NHS Cervical Screening Programme
Guidance for the training of cervical sample takers

Public Health England leads the NHS Screening Programmes
About Public Health England

Public Health England exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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## Glossary of terms/acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full details</th>
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<tbody>
<tr>
<td>ACCS</td>
<td>Advisory Committee on Cervical Cancer Screening</td>
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<tr>
<td>AGUS</td>
<td>Atypical glandular cells of unknown significance</td>
</tr>
<tr>
<td>ASCUS</td>
<td>Atypical cells of undetermined significance</td>
</tr>
<tr>
<td>CASH</td>
<td>Contraception and sexual health</td>
</tr>
<tr>
<td>CGIN</td>
<td>Cervical glandular intraepithelial neoplasia</td>
</tr>
<tr>
<td>CIN</td>
<td>Cervical intraepithelial neoplasia</td>
</tr>
<tr>
<td>CIN1</td>
<td>Cervical intraepithelial neoplasia grade 1</td>
</tr>
<tr>
<td>CIN2</td>
<td>Cervical intraepithelial neoplasia grade 2</td>
</tr>
<tr>
<td>CIN2+</td>
<td>Cervical intraepithelial neoplasia grade 2+</td>
</tr>
<tr>
<td>CIN 3</td>
<td>Cervical intraepithelial neoplasia grade 3, sometimes called high-grade or severe dysplasia. Also called cervical squamous intraepithelial neoplasia 3 and stage 0 cervical carcinoma in situ.</td>
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<tr>
<td>CPD</td>
<td>Continuing professional development</td>
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<tr>
<td>CWT</td>
<td>Cancer waiting times</td>
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<tr>
<td>FGM</td>
<td>Female genital mutilation</td>
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<tr>
<td>GUM</td>
<td>Genito-urinary medicine (clinic)</td>
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<tr>
<td>HCP</td>
<td>Health care professional</td>
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<tr>
<td>HG-CGIN</td>
<td>High grade cervical glandular intraepithelial neoplasia</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>HPV</td>
<td>Human papillomavirus</td>
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<tr>
<td>HRT</td>
<td>Hormone replacement therapy</td>
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<tr>
<td>HR-HPV</td>
<td>High-risk human papillomavirus</td>
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<tr>
<td>IUD</td>
<td>Intra-uterine contraceptive device</td>
</tr>
<tr>
<td>IMB</td>
<td>Inter-menstrual bleeding</td>
</tr>
<tr>
<td>LBC</td>
<td>Liquid-based cytology</td>
</tr>
<tr>
<td>LLETZ</td>
<td>Large loop excision of the transformation zone</td>
</tr>
<tr>
<td>LMP</td>
<td>Last menstrual period</td>
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<tr>
<td>NHSCSP</td>
<td>NHS Cervical Screening Programme</td>
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<tr>
<td>PAMVR</td>
<td>Physician Associate Voluntary Register</td>
</tr>
<tr>
<td>PMB</td>
<td>Post-menopausal bleeding</td>
</tr>
<tr>
<td>PNL</td>
<td>Prior notification list</td>
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<tr>
<td>PHE</td>
<td>Public Health England</td>
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<tr>
<td>SCJ</td>
<td>Squamocolumnar junction</td>
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<tr>
<td>TOP</td>
<td>Termination of pregnancy</td>
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<tr>
<td>TZ</td>
<td>Transformation zone</td>
</tr>
<tr>
<td>UK NSC</td>
<td>UK National Screening Committee</td>
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Aims of this guidance

This resource offers training guidance for new cervical sample takers involved in the NHS Cervical Screening Programme (NHSCSP). It aims to:

- outline the sample taker’s and training provider’s responsibilities in the NHSCSP
- promote training that is consistent with national policy recommendations
- advise on the training requirements and best practice for sample takers in the NHSCSP
- outline the audit and documentation training requirements for sample takers in the NHSCSP

This guidance replaces the previous NHSCSP publication ‘A Resource Pack for Trainers’ (April 2006). It provides a common core of learning for all sample takers to ensure consistency of sample taking and provides learning to a minimum recognised standard across the NHSCSP. It is designed to be used by appropriately regulated higher education providers and trainers. It is not intended to be used by clinical staff for unsupervised training.

This guidance represents best practice for the training of sample takers, for use in the training of:

- registered nurses
- registered midwives
- registered physicians associates
- medical doctors

Registered nurses, midwives and physician associates should complete a recognised theoretical course followed by a period of supervised practical training, both elements of which should be in accordance with this guidance. All doctors are expected to have completed an adequate level of theoretical and practical training as part of their specialist training. It is, however, recommended that doctors undertake this recognised cervical screening training.

The NHSCSP requires physician associates to be registrants on the Physician Associate Managed Voluntary Register (PAMVR) to be eligible to undertake cervical sample taker training. It is the education provider’s responsibility to ensure that a physician associate is registered at the application stage.

