □ If *Yes,* please describe them below.
No □

……
……

Your experiences of cervical cancer screening and cervical cancer.

21. Have you ever had a smear test? *Please tick a box*

Yes □
No □

22. If you have previously had a smear test, how long ago did you have your last smear? *Please tick a box*

Under 3 years □
3-4 years □
4+ years □

23. Have you ever had an abnormal smear test result? *Please tick a box.*

Yes □

No □

24. Have you ever received treatment for abnormal cervical cells? *Please tick a box.*

Yes □

No □

25. Has anyone close to you ever had abnormal cervical smear results? *Please tick a box*

Yes □

No □

26. Has anyone close to you ever been diagnosed with cervical cancer? *Please tick a box*

Yes □

No □

27. Has anyone close to you ever died from cervical cancer? *Please tick a box*

Yes □

No □

Demographic details

Finally we would like to ask you a few background questions.

28. What is your age?

……

29. What is your postcode

What is the highest level of education you have?

Left school at or before age 15 □
GCSE or O level or equivalent □
A level or equivalent □
Further education but not a degree □
Degree or higher (e.g. Masters, PhD) □
None of the above □

……

30. Do you own your own home? *Please tick a box*

Yes □
No □

31. Which of the following do you feel best describes your ethnic group? *Please tick one or more boxes*

English	□	Caribbean	□	Arab	□
Irish	□	African	□	Chinese	□
Scottish	□	African Indian	□	Bangladeshi	□
Welsh	□	Indian	□	Any other group	□
British	□	Pakistani	□		

Thank you very much for completing the survey. Your contribution to this research is invaluable and will help make decisions regarding future cervical screening.

Could you please return the survey using the PRE-PAID and addressed envelope provided.

We look forward to receiving your survey.

Appendix 3.4 : Content Validity Analysis Protocol

Background

We have developed a survey to investigate women's attitudes and beliefs towards Human Papillomavirus (HPV) self-sampling. Many of the questions in the survey will be based around constructs of the extended Health Belief Model and will particularly focus on the concept of self-efficacy. The survey will also investigate women's knowledge of HPV infection, screening behaviour and family history of cervical cancer.

Purpose of this protocol

This protocol covers the assessment of content validity. Content validity provides evidence of the extent to which the components of the instrument are relevant to, and representative of, the construct of interest.[1] In this definition, the term 'construct' refers to the concept or variable that is the target of the survey. 'Relevance' refers to the appropriateness of the items in relation to both the construct and the function of the survey. 'Representativeness' refers to the degree to which the items reflect and measure all facets of the construct.

The measure is not a comprehensive assessment of all possible factors that might influence women's attitudes towards HPV self-sampling and their predicted intention to self-sample. Rather, items have been selected to represent key theoretical constructs, reflecting the extended Health Belief Model[2-4] and screening behaviour and experiences that may be the determinants of women's attitudes and intentions.

Content validity takes the form of a quantitatively based judgement. This is often carried out by experts who are asked to ally assess if the items in a survey reflect the area of interest and will successfully meet the aims of the research. Content validity is similar to face validity, but the process differs in that face validity more usually refers to the superficial validity, based on intuitive judgements of a target audience, or other untrained observers.

An assessment of content validity is generally carried out using a panel of expert raters who score the survey items on several different criteria.[1 5 6] The proportion of raters giving high scores is known as the content validity index.

This protocol outlines the methods to be used for measuring content validity index for a survey measure in UK English.

Methods

The content validity of the survey will be investigated by asking raters to assess each item in terms of relevance and representativeness. We will then calculate the content validity index for each item and group: the percentage of raters who give a high score in terms of relevance and representativeness.

Panel of raters

The panel of raters should consist of six or more academics with some experience in the field of measurement of knowledge, attitudes and beliefs. Ideally, ten raters should

be recruited because the probability of drawing spurious conclusions due to chance agreement diminishes to a negligible level with this number.[7] However, six raters is considered adequate if positive agreement is at least 78%.[7]

The raters may be doctoral students, post-doctoral researchers or more senior academics. They need not be screening behaviour or cervical cancer experts, but should have some knowledge of the field of awareness and beliefs about cervical cancer and screening behaviour. They must have a good mastery of English.

Description of constructs

The survey aims to measure the following constructs:

- *Perceived severity*: Perception of comparative severity of HPV infection or cervical cancer.
- *Self-efficacy:* A belief regarding one's ability to exert effective control over behaviours associated with self-sampling or attending smear testing.
- *Perceived susceptibility:* Perception of comparative personal susceptibility of cervical cancer or HPV infection.
- *Perceived benefits:* Beliefs about the benefits associated with self-sampling or attending for smear testing.
- *Perceived barriers:* Beliefs about the barriers associated with self-sampling or attending for smear testing.
- *Intention:* The overall predicted intention to HPV self-sample (hypothetical).
- *Cues to action:* External event that prompts a desire to make a health decision: whether to attend smear testing.
- *Baseline knowledge:* An assessment of participant knowledge about HPV or cervical cancer aetiology and prognosis, with the provision of minimal information (information sheet and survey).
- *Screening history:* An assessment of participants past smear test attendance and adherence to the recommended 3yearly testing.
- *Treatment history:* An assessment of previous cervical cell abnormalities.
- *Family history:* An assessment of participant experiences associated with cervical abnormality and cervical cancer.

Scoring

Each rater will **independently** score each of the items in the HPV self-sampling survey (items QV1 to QV27, with the exception of Q 9 which is a free text field question). Items 28-31 have been excluded from the content validity analysis as they are questions asking about demographic details. The survey can be located in Appendix 1 and must be scored using the score instruction sheet provided in Appendix 2, the content validity score card is provided in Appendix 3. Scoring must take place according to the following criteria:

    - Relevance: the appropriateness of the items in relation to both the construct and the function of the survey
- Representativeness: whether the items cover a representative sample of the construct

Raters should score each domain on a scale of 1 to 4 (from poor to very good – defined in scorecard). Raters should provide comments, particularly if they give a score of less than 3 to any item.

Analysis

For each item, we will calculate the number of raters giving a rating of 3 or 4 for relevance and representativeness. We will divide this by the total number of raters to give a content validity index for relevance and representativeness. A low content validity index will, therefore, arise if few raters score an item 3 or 4.

Definition of adequate content validity

There is no universal agreement on the definition of adequate content validity; we will consider content validity to be adequate if the index is greater than 78%.[4] This is a level at which chance agreement is unlikely to explain the high score.[4]

Action taken if content validity index <78%

If the content validity is less than 78% for any of the items on any dimension, we will seek to improve the wording of the item and consider:

- whether the item(s) in the domain are not comprehensive enough to collect data on the construct
- whether the domain measures other constructs than the one of interest

If it is not possible to reach agreement on the most appropriate wording of component items it may be appropriate to test different versions during the cognitive interviewing phase.

Timescale

June 2011.

References

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(5) Norman P, Brain K. An application of an extended health belief model to the prediction of breast self-examination among women with a family history of breast cancer. Br J Health Psychol 2005;10:1-16.

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(7) Grant JS, Davis LL. Selection and use of content experts for instrument development. Res Nurs Health 1997; 20(3):269-274.

(8) Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Res Nurs Health 2007; 30(4):459-467.

(9) Andersen MR, Drescher CW, Zheng Y et al. Changes in Cancer Worry associated with participation in ovarian cancer screening, Psycho-Oncol 2007; 16:814-820.

Content validity instructions

The following constructs are investigated in the HPV self-sampling survey. Please find a definition of the constructs below:

- *Perceived severity*: Perception of comparative severity of HPV infection or cervical cancer.
- *Self-efficacy:* A belief regarding one's ability to exert effective control over behaviours associated with self-sampling or attending smear testing.
- *Perceived susceptibility:* Perception of comparative personal susceptibility of cervical cancer or HPV infection.
- *Perceived benefits:* Beliefs about the benefits associated with self-sampling or attending for smear testing.
- *Perceived barriers:* Beliefs about the barriers associated with self-sampling or attending for smear testing.
- *Intention:* The overall predicted intention to HPV self-sample (hypothetical).
- *Cues to action:* External event that prompts a desire to make a health decision: whether to attend smear testing.
- *Baseline knowledge:* An assessment of participant knowledge about HPV or cervical cancer aetiology and prognosis, with the provision of minimal information (information sheet and survey).
- *Screening history:* An assessment of participants past smear test attendance and adherence to the recommended 3yearly testing.
- *Treatment history:* An assessment of previous cervical cell abnormalities.
- *Family history:* An assessment of participant experiences associated with cervical abnormality and cervical cancer.

Scoring of questions

Please score according to the following criteria:

Relevance: the appropriateness of the questions in relation to both the construct and the function of the survey

1. The question is not relevant and is not appropriate for the construct or to the function of the survey.
2. The question needs major revisions in order to be relevant to the construct or to the function of the survey.
3. The question needs minor revisions in order to be relevant to the construct or to the function of the survey
4. The question is relevant to the construct and to the function of the survey

Representativeness: the questions and response scales reflect and measure a representative sample of the construct

1. The question and/or response scale is not representative.

2. The question and/or response scale needs major revisions to make it representative

3. The question and/or response scale need minor revisions to make it representative

4. The question and/or response scale is representative

Content validity scoring card

Construct	Item number	Domain	SCORE		Notes (please note why you have given a low score, and provide suggestions for improvement if possible)
			Relevance	Representativeness	
Intention	QV 1	Intention to HPV self-sample.			
Self-efficacy	QV 2	Self-sampling result accuracy.			
Self-efficacy	QV 3	Understanding self-sampling procedure instructions.			
Self-efficacy	QV 4	Executing self-sampling procedure.			
Self-efficacy	QV 5	Self-sampling: Sample storage			
Self-efficacy	QV 6	Self-sampling: Time management.			
Self-efficacy	QV 7	Self-sampling: Sample quality			
Self-sampling	QV 18	Cervical cancer: symptom identification			

Construct	Item number	Domain	SCORE		Notes (please note why you have given a low score, and provide suggestions for improvement if possible)
			Relevance	Representativeness	
Self-efficacy	QV 20	Reducing cervical cancer risk: lifestyle modification			
Perceived Benefits	QV 8a)	Perceived benefits to self-sampling: additional arrangements.			
Perceived Benefits	QV 8(c)	Perceived benefits to self-sampling: confidentiality.			
Perceived benefits	QV 8(d)	Perceived benefits to self-sampling: embarrassment.			
Perceived benefits	QV 8(f)	Perceived benefits to self-sampling: reduction in pain			
Perceived benefits	QV 19(a)	Perceived benefits to cervical smear testing: early cancer identification			
Perceived barriers	8 (b)	Perceived barriers to self-sampling: fear of pain			
Perceived barriers	QV 8 (e)	Perceived barriers to self-sampling: trust in results.			

Construct	Item number	Domain	SCORE		Notes (please note why you have given a low score, and provide suggestions for improvement if possible)
			Relevance	Representativeness	
Perceived barriers	QV19(c)	Perceived barriers to smear test attendance: embarrassment.			
Perceived susceptibility	QV 10	Perceived susceptibility to HPV infection.			
Perceived susceptibility	QV 17	Perceived susceptibility to cervical cancer.			
Perceived severity	QV 16	Perceived severity of HPV infection.			
Perceived severity	QV19(d)	Perceived severity of cervical cancer.			
Cues to action	QV19(b)	Cues to action: smear test attendance			
Baseline Knowledge	QV 11	Knowledge of HPV.			
Baseline Knowledge	QV 12	Transmission of HPV infection.			
Baseline Knowledge	QV 13	Role of HPV in cervical cancer.			

Construct	Item number	Domain	SCORE		Notes (please note why you have given a low score, and provide suggestions for improvement if possible)
			Relevance	Representativeness	
Baseline Knowledge	QV 14	Treatment of HPV infection.			
Baseline knowledge	QV 15	HPV etiology			
Screening history	QV 21	Smear test attendance.			
Screening history	QV 22	Last smear test attendance.			
Screening history	QV 23	Experience of abnormal result.			
Treatment history	QV 24	Experience of cervical treatment.			
Family history	QV 25	Family history of cervical abnormalities.			
Family history	QV 26	Family history of cervical cancer			
Family history	QV 27	Family history of cervical cancer prognosis.			

Appendix 3.5 : CVA scores

Question no	Rater 1 RM		Rater 2 FL		Rater 3 JW		Rater 4		Rater 5		Rater 6		Rater 7		Rater 8		Rater 9		**Total % 3 or 4**	
	A	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**
1	4	4	4	4	4	4	4	4	4	4	3	3	4	4	4	3	3	4	**100**	**100**
2	4	4	4	4	3	3	2	4	1	1	2	3	2	3	4	3	4	4	**55**	**89**
3	4	4	2	4	4	4	3	4	4	4	4	4	4	4	4	3	4	3	**89**	**100**
4	4	4	4	3	4	4	4	4	4	4	4	4	4	4	4	3	4	4	**100**	**100**
5	4	4	3	4	4	4	4	4	4	4	4	4	4	4	4	3	4	4	**100**	**100**
6	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	3	4	4	**100**	**100**
7	4	4	3	4	4	4	2	4	3	3	2	2	2	2	4	3	3	4	**67**	**78**
8 (a)	4	4	4	4	4	4	4	4	3	3	4	4	4	4	3	2	4	4	**100**	**89**
(b)	4	4	4	4	4	4	4	4	4	3	4	4	4	4	4	2	4	4	**100**	**89**
(c)	4	4	4	3	4	4	2	4	3	4	4	4	4	4	4	3	4	4	**89**	**100**
(d)	4	4	3	4	4	4	4	4	4	4	4	4	4	4	4	2	4	4	**100**	**89**
(e)	4	4	4	4	4	4	4	4	4	3	4	4	4	4	4	4	4	4	**100**	**100**
(f)	4	4	3	4	4	4	4	4	4	4	3	3	4	4	4	2	4	4	**100**	**89**
10	4	4	4	3	4	4	4	4	3	4	4	4	4	4	4	2	4	4	**100**	**89**
11	4	4	4	4	4	4	4	4	4	4	2	2	4	4	4	2	4	4	**89**	**78**
12	4	4	4	4	4	4	4	2	4	4	4	4	4	4	3	3	4	3	**100**	**89**
13	4	4	2	3	4	4	2	2	4	4	4	4	3	3	4	3	4	4	**78**	**89**
14	4	4	4	4	4	4	4	3	4	4	4	2	4	4	4	4	4	4	**100**	**89**
15	4	4	1	1	4	4	4	3	4	1	4	2	4	4	4	4	4	4	**89**	**67**
16	4	4	4	4	4	4	4	1	3	4	4	3	2	3	3	2	4	4	**89**	**78**
17	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	**100**	**100**
18	3	3	4	4	4	4	4	3	1	1	2	2	4	4	4	2	4	4	**78**	**67**
19 (a)	4	4	4	4	4	4	4	4	4	2	4	4	4	4	4	3	4	4	**100**	**89**