A cervical screening test is an intimate examination. A trained and competent registered professional can provide the appropriate communication, empathy, skill and assurance
required for each individual. A competency framework for cervical cytology sampling
developed by Skills for Health acknowledges that sample taking is not a standalone task
but requires an appropriate level of clinical skill and experience. The competency
framework CHS37 ‘Obtaining cervical cytology samples from women’ can be found at:
https://tools.skillsforhealth.org.uk/competence/show/html/id/1030/

This guidance complies with the competency framework.

Please note: The terms ‘women’ and ‘woman’ in this guidance denote anyone eligible
for cervical screening. This includes women and trans men who still have a cervix.

Organisation and delivery of training

Initial training

Training for sample takers should comprise theoretical learning followed by a period of
practical training.

Independent training providers should ensure their training provision is endorsed and
regulated by an appropriate professional body. An appropriately regulated higher
education provider (or similar professional body) should deliver training in screening
theory. Training should be quality assured. The training institution should be able to
demonstrate the ability to meet the competencies set out in this guidance.

Input to the programme should include all the appropriate professionals involved
throughout the cervical screening programme.

The length of the course will depend on the prior knowledge and experience of the
trainee. It is recommended that training consists of at least one full day of face-to-face
learning plus specified pre-course learning or reading activity.

Practical training should take place in the clinical area where the trainee is based. It
should be supervised by the mentor (see criteria for sample taker mentoring below).
Trainees should keep a record of their training. During practical training the trainee
should visit the colposcopy clinic, documenting and reflecting on their visit in their
training record book. Laboratory visits are also recommended. If this is not possible, a
virtual laboratory tour via a media link is an acceptable alternative. This should take
place in addition to the theoretical training.
Training mentors/supervisors

Cervical screening training mentors (called ‘supervisors’ in some areas) will enable and support best practice in relation to the practical elements of the cervical screening training programme. Mentors will sign off trainees as being competent and proficient in cervical screening practice. Sign-off confirms to the programme provider that the trainee is proficient in the competencies within the competency framework ‘CHS37 – obtaining cervical cytology samples’ and is capable of safe and effective practice.

Mentors must be a registered nurse, doctor or physician associate. Mentors should have effective teaching and communication skills and ideally hold a relevant mentoring and/or teaching qualification. They must:

- be practising sample takers
- have had 12 months’ continuous experience following completion of initial training
- have undertaken a minimum of 50 samples following completion of initial training

Additionally, the mentor must be able to show continuing competence in taking samples for cervical screening with particular reference to:

- equipment and sample preparation
- sampling technique
- transformation zone sampling
- audit of results and feedback from trainees

Maintaining competence as a mentor

A mentor should undertake a cervical screening update training at least every three years. As practicing sample takers they should ensure continued competence in accordance with their professional codes of conduct. They should undertake continuous self-evaluation. They should audit and reflect on their individual rates of inadequate and abnormal test results compared with the rates reported by the local laboratory.

Trainee training records

Training records are vital to the cervical screening training process. Each trainee must keep a record of their training in a personal clinical training record book. This should include a record of:

- the theoretical training
- the colposcopy clinic visit
Guidance for the training of cervical sample takers

- the laboratory visit or virtual tour
- all practical training

The practical training record should include all the observed, supervised and unsupervised samples and final assessment. Training providers may provide training record books as part of the course resource.

Refer to the appendices for templates to use for recording training.

**Practical training**

The training mentor should accompany the trainee for the first practical session/s. The trainee should:

- identify training needs in discussion with the mentor
- observe at least two samples being taken
- take a minimum of five samples under supervision

The mentor and trainee then decide whether the trainee may proceed without further direct supervision. Once they have confirmed this, the trainee should arrange to take and document a minimum of 20 unsupervised samples. Easy access to a trained colleague is essential throughout this period.

**Final assessment**

All training should be completed within a nine-month period.

Both mentor and trainee should maintain regular contact and to discuss progress towards meeting identified training needs, including identifying any problems. A final evaluation session should be undertaken, which should include a final clinical assessment. Before the final assessment, the trainee must have completed a minimum of 20 adequate cytology samples with evidence of transformation zone sampling (in women under 50 years old).

Final assessment requires a minimum of three samples.
Failure to complete training

Trainees who are unable to complete the training within nine months should be referred back to the training provider. It is up to the trainer to decide if an extension may be granted. If the trainee does not complete training by 12 months, they should repeat the theory and practical training course.

Any trainees who fail to gain competency after completing the course will need to repeat the course in full.

Any trainee unable to complete the course in the designated time should stop taking samples. They should inform their employer and laboratory.

The training provider has a responsibility to inform the trainee’s employer and local laboratory service provider of individuals who have been unable to complete the course satisfactorily.

Maintaining competence

Sample takers should undertake continuous self-evaluation to help ensure continued competence in accordance with their professional codes of conduct. They should audit and reflect on their own rates of inadequate tests and abnormal test results compared with the rates reported by the local laboratory.

If a sample taker has successfully completed all initial training and assessments but has any extended period of time away from practice, they should complete a training update in cervical screening to ensure they are familiar with any changes in the programme. The sample taker will need peer review for a short period of time, to cover the initial five samples taken.

Update training

Sample takers should undertake a minimum of one half-day update training every three years. E-learning modules may be used if they fulfil national and local requirements and should equate to three hours of learning. An appropriately regulated higher education provider or similar professional body should deliver quality-assured update training. Appropriate professionals involved throughout the NHS cervical screening programme should provide input to the update training programme. Independent training providers should ensure their training provision is endorsed and regulated by a royal college and/or professional body. Whether E-Learning or face-to-face sessions, the update training must cover:

- current developments in the NHSCSP, nationally and locally
• recent literature relevant to sample taking, sampling devices, human papillomavirus (HPV) infection, vaccination and individual's needs
• changes to screening policies and procedures
• identification of personal learning needs
• qualitative assessment of 20 recent consecutive samples produced by the sample taker, looking at reflective practice, ideally transformation zone sampling and positive pick-up rates
• learning from incidents in the programme

Note: the NHSCSP will provide a nationally approved and free to access E-Learning resource in 2017. Sample takers will be able to use this for the above continuing professional development (CPD).

Screening theory

Theoretical training for sample takers must cover all the competencies outlined in the Skills for Health competency framework. The length of the course will depend on prior knowledge and experience, but it is expected to last at least one full day or equivalent. The training should cover all aspects of the programme and should include the subject areas outlined below.

Session A: The NHS Cervical Screening Programme

A1: Aims of the NHS Cervical Screening Programme (NHSCSP)

The aim of the NHSCSP is to reduce the number of people who develop invasive cervical cancer (incidence) and the number of people who die from it (mortality). It does this by offering regular screening to eligible people to identify and treat conditions which might otherwise develop into invasive cancer.

A2: History of the cervical screening programme

Trainees should have background knowledge of the screening programme, including the following significant developments:

1. Cervical screening began in the mid-1960s
2. The NHSCSP was set up in 1988 with the introduction of computerised call and recall systems
3. Liquid-based cytology (LBC) was introduced in the programme in 2004. This has significantly reduced the amount of inadequate cervical screening results.

4. The national HPV vaccination programme was introduced in 2008. England started offering HPV vaccination to all girls aged 12 to 13. The objective of the HPV vaccination programme is to provide HPV vaccine to females before they reach an age when the risk of HPV infection increases and they are put at subsequent risk of cervical cancer.

5. The cervical screening programme introduced HPV triage and test of cure in 2012.

6. Approval has been granted for the introduction across England of HPV primary screening in 2019.

A3: Current statistics/success of the programme

Trainees should be familiar with current information about:

- the total number of women aged 25 to 64 invited for screening in England
- the number of women aged up to 65 tested in England
- the percentage of eligible women aged 25 to 64 screened at least once in the previous five years
- the annual cost of cervical screening, including the cost of treating cervical abnormalities in England

The training provider must provide current information/data.

A4: Important elements in the success of the programme

Trainees should be familiar with both the accomplishments and issues of the screening programme including:

- the identification and invitation of all eligible individuals at appropriate screening intervals (eligible individuals are those aged between 25 and 64 years who have a cervix)
- the achievement of at least 80% coverage of eligible individuals
- the availability of information for individuals to help them make an informed choice about whether or not to come for cervical screening
- the importance of a team approach to ensure continuity of care for the individual
- quality assurance processes supported by clear administrative and clinical protocols
- acknowledging the barriers to screening
- being aware of the psychological aspects of intimate examinations
A4a: The individual’s perspective: what influences cervical screening uptake?

The sample taker plays a crucial role in the individual’s experience. This includes putting them at ease, giving correct information and discussing results and possible treatment options should the results be abnormal. A negative experience could result in confusion regarding HPV (its links to causing cervical cancer and risk factors around contracting it), anxiety about the procedure itself and could potentially stop an individual choosing to re-attend.

There are many barriers that prevent women attending cervical screening. The trainer should discuss:

- accessibility – finding time to attend (getting an appointment at a convenient time) and choice of where to be screened (sexual health clinic, GP surgery)
- fear – fear of the test itself, embarrassment, fear of the test being painful, a previous bad experience at screening, post-natal concerns due to trauma during birth, a history of sexual assault or rape
- pain – experiencing pain or discomfort during the test is a reason why women may not re-attend. This is particularly important for post-menopausal women.
- knowledge and education of screening – relevancy of screening, knowledge of the test and understanding the role of screening in preventing cancer, levels of health literacy
- cultural impact – relevancy according to marital status or sexual activity, fear the sample taker may be male, community/social pressure and stigma

The trainer should signpost trainees to data and information available at: https://www.jostrust.org.uk/about-us/our-research.
For more on people’s experiences of screening go to the Jo’s Cervical Cancer Trust online forum: https://www.jostrust.org.uk/forum.