(b)	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	**100**	**100**
(c)	3	3	4	4	4	4	4	4	4	3	3	3	4	4	4	4	4	4	**100**	**100**
(d)	3	3	4	3	4	4	2	3	4	4	4	4	2	2	3	2	4	4	**78**	**78**
20	4	3	3	3	4	4	4	4	1	1	4	4	4	4	2	2	4	4	**78**	**78**
21	4	4	4	4	4	4	2	3	4	4	4	4	4	4	4	4	4	4	**89**	**100**
22	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	**100**	**100**
23	4	4	4	4	3	4	4	4	4	3	4	4	4	4	4	4	4	4	**100**	**100**
24	4	4	4	4	4	4	4	4	4	3	4	4	4	4	4	4	4	4	**100**	**100**
25	3	3	4	3	3	3	4	4	3	4	3	3	3	3	4	4	4	4	**100**	**100**
26	3	3	4	4	3	3	4	4	4	4	4	4	3	3	4	3	4	4	**100**	**100**
27	3	3	4	4	3	3	4	4	4	4	4	4	3	3	4	3	4	4	**100**	**100**

Appendix 3.6: Content Validity Analysis; Rater Comments

Construct	**Question number**	**Relevance** (% of raters awarding 3/4)	**Representativeness** (% of raters awarding 3/4)	**Comments**
Intention	1. Overall, how likely do you think that you would be to use a home testing kit? (please circle) *Please circle a number.* 1 2 3 4 5 Not at Very likely likely	100	100	R6: I think this needs a slight adjustment of wording eg Overall, how likely do you think it is that you would use a home testing kit R8: Clumsy wording. Quiet sophisticated linguistically and too many words. Eg could use How likely are you to use a home testing kit? R9: To focus home testing on the self sampling from the cervix for HPV the phrasing of the question may need to be more specific eg. 'HPV self-sampling cervical test kit'.
Self-efficacy	2. How sure are you that doing the test yourself will provide accurate results? *Please circle a number.* 1 2 3 4 5 Not sure Very sure	55	89	R3: Does this measure self-efficacy or potentially beliefs in self-administered versus clinically administered tests (i.e. belief in better quality of tests from clinic (independent from ability of self)

	at all			versus belief in ability of self-sampling)? – Consider rewording R4: Could also be measuring participants attitude towards the effectiveness of the test and not just the individual's ability to do the test correctly R5: This item seems to measure their belief in the effectiveness of self-sample rather than their ability to do the test well. So I don't think this is self-efficacy. You could re-phrase to ask 'how sure are you that you are able to do the self test well enough to provide an accurate result?'. This may overlap somewhat with QV7. R6: I don't think this question necessarily relates to one's own ability to exert control over behaviour, it could be interpreted to mean how well do they perceive the home kit itself as a valuable diagnostic tool R7: Could be re-worded slightly to make it clearer and less wordy. E.g. How likely are you to use home testing kits?

				R8: As above. Also, use of word 'sure'. Ambiguous affective and conceptual relevance in relation to perception unless literature can clarify 'surety'. Would suggest considering 'certain' / 'confident' / or similar. But need to check this in relevant literature. Previous experience shows that people will rate the same question using 'certainty, and 'confident' differently – i.e. people can be certain but not confident etc. So these words are critical to study. Are you looking for surety, certainty (self-efficacy), confidence…or what? As far as I am aware self-efficacy usually uses 'certain' as the key word.
Self-efficacy	3. How sure are you that you will be able to understand the instructions provided in the home test kit? *Please circle a number.* 1 2 3 4 5 Not sure at all Very sure	89	100	R2: Is there an example of the instructions included in the survey? Don't know if you can understand it until you see what it says R4: Could possibly measure the literacy, i.e., if they feel they would not be able to understand the instructions R 7: This item could be confused with the efficacy and trustworthiness

				of the testing kit, not my own self-efficacy to perform the test myself R8: As above. Also, when measuring SE it is standard practice to use a ten (10) point rating scale. The fewer the questions the more important this becomes. That having been said, I have used a four (4) point rating scale (nominal) with good results. However, this was based on 20 years of literature that indentified 5 relevant factors with a great deal of certainty. I think these questions need further consideration in terms of the scale, the wording, and the items themselves. R9: I believe the women will not be receiving the kits and so will not have an example of the types of instructions that they will need to follow. Without that information, how meaningful will the outputs be from this question?
Self-efficacy	4. How sure are you that you will be able to carry out the sampling procedure (placing swab in vagina)? *Please circle a number.* 1 2 3 4 5	100	100	

	Not sure Very sure at all			
Self-efficacy	5. How sure are you that you will be able to place the swab into the tube containing the special liquid without touching or dropping the swab? *Please circle a number.* 1 2 3 4 5 Not sure Very sure at all	100	100	R2: Maybe just say – after you have sampled the swab?
Self-efficacy	6. How sure are you that you will be able to send off the completed test within the time allowed (2 weeks)? *Please circle a number.* 1 2 3 4 5 Not sure Very sure at all	100	100	
Self-efficacy	7. How sure are you that your completed test kit will be good enough for testing? *Please circle a number.* 1 2 3 4 5 Not sure Very sure at all	67	78	R2: Will they know what that means? If they don't know what the screen really does how will they know it is good enough for testing? R4: Could also be measuring participants attitude towards the

				effectiveness of the test and not just the individual's ability to do the test R5: This question could be understood as asking if they think HPV self testing per se is good enough for testing. I would suggest re-phrasing to 'How sure are you that you will be able to do the test well enough for testing?' R6: As above, I don't think this question necessarily relates to one's own ability to exert control over behaviour, it could be interpreted to mean how well do they perceive the home kit itself as a valuable diagnostic tool R7: Be careful with this item, some people may think that you are talking about good and bad test results, e.g. a good test result means I don't have HPV a bad one means I do. This items needs to be more explicit that you are talking about how well I will perform the test myself, to make it adequate enough for testing in the lab. R9: Again with this question as the women will have no concept of the

				device, asking and interpreting their responses in terms of how effective they would be at using it, seems difficult.
Perceived benefits	8 (a) .Using a home kit is convenient, as it can be done at home I would not have to take time off work/arrange childcare. *Please circle a number.* 1 2 3 4 5 Strongly Strongly disagree agree	100	89	R2: Maybe try not to repeat home? R5: Another additional arrangement not described here might be having to make/get a Drs appointment. This could be added to the question or it could be left as 'Using a self-test kit is convenient because it can be done at home' or Using a self-test kit is convenient because I do not have to make arrangements (eg. Drs appointment/childcare/time off work)'. R8: Poor use of English. Punctuation makes question read badly. This is two questions, not one.
Perceived barriers	(b) I am worried that I may hurt myself using the home kit. *Please circle a number.* 1 2 3 4 5 Strongly Strongly disagree agree	100	89	R5: Does there need to be a similar question with regards to going for a cervical smear (i.e. is having someone do the cervical smear test is less painful than using the self test kit)

				R8: Use of English. 'may' I wonder if this should be 'could'. 'may'/'might' implies permission and choice. 'can'/'could' is more related to outcome of a possible action.
Perceived benefits	(c) Using a home kit can help make sure no-one will know that I am being screened for cervical cancer. *Please circle a number.* 1 2 3 4 5 Not Strongly relevant agree	89	100	R4: I find this question confusing as it mentions that the home kit is screening for cervical cancer, should this be screening for HPV? Also if a person does not mind people knowing about having screening would they answer strongly disagree? If so can this be interpreted as them not seeing home testing as a benefit? R5: In comparison to going for a smear test? R8: Poor use of English.
Perceived benefits	(d) Using a home kit is less embarrassing than having a GP or nurse carrying out a smear test. *Please circle a number.*	100	89	R2: Need a "don't know" for those who haven't had a smear test yet or phrase it to include "Using a home kit is / I think will be less embarrassing"

	1 2 3 4 5 Strongly Strongly disagree agree			R8: Poor use of English (NOT 'carrying out'; could be 'carry out' or just '…do a smear test'. If you are asking sensitive questions then the wording of the questions is crucial as the wording will have an impact whether or not the respondent is aware of it. I's suggest this survey is piloted specifically for the use of language. A cognitive analysis with a group is advisable.
Perceived barriers	(e) I wouldn't trust the results of the home kit. *Please circle a number.* 1 2 3 4 5 Strongly Strongly disagree agree	100	100	R5: Would they trust a cervical smear test more? Add a similar question with regards to a smear test or draw a comparison in the question
Perceived benefits	(f) Using a home kit seems less painful than a smear test. *Please circle a number.* 1 2 3 4 5 Strongly Strongly disagree agree	100	89	R2: "less painful than a smear test carried out by a nurse or GP" R4: Might be dependent on the participant having a smear test in the past? R6: I think the wording needs to be adjusted slightly, "sounds" rather than "seems", presuming this survey

				comes before they use the home testing kit R8: This question could lead to the assumption that the person has used a home kit before. Is that the intention?
Perceived susceptibility	10 How likely do you think you are to be infected with HPV? *Please circle a number.* 1 2 3 4 5 *Not at all likely* *Very Likely*	100	89	R2: Maybe say – in your life time? Or give another time scale R5: Changing the wording of this to the same format as QV17 might help. It would then be in comparison to other women and also with a specific time frame (in your life) which might be useful when it comes to analysis. R8: This question can be read two ways; 1) You are asking if I think I have been infected; 2) you are asking if I think I could become infected. Which one is it?
Baseline Knowledge	11 Before taking part in this study had you heard of Human Papillomavirus (HPV)? *Please tick a box* Yes	89	78	R6: "Hearing" about something doesn't imply you have knowledge of it. Might be better worded "How

	No			would you rate your knowledge of HPV" R8: 'Before' is used twice. Poor English.
Baseline Knowledge	12 If you had to guess, how do you think HPV spreads from person to person? *Please tick all that apply.* Through breathing the same air as someone who is infected (like catching a cold) Through intimate skin-to skin contact (sexual) Through sitting on dirty toilet seats Through kissing	100	89	R4: I think some of the responses for 12 are too vague. Perhaps be useful to have e.g., for one such as sexual contact (intercourse, oral sex…) which would reduce the potential ambivalence of the kissing option (people might include kissing intimate parts which I would think would come under the sexual contact. Also, I think the responses should be YES/NO/I DO NOT KNOW for each option. This way you would be able to gauge complete baseline knowledge (and true missing responses). You could also give people a comment box so they have the option to comment on other causes they may feel are important. R8: What if the person knows and doesn't have to guess. You can simply use a forced choice question

				(i.e. no 'don't know' option). Just ask, how do you think… R9: Colds are transmissible through droplets from infected individuals rather than directly through the air. I think the responses may need re-phrasing slightly.
Baseline Knowledge	13 How important do you think HPV is in developing cervical cancer? *Please circle a number from 1 (Not at all important) to 5 (Very important)* 1 2 3 4 5 *Not important* *Very important*	78	89	R2: Not sure if this will be understood, maybe instead of important which is a positive word, use high risk or another more negative term? R4: If participants answer 'not at all important' what does this mean, that they do not think HPV causes cancer? You have however, told them at the start that it does which may influence their response.
Baseline Knowledge	14 Do you think that HPV can be treated with medicines? *Please tick a box.*	100	89	R4: Is there only one correct answer for this?

	Yes No			R5: There is no mention in the knowledge construct of cervical cancer. This question could therefore be split in two so that there is also a question ' Do you think that cervical cancer can be treated with medicines?' R6: I think you need a don't know option, having Yes or No responses suggests that you have some knowledge
Baseline Knowledge	15. Do you think that HPV can clear up by itself? *Please tick a box.* Yes No	89	67	R2: You tell them this in the intro to the survey, so this will not give you any reliable answers as everyone who reads the information will say that yes it can clear up by itself R4: Is there only one correct answer for this? You have told them this at the start which may influence their response. R5: This question is relevant, but I don't think it measures the etiology of HPV. Something like HPV is caused by a) a virus, b) bacteria, c)other…. Etc similarly there could be a question for cervical cancer? R6: I think you need a don't know option, having Yes or No responses

				suggests that you have some knowledge R8: Should this be aetiology?
Perceived Severity	16. How serious of an infection do you think HPV is? *Please circle a number.* 1 2 3 4 5 *Not at all severe* *Extremely severe*	89	78	R2: Maybe re-word it? "How serious do you think a HPV infection is?" R4: I think it should be serious and not severe. R5: This could be made comparative to other diseases so it is similar to QV19d R6: Responses need to relate to seriousness, R7: Anchors don't match the question. E.g. serious and severe. R8: Poor English. Reword. '…serious of an infection…' – the English is probably correct but it reads badly and does not make sense as a quick read. Try 'How serious do you think an HPV infection is?' or 'How serious an infection do you think…'
Perceived susceptibility	17. Compared to most other women your age, how likely do you think it is that you will get cervical cancer at some time in your life? Would you say you are…? *Please circle* 1 2 3 4 5 Much less A little less About the A little more Much more	100	100	

	likely likely same likely likely			
Self-efficacy	18. How confident, are you that you would notice a symptom of cervical cancer? 1 2 3 4 5 Not Slightly About Fairly Very at all confident the confident confi- confident same dent	78	67	Rater 1: Is it worth asking if they know what symptoms are? R4: Is this not dependent on if they know the symptoms of cervical cancer therefore I am not sure a 'Not at all' confident response would indicate low self-efficacy? R5: I don't see the relevance of this question with regards to the definition of self-efficacy being used as it is asking about a behaviour (symptom detection) associated with cervical cancer not self-sampling or smear testing. R6: This sounds more like 'knowledge' rather than self-efficacy R7: Think this is self efficacy as well? R8: Are you looking at confidence or certainty? If it is definitely confidence then this is fine. Why confidence and not certainty? Why not make this a SE question? What will confidence tell you? Do you want to compare and contrast confidence and SE? Confidence and surety?

	19 Please tell us whether you agree or disagree with each of the following statements by circling a number from 1 (strongly disagree) to 5 (strongly agree).			
Perceived benefits	(a) Going for regular smear tests means that cervical cancer can be found early on. 1 2 3 4 5	100	89	R2: The numbers need to be moved across slightly to make it clearer R5: Should there be an equivalent question for HPV self testing kit? E.g. Completing a self-testing HPV test means that cervical cancer can be found early on? R8: Use of word 'found'? Is this the best word? Found or diagnosed? Indications found or the cancer actually diagnosed or actual cancer found?
Cues to action	(b) The three yearly reminders I get help me remember to attend my cervical screening appointments.	100	100	

	1 2 3 4 5			
Perceived barriers	(c) Having a smear test is embarrassing and that puts me off attending. 1 2 3 4 5	100	100	R1: Similar to QV 8 (d)? R5: This its partially covered in QV8d for the comparison to using the self-test kit R6: I think "having a smear test is embarrassing" relates to the construct but "puts me off attending" is a consequence of that R8: But scale should be anchored on the instrument – Srongly Disagree and Strongly Agree should be at top of scale so that they are visible at all timew
Perceived severity	(d) If I got cervical cancer, it would be more serious than other diseases. 1 2 3 4 5	78	78	R1: Depends which disease - what about other cancers? R2: is disease the right word? Illness… condition..? R4: Question is vague (there are so many diseases you are asking people to compare this to) and therefore I think hard for people to answer and for you to interpret.(what would a 3 mean?_ Not sure what an alternative

				would be, could you ask people to rank the importance of severity to them of other diseases including cervical cancer? R7: Not sure about this. Wouldn't someone think it was a serious disease regardless of whether they actually got it or not, and therefore, taking preventative measures like screening? R8: More serious than which other diseases? The question works, but it could raise questions which in turn leads to messy responses due to dissonance.
Self-efficacy	20. Have you made any lifestyle choices to try and reduce your risk of cervical cancer? Yes If *Yes,* please describe them below. No	78	78	R1: Meaning slightly ambiguous R2: Could give an example? R5: As in QV18, this is regarding cervical cancer rather than self-sampling or smear testing. Also it seems to be asking about actual behaviour change in the past rather than future behaviour/ability to carry out behaviour in the future Overall the self-efficacy construct items could be improved in their representativeness by including

				items on smear testing too (e.g.s How sure are you will be able to attend for/make an appointment for a smear test?) R8: What does this have to do with SE? Why not a short list of key choices including 'all of the above; none of the above; other? Open questions such as this tend to produce standard responses that usually lack relevance. This is NOT a SE question. Please make sure your constructs are correctly identified. I think you may need to polish up the construct validity.
Screening history	21. Have you ever had a smear test? *Please tick a box* Yes No Not Known	89	100	R6: Again Don't know option missing

Screening history	22. If you have previously had a smear test, how long ago did you have your last smear? *Please tick a box* Under 3 years 3-4 years 4+ years Not Known	100	100	R6: Again Don't know option missing
Screening history Construct name change: Screening Results	23. Have you ever had an abnormal smear test result? *Please tick a box.* Yes No Not Known	100	100	R2: Maybe provide a "prefer not to say" box R3: Your current construct definition does not include screening experience/results (only 'attendance' and 'adherence'); however I feel this is an important question and the construct could be amended to include 'experience' or 'results', as these do fall under 'screening history'. Currently, the construct is not fully represented by this question; however I have awarded a 3, since it is not the question/scale that should be revised, but the construct. R4: You do not ask them if they have had cervical cancer nor if they have been diagnosed with HPV, do you

				think this may impact on their responses? R5: Do you want to include a measure of how many times this has happened?
Treatment history	24. Have you ever received treatment for abnormal cervical cells? *Please tick a box.* Yes No Not Known	100	100	R2: Again, "prefer not to say" R5: Do you want to include a measure of how many times this has happened?
Family history Construct name change: Experience Construct domain change: Family/ Friend history of cervical cancer	25. Has anyone close to you ever had abnormal cervical smear results? *Please tick a box* Yes No Not Known	100	100	R1: For all 3 of these questions: if only interested in family history this needs re-wording otherwise you won't be able to distinguish family from e.g. close friends R2: "Don't know" could be an option, may not be something that is discussed in some families R3: The wording of this question does NOT ask about 'Family history' as it asks about 'anyone close to you', which may be interpreted as a close friend/other non-blood relation, which would not be defined as family history per se. I do however think these questions are relevant to

				the function of the survey and experience with cervical issues/cancer outside the family are also important, therefore I propose a renaming of the construct to something along the lines of 'experience'. (Note: the current description of the construct does not require the person to be a 'family member' at the moment, so this does fit just fine. It is just the heading that is not quite fitting.). Currently, the question is not really relevant or representative of the construct of 'family history'; however I have awarded a 3, since it is not the question/scale that should be revised, but the construct. R5: You might want to add a 'don't know' option or rephrase the questions 'As far as you know has anyone….. R6: Needs clarity, on those close to you eg friends and family R7: You might want to determine how close you mean. Some people will think of their close friends, neighbours living close by etc. not

				their family. You should state that that you mean family and define how close, e.g. fist degree relatives etc. or ask them to state what relation they were to the person.
Family history Construct name change: Experience Construct domain change: Family/ Friend history of cervical cancer	26. Has anyone close to you ever been diagnosed with cervical cancer? *Please tick a box* Yes No Not Known	100	100	R1: For all 3 of these questions: if only interested in family history this needs re-wording otherwise you won't be able to distinguish family from e.g. close friends R8: 'close to you' – what does that mean? Geographically close? Family member? Friend?
Family history Construct name change: Experience	27. Has anyone close to you ever died from cervical cancer? *Please tick a box* Yes No Not Known	100	100	R1: For all 3 of these questions: if only interested in family history this needs re-wording otherwise you won't be able to distinguish family from e.g. close friends

Construct domain change: Family/ Friend history of cervical cancer				R8: As above. ('close to you' – what does that mean? Geographically close? Family member? Friend?)

Appendix 3.7: Cognitive Interview Information sheet and consent form

Participant Information Sheet: Cognitive Interview

Study Title: Women's attitudes towards HPV self-sampling.

Background

We have developed a survey to investigate women's attitudes and beliefs towards Human Papillomavirus (HPV) self-sampling.

Human Papillomavirus (HPV) is a very common infection. In most cases HPV does not cause any problems, but in some women it can cause cervical cancer. There are kits that you can use to test for HPV at home (HPV self-sampling). You would then send the kit to a laboratory to be tested and would be told your results through a letter in the post.

We would like to invite you to take part in an interview to see if the survey we have developed makes sense and is easy to answer.

Why have I been chosen?

You have been asked to take part because you are a woman aged between 20-64 years, which is the age range in which women are eligible for cervical screening.

Do I have to take part?

It is up to you to decide if you want to take part in this study. You are free to pull out of this study at any point and do not have to give a reason.

What will happen to me if I take part?

The aim of the interview is to see if any questions in the survey are difficult to answer or understand and may need to be changed.

You will be asked to complete each question of the survey one at a time. The researcher (Mrs Denitza Williams) will ask specific questions relating to how easy or not it was to answer each question and how you managed to get to that answer. The interview should last no more than 1 hour.

The discussion will be audio taped, however all details will be anonymised, so no one will know what you have said.

The interview may be carried out face-to face or over the telephone. If it is carried out over the telephone, the survey will be sent to you through the post before the interview. You will be asked not to read the survey until the telephone interview has started.

If the interview is to be carried out face-to face then you will be given the survey at the time of the interview.

What are the possible disadvantages of taking part?

Taking part in this study will require you to complete a survey and talk about how you answered the questions. It is highly unlikely that anything should go wrong. If you would like to talk about any of the issues raised in this study, a contact name and details are provided at the end of this information sheet.

What are the possible benefits to taking part?

There will be no direct clinical benefit to you from taking part in this study. However, information we gather through this study will help us develop our survey better and therefore ensure that women who will be sent this survey are able to understand it and answer it easily.

What if I don't want to carry on or if there is a problem?

You can pull out of this study at any time and it will not affect your future care. It is highly unlikely that you may be upset or inconvenienced by this study. However, if you feel that you need to make a complaint about the way you have been approached or treated by the researcher, you should contact: Prof. C. Butler, Head of Department,

Department of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff.

In the event that something does go wrong and you are harmed in this interview, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you have grounds for legal action for compensation against Cardiff University but you may have to pay legal costs. The normal National Health Service complaints mechanisms will also be available to you. Details can be obtained from your hospital.

What will happen to the results of the interview?

The comments you provide to us in this interview will be used to change any questions that may have been problematic.

Who is organising and funding this study?

The study is organised by Denitza Williams at Cardiff University. It is directed by an advisory group and is funded by the Medical Research Council. No-one will be paid for including you in this study.

Who has reviewed this study?

This study has been examined by the Medical Research Council and it has received ethical permission by The South East Wales Research Ethics Committee and Cardiff University Medical and Dental School Ethics Committee.

Who should I contact for more information about this study?

If there is anything that is not clear or you would simply like more information please contact Denitza Williams on 02920687851 or stoilovado@cf.ac.uk.

For free impartial information and support about cervical cancer, please contact Jo's Cervical Cancer Trust: Email: info@jostrust.org.uk Tel:020 7936 7498.

Cardiff University Headed Paper

CONSENT FORM

Title of Project: Women's attitudes towards HPV self-sampling

Name of Researcher: Denitza Williams

Please initial box

1. I confirm that I have read and understand the information sheet dated 17/03/2014 (version 1) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐

4. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Appendix 3.8: Cognitive Interviews Standard Operating Procedure

- Present participant with the survey.
- Allow time to read the information provided on the first page.
- The interviewer reads the following: *'Firstly, thank you for agreeing to take part in this interview. I would like to remind you that you can stop the interview at any point, without giving a reason. This will have no impact on your healthcare. If it is ok with you, I would like to tape-record our conversation. All identifiable information will be removed to ensure that no-one will know that you have talked to us.*
  The interview shouldn't last any longer than an hour.
  The focus of this interview is to see if the questions make sense and are easy to understand and respond to. We are not interested in the answers you give to the question, but we are interested in how you got to that particular answer.
  Are you happy to proceed?'

- If participant is happy to proceed then ask them to fill in and sign the consent form.

- The following should then be said ' *I would like you to read through each question one at a time and fill in its answer. I would like you to report aloud everything you are thinking about when answering the question. I would also like you to comment on the question, for example on things like the way it's worded and how you hard or easy it was to answer it. I may then ask you what you understand by certain words in the question, how you managed to get to the answer that you have given or I may ask you to rephrase the question in your own words. There are no right or wrong answers.'*

Appendix 3.9: Probes used in examining the survey and cognitive processes explored.

Probe question	Cognitive process explored
'Can you repeat the question in your own words'	Exploration of participant's ability to recall information confidently.
'How easy/hard was this question to answer'	Determination of the likely level of difficulty in answering a question and subsequent likelihood of guessing
'How sure are you of your answer'	Determination of confidence in answer.
'What do you understand by the phrase ....'	Exploration of question term comprehension.
'Do the answer categories make sense to you?'	Exploration of how participants 'mapped' response to response categories provided.
'What makes you think that/ Why do you think this' 'How did you arrive to answer x'	Exploration of individuals' overall cognitive strategy in answering a particular question.
'How well do you remember this'	Exploration of recall of relevant information.

Appendix 3.10: Cognitive Interview Schedule

<u>Interview Schedule: Question number followed by possible probes and their function</u>

Please note that as well as scripted probes, spontaneous probes will also be used throughout interviews.

1. I want to use a self-sampling kit for HPV. *Please circle a number.*

Not at all likely				Very likely
1	2	3	4	5

- *How hard was this question to answer?*

(to determine level of difficulty/likelihood of guessing)

2 I expect that I would use a self-sampling kit for HPV? *Please circle a number.*

Not at all likely				Very likely
1	2	3	4	5

- *What do you understand by the phrase 'I expect that'?*

(to determine level of term comprehension)

- *Do the answer categories make sense to you?*

(mapping of the response)

3. If made available to me, I intend to use the self-sampling kit for HPV? *Please circle a number*

Not at all likely				Very likely
1	2	3	4	5

- *Can you repeat the question in your own words?*

(testing how well the subject comprehends the question)

- *How sure are you of your answer?*

(to determine overall level of confidence)

4. How likely are you to use the self-sampling kit instead of going for a smear test? *Please circle a number.*

Not at all likely				Very likely
1	2	3	4	5

- *What does the term a 'smear test' mean to you?*

(to determine level of term comprehension)

5. How certain are you that you will do the test well enough? *Please circle a number.*

Not certain				Very certain
1	2	3	4	5

- *Can you repeat the question in your own words?*

(to test how well the participant understands the question)

- *What do you understand by the term' well-enough'?*

(to determine level of term comprehension)

6. How certain are you that you will be able to carry out the sampling procedure (placing swab in vagina)? *Please circle a number.*

Not certain				Very certain
1	2	3	4	5

- *What does 'certain' mean to you*?

(to determine level of term comprehension)

7. How certain are you that you will be able to place the swab into the tube containing the special liquid without touching or dropping the swab? *Please circle a number.*

Not certain				Very certain
1	2	3	4	5

- *Can you repeat the question in your own words?*

(to determine level of question comprehension)

8. How certain are you that you will be able to send off the completed test within the time allowed (2 weeks)? *Please circle a number.*

Not certain				Very certain
1	2	3	4	5

- *How sure are you of your answer?*

(confidence probe)

9. Below are a few comments about doing HPV self- sampling. Please tell us how much you agree or disagree with each comment by circling a number from 1 (strongly disagree) to 5 (strongly agree).

a. Using a self-sample kit is convenient because it can be done at home and means that I would not have to make arrangements (e.g. going to a GP surgery/taking time off work /arranging childcare. *Please circle a number.*

Strongly disagree				**Strongly agree**
1	2	3	4	5

- *What does the term 'arrangements' mean to you?*

(to determine level of term comprehension)

b. I am worried that I could hurt myself using the self-sample kit. *Please circle a number.*

Strongly disagree				**Strongly agree**
1	2	3	4	5

- *What do you understand by the term 'hurt myself' in this context*

(to determine level of term comprehension)

c. Using a self-sample kit means that no-one will know that I am being screened for cervical cancer. *Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

- *What do you understand by 'no-one will know'. Who would be 'no-one.'*

(to determine level of term comprehension)

d. Using a self-sample kit would be less embarrassing than having a GP or nurse do a smear test. *Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

e. I wouldn't trust the results of the self-sample kit. *Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

- *Can you repeat the question in your own words?*

(to determine level of question comprehension)

f. I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory. *Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

- *What does the term 'laboratory' mean to you.*

(to determine level of term comprehension)

11. Compared to most women your age, how likely do you think it is that you will be infected with HPV? *Please circle a number.*

Much less likely	A little less likely	About the same	A little more likely	Much more likely
1	2	3	4	5

- *What makes you think that?*

(to determine overall cognitive strategy used)

- *What do you understand by 'most other women your age'.*

(to determine level of term comprehension)

13. If you had to guess, how do you think HPV spreads from person to person?
Please tick all that apply.

Through breathing the same air as someone who is infected (like catching a cold)	
Through sexual contact (e.g. intercourse, oral sex)	
Through sitting on dirty toilet seats	
Through kissing	

- *What do you understand by the phrase 'spreads from person to person'*

(to determine level of term comprehension)

- *How sure are you of your answer?*

(confidence probe)

14. How much of a risk factor do you think HPV is in developing cervical cancer? *Please circle a number.*

Not important at all				Very important
1	2	3	4	5

- *What do you understand by 'risk factor'?*

(to determine level of term comprehension)

15. Do you think that HPV can be treated with medicines? *Please tick a box.*

Yes	
No	
Don't know	

- *How did you arrive to your answer x?*

(to determine overall cognitive strategy used)

16. Do you think that HPV can clear up by itself? *Please tick a box.*

Yes	
No	
Don't Know	

- *Why do you think this?*

(to determine overall cognitive strategy used, to check if the person is guessing)

17. How serious an infection do you think HPV is? *Please circle a number.*

Not at all serious				Extremely serious
1	2	3	4	5

- *What do you understand by 'serious'.*

(to determine level of term comprehension)

- *What does the term 'infection' mean to you?*

(to determine level of term comprehension)

18. Compared to most other women your age, how likely do you think it is that you will get cervical cancer at some time in your life? Would you say you are…? *Please circle*

Much less likely	A little less likely	About the same	A little more likely	Much more likely
1	2	3	4	5

- *Can you repeat this question in your own words?*

(to determine level of question comprehension)

- *Who do you see as 'most other women'?*

(to determine level of term comprehension)

- *What do you understand by the term 'your age'.*

(to determine level of term comprehension)

19. How confident, are you that you would notice a symptom of cervical cancer?

Not at all confident	Slightly confident	About the same	Fairly confident	Very confident
1	2	3	4	5

- *How easy/hard was this question to answer?*

(to determine overall level of confidence)

- *What makes you think this?*

(to determine overall cognitive strategy used)

20. Please tell us whether you agree or disagree with each of the following statements by circling a number from 1 (strongly disagree) to 5 (strongly agree).

a) Going for regular smear tests means that cervical cancer can be found early on.