Trainers should use these resources to highlight the barriers to screening, for example, through use of quotes and personal testimonies. Discussion of ways to overcome these barriers should take place.
A5: Recommended screening intervals

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Frequency of screening</th>
</tr>
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<tbody>
<tr>
<td>24.5</td>
<td>First invitation</td>
</tr>
<tr>
<td>25 to 49</td>
<td>Three-yearly</td>
</tr>
<tr>
<td>50 to 64</td>
<td>Five-yearly</td>
</tr>
<tr>
<td>65+</td>
<td>Invitation as required for women who have had recent abnormal tests. Women who have not had an adequate screening test reported since age 50 may be screened on request.</td>
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</tbody>
</table>

We send out a woman’s first invitation for routine screening six months before she turns 25. This ensures that the individual can be screened by the age of 25.

All subsequent invitations to screening are sent around six weeks before the individual’s test due date.

A delay of several months may occur between the issuing of invitations to women and the date of their screening test. Sending invitations well before test due dates reduces possible delays.

Transgender (trans) men who still have a cervix are eligible for screening. Trans men registered with their GP as female will receive automatic screening invitations. Trans men registered as male won’t get an invitation, but remain entitled to screening and are welcome to arrange an appointment with their GP practice every three to five years (depending on their age). (See also section D9.)

Women under the age of 25 are not invited for cervical screening for a number of reasons:

1. Cervical cancer is very rare in women under 25. Each year in the UK approximately two out of every 100 women diagnosed are under 25. In countries where screening starts at 20, rates of cervical cancer in women under 25 are not significantly different than in countries that start screening at 25.
2. Infection with high risk HPV is very common in women under 25 and may cause abnormal cell changes of the cervix. But for most women these cervical abnormalities will regress as the immune system clears the HPV infection.
3. An abnormal screening result and treatment for cervical abnormalities can cause anxiety for many individuals. As most young women will clear abnormalities without treatment, screening, identifying and treating changes in women under 25 would cause more harm than benefit.
4. The International Agency for Research on Cancer recommends that women should not start cervical screening before the age of 25
5. In 2012, the UK NSC advised the NHSCSP that screening under 25 does more harm than good and recommended that there is a consistent screening age across the whole of the UK. From June 2016 all four nations screen from age 25
6. The number of younger women diagnosed with cervical cancer is likely to reduce due to the NHS HPV vaccination programme introduced in 2008 which routinely offers the vaccine to girls aged 12 to 13
7. Any individual under 25 who has symptoms or is concerned about their risk of developing cervical cancer or about sexual health generally should contact their GP or genito-urinary medicine (GUM) clinic. Screening is not a test for symptoms

‘The Clinical Practice Guidance for the Assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding’ (Department of Health, 2010) states that women experiencing vaginal bleeding after sex and in-between periods require a pelvic examination. Vaginal bleeding is extremely common and can be caused by a range of different problems, including cervical ectropion, hormonal changes due to the contraceptive pill or benign cervical polyps or sexually transmitted infections such as chlamydia. The guidance explains the types of questions that practice nurses and GPs need to ask in order to establish if symptoms could be related to cervical cancer. A trained nurse, doctor or registered physician associate may perform a speculum examination. A trained GP can perform a pelvic exam.

We do not invite women over the age of 64 for cervical screening because:

- the natural history and progression of cervical cancer means that it is highly unlikely that such women will go on to develop the disease; women aged 65 and over who have had three consecutive negative tests are therefore taken out of the call and recall system
- women aged 65 and over who have never been screened are entitled to a test if they request one

**Women who are not sexually active**
The NHSCSP invites all eligible women between the ages of 25 and 64 for cervical screening. However, if an individual has never been sexually active, research evidence shows that their chance of developing cervical cancer is very low indeed. This is not ‘no risk’, only very low risk. In these circumstances, an individual might choose to decline the invitation for cervical screening.

If an individual is not currently sexually active but has had sexual partners in the past, it is recommended that they continue to attend for screening.
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Non-NHS cervical screening tests
Tests carried out privately or abroad do not affect an individual’s entitlement to an NHS screening test. The NHS has no responsibility for the quality of non-NHS tests, although the results may be recorded on an individual's NHS screening record to complete their screening history.

A6: Unscheduled screening tests
If an individual is in the age group to be screened and has had a test in the previous routine screening interval (three to five years), additional tests should not be carried out. The following are not circumstances for additional tests:

- when attending for contraceptive advice or services
- when attending for advice on hormone replacement therapy
- during pregnancy or when attending for postnatal services
- women with genital warts
- women with vaginal discharge
- women with infection
- women who have had multiple sexual partners
- women who are heavy cigarette smokers

If unscheduled samples are taken they will not be accepted by the laboratory. However, the sample taker should explore the reason/s for the individual requesting screening.