Strongly disagree				Strongly Agree
1	2	3	4	5

- *What do you understand by 'found early on'?*

(term comprehension)

b) The three yearly reminders I get help me remember to attend my smear test appointments.

Strongly disagree				Strongly Agree

1	2	3	4	5

c) Having a smear test is painful.

Strongly disagree				**Strongly Agree**
1	2	3	4	5

- *Why do you think this?*

(overall cognitive strategy used)

- *How well do you remember this?*

(recall of relevant information)

d) Going for smear tests can be difficult because I have to make arrangements (e.g. time off work, childcare).

Strongly disagree				**Strongly Agree**
1	2	3	4	5

- *Can you repeat the question in your own words.*

(question comprehension)

e) Going for smear tests provides me with reassurance.

Strongly disagree				Strongly Agree
1	2	3	4	5

- *What does 'reassurance' mean to you?*

(term comprehension)

f) I trust the nurse/GP to take an adequate sample.

Strongly disagree				Strongly Agree
1	2	3	4	5

- *What to you is an 'adequate sample'.*

(term comprehension)

g) I worry about my sample getting lost.

Strongly disagree				Strongly Agree
1	2	3	4	5

Why do you think this?
(overall cognitive strategy)

h) Having a smear test is embarrassing

Strongly disagree				Strongly Agree
1	2	3	4	5

- *What do you understand by 'having a smear test' i.e. the procedure, going for a smear, arranging the appointment etc*

(term comprehension)

i) If I got cervical cancer, it would be more serious than other cancers.

Strongly disagree				Strongly Agree
1	2	3	4	5

- *Why do you think this?*

(overall cognitive strategy)

j) I don't trust the results of the smear test.

Strongly disagree				Strongly Agree
1	2	3	4	5

- *What do you understand by 'trust'*

(term comprehension)

k) I worry that others (e.g. family members, friends, people at the GP surgery) will know that I am being screened for cervical cancer.

Strongly disagree				**Strongly Agree**
1	2	3	4	5

- *How hard/easy was this to answer?*

(level of difficulty, and likelihood of estimation/guessing

21. Have you made any lifestyle choices to try and reduce your risk of cervical cancer?

Please tick any that are relevant

Attending smear appointments	
Practicing safe sex	
Limiting number of sexual partners	
Not smoking	
Getting immunized against HPV	
Other (please describe)	
I have not made any specific lifestyle choices to reduce my risk of cervical cancer	

- *Why did you decide to x ?*

(to determine cognitive processes/social desirability)

22. Have you ever had a smear test? *Please tick a box*

Yes	
No	
Don't know	

23. If you have previously had a smear test, how long ago did you have your last smear? *Please tick a box*

Under 3 years	
3-4 years	
4+ years	
Don't know	

- *How did you figure out that it was x years?*

(to determine overall recall strategy)

- How sure are you of this?

(to determine ability to recall information confidently)

24. Have you ever had an abnormal smear test result? *Please tick a box.*

Yes	
No	
Don't know	

- What does 'abnormal' mean to you?

(to determine term comprehension)

25. Have you ever received treatment for abnormal cervical cells? *Please tick a box.*

Yes	
No	
Don't know	

- What does ‘treatment’ mean to you?

(to determine term comprehension)

26. Has any family member/friend ever had abnormal cervical smear results?
Please tick a box

Yes	
No	
Don’t know	

- What does family ‘member/friend’ mean to you?

(to determine term comprehension)

27. Has any family member/friend ever been diagnosed with cervical cancer?
Please tick a box

Yes	
No	
Don’t know	

- Did you find this question hard to answer?

(to determine possibility of any psychological harm)

28. Has any family member/friend ever died from cervical cancer? *Please tick a box*

Yes	
No	
Don’t know	

- Did you find this question to answer?

(to determine possibility of any psychological harm)

Questions 29-33

No specific probes

Appendix 3.11: Final Questionnaire

Version 5 01/10/12

Research study: Women's attitudes towards HPV self-sampling

Smear tests offer the best protection against developing cervical cancer and save thousands of lives each year. Not going for a smear test is one of the biggest risk factors for developing cervical cancer. This is why it is important that all women attend their smear appointments.

However, things in research are constantly changing and there may be a possibility that in the years to come women may be offered a different type of cervical screening test, HPV self-sampling.

Please note: This test is not currently available through the NHS and may never be.

This test looks at the presence of a virus called Human Papillomavirus (HPV) in the vagina. HPV is a very common infection that most women will have at some point in their lives. Most of the time this infection will not cause any problems and will clear up on its own, but in some cases it can cause cervical cancer.

HPV could be tested for by using a kit at home. This kit is called a self-sampling kit. The kit would allow a woman to collect a sample from her vagina, which would then be sent off to be tested for the presence of HPV in a laboratory

To carry out the home test a woman would need to put a swab (a cotton bud with a long handle) into the vagina. She would then need to put the swab into a sealed tube with a liquid already inside, and post it to a laboratory using a special pre-addressed envelope.

The introduction of HPV self-sampling is being discussed however **no policy** has been set yet. This is why we would like to ask you a few questions about these kits and your views on cervical cancer and screening. Some of the questions are a little sensitive but it's important for us to know about your views so please try and fill in as much as you can. All responses will be kept strictly confidential. Your opinions are very important and will help us to plan future health services to reduce cervical cancer.

Please read the instructions for each question carefully. There are questions on both sides of each page. You will mostly need to tick a box or circle a number and the questionnaire shouldn't take too long to complete. This questionnaire is not a test, but we are interested in your views and would like you to answer questions as honestly as possible.

Please remember that the self-sampling kit is not currently available and that attending smear appointments offers the best protection from developing cervical cancer.

Once you have completed the questionnaire, please return it to us in the PRE-PAID and addressed envelope provided.

If you wish to take part could you firstly fill in your name, address and contact details below:

Full name: .....

Address:.....

.....

Contact Number:.....

E-mail address:.....

Your views on HPV self-sampling

Please read each question carefully and circle a number from 1 to 5.

1. I would be likely to use a self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

2. How likely would you be to use the self-sampling kit instead of going for a smear test?

Not at all likely				Very likely
1	2	3	4	5

3. How certain are you that you would do the test well enough?

Not certain				Very certain
1	2	3	4	5

4. I expect that I would use a self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

5. How certain are you that you would be able to carry out the sampling procedure (placing swab in vagina)?

Not certain				Very certain
1	2	3	4	5

6. How certain are you that you would be able to place the swab into the tube containing the special liquid without touching or dropping the swab?

Not certain				Very certain
1	2	3	4	5

7. How certain are you that you would be able to carry out the self-sampling procedure despite other commitments (e.g. work/children)?

Not certain				Very certain
1	2	3	4	5

8. How certain are you that you would be able to send off the completed test within the time allowed (2 weeks)?

Not certain				Very certain
1	2	3	4	5

9. If made available to me, I would use the self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

10. Below are a few comments about doing HPV self- sampling. Please tell us how much you agree or disagree with each comment by circling a number from 1 (strongly disagree) to 5 (strongly agree).

a. Using a self-sample kit is convenient because it can be done at home and means that I would not have to make arrangements (e.g. going to a GP surgery/taking time off work /arranging childcare.)

Strongly disagree				Strongly agree
1	2	3	4	5

b. I am worried that I would hurt myself using the self-sample kit. *Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

c. Using a self-sample kit would mean that no-one will know that I am having cervical screening.

Strongly disagree				Strongly agree
1	2	3	4	5

d. Using a self-sample kit would be less embarrassing than having a GP or nurse do a smear test.

Strongly disagree				Strongly agree
1	2	3	4	5

e. I wouldn't trust the results of the self-sample kit.

Strongly disagree				Strongly agree
1	2	3	4	5

f. I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory.

Strongly disagree				Strongly agree
1	2	3	4	5

11. If you have any other comments about the HPV self-sampling kits, please write them below:

.....

.....

.....

Your views on HPV

We would like to ask you a few questions about HPV. Please remember that this is not a test and we would just like to get to know a bit more about you and your views.

12. Compared to most women your age, how likely do you think it is that you will come into contact with HPV? *Please circle a number*

Much less likely	A little less likely	About the same	A little more likely	Much more likely
1	2	3	4	5

13. Before taking part in this study had you heard of Human Papillomavirus (HPV)? *Please tick a box*

Yes	
No	

14. If you had to guess, how do you think HPV spreads from person to person? *Please tick all that apply.*

Through breathing the same air as someone who is infected (like catching a cold)	
Through sexual contact (e.g. intercourse, oral sex)	
Through sitting on dirty toilet seats	
Through kissing	

15. How important do you think HPV is in developing cervical cancer? *Please circle a number.*

Not important at all				Very important
1	2	3	4	5

16. Do you think that HPV can be treated with medicines? *Please tick a box.*

Yes	
No	
Don't know	

17. Do you think that HPV can clear up by itself? *Please tick a box.*

Yes	
No	

Your thoughts about cervical cancer

18. Have you had the HPV vaccine?

Yes	
No	

19. How serious an infection do you think HPV is? *Please circle a number.*

Not at all serious				Extremely serious
1	2	3	4	5

20. Compared to most other women your age, how likely do you think it is that you would get cervical cancer at some time in your life? Would you say you are...? *Please circle*

Much less likely	A little less likely	About the same	A little more likely	Much more likely
1	2	3	4	5

21. How confident are you that you would notice a symptom of cervical cancer?

Not at all confident	Slightly confident	Unsure	Fairly confident	Very confident
1	2	3	4	5

22. Please tell us whether you agree or disagree with each of the following statements by circling a number from 1 (strongly disagree) to 5 (strongly agree).

	Strongly disagree				Strongly agree
a) Going for regular smear tests means that cervical abnormalities would be found early on.	1	2	3	4	5
b) The reminders I get help me remember to attend my smear test appointments.	1	2	3	4	5

	Strongly disagree				Strongly disagree
c) Having a smear test is painful.	1	2	3	4	5
d) Going for smear tests can be difficult because I have to make arrangements (e.g. time off work, childcare).	1	2	3	4	5
e) Going for smear tests provides me with reassurance.	1	2	3	4	5
f) I trust the nurse/doctor to take a good sample.	1	2	3	4	5
g) I worry about my sample getting lost	1	2	3	4	5
h) Having a smear test is embarrassing	1	2	3	4	5
i) If I got cervical cancer, it would be more serious than other cancers.	1	2	3	4	5
j) I don't trust the results of the smear test.	1	2	3	4	5
k) I worry that others (e.g. family members, friends, people at the GP surgery) will know that I am having cervical screening.	1	2	3	4	5

Your experiences of cervical screening and cervical cancer

23. Have you ever had a smear test? *Please tick a box*

Yes	
No	
Don't know	

24. If you have previously had a smear test, how long ago did you have your last smear? *Please tick a box*

Under 3 years	
3-4 years	
4+ years	
Don't know	

25. Have you ever had an abnormal smear test result? *Please tick a box.*

Yes	
No	
Don't know	

26. Have you ever received treatment for abnormal cervical cells? *Please tick a box.*

Yes	
No	
Don't know	

27. Has any family member/friend ever had abnormal cervical smear results? *Please tick a box*

Yes	
No	
Don't know	

28. Has any family member/friend ever been diagnosed with cervical cancer? *Please tick a box*

Yes	
No	
Don't know	

29. Has any family member/friend ever died from cervical cancer? *Please tick a box*

Yes	
No	
Don't know	

We would like to speak to women face-to face about their views on cervical cancer, cervical screening and the self-sampling kits. We would really appreciate chatting to you. There is no obligation to take part and you can change your mind at any point. (The interviews can be carried out in the English Language only)

Would you be interested in talking to us further?

Yes	
No	

About you

Finally we would like to ask you a few background details to make sure that we are getting a wide range of views from different women

30. What is your age? ☐

31. What is your postcode? ☐

32. What is the highest level of education you have?

Left school at or before age 15	
GCSE or O level or equivalent	
A level or equivalent	
Further education but not a degree	
Degree or higher (e.g. Masters, PhD)	

33. Do you own your own home? *Please tick a box*

Yes	
No	

34. Which of the following do you feel best describes your ethnic group? *Please tick one or more boxes*

English	
Irish	
Scottish	
Welsh	
British	
Other European	

Caribbean	
African	
African Indian	
Indian	
Pakistani	
Bangladeshi	

Arab	
Chinese	
Any other group	

Could you please return the questionnaire using the PRE-PAID and addressed envelope provided. Thank You!

Please remember that the HPV self-sampling test is not currently available.

Appendix 4.1: Cervical Screening Wales recruitment card.

MRC Medical Research Council

Cervical screening - Your opinion counts!

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Are you a woman aged 20-64?

You can be part of a research study looking at what women think about a **different type of cervical screening test** which in the future may be able to be undertaken at home.

This method of sampling is currently not part of the Cervical Screening Programme so it's important that you attend your regular smear appointment, but **your views would be important to us.**

What would you need to do?

> Please fill in the other side of this card.
> You will be sent information about the new method of testing and asked to tell us what you think about it by filling out a questionnaire.

If you would like to receive further information about taking part in this study, please complete this reply slip and return it to us in the freepost envelope provided. If you have any questions please contact Mrs Denitza Williams on 029 2068 7851 or stoilovado@cf.ac.uk

☐ I would like to receive information about taking part in this study looking at my views on a home cervical screening test.

Name.....**Age**.....

Address.....

.....

Postcode..... **Email**.....

Recruitment Leaflet, Version 1.1 08.11.2012 / CU2013

Appendix 4.2: Relationships between extended Health Belief Model constructs in relation to HPV self-sampling.

Items		Statistic
Perceived severity of HPV	Perceived benefits of HPV self-sampling.	r= -.117, n=192, p=.106
	Perceived barriers to HPV self-sampling.	r= .070, n=188, p=.341
	Perceived susceptibility to HPV	r= .113, n=189, p=0.123
	Perceived self-efficacy	t(186.491) = -0.234, p=0.816
Perceived benefits to HPV self-sampling	Perceived susceptibility to HPV	r= .167, n=192, **p=0.020**
	Perceived barriers to HPV self-sampling.	r= -0.281, n=189, **p=0.000**
	Perceived self-efficacy	t(.170.617) =-1.282, p=.201
Perceived barriers to HPV	Perceived self-efficacy	t(188) =4.246, **p=0.000**
	Perceived susceptibility	r= -.014, n=189, p=0.845

Appendix 4.3: Cross tabulation of most influential variables in the regression model.

Educational Level	**Intention to self-sample**	**Lower Self-efficacy (N, %)**	**Higher Self-efficacy (N, %)**	Total (N, %)
GCSE	**Lower**	15 (88.2)	2 (11.8)	17 (100)
	Higher	4 (16.7)	20 (83.3)	24 (100)
Further Education	**Lower**	21 (91.3)	2 (8.7)	23 (100)
	Higher	19 (41.3)	27 (58.7)	46 (100)
Degree or above	**Lower**	14 (93.3)	1 (6.7)	15 (100)
	Higher	23 (37.7)	38 (62.3)	61(100)

Appendix 5.1: South-East Wales Local Research Ethics Approval

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR
Gwasanaeth Moeseg Ymchwil | RES | Research Ethics Service

South East Wales Research Ethics Committee C
6th Floor Churchill House
17 Churchill Way
Cardiff
CF10 2TW

Telephone : 02920 376823
E-mail : carl.phillips@wales.nhs.uk
Website : www.nres.nhs.uk

Emailed to:- StoilovaDO@cardiff.ac.uk

27 November 2012

Dr Myfanwy Davies
Research Fellow
School of Social Sciences
Neuadd Ogwen
Room 203, Bangor University
LL57 2DG

Dear Dr Davies

Study title:	**Exploring attitudes to HPV self-sampling among a socially-stratified sample of Welsh women.**
REC reference:	**11/WA/0213**
Protocol number:	**SPON 985-11**
Amendment number:	**Amendment 1**
Amendment date:	**11 October 2012**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical Opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Summary of Amendments as aid to REC		
Leaflet	1.1	08 November 2012
Questionnaire	5	01 October 2012
Letter of invitation to participant	3	01 October 2012
Participant Information Sheet: (Interview)	3	01 October 2012
Participant Information Sheet: (Questionnaire)	4	01 October 2012
Protocol	5	01 October 2012
Notice of Substantial Amendment (non-CTIMPs)	Amendment 1	11 October 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D Approval

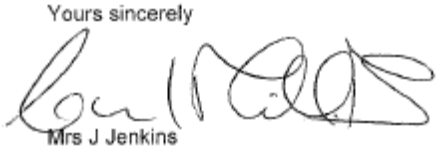
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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.

11/WA/0213:	**Please quote this number on all correspondence**

Yours sincerely



Mrs J Jenkins
Chair, Panel C
South East Wales Research Ethics Committee C

Enclosures: List of names and professions of members who took part in the review

Copied:- R&D Office, Cardiff University (resgov@cardiff.ac.uk)

R&D office for Cardiff & Vale University Health Board (cav_research.development@wales.nhs.uk)

Myfanwy.davies@bangor.ac.uk

Appendix 5.2: Public Health Wales Research and Development Approval

GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales

Ymchwil a Datblygu
Cyhoeddus Cymru, Uned 1 Cwrt Charnwood
Heol Billingsley, Parc Nantgarw, Caerdydd CF15 9QZ

Research and Development
Public Health Wales, Unit 1 Charnwood Court
Heol Billingsley, Parc Nantgarw, Cardiff CF15 7QZ
Ffôn/Tel: 01443 824165 Ffacs/Fax: 01443 824161
Gwefan/Web: www.iechydcyhoedduscymru.org
www.publichealthwales.org

Dr Sharon Hillier
Deputy Director of Screening Division
Public Health Wales
18 Cathedral Road
Cardiff
CF11 9LJ

Monday 14th January 2013

Dear Dr Sharon Hillier

Re: 2012PHW0023 Women's Attitudes Towards HPV Self-Sampling

The above project was assessed by the Research Risk Review Committee held on Wednesday 9th January at which the following Committee members were present:

Dr Edward Guy (Committee Chair)
Kathryn Ashton, (R&D Coordinator, Public Health Wales)
Catherine Turpin (R&D Secretary, Public Health Wales)
Dr Jim Fitzgibbon (Lay Member)
Nicola Heales (Lay Member)
Dr Aimee Grant (Public Health Wales, Senior Health Promotion Practitioner)

Documents reviewed
The documents reviewed at the meeting were:

Document	*Version number*	*Version Date*
Public Health Wales Internal Project Context sheet	1	
NHS SSI Form	260566	10 Dec 2012
NHS R&D Form	14/338	03 Dec 2012
Protocol	5	01 Oct 2012
Participant Invitation letter (Interview)	1	25 May 2011
Consent form Questionnaire	1	25 May 2011
Interview Schedule	1	28 June 2011
Interview Consent form	1	17 May 2011
Invitation letter	3	01 Oct 2012
Participant Information Sheet	4	01 Oct 2012
Participant Information Interview Sheet	3	01 Oct 2012
Questionnaire	5	01 Oct 2012
Recruitment leaflet	1.1	08 Nov 2012
Peer Review FW		09 Jun 2011
Peer Review SH		08 June 2011
NISCHR PCU Favourable ethical opinion letter	30 Dec 2011	30 Dec 2011
Favourable REC amendment 2 opinion letter	27 Nov 2012	18 Dec 2012
Internal Public Health Wales financial approval letter		13 Dec 2012

I am pleased to confirm that the study has been **approved** by the Committee and may commence within Public Health Wales.

Approval lapses if the project does not commence within 12 months of Trust approval. The Committee reserves the right to be provided with information on the progress of the project at any time.

Comments for Consideration
On review of your study, the Committee had a number of comments for your consideration regarding the conduct of your study:

- Ensure that the researcher conducting the interviews are aware of and follow procedures within the Cardiff University Lone Workers Policy.

Random audits may be carried out to ensure that the project complies with the relevant Research Governance Framework standards. If any amendments to the project are required, amended versions of all documentation should be forwarded to the R&D Office for consideration and approval prior to any changes taking place. Any serious adverse incidents relating to the project must be reported to the R&D office.

Please inform the R&D office when the project is completed. A final written report is required at this time before the project can be closed.

If you require any further information please contact Catherine Turpin Public Health Wales R&D Office, Unit 1 Charnwood Court, Heol Billingsley, Parc Nantgarw, Cardiff CF15 7QZ.

Yours sincerely

Dr Edward Guy
Chair - Research Risk Review Committee
Public Health Wales NHS Trust

Appendix 5.3: Participant: Invitation letter, information sheet and consent form

Invitation letter

Institute of Primary Care & Public Health
Institute Director Professor Christopher Butler
Adran Gofal Cynradd a Iechyd y Cyhoedd
Pennaeth Adran Yr Athro Christopher Butler

Institute of Primary Care & Public Health
Cardiff University
School of Medicine
Neuadd Meirionnydd
Heath Park
Cardiff CF14 4XN
Tel Ffôn +44(0)29 2068 7168
Fax Ffacs +44(0)29 2068 7219
E-mail E-bost pcphadmin@cf.ac.uk

Adran Gofal Cynradd a Iechyd y Cyhoedd
Prifysgol Caerdydd
Yr Ysgol Feddygaeth
Neuadd Meirionnydd
Parc y Mynydd Bychan
Caerdydd CF14 4XN

Dear

You kindly completed a questionnaire for us investigating women's attitudes towards HPV self-sampling. Thank you! On your questionnaire you indicated that you were interested in also taking part in an interview study.

This letter is to provide you with information about the interview and to ask you if you would be willing to take part. In the interview we would like to informally discuss your views towards HPV self-sampling. The interview would take place at a time and a place to suit you (for example your home or a local community centre) and should last no more than an hour. We would also offer a payment of £15.00 for your time. Your views would be treated in the strictest of confidence. Enclosed is an information sheet to provide you with further details about the interview.

If you are willing to take part, could you please complete the attached consent form and return it in the PRE-PAID envelope. You will then be contacted to arrange an interview. Whether or not you choose to take part will have no effect on your normal medical care or your cervical screening invitations.

Please be aware that we will only be able to conduct interviews in English.

If you have any queries about this research please call Mrs Denitza Williams on 02920687851

Yours sincerely,

Mrs Denitza Williams

Information sheet

Institute of Primary Care & Public Health
Institute Director Professor Christopher Butler
Adran Gofal Cynradd a Iechyd y Cyhoedd
Pennaeth Adran Yr Athro Christopher Butler

Institute of Primary Care & Public Health
Cardiff University
School of Medicine
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Participant Information Sheet

Research Study: Women's attitudes towards HPV self-sampling

You are being invited to take part in an interview looking at the views of women about a different method of cervical screening, called HPV self-sampling.

Please remember that this test is not currently available so it's important that you attend for a smear appointment, when invited by Cervical Screening Wales.

Interviews are being carried out as part of an educational project called a PhD. Before you decide if you want to take part in an interview, it is important for you to understand why the research is being done and what it will involve. Take time to read the following information carefully and discuss it with others if you wish. Part 1 of this information sheet tells you the purpose of the interview and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the interview.

If there is anything that is not clear or you would like more information please contact Denitza Williams, Department of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS. Tel: 02920687851.

Human Papillomavirus (HPV) is a very common infection. In most cases HPV does not cause any problems, but in some women it can cause cervical cancer. It is proposed that in the future there may be kits that you can use to test for HPV at home (HPV self-sampling). You would then send the kit to a laboratory to be tested and would be told your results through a letter in the post.

Part One

What is the purpose of this interview?

The main aim of the interview is to find out women's attitudes towards HPV self-sampling kits. We would like to speak to you to find out your thoughts on HPV self-sampling, and how confident or not women would feel in carrying out this test and the results provided.

Why have I been contacted?

We have contacted you because when you completed our questionnaire you indicated that you may be interested in taking part in an interview. Thank you!

Do I have to take part?

No. It is up to you to decide if you want to take part in this study. You are free to pull out of this study at any point and do not have to give a reason. Pulling out of this study will not affect your medical care.

If you are interested in taking part, please keep this information sheet and sign and return the enclosed consent form in the envelope provided.

What will happen to me if I take part?

Taking part would mean agreeing to be interviewed by Mrs Denitza Williams about your views regarding HPV self-sampling. Before the interview you will be given a copy of this information sheet, provided with a chance to ask any questions and if you agree in taking part you will be asked to sign a consent form.

The interview will last up to 1 hour and it can be held at your own home, or if you would prefer a community centre or Cardiff University. You will be asked questions about your views on HPV self-sampling in general and how your experience with having a smear test (or never having one) may influence your opinions. We will ask if you would feel confident in doing a screening test such as HPV self-sampling yourself at home.

Mrs Williams will tape-record discussions and will later write down everything that has been said. What you say will be kept secret and only made available to the research team. We will use your words in a report or article to report the opinions of women, however we will use false names, so that no-one will know that we have spoken to you.

The audiotapes will be stored in a locked filing cabinet in the research office. Only the research team will have access to the audiotapes. Following Medical Research committee guidelines, audiotapes will be stored for 10 years following completion of the study, after which they will be destroyed.

You are free to withdraw from the interview at any point and your medical care and cervical screening invitations will not be affected.

Will my GP be involved?

We will not inform your GP of your involvement in this study.

What are the possible disadvantages of taking part?

Taking part in this study will require you to talk about your attitudes towards HPV self-sampling and cervical screening, which some people may find upsetting. It is highly unlikely that anything should go wrong. If you would like to talk about any of the issues raised in this study, a contact name and details are provided at the end of this information sheet.

What are the possible benefits to taking part?

There will be no direct clinical benefit to you from taking part in this study. However, information we gather through this study will help us to understand women's attitudes to HPV self-sampling. This information will help health professionals understand if this method may be acceptable to women. We will offer a small payment of £15.00 for your time during the interview.

What if I don't want to carry on or if there is a problem?

You can pull out of this study at any time and it will not affect your future care. It is highly unlikely that you will be upset or inconvenienced by this study. However, if you become distressed at any point, you will have the opportunity to stop the interview. Depending on the nature of your concern, you will be advised to either discuss matters further with the researcher, contact your GP, be provided with the contact details of Cervical Screening Wales or a relevant cervical screening charity, namely Jo's trust.

However, if you feel that you need to make a complaint about the way you have been approached or treated by the researcher, you should contact: Prof. C. Butler, Head of Department, Department of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS.

In the event that something does go wrong and you are harmed in this research study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you have grounds for legal action for compensation against Cardiff University but you may have to pay legal costs.

What will happen to the results of the research study?

Results from this study will be reported in scientific, policy and professional journals. You may request a copy of the study results.

Who is organising and funding this study?

The study is organised by Denitza Williams at Cardiff University. It is directed by an advisory group and is funded by the Medical Research Council. No-one will be paid for including you in this study.

Who has reviewed this study?

This study has been examined by the Medical Research Council and it has received ethical permission by The South East Wales Research Ethics Committee.

Who should I contact for more information about this study?

If there is anything that is not clear or you would simply like more information please contact Denitza Williams, Department of Primary Care and Public Health, Cardiff University Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS. Email: stoilovado@cf.ac.uk Tel:02920687851

Further information on cervical cancer is available from Jo's Cervical Cancer Trust http://www.jostrust.org.uk/ and their helpline number is 0808 802 2000.

Institute of Primary Care & Public Health
Institute Director Professor Christopher Butler
Adran Gofal Cynradd a Iechyd y Cyhoedd
Pennaeth Adran Yr Athro Christopher Butler

Study ID number

CONSENT FORM

Research study: Women's attitudes towards HPV self-sampling.

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1. I WANT to take part in the interview study ☐

To arrange an interview time you can contact me on:

Tel no:

Name:

Address:

Signature

Date:

2. I DO NOT want to take part in the interview study and do not wish to be contacted further. ☐

Name:

Signature:

Date:

INVESTORS IN PEOPLE | BUDDSODDWYR MEWN POBL

Appendix 5.4: Interview schedule

Interview schedule rationale

Semi-structured interviews will facilitate in-depth exploration of the factors associated with intention to self-sample and will be guided by an interview schedule.
The interview schedule will be based on the original constructs of the Health Belief Model (perceived: susceptibility to and severity of HPV infection/cervical cancer, benefits/barriers to HPV self-sampling and cervical screening, self-efficacy in carrying out the self-sampling test). A particular focus will be given to the significant factors identified during the multivariate analysis of the questionnaire data.

Interview Schedule Structure

Questions were ordered to try and avoid any influence posed by questions pertaining to HPV knowledge when discussing intention to self-sample and perceived self-efficacy. This has resulted in the intention question being the first question that the interviewees are asked with the second question investigating perceived self-efficacy.

The first half of the interview is focused around HPV whilst the second half of the interview is focused on cervical screening in general. It is hoped that this will minimise any order effects that might have been imposed by cervical screening questions on answers provided relating to HPV questions. However, it is acknowledged that interviews are flexible and reflexive and therefore it is predicted that the interview schedule might need to be amended following each interview.

Question number	**Theme/Construct Investigated**
1	Intention to self-sample
2,3,4	Self-efficacy
5	Benefits to self-sampling
6	The effect of self-efficacy on benefits to self-sample
7	Barriers to self-sampling
8	Previous experience with other self-sampling kits
9,10,12	HPV knowledge
11	Attitude: HPV causes cervical cancer
13	Attitude: cervical cancer in general
14	Attitude: smear tests
15	Benefits to smear testing
16	Barriers to smear testing
17	Overall attitude towards HPV self-sampling
18-23	Intervention
24	Anything further to add

The self-sampling procedure will be explained before the interview commences.

The interviewer will be aware of the participant's intention to self-sample and their perceived self-efficacy before the interview has commenced (by referring to the participants questionnaire before meeting with the participant).

Wherever possible questions will be related back to the interviewee's perception of self-efficacy in carrying out self-sampling and the way this may influence overall intention.

PROLOGUE

Introduce myself, explain where I am from and ensure that the participant is comfortable.

Check that the participant understands the reason for the interview and provide an opportunity to ask any questions.

Alert the participant that I am a researcher on the psychological study so can answer questions about this study but that I'm not medically trained, so I do not have the expertise to answer questions of a clinical nature.

The focus of the interview then needs to be set. This will be based on the following script:

Recently you agreed to take part in the **Women's attitudes towards HPV self-sampling** study. Thank you for agreeing to take part.