A7: Population screening programmes – GOV.UK website
Find information about the NHSCSP at:
https://www.gov.uk/topic/population-screening-programmes

The information includes an overview of the cervical screening programme, copies of cervical screening information leaflets, professional guidance, guidance on informed consent for screening and managing incidents in the NHS screening programmes.
Session B: The background to cervical screening

B1: Epidemiology, natural history of cervical cancer including human papillomavirus

Epidemiology
Trainers should provide an overview of epidemiology, covering information such as:

- cancer of the cervix uteri is the second most common cancer among women worldwide; approximately 80% of cases occur in developing countries and in many regions cervical cancer is the most common cancer in women
- in Europe, around 24,400 women were estimated to have died from cervical cancer in 2012. The UK mortality rate is the ninth lowest in Europe
- worldwide, more than 265,000 women are estimated to have died from cervical cancer in 2012, with mortality rates varying across the world
- cervical cancer is the twelfth most common cause of cancer deaths in women in the UK accounting for about 2% of all cancers in women in the UK
- over 3200 women were diagnosed with cervical cancer in 2013 in the UK
- deaths from cervical cancer have fallen in England by over 70% since the early 1970s, with the lowest number (721) recorded in 2013
- 83% of women survive cervical cancer for at least one year
- 67% of women survive for five years or more for patients diagnosed with cervical cancer during 2010-2011 in England and Wales
- it is estimated that cervical screening saves approximately 4500 lives per year in England
- over three-quarters (78%) of cervical cancer cases were diagnosed in 25 to 64 year olds, and an average of 11% of cases were diagnosed in women aged 75 years and over in the UK between 2010 and 2012

Data sourced from:
National Cancer Intelligence Network (NCIN)
ncin.org.uk/cancer_type_and_topic_specific_work/cancer_type_specific_work/gynaecological_cancer/gynaecological_cancer_hub/resources/cervical_cancer#keyfacts
Cancer Research UK-Cancer statistics for professionals (Accessed August 2016)
http://www.cancerresearchuk.org/health-professional/cancer-statistics

Natural history of cervical cancer
Cancer of the cervix can take many years to develop. Cervical screening is designed to detect cell changes called cervical intraepithelial neoplasia (CIN), which may develop into cervical cancer if left untreated.

Changes in the glandular cells which line the cervical canal are reported as cervical glandular intraepithelial neoplasia (CGIN). These cells may develop into
adenocarcinoma if left untreated. CGIN is much less common than CIN. Screening by cervical cytology is a less reliable way to detect CGIN than CIN.


**Human papillomavirus**

There are around 100 types of HPV. Most do not cause significant disease in humans. However, some subtypes (notably types 16 and 18) have been confirmed as agents causing cervical cancer. Unlike subtypes 6 and 11 (which cause genital warts) these ‘high-risk’ (HR) types do not produce visible symptoms.

Almost all cervical cancers (99.7%) contain high risk (HR) HPV DNA. Looking at cases of cervical intraepithelial neoplasia (CIN), the higher the grade of CIN, the more frequently HR-HPV is found. This suggests that women who do not have HR-HPV are extremely unlikely to develop cervical cancer in the short to medium term.

HR-HPV infection is common, especially in women under 35. In most cases, infection is transient, and is cleared by the woman’s immune system. However, for reasons that are not yet known, around 20% to 30% of women do not clear the virus. This group is at most risk of CIN that may eventually develop into cervical cancer.

**Method of HR-HPV infection**

Most cases of HR-HPV are sexually transmitted. HR-HPV is easily transmitted during sexual contact between men and women and between same-sex partners. However, there are two important factors to bear in mind:

1. HR-HPV is asymptomatic, so it may have been present and undetected for many years. Infection could have nothing to do with a woman’s current relationship
2. A partner may have acquired the virus many years earlier and passed it on unknowingly

Women may therefore be reassured that a positive test result for HR-HPV types need not imply infidelity or promiscuity by either partner.

**B2: Risk factors for cervical cancer**

Factors that increase risk include:

- not attending for screening
- persistent infection with high-risk human papillomavirus
- many sexual partners (or a sexual partner with many sexual partners)
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- smoking
- immunosuppressive disorders, including HIV infection
- the contraceptive pill
- having children at a young age
- sexual debut at a young age

Factors that reduce risk include:

- regular attendance for screening
- regular condom use
- late first pregnancy
- total hysterectomy for other reasons

B3: Principles of screening

The World Health Organisation (WHO) published a paper by Wilson and Jungner in 1968, outlining 10 criteria upon which to base the decision whether to screen for a condition:

1. The condition sought should be an important health problem
2. There should be an accepted treatment for patients with recognised disease
3. Facilities for diagnosis and treatment should be available
4. There should be a recognisable latent or early symptomatic stage
5. There should be a suitable test or examination
6. The test should be acceptable to the population
7. The natural history of the condition, including development from latent to declared disease should be adequately understood
8. There should be an agreed policy on whom to treat as patients
9. The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
10. Case finding should be a continuing process and not a ‘once and for all’ project