Just to remind you, we are interviewing women who are eligible for cervical screening and who live in South-East Wales. We will ask women about their feelings about cervical cancer and screening in general, how they think people get cervical cancer, and how they feel about the proposed HPV self-screening kit, and if they have had experiences of any other types of self- sampling kits. We will then look at arguments for and against self-sampling which are important to each woman. It is entirely up to you if you decide to take part in the interview. The results will be used to help inform researchers and medical professionals about women's attitudes towards self-sampling. The interview should take less than an hour to complete. We will use a tape recorder to record it but we will make sure that your identity is kept confidential. The recording will be kept safely and only used by the research team. You can pull out of the interview at any time, and you don't have to give a reason. The interview will last up to 1 hour.

Are you happy to continue?

HPV SELF-SAMPLING

Rationale: Exploring intention to self-sample, perceived self-efficacy, benefits and barriers to self-sampling and how these are influenced by self-efficacy.

1. How do you feel about HPV self-sampling?

   Prompts: How likely would you be to use the self-sampling kit? Why do you think that you would you be (likely/less likely)? What do you think doing self-sampling involved?

2. How do you feel about carrying out the self-sampling yourself?

   Prompts: Which part of the sampling would you be more confident in doing? Which part of the sampling would you be less confident in doing? Probe for understanding instructions, obtaining the cells with the swab, placing the swab in the container without touching anything else, returning the kit within 2 weeks of taking the sample, and any other aspects.

3. How would you feel about sending the sample in the postage paid envelope?

   Prompts: Would you worry about it getting lost? Would you feel embarrassed? Would you worry while waiting for results?

4. How would you feel about the results that you will receive?

   Prompts: Will anything affect your trust in the results? Will you trust the results the same/less or more than the results from a cervical smear test- Can you tell me about that?

5. Do you feel there are any benefits to HPV self-sampling/ having a kit at home to self-sample?

   Prompts: What things do you think are good about being able to do the kit at home? If the self-sampling kit was made available would it change your screening attendance habits? Can you tell me a bit more about this?

6. How do you think that your confidence would have an effect on the good things you feel about self-sampling?

   Prompts: Can you tell me a bit more about that? How may that affect your intention to self-sample?

7. Can you imagine having any issues/problems with doing HPV self-sampling?

   Prompts: Would you worry that you may hurt yourself carrying out the procedure? Would you be worried about the kit getting lost in the post? Would you trust the results? Why would you not trust the results (if possible relate back to the answers given in Question 2)

8. Have you ever used any kind of self-sampling kit before and how did you feel about it? For example, a pregnancy test kit?

   Prompts: How did you find it to use? Can you tell me more about how you confident you felt doing the test and in the results.

HPV KNOWLEDGE AND CERVICAL CANCER

Rationale: Establishing extent of HPV and cervical cancer knowledge.

9. What do you think causes cervical cancer?

   Prompt: Why do you believe (X) causes cervical cancer?

10. The main cause of cervical cancer is HPV, can you tell me what you know about HPV at all?

    Prompts: Had you heard of HPV before taking part in this study- if so- What did you know about it? How do you think HPV can clear up? Do you feel that HPV could clear up my itself? How serious do you think HPV infection is? How important do you think HPV is in cervical cancer? Can you tell me a little more about that?

11. How do you feel about HPV causing cervical cancer?

    Prompts: Would it affect your view of cervical cancer? How may it affect your view?

12. How do you think a person may get infected with HPV?

    Prompts: Can you tell me a little more about that?

CERVICAL CANCER AND SCREENING ATTITUDES

Rationale: Establishing effect of previous screening on intention to self-sample.

13. How do you feel about cervical cancer in general?

    Prompts: Do you know of anyone who has been diagnosed? How serious do you think it is? Do you ever worry about getting cervical cancer?

14. How do you feel about smear tests?

    Prompts: Do you go for a smear test? Why do you go/not go? What are the good/bad things about smear tests?

15. What do you think are the benefits to having smear tests?

    Prompts: Can you tell me a little bit more about that?

Trust in the doctor to take a good enough sample for testing? Having smear tests means that cervical abnormalities would be picked up earlier on? Does having a smear test provide you with reassurance?

16. Do you see any problems with having smear tests at all?

    Prompts: Have you ever had any practical issues arranging a smear test? Have you ever had any strong emotional feelings regarding smear tests? How do you feel about the results of a smear test?

17. Overall, how do you feel about the possible introduction of HPV self-sampling kits as a method of cervical screening?

    Prompt: Is there anything that you feel we have not discussed that you would like to add?

18. If HPV self-sampling was available, what kind of information would you like to see on a leaflet that would be alongside the kit?

19. Is there anything further that you would like to add?

Future contact

Ensure that participant knows how to contact researcher for further help/information/to add further information.
Check if it is okay to contact participant after listening to the conversation if there is anything the researcher may want to clarify.

Ask participant if they would be happy to be contacted following intervention development for usability testing of the intervention.

Thank the participant for their time!

Appendix 5.5: Thematic Framework

1st Level theme	2nd Level theme	3rd Level theme		
Own intention to self-sample *(Explicit reference to own intention to self-sample)*	Attitudes towards transition from habitual behaviour			
	The belief that the test/instructions are going to be easy			
	Perceived availability of cervical smear			
	Dependent on trials/research			
	Becoming the norm			
	History of abnormalities *(Intention directly affected by previous history of cervical abnormalities)*			
	Pragmatism: dependent on availability of alternative *(intention contextualised in the absence/presence of smear tests)*			
	Access to professional expertise			

	(preference for a smear test due to professionals carrying it out)	
	Good idea	
	Knowledge	
	Instructions	
	Other	
Other's perceived intention to self-sample *(Explicit reference to perception of other's intention to self-sample)*	Convenience	
	Comfort	
	Knowledge	
	Age	
	Symptoms	

	Expertise (smear is done properly due to health professional)			
	Privacy			
	Embarrassment			
	Pragmatism (intention contextualised in absence/presence of smear tests)			
	Becoming the norm			
	Support (availability of support for those who are not confident)			
	Other			
Understanding of self-sampling *(Placing self-sampling in context of other screening methods)*	Comparison with smear	Perceived parallels with smear test		
		Confidence in HPV self-sampling vs smear test results		
	Comparison with screening for other cancers/ technologies			
	3 steps of HPV self-sampling *(understanding of the self-sampling procedure)*			
	Other			
Perceived Self-efficacy *(Components of self-efficacy and its effect on intention to self-sample)*	High self-efficacy *(the belief that the individual is able to carry out self-efficacy)*	Previous use of technologies (e.g. tampons, pg tests)		
		Previous experience of childbirth		

		Receiving a result *(receipt of a result for a self-sampling kit, providing reassurance that the individual has carried out the test correctly)*			
		Autonomy *(the belief that cervical screening is so important that the individual will make sure they get it right)*			
		Practice			
		Information			
		Age			
	Low self-efficacy *(the belief that the individual is not able to carry out self-sampling properly)*	Lack of professional expertise			
		Lack of practice			
		Worry over carrying out test properly			
		Consequences of not doing test properly			
		Lack of confidence in result			
		Access to professional expertise (access to professional after/during sampling)			
	Effect of self-efficacy on intention	Moderator			

		Mediator	
	Previous use of sampling technologies		
	Other		
Barriers to HPV self-sampling *(other than those related to self-efficacy)*	Operational Factors *(the logistical issues involved with the self-sampling programme and how they may affect intention to self-sample)*	Sample being lost in the post	
		Doubt of postal workers willing to handle samples	
		Sample contamination or damage during transit	
		Possibility of tampering with sample during transit	
		Identity theft	
		'Expert systems'	Preference for Lack of
		Confirmation	

	Confidence in self-sampling programme *(quality and reasoning behind programme*)	*(of receipt of kit by the laboratory)*		
		Continuity (e.g. are reminders still sent or are same people involved in programme)		
		Access to expert support *(during HPV self-sampling e.g. telephone or after receiving self-sampling result)*		
		Reassurance of Research and trials		
		Lack of confidence in reasons for offering self-sampling	Cost-cutting	Self-sampling not optional
			Cutting corners	
			Withdrawal of service	
	Potential for contamination	Unclean environment		
		Dropping kit (swab)		
	Delay in completing test	Privacy		

	Potential for harm (e.g. causing bleeding)		
	Own responsibility		
	New		
	Test efficacy compared to cervical smear		
	Test efficacy		
	Lack of knowledge		
	Double effort (having to attend clinic despite doing ss)		
	Other		
	Benefits to smear tests *(perceived benefits to smear tests that may act as barriers to self-sampling)*	Pick up a problem (cervical abnormality)	
		Gynaecological Health Check	
		Expert reassurance	All seeing
		Previous history of abnormalities	
		Expertise	

		Habitual behaviour	
		Procedure is acceptable	
		Age	
		Effect of having children- smear tests not as embarrassing	
Facilitators to self-sampling *(Perceived advantages to self-sampling compared to smear tests facilitators)*	Convenience		
	Comfort		
	Less embarrassing than smear		
	Less uncomfortable than smear		
	Less invasive than smear		
	Time efficient: Can be done whenever one has a chance (no planning required)		
	Altruism	Can free up medical practitioners time	
		Can help save money	
	Barriers to smear tests	Embarrassing	

	(Negative perceptions of smear tests that may act as facilitators to self-sampling)	Painful	
		Inconvenience	
		Lack of confidence in health Professionals	
		Effect of having children (negative)	
		Waiting for results	
		Timetabling	
		Psycho-sexual issues	
	Perceived service continuity (similar service procedures as smear test)		
	Confidence in postal services		
	Availability of research data		

	Devolved responsibility			
	Family support			
Cervical cancer perceptions *(attitudes to causality, prevalence and impact)*	Causality *(perceptions of cervical cancer causes*)	None attributed	No idea	
			Still unidentified	
			Something that just happens	
		Genetics		
		A 'trigger'		
		Lifestyle		
		Having children		
		Weak/weakened immune system		
		Sex		

		HPV	
	Prevalence	Affects younger women (more than other cancers)	
		High perceived prevalence	
	Prognosis	Cervical cancer impact	
	Symptoms	Cervical cancer is symptomless	
	Reducing risk: Protective behaviour		
	Cervical cancer is scary		
	Personal experience	Uncertainty	
		Family member	
	Need for education		
	Fatalism		
HPV perceptions *(attitudes towards HPV and self-sampling)*	Previous knowledge of HPV	None	

		Minimal (heard of it, reference to vaccination)	
	HPV transmission *(perceptions about how HPV may be transmitted)*	Air bound, a virus like a cold	
		Insertion of foreign bodies e.g. tampon	
		Something that's already in the body	
		Touching infected places/individuals	
		Sexual contact	Multiple partners
			Unprotected
	HPV awareness *(perceptions relating to the knowledge that a virus causes cervical cancer)*	Treatable	
		Cervical cancer is less threatening because a virus is treatable	
	Incongruity- 'how have I got that'		
	Need for education		
	HPV vaccination		
	HPV prevalence		
	Prognosis		
	Disbelief		

	(that HPV causes cancer)		
	Other		
Participant suggestions *(in relation to intervention content to help build confidence and self-efficacy)*	Website		
	Helpline		
	Simple language		
	Content		
	Colour		
	Layout		
	Increase self-efficacy		
	Professional finish (leaflet to be glossy and look professionally made)		
	Trial results	Statistics	
	Expectations	Of individual	
		Of professionals	
	Visual/Auditory aids	Pictures/diagrams	
		Video	
General cancer perceptions	Fatalism		
	Causality		
	The young		
	Positive perceptions of cancer screening		

Appendix 5.6 Thematic Charting: Perceived facilitators and barriers to HPV self-sampling

<table>
<tr>
<td rowspan="3">Barriers to HPV self-sampling (other than those related to self-efficacy)</td>
<td rowspan="3">Operational Factors
(the logistical issues involved with the self-sampling programme and how they may affect intention to self-sample)

“I mean the only thing I’d be thinking of, if you put the swab in the test tube would it be accurate enough...you know if you were post it in the doctors it would be sent off in a day, if it was in the post would they have it for a couple of days, if you see that’s the only thing I’m thinking, would it affect it slightly the results, if it was left you know, you know if someone had left it in a bag for a week you know[…]” P18</td>
<td>Sample being lost in the post

“I think possibly the sending it off would worry me hoping it reached where it was reaching and not got lost in the post[…]” P10</td>
<td rowspan="3"></td>
</tr>
<tr>
<td>Doubt of postal workers willing to handle samples

“[…] “I’m not taking that to get delivered, I’ll leave that one in the box” like they’d put it in the box and pretend they’d never seen it”” P4</td>
</tr>
<tr>
<td>Sample contamination or damage during transit

“I’ve had mail sometimes come through and it’s soaking wet and opened you know it’s that, not just the packaging damaged is the sample itself gonna be damaged? Or contaminated maybe? P3”</td>
</tr>
</table>

		Possibility of tampering with sample during transit *"well if it did get lost in the post and you know accessed the wrong people for instance you know, possibly there could be access to my own health records by my NHS number or via my name you know just things like that" P10*		
		Identity theft *"well if it did get lost in the post and you know accessed the wrong people for instance you know, possibly there could be access to my own health records by my NHS number or via my name you know just things like that" P10*		
		'Expert systems'	Preference for *"I think I would prefer to take it to like a doctors and they can send it to the hospital, or send it to wherever it needs to go" P1*	
			Lack of	

			"I would be worried that women maybe um might move, might to a different area, how are you going to catch up with that person? Young women that go off and they're sleeping with their staying with their partners in a flat somewhere and they move on again, I wonder whether, how you're going to catch up with them? Is it gonna be like right through your GP? You know are they gonna know through the GP where these people are, where the women are?" P6	
	Confidence in self-sampling programme *(quality and reasoning behind programme*) *"P – yeah it the whole, not just in the test itself, but the whole process associated with the test, I would just be sort of like, then I might worry about whether or not it was any good[…]" P5*	Confirmation *(of receipt of kit by the laboratory)* *"[…]I'd want reassurance that I know my sample has arrived somewhere" P3*		
		Continuity (e.g. are reminders still sent or are same people involved in programme) *"are they going to the same person, I mean so I get my sample and I've sent it off, would it go to the same place as when I have a smear test? Cos if it does then obviously the same people are doing it?" P1*		

		Access to expert support *(during HPV self-sampling e.g. telephone or after receiving self-sampling result)* *" I think that perhaps initially it's done, you know you get the opportunity if you wanted to do it with a medically trained person maybe? " P9* *"I think it would be a good idea um again I think around the option of try it, give it a go, knowing that you've got the option of still going to your GP I think possibly dual[…]" P3*		
		Reassurance of Research and trials *"yeah I suppose, yeah I would want it to explain how we know that it's as effective as a smear test, not in matters of detail, but just why is it as good really" P7* *"yeah I suppose, yeah I would want it to explain how we know that it's as effective as a smear test, not in matters of detail, but just why is it as good really, because otherwise you're not going to have any confidence you know the confidence is not there is it, and then when you start to get issues I suppose of people not doing it, although I would do*		

		it anyway, but it's just you know yeah" P7			
		Lack of confidence in reasons for offering self-sampling *"going from thinking, being quite positive about it and thinking like "yeah you know it's a good thing and it's saving the NHS money" all hail the NHS and all the rest of it, to sort of "it's just been rushed through it's just another one of those politically motivated things, oh it's gonna be rubbish it's not gonna be any good and it's all gonna fall apart in a couple of years anyway" P5*	Cost-cutting *"um I'm not sure, is the benefit to doing self-sampling as in a benefit to health because people would do it more often, or is it a benefit of because it was reduce costs within the NHS or is it just a mixture of both? I don't know quite what was driving, driving the um research" P9*	Self-sampling not optional "if it's, very happy with it if it's optional, um less happy if it's forced[…] P5	
			Cutting corners *"'m just realistic about it in as much as my perception of it is that we need we've got to cut corners somewhere and if we can as the NHS has got to cut corners somewhere cos it's too expensive and you know, I don't want to see it disappear as a person, I don't want to see it disappear as an institution and so if if this helps keep it alive and stops it from being like a case of if you're poor you can't go to the doctor, or we end up in a situation that if you're poor you don't just have to take*		

			your own sample, you have to analyse your own sample ((laughs)) you know because there's no funding for people, that's you know, I'd rather keep the service going in some capacity than not going at all […]" P5		
			Withdrawal of service *"P – are they taking away my rights to have those smear tests, um you know as I should do so I would think, yeah I would think like that" P13*		
	Potential for contamination *"I would be worried about contaminating it somehow" P15*	Unclean environment *"[…]there would be things around hygiene I suppose and things like that, cos you think you know you wash your hands, it's cross contamination it's things like that again, in surgeries you wonder sometimes how clean they are, but you automatically assume I'm in a surgery, health environment, everything is fine." P3*			
		Dropping kit (swab)			

		"[…]it's around making sure you're not touching, or dropping it you know when you finished doing it because it's like the door-bell could go and I'd think oh I've got to answer that and I'd put it down on a surface[…]" P3	
	Delay in completing test *"I'd probably put it in a cupboard somewhere and I'd be thinking it would pop into my head "oh I need to do that" and then something else would pop in[…]" P14*	Privacy *"you know you need to have a privacy in your home, you've got the children are you rushing when you're doing it[…]" P3*	
	Potential for harm (e.g. causing bleeding) *"um just being wary that you weren't going to actually hurt yourself" P14*		
	Own responsibility *"yeah, yeah, because it's quite isolating doing this you know"P4* *"um again it's around the onus on yourself to make sure you do go and send it[…]" P3*		

	New *"um no I just think it would need to kind've be um quite well publicised if it, if it did go ahead because you know a lot people are very wary about anything that's new[…]" P15*		
	Test efficacy compared to cervical smear *"I've got no issue at all with the self-sampling, as long as somebody explains to me that it is equally as valid a test for you know HPV, abnormal cells as having it done in the surgery*" P7		
	Test efficacy *"um again I think, because it's new I think long-term with evidence demonstrating that it's just the same as on a par, I'd have no problem with that, with the evidence, you know with the results, um […]" P3*		
	Lack of knowledge		

	"I'd like to know what the chances are of me getting it right you know myself and if I didn't get it right, what that would mean[…]" P5 *"So it's knowing what's involved in the kit I suppose as well you know […]" P3*		
	Double effort (having to attend clinic despite doing ss) "yeah it's just the hassle of it getting lost in the post, and having to do the test again[…]" P2 "if they say "sorry you need to do it again" or whatever, um then you might think, oh actually no I'd rather go to the doctors, at least know that it's done and I haven't got to have it re-done" P14		
	Other *"so it's one of those "if it's not broke, don't fix it" so for me it works out exactly the way it is" P12*		
	Benefits to smear tests	Pick up a problem (cervical abnormality)	

	(perceived benefits to smear tests that may act as barriers to self-sampling) *"well just because you know this system works, it's good for me" P14*	*"yes, well like yes, it's um, oh it's just knowing that you know it's gonna pick up something, or not pick up something" P1*	
		Gynaecological Health Check *" yeah, yeah, because there might be problems you know infections, or um you know well anything really that they could see, like I've got a coil fitted, so they could check that that's in place, you know things just like a general health check maybe?" P1*	
		Expert reassurance "I think the knowledge that someone that's trained to do it, would probably you know it kind of reassures you that they're doing a proper job[…]" P2	All seeing *"maybe they know what they're looking for if there is issues, I don't know um so that's my feeling on why I would go for a nurse" P1*
		Previous history of abnormalities *"me personally, I would like to have one even if it was every 2 years, because I've had abnormal cells in the past, I'd feel reassured by just having that little bit of a backup um[…]" P16*	
		Expertise	

		"so when you go for your smear it seems to be a sort of exact science of where they're getting cells" P12	
		Habitual behaviour *"but I'm so used to going every 3 years? Every 3 years, that you know it's become normal now routine[…]" P10*	
		Procedure is acceptable *"P – for me it I'm quite easy, it don't bother me going for a screening or a something like that, surgery because I know that it is essential for my health you know so it doesn't bother me[…]" P10*	
		Age *"you know and maybe that's because I'm older as well, obviously when you're 20 odd it's all embarrassing[…]" P12*	
		Effect of having children- smear tests not as embarrassing	

		"I mean sometimes when you have a smear test it can be embarrassing, I say embarrassing, I mean prior to me having children it was embarrassing, after children, don't care[…]" P1	

Appendix 6.1 : Pre and post intervention questionnaires

PI Questionnaire

Questionnaire I.D. Number

PLEASE ANSWER THIS QUESTION FIRST, BEFORE TURNING OVER AND STARTING THE QUESTIONNAIRE. ONCE YOU HAVE STATED YOUR ANSWER, PLEASE DO NOT RETURN AND EDIT.

What do you think causes cervical cancer?

.....

.....

.....

.....

.....

Once you have completed this question, you may turn over the page and begin the questionnaire. Thank you.

Please do not leave any questions unanswered.

HPV= Human papillomavirus

1 HPV is very rare. *Please tick*

True ☐ False ☐

2 HPV always has visible signs or symptoms. *Please tick*

True ☐ False ☐

3 HPV can cause cervical cancer. *Please tick*

True ☐ False ☐

4 How important do you think HPV is in developing cervical cancer? *Please circle*

Not important at all				Very important
1	2	3	4	5

5 HPV can be passed on by genital skin-to-skin contact**.** *Please tick*

True ☐ False ☐

6 There are many types of HPV. *Please tick*

True ☐ False ☐

7 HPV can cause HIV/AIDS. *Please tick*

True ☐ False ☐

8 HPV can be passed on during sexual intercourse**.** *Please tick*

True ☐ False ☐

9 HPV can cause genital warts. *Please tick*

True ☐ False ☐

10 Men cannot get HPV**.** *Please tick*

True ☐ **False** ☐

11 Using condoms reduces risk of getting HPV**.** *Please tick*

True ☐ **False** ☐

12 HPV can be cured with antibiotics. *Please tick*

True ☐ **False** ☐

13 Having many sexual partners increases the risk of getting HPV. *Please tick*

True ☐ **False** ☐

14 HPV usually doesn't need any treatment**.** *Please tick*

True ☐ **False** ☐

15 Most sexually active people will get HPV at some point in their lives**.** *Please tick*

True ☐ **False** ☐

16 A person could have HPV for many years without knowing it. *Please tick*

True ☐ False ☐

17 Having sex at an early age increases risk of getting HPV. *Please tick*

True ☐ **False** ☐

18 Someone who has had the HPV vaccine cannot develop cervical cancer. *Please tick*

True ☐ **False** ☐

19. How serious an infection do you think HPV is? *Please circle.*

Not at all serious				Extremely serious
1	2	3	4	5

20. Compared to most other women your age, how likely do you think it is that you would get cervical cancer at some time in your life? Would you say you are…? *Please circle*

Much less likely	A little less likely	About the same	A little more likely	Much more likely
1	2	3	4	5

Please turn over

Please read the information below and answer the questions on the next page.
PLEASE DO NOT GO BACK AND RE-EDIT ANY OF YOUR PREVIOUSLY ANSWERED QUESTIONS.

Smear tests offer the best protection against developing cervical cancer and save thousands of lives each year. Not going for a smear test is one of the biggest risk factors for developing cervical cancer. This is why it is important that all women attend their smear appointments.

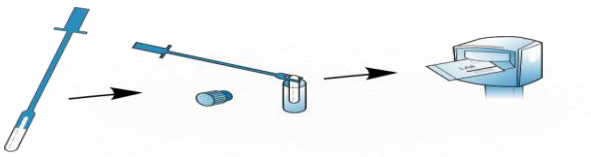
However, things in research are constantly changing and there may be a possibility that in the years to come women may be offered a different type of cervical screening test, HPV self-sampling.

Please note: This test is not currently available through the NHS and may never be.

This test looks at the presence of a virus called Human Papillomavirus (HPV) in the vagina.

HPV could be tested for by using a kit at home. This kit is called a self-sampling kit. The kit would allow a woman to collect a sample from her vagina, which would then be sent off to be tested for the presence of HPV in a laboratory

To carry out the home test a woman would need to put a swab (a cotton bud with a long handle) into the vagina. She would then need to put the swab into a sealed tube with a liquid already inside, and post it to a laboratory using a special pre-addressed envelope.



The introduction of HPV self-sampling is being discussed however **no policy** has been set yet. This is why we would like to ask you a few questions about these kits and your views.

Please proceed with answering the questions on the following pages. Thank you.

Your views on using a self-sampling kit for HPV

Please circle below

21 I would be likely to use a self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

22 If made available to me, I would use the self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

23 I expect that I would use a self-sampling kit for HPV**.**

Not at all likely				Very likely
1	2	3	4	5

24 How certain are you that you would do the test well enough?

Not at all certain				Very certain
1	2	3	4	5

25 How certain are you that you would be able to carry out the sampling procedure (placing swab in vagina)?

Not at all certain				Very certain
1	2	3	4	5

26 How certain are you that you would be able to place the swab into the tube containing the special liquid without touching or dropping the swab?

Not at all certain				Very certain
1	2	3	4	5

27 How certain are you that you would be able to send off the completed test within the time allowed?

Strongly disagree				Strongly agree
1	2	3	4	5

28 Using a self-sample kit would mean that no-one will know that I am having cervical screening.

Not at all certain				Very certain
1	2	3	4	5

29 Using a self-sample kit would be less embarrassing than having a GP or nurse do a smear test.

Strongly disagree				Strongly agree
1	2	3	4	5

30 I am worried that I would hurt myself using the self-sample kit*. Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

31 I wouldn't trust the results of the self-sample kit.

Strongly disagree				Strongly agree
1	2	3	4	5

32 I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory.

Strongly disagree				Strongly agree
1	2	3	4	5

Thank you, please return the questionnaire in the envelope and seal it. Proceed to open envelope 2.

POI questionnaire

Questionnaire I.D. Number

Name:

Age:

Ethnicity:

PLEASE ANSWER THIS QUESTION FIRST, BEFORE TURNING OVER AND STARTING THE QUESTIONNAIRE. ONCE YOU HAVE STATED YOUR ANSWER, PLEASE DO NOT RETURN AND EDIT.

What do you think causes cervical cancer?

……

……

……

……

……

Once you have completed this question, you may turn over the page and begin the questionnaire. Thank you.

Please do not leave any questions unanswered.

HPV= Human papillomavirus

1 HPV is very rare. *Please tick*

True ☐ False ☐

2 HPV always has visible signs or symptoms. *Please tick*

True ☐ False ☐

3 HPV can cause cervical cancer. *Please tick*

True ☐ False ☐

4 How important do you think HPV is in developing cervical cancer? *Please circle*

Not important at all				**Very important**
1	2	3	4	5

5 HPV can be passed on by genital skin-to-skin contact**.** *Please tick*

True ☐ False ☐

6 There are many types of HPV. *Please tick*

True ☐ False ☐

7 HPV can cause HIV/AIDS. *Please tick*

True ☐ False ☐

8 HPV can be passed on during sexual intercourse**.** *Please tick*

True ☐ False ☐

9 HPV can cause genital warts. *Please tick*

True ☐ False ☐

10 Men cannot get HPV**.** *Please tick*

True ☐ **False** ☐

11 Using condoms reduces risk of getting HPV**.** *Please tick*

True ☐ **False** ☐

12 HPV can be cured with antibiotics. *Please tick*

True ☐ **False** ☐

13 Having many sexual partners increases the risk of getting HPV. *Please tick*

True ☐ **False** ☐

14 HPV usually doesn't need any treatment**.** *Please tick*

True ☐ **False** ☐

15 Most sexually active people will get HPV at some point in their lives**.** *Please tick*

True ☐ **False** ☐

16 A person could have HPV for many years without knowing it. *Please tick*

True ☐ False ☐

17 Having sex at an early age increases risk of getting HPV. *Please tick*

True ☐ **False** ☐

18 Someone who has had the HPV vaccine cannot develop cervical cancer. *Please tick*

True ☐ **False** ☐

19. How serious an infection do you think HPV is? *Please circle.*

Not at all serious				Extremely serious
1	2	3	4	5

20. Compared to most other women your age, how likely do you think it is that you would get cervical cancer at some time in your life? Would you say you are…? *Please circle*

Much less likely	A little less likely	About the same	A little more likely	Much more likely
1	2	3	4	5

Your views on using a self-sampling kit for HPV

Please circle below

21 I would be likely to use a self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

22 If made available to me, I would use the self-sampling kit for HPV.

Not at all likely				Very likely
1	2	3	4	5

23 I expect that I would use a self-sampling kit for HPV**.**

Not at all likely				Very likely
1	2	3	4	5

24 How certain are you that you would do the test well enough?

Not at all certain				Very certain
1	2	3	4	5

25 How certain are you that you would be able to carry out the sampling procedure (placing swab in vagina)?

Not at all certain				Very certain
1	2	3	4	5

26 How certain are you that you would be able to place the swab into the tube containing the special liquid without touching or dropping the swab?

Not at all certain				Very certain
1	2	3	4	5

27 How certain are you that you would be able to send off the completed test within the time allowed?

Strongly disagree				Strongly agree
1	2	3	4	5

28 Using a self-sample kit would mean that no-one will know that I am having cervical screening.

Not at all certain				Very certain
1	2	3	4	5

29 Using a self-sample kit would be less embarrassing than having a GP or nurse do a smear test.

Strongly disagree				Strongly agree
1	2	3	4	5

30 I am worried that I would hurt myself using the self-sample kit*. Please circle a number.*

Strongly disagree				Strongly agree
1	2	3	4	5

31 I wouldn't trust the results of the self-sample kit.

Strongly disagree				Strongly agree
1	2	3	4	5

32 I would be worried about the self-sampling kit getting lost in the post and not reaching the laboratory.

Strongly disagree				Strongly agree
1	2	3	4	5

The leaflet

32 Did you refer back to the HPV self-sampling leaflet when answering these questions? Please tick one box:

Yes ☐ **No** ☐

33 Overall, did you find the leaflet useful?

Yes ☐ **No** ☐

Please tell us more:

……

……

……

……

34 Did you find the leaflet easy to understand?

Yes ☐ **No** ☐

Tell us more

……

……

……

……

35. Did you think the amount of information in the leaflet was:

Too much ☐

Too little ☐

Just right ☐

Please tell us why you thought this:

……

……

……

……

36 Did the leaflet make you feel **more** confident in doing HPV self-sampling?

Yes ☐ **No** ☐

Tell us more

……

……

……

……

37 Did you think 'Miriam's story' was helpful?

Yes ☐ **No** ☐

Tell us more

……

……

……

……

38 Was there anything you wanted to know more about?

……

……

……

……

39 Were any sections of the leaflet less useful?

……

……

……

……

40 Do you have any suggestions for improving the leaflet?

……

……

……

……

……

……

Thank you for your time!