B4: Effectiveness and limitations of cervical screening

Cervical screening is a beneficial programme which saves lives by preventing the development of cervical cancer. It should, however, also be acknowledged that it has some limitations and drawbacks, such as:

- cervical screening can detect minor abnormalities in cervical cells which would have cleared up on their own without women ever knowing about them
- many women worry when a minor abnormality is found
• cervical screening is not a diagnostic test and does not pick up every abnormality of the cervix
• regular cervical screening can prevent around 75% of cervical cancers developing, but it does not prevent every case
• some women find having the test a painful, uncomfortable or embarrassing experience

B5: Future developments for cervical screening

High-risk human papillomavirus (HR-HPV) testing is proven to be superior to cytology in terms of sensitivity for high grade cervical intraepithelial neoplasia (CIN) and high negative predictive value.

The ARTISTIC trial (A Randomised Trial of HPV Testing in Primary Cervical Screening) investigated HPV as a primary screening test. The trial was to provide evidence about the contribution which HPV testing could make to the cervical screening programme, either in addition to cervical cytology, or as a standalone test.

The UK NSC advises ministers and the NHS in the four UK countries about all aspects of population screening and supports implementation of screening programmes. In November 2015 the UK NSC recommended the cervical screening programme should adopt HPV as the primary screening test. Using HR-HPV testing in this way has several benefits. HR-HPV testing is known to be more sensitive for high-grade CIN than cytology and gives a high negative predictive value, thus potentially allowing women to be screened less frequently in the future. HPV primary screening may also be a more appropriate screening modality when HR-HPV vaccinated women start to enter the cervical screening programme.

Primary HPV testing by the use of HPV self-sampling kits is a strategy that may encourage women who have not previously attended to be screened.
Session C: Organisation of the NHS Cervical Screening Programme

Figure 1 below outlines the core and supporting activities relating to the NHS Cervical Screening Programme

Figure 1: NHSCSP activities

- Core activity
- Supporting activity

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<th>Core activity</th>
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C1: Screening protocols

Each practice or clinic where cervical samples are taken should have access to copies of screening protocols based on the national guidance for the cervical screening programme. Copies of current guidance can be accessed online at: https://www.gov.uk/government/collections/cervical-screening-professional-guidance
Sample takers should know:

- the arrangements for call and recall
- the arrangements for women to be notified of their test results
- the content of standard letters and leaflets
- how to fill in the test request form correctly
- the importance of correct handling and labelling of the sample
- how to obtain supplies and which ones are recommended for use
- approximate times for the return of results from the local laboratory
- failsafe procedures for all test results
- local arrangements for referral to colposcopy
- that this is an appropriate sample within the appropriate screening interval

C2: Sample taker responsibilities

Sample takers are responsible for:

- only taking samples if they have met the initial training and subsequent three-yearly national update training requirements
- identifying any personal training needs
- keeping up-to-date with changes in the programme and current best practice
- maintaining competency and monitoring their own practice by undertaking sample taker audit
- accountable for all use of their allocated sample taker code
- ensuring that the woman is provided with the necessary information and advice to assist her in making an informed choice about whether to accept the offer of screening
- taking the cervical sample in the appropriate manner
- ensuring the woman is informed of her test result
- ensuring that the test result is followed up appropriately
- communicating appropriately with the woman if her sample is rejected and advise when another sample should be taken
- ensuring referrals take place for woman who require further investigation and treatment
- cooperating with failsafe enquiries in a timely manner
- ensuring reasonable adjustments are offered for women who need additional support
- ensuring adverse events and incidents are recorded, discussed and investigated
C3: Commissioning

NHS England (NHS E) works closely with PHE and the Department of Health to provide and commission a range of public health services.

The public health functions agreement (section 7A) is an annual agreement between the Secretary of State for Health and NHS England. It sets out the arrangements under which the Secretary of State delegates responsibility to NHS England for certain public health services including cervical screening. The agreement aims to improve public health outcomes and reduce health inequalities and to contribute to a more sustainable public health, health and care system.

Section 7A outlines the arrangements for commissioning the cervical screening programme. The specification includes all stages of the screening pathway. The service provided by organisations must be consistent with national guidance from the screening programme (including NHSCSP best practice guidance).