Your comments will be used to improve the HPV self-sampling leaflet.

Appendix 6.2: Interview Schedule for women

What do you think about the leaflet?

Does it explain its purpose? What do you think the purpose of the leaflet is?

When do you think the leaflet will be used?

Does the leaflet affect what you think about self-sampling in general?

What effect does it have? What part of the leaflet made you feel this way?

How does the leaflet make you feel about doing HPV self-sampling?

Does it make you feel more or less inclined to do self-sampling?

How does it affect your intention? Is there a particular part of the leaflet that has the most effect on your intention?

How does the leaflet make you feel about being able to do HPV self-sampling?

Does it make you more or less confident?

Why does it make you feel that way? Which part/s of the leaflet makes you feel that way?

How does the leaflet make you feel about the way the HPV self-sampling programme will be set-up?

Does it make you feel more or less confident about the set-up?

Why does it make you feel this way? What part/s of the leaflet make you to feel this way?

Do you find the leaflet easy to understand?

How clear do you find the content?

How easy or difficult to follow do you find the content?

What do you think about the way the information is structured?

To what extent is the factual information understandable and acceptable?

Do you think the information in the leaflet is easily understandable for all people who may be facing this decision?

What do you think about the different sections of the leaflet?

What do you think of the question and answer sections?

What do you think of the 'story' section?

Are there sections of the leaflet that need changing?

Language, font, format, size, graphic elements, information clarity (statistics)?

Do you have any suggestions for improvement?

Are there any important questions or pieces of information missing from the leaflet?

Is there anything you do not like about the leaflet? Why? How could it be improved?

Do you have any other comments or suggestions?

Can I get back to you about the leaflet and or if there is anything to clarify from the interview?

Appendix 6.3: Interview schedule for providers

What do you think about the leaflet?

Does it explain its purpose? What do you think the purpose of the leaflet is?

When do you think the leaflet will be used?

How do you think the leaflet would be best implemented?

Why do you think this would be the best point of implementation?

Is there any information on the leaflet that is inaccurate/ misleading?

Information about HPV? Information about ease of self-sampling?

Are the service provision Q&A sections (e.g. How will I know if my kit has been lost?) feasible/realistic?

Can you tell me a bit more about how you envisage HPV self-sampling being implemented into the cervical screening programme? Is this reflected in the information provided in the leaflet?

What do you think about the layout of information in the leaflet?

Is there anything (text/graphics) that you feel should be moved? If so, where do you think it should be placed?

Do you find the leaflet easy to understand?

How clear do you find the content?

Do you think the information in the leaflet is easily understandable for all people who may be facing this decision?

What do you think about the different sections of the leaflet?

What do you think of the question and answer sections?

What do you think of the 'story' section?

Are there sections of the leaflet that need changing?

Language, font, format, size, graphic elements, information clarity (statistics)?

Do you have any suggestions for improvement?

Are there any important questions or pieces of information missing from the leaflet?

Is there anything you do not like about the leaflet? Why? How could it be improved?

Do you have any other comments or suggestions?

Can I get back to you about the leaflet and or if there is anything to clarify from the interview?

Appendix 6.4: Ethical Approval

School of Medicine
Dean Professor John Bligh BSc MBChB MA(Lit) MMEd MD FRCGP HonAcadMEd
Ysgol Meddygaeth
Deon Yr Athro John Bligh BSc MBChB MA(Lit) MMEd MD FRCGP HonAcadMEd

Cardiff University
School of Medicine
Heath Park
Cardiff CF14 4XN
meddean@cardiff.ac.uk
Prifysgol Caerdydd
Ysgol Meddygaeth
Parc Mynydd Bychan
Caerdydd CF14 4XN

Friday 24th October 2014

Denitza Williams
Institute of Primary Care & Public Health
3rd Floor, Neuadd Meirionnydd
School of Medicine, Cardiff University
Heath Park

Dear Denitza,

Re: Women's attitudes towards HPV self-sampling – Pilot field testing

SMREC Reference Number: 14/43

This application was reviewed by the Committee on Wednesday 15th October 2014.

Ethical Opinion

On review, the Committee were happy to grant ethical approval provided:

1. That you review and reword the Participant Information Sheet for the Healthcare Professionals as it was felt that it was aimed more towards the lay participants, particularly in reference to the inclusion of "Will my GP be involved?"
2. That the statement on the Participant Information Sheets regarding no compensation is amended as it was felt that this was a bit excessive in light that this is for a questionnaire only.
3. Also, it was thought that the bold-faced disclaimer on page 1 of the Participant Information Sheets could be better incorporated as a question and answer statement under Part One.

Please send any revised documentation to the Committee Secretary, Miss Claire Batten.

Conditions of Approval

The Committee must be notified of any proposed amendments to the methodology and protocols outlined in your submission. Also, any serious or unexpected adverse reactions that may arise during the course of the study must be reported to the Committee.

Documents Considered

Document Type:	Version:	Date Considered:
Application Form	V1 30/09/14	15/10/2014
Supporting Document	V1 30/09/14	15/10/2014
Appendix 1: Pre-intervention questionnaire	V1 30/09/14	15/10/2014
Appendix 2: Draft intervention	V1 30/09/14	15/10/2014
Appendix 3: Post intervention questionnaire	V1 30/09/14	15/10/2014
Appendix 4: Interview schedule for providers	V1 30/09/14	15/10/2014
Appendix 5: Interview schedule for women	V1 30/09/14	15/10/2014
Information Sheet for health professionals	V1 30/09/14	15/10/2014
Information Sheet for women	V1 30/09/14	15/10/2014
Consent Form	V1 30/09/14	15/10/2014

With best wishes for the success of your study.

Yours sincerely,

Dr Jonathan Hewitt
Chair, School of Medicine Research Ethics Committee

INVESTORS

Appendix 6.5: Information sheet for women

Research Study: Women's attitudes towards HPV self-sampling- Pilot field testing

Information sheet for women

You are being invited to take part in a study looking at the views of women about a different method of cervical screening, called HPV self-sampling, as well as the efficacy of a leaflet developed to encourage women to take part in self-sampling.

Before you decide if you want to take part in this study, it is important for you to understand why the research is being done and what it will involve. Take time to read the following information carefully and discuss it with others if you wish. Part 1 of this information sheet tells you the purpose of the study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study.
If there is anything that is not clear or you would like more information please contact Denitza Williams, Department of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS or on 02920687142.
Part One

Is HPV self-sampling currently available?

HPV self-sampling is **not** currently available, so it's important that you attend for a smear appointment when invited by Cervical Screening Wales.

What is the purpose of this study?

We would like to find out if a leaflet given to women may affect their HPV knowledge and intentions to self-sample. We would also like to know what women think of the leaflet and what they may like to change on the leaflet.

Why have I been chosen?

You have been asked to take part because you are a woman aged between 20-64 years.

Do I have to take part?

No. It is up to you to decide if you want to take part in this study.
You are free to pull out of this study at any point and do not have to give a reason. Pulling out of this study will not affect your medical care or your invitation to screening by Cervical Screening Wales.

If you are interested in taking part, please keep this information sheet and sign the consent form.

What will happen to me if I take part?

Taking part would mean completing a questionnaire, having a look at an informational leaflet about HPV and self-sampling and then completing the same questionnaire again.

You will then be interviewed about your thoughts regarding the information leaflet.

The whole study should take no longer than an hour, however if you feel that taking part in both tasks would be too arduous, you may choose to only participate in the interview.

Will my GP be involved?

We are not intending to inform your GP of your involvement in this study.

What are the possible disadvantages of taking part?

Taking part in this study will require you to complete two questionnaires, look at a leaflet and discuss your thoughts regarding the leaflet. It is highly unlikely that anything should go wrong. If you would like to talk about any of the issues raised in this study, a contact name and details are provided at the end of this information sheet.

What are the possible benefits to taking part?

There will be no direct clinical benefit to you from taking part in this study. However, information we gather through this study will help us to understand if the information leaflet developed is able to increase women's knowledge about HPV and their intentions to self-sample. It will also help us understand if the leaflet is easy to use and understand and what improvements may need to be made.

You will be given £10 as a 'thank-you' for participating in the study.

What if I don't want to carry on or if there is a problem?

You can pull out of this study at any time and it will not affect your future care. It is highly unlikely that you may be upset or inconvenienced by this study. However, if you feel that you need to make a complaint about the way you have been approached or treated by the researcher, you should contact: Professor Adrian Edwards, Institute Director, Institute of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS.

What will happen to the results of the research study?

Results from this study will be reported in scientific, policy and professional journals. You may request a copy of the study results.

Who is organising and funding this study?

The study is organised by Denitza Williams at Cardiff University. It is directed by an advisory group and is funded by the Medical Research Council. No-one will be paid for including you in this study.

Who has reviewed this study?

This study has received ethical permission from The School of Medicine Research Ethics Committee, Cardiff University.

Who should I contact for more information about this study?

If there is anything that is not clear or you would simply like more information please contact Denitza Williams, Department of Primary Care and Public Health, Cardiff University, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS. Email: stoilovado@cf.ac.uk Tel:02920687142 or 07877857292.

Further information on cervical cancer is available from Jo's Cervical Cancer Trust http://www.jostrust.org.uk/ and their helpline number is 0808 802 8000.

Appendix 6.6: Information sheet for professionals

Research Study: Women's attitudes towards HPV self-sampling- Pilot field testing

Information sheet for health professionals

You are being invited to take part in a study exploring health professional's attitudes towards a leaflet developed to encourage women to take part in HPV self-sampling (should it be available in the future).

Before you decide if you want to take part in this study, it is important for you to understand why the research is being done and what it will involve. Take time to read the following information carefully and discuss it with others if you wish. Part 1 of this information sheet tells you the purpose of the study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study.
If there is anything that is not clear or you would like more information please contact Denitza Williams, Department of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS or on 02920687142.

Part One

What is the purpose of this study?

We would also like to know what health professionals think about the proposed leaflet and to discuss how the leaflet would be best implemented if HPV self-sampling was available through the NHS.

Why have I been chosen?

You have been asked to take part because you are a health professional with expertise in cervical screening.

Do I have to take part?

No. It is up to you to decide if you want to take part in this study.
You are free to pull out of this study at any point and do not have to give a reason.

If you are interested in taking part, please keep this information sheet and sign the consent form.

What will happen to me if I take part?

Taking part would mean being interviewed about your thoughts regarding the information leaflet.

The interviews can be conducted over the telephone or face-to-face. The whole study should take no longer than 30 minutes.

What are the possible disadvantages of taking part?

Taking part in this study will be asked to comment on a HPV self-sampling leaflet. It is highly unlikely that anything should go wrong. If you would like to talk about any of the issues raised in this study, a contact name and details are provided at the end of this information sheet.

What are the possible benefits to taking part?

There will be no direct clinical benefit to you from taking part in this study. However, information we gather through this study will help us to understand what improvements may need to be made to the leaflet.

You will be given £10 as a 'thank-you' for participating in the study.

What if I don't want to carry on or if there is a problem?

You can pull out of this study at any time. It is highly unlikely that you may be upset or inconvenienced by this study. However, if you feel that you need to make a complaint about the way you have been approached or treated by the researcher, you should contact: Professor Adrian Edwards, Institute Director, Institute of Primary Care and Public Health, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS.

What will happen to the results of the research study?

Results from this study will be reported in scientific, policy and professional journals. You may request a copy of the study results.

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Who has reviewed this study?

This study has received ethical permission from The School of Medicine Research Ethics Committee, Cardiff University.

Who should I contact for more information about this study?

If there is anything that is not clear or you would simply like more information please contact Denitza Williams, Department of Primary Care and Public Health, Cardiff

University, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS. Email: stoilovado@cf.ac.uk Tel:02920687142 or 07877857292.

Further information on cervical cancer is available from Jo's Cervical Cancer Trust http://www.jostrust.org.uk/ and their helpline number is 0808 802 8000.

Appendix 6.7

Cardiff University Headed Paper

CONSENT FORM

Title of Project: Women's attitudes towards HPV self-sampling

Name of Researcher: Denitza Williams

Please initial box

1. I confirm that I have read and understand the information sheet dated 17/03/2014 (version 1) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐

4. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
		Signature
Researcher	Date	Signature

Appendix 6.8: Final version of draft HPV self-sampling intervention

Why is it important to take part in cervical screening?

Cervical screening can reduce your chance of getting cervical cancer.

Who is organising HPV self-sampling?

NHS Cervical Screening Services, the same people who are responsible for your smear tests.

What is HPV self-sampling?

HPV self-sampling is a quick and easy way of cervical screening that you can do at home. You will be sent a free self-sampling kit through the post by Cervical Screening Wales. HPV self-sampling looks for certain types of a virus called HPV.

What is HPV?

HPV (human papillomavirus) is the main cause of cervical cancer. There are many different types of HPV, some can cause changes to the cells of the cervix. If these changes are not treated they can lead to cervical cancer.

How can I get HPV?

HPV is a virus that is passed on through sexual contact. HPV is very common and most men and women will come into contact with it (even those who have only ever had one partner).

Can HPV be treated?

Changes in the cervix caused by HPV can be treated, but not the actual HPV. In most cases, the body's immune system clears up HPV on its own.

I have had the HPV vaccine, do I need to do HPV self-sampling?

Yes. You still need to take part in cervical screening if you have had the HPV vaccine.

What is good about HPV self-sampling?

You can do self-sampling at home. Self-sampling is less uncomfortable than smear tests. You do not have to book a clinic appointment, arrange childcare, or take time off work.

Is HPV self-sampling as good as a smear test?

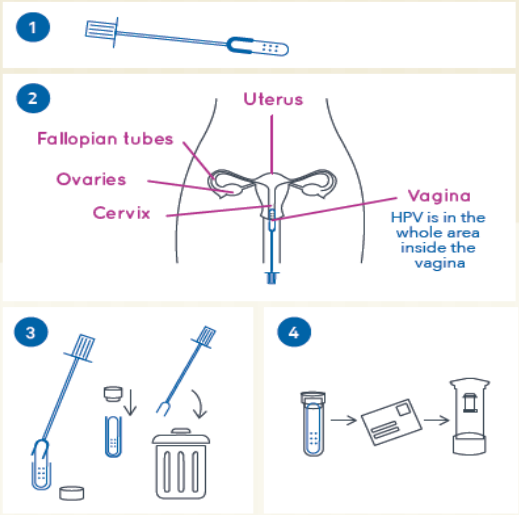
You may be used to going for smear tests but HPV self-sampling is a new type of screening test. Research has shown that HPV self-sampling is a good way of cervical screening [1].

I am not a doctor/nurse, can I do HPV self-sampling?

Most women can do HPV self-sampling properly [2]. You do not need to be a doctor/nurse to do HPV self-sampling. The self-sampling is very easy and the kit includes simple and clear instructions.

What if I do not reach far enough inside or I miss something?

HPV self-sampling is different to smear tests. You do not need to reach far inside your vagina. HPV is a virus so it will be in the whole area inside your vagina.



WHAT IS IT ALL ABOUT? ♀ TELL ME MORE ♀ 99 OUT OF 100 WOMEN CAN DO HPV SELF-SAMPLING PROPERLY ♀