For cervical screening NHS England must ensure that arrangements are in place to:

- verify the appropriateness for the screening of women on call and recall lists
- ensure that eligible women who are not on NHS lists have access to screening, and that local arrangements are made to cover residential institutions, including prisons
- ensure that all equipment used complies with national equipment standards
- ensure that staff working in the programme are trained to meet the required standards of competence and are actively involved in continuing personal and professional development

This includes collaborating with laboratories to ensure the provision of:

- sample taker registers
- feedback both by individual sample taker and by general practice/clinic on reporting profiles, workload, and error rates (for example incomplete patient identity details)

Information on public health commissioning including the current section 7A agreement and ‘Service Specification No.25 Cervical Screening’ can be accessed at: https://www.england.nhs.uk/commissioning/pub-hlth-res/
C4: Call and recall

A fundamental principle of any screening programme is to ensure that all individuals who are eligible for screening receive appropriate invites to participate in a timely manner. This is an administrative process and often referred to as the ‘call and recall’ function where:

- ‘call’ is the initial invite to participate in screening for the first time
- ‘recall’ is the invitation to participate in future rounds of screening at appropriate intervals dictated by programme policy

The call and recall system:

- generates lists of women who are due to be invited for cervical screening
- sends invitation letters and reminder letters to women due for screening
- records test results on a woman’s screening history
- sends result letters to women to inform them of their test result

C5: General practice

GP practices are responsible for:

- understanding contractual obligations and responsibilities
- ensuring that all members of staff involved in delivery of the cervical screening programme:
  - comply with national guidance and quality standards.
  - participate in audit
  - are aware of mechanisms by which they can raise concerns, identify risks and report incidents
  - are adequately trained
  - attend regular updates
- keeping adequate records to show that the employer has monitored the above
- reporting areas of concern to their local commissioners
- ensuring that all sample takers provide women with the necessary information and are able to advise women in making an informed choice about whether to accept the offer of screening
- making adequate arrangements and reasonable adjustments as required, to enable patients to access cervical screening
- ensuring processes are in place to inform women of their test results
- ensuring failsafe is in place so test results are followed up appropriately
- ensuring adequate referral processes are in place so women who require further investigation and treatment are managed appropriately
- ensuring processes are in place to respond to failsafe enquiries
• working to improve the uptake and coverage of the cervical screening programme

There may be circumstances where a woman does not wish her test result to be sent to her home address or may not have a correspondence address. The sample taker should agree with the woman on an appropriate arrangement for her to collect her test result and should document the details on the test request.

C6: Other clinicians who provide cervical screening services

Clinicians who provide cervical screening services in other settings (such as CASH clinics or GUM clinics) are responsible for:

• ensuring that women are provided with information and advice to enable them to make an informed choice about whether to accept the offer of screening
• making arrangements for taking cervical samples
• referring women for further investigation if necessary
• cooperating with laboratory failsafe enquiries

In exceptional circumstances where a woman does not wish her test result to be sent to her home address or notified to her GP, the sample taker should agree with the woman on an appropriate arrangement for her to collect her test result and appointment details for any necessary follow-up. They should document the details on the test request.

C7: Cytology laboratories

Cytology laboratories that participate in the NHSCSP:

• screen cervical samples and perform HPV testing which are accompanied by an adequately completed test request form or electronic request
• allocate a result code and recommendation for management depending on the degree of abnormality seen
• notify test results and recommendations for management to the call and recall system using standard action and result codes
• inform the GP or clinician responsible for requesting the test if a woman requires urgent referral for colposcopy
• set up and operate a laboratory failsafe system for women who require further investigation or treatment
• provide laboratory visits or a virtual tour
• may have arrangements for direct referral for colposcopy
C8: Colposcopy clinics

Colposcopy clinics that participate in the NHSCSP:

- investigate and treat women with abnormal test results
- provide follow-up after treatment or discharge women back to routine recall
- cooperate with laboratory failsafe enquiries
- may take cervical samples from women referred because their cervix is difficult to visualise

A woman may be referred for colposcopy without waiting for her test result if an abnormality of the cervix is identified when the cervix is visualised, or if she has symptoms which are suspicious of abnormality.

C9: Hospital-based programme co-ordinators

The hospital-based programme co-ordinator role is a requirement of the programme. This role may be based in a cytology or histology laboratory or in a colposcopy clinic and is responsible for:

- ensuring that systems are in place for transferring test results from the laboratory to the call and recall system
- collating histology results with cytology test results
- ensuring that laboratory failsafe measures are initiated if necessary
- taking a lead role in the audit of invasive cervical cancers

C10: Quality assurance

Quality assurance of screening programmes in England became the responsibility of PHE in April 2013. The PHE Screening Quality Assurance Service (SQAS) is part of the screening division within the Health and Wellbeing directorate and works alongside NHS screening programme teams.

Cervical screening QA begins with the identification of eligible women and includes sample taking, cytology, colposcopy and histopathology. It ends with the diagnosis of cancer, completion of the screening programme at 65 years of age, or the ending of a surveillance period, whichever is later.

The SQAS is responsible for:

- evaluating the quality of local cervical screening programmes
- supporting quality improvement activities
- arranging QA visits to laboratories and colposcopy clinics
• monitoring primary care elements of local cervical screening programmes
• advising on incident management, sharing the lessons learnt/recommendations

C11: National co-ordination

PHE Screening leads the national population screening programmes, which are delivered by the NHS. The NHSCSP is 1 of 11 population screening programmes, and is one of the Young Person and Adult (YPA) programmes together with NHS breast, bowel cancer, diabetic eye and abdominal aortic aneurysm screening. PHE Screening is responsible for:

• improving the overall performance of the programme
• publishing guidance and developing standards designed to assure a high quality of cervical screening
• producing and improving communications and information within the programme and to individuals eligible for screening

Session D: Equality of access to cervical screening

D1: Making an informed choice

All women must be given the opportunity to make an informed choice about whether or not to attend for cervical screening. The decision should be based on an understanding of:

• why they are being offered screening
• what happens during the test
• the benefits and risks of screening
• the potential outcomes (including types of result, further tests and treatment)
• what happens to their screening records

If a woman is provided with the above information about the programme and chooses not to attend screening, then this is a valid choice and must be respected.
Guidance for the training of cervical sample takers

D2: Information accompanying the cervical screening invitation

We send an information leaflet with every invitation letter to women called or recalled for routine screening. The leaflet includes an explanation of the benefits and difficulties of cervical screening, what happens during the test, and what an abnormal result might mean. The leaflet also informs women about the use of screening records for audit and other purposes.

A copy of the current leaflet is available at: https://www.gov.uk/government/publications/cervical-screening-description-in-brief
A range of language translations is also available, and alternative formats can be made available on request (such as easy read leaflets or braille versions).

D3: Checking for understanding

Sample takers should support informed choice by checking that women who attend for cervical screening:

- understand the purpose of the cervical screening test and its benefits and limitations
- understand that the procedure involves taking a sample of cells from the cervix to look for abnormalities
- understand it is not a test for diagnosing cervical cancer

Sample takers may need to provide additional information and support to women on an individual basis.

D4: Women from minority ethnic groups

There is evidence that many women from minority ethnic groups have had negative experiences of cervical screening. Language and cultural differences can affect understanding. It is important that sample takers are aware of this and take measures to try and ensure all women understand the purpose of the screening programme and the procedure for taking the sample.

Sample takers should be aware of the importance of:

- training for primary care teams in cultural awareness
- the inclusion of cervical screening in health education for minority ethnic women
- providing written information about screening in an appropriate language (if possible)
- language support, if appropriate, for women during sample taking
D4a: Female genital mutilation (FGM)

FGM is mutilation of the labia majora, labia minora or clitoris. The practice is prevalent in many African countries, parts of the Middle East and Asia. It may also be referred to as ‘cut’, ‘circumcision’ or ‘female circumcision’. FGM has been illegal in the UK since 1985. There are four recognised types.

Type 1: Clitoridectomy: part or total removal of the clitoris.
Type 2: Excision part or all of the clitoris and labia minora with or without excision of the labia majora.
Type 3: Infibulation: a narrowing of the vaginal opening with the creation of a covering seal formed by cutting and repositioning the labia minora and/or majora, with or without removal of the clitoris
Type 4: Other, including pricking, incising, scraping, or cauterising the female genital area for non-medical reasons

Sample takers may have difficulty in passing the speculum in women who have undergone FGM.

Complications from FGM may include:

- difficulty passing urine and a history of recurrent or chronic urinary infections
- difficulty with menstruation
- superficial dyspareunia or apareunia
- recurrent abscesses or cysts particularly in the clitoral area
- complications in pregnancy and childbirth
- ongoing psychological trauma from the time of the initial FGM

If medical complications are encountered, sample takers should consider referral to a local FGM service to confirm FGM status and possible need for de-infibulation. There are 10 clinics across London and five clinics in the rest of the country. Alternatively, consider onward referral to specialist gynaecology and/or counselling services.

It is important for the sample taker to be aware that a woman who has undergone FGM may be a vulnerable adult. If the sample taker considers this to be the case, or if there may be a risk to other female family members, they should complete a safeguarding risk assessment or discuss the case with their safeguarding officer and share the information with multi-agency partners, for example, health visitors, school nurses or practice nurses, to initiate a safeguarding response.
Reporting of FGM in women under 18 is mandatory but out of scope of the screening population. There is a requirement to record data on FGM as set out in the DH guidance available at:

D5: Women with learning disabilities

Sample takers should understand that women with learning disabilities:

- have the same right of access to cervical screening as other women
- cannot be assumed to be sexually inactive
- are entitled to information to make their own decision about cervical screening
- may require reasonable adjustments to support their cervical screening

Sample takers should be able to seek specialist advice if necessary.

An 'easy read' leaflet is available which has been designed to be used by women with learning disabilities alongside family members or carers. The leaflet is intended to help them to make their own decisions about cervical screening, and to prepare them for the screening process. The leaflet can be accessed at:

Further resources are available from:
www.jostrust.org.uk/smeartestfilm
https://www.jostrust.org.uk/download/file/fid/73710

Trainers may wish to seek additional information about any local initiatives that support people with learning disabilities.

D6: Preparation for women with learning disabilities

Sample takers who work with women with learning disabilities should be confident and experienced in taking cervical samples. They should be aware of the importance of:

- establishing that the woman has an understanding of cervical screening
- preparing the woman to have the test

A preliminary visit to the practice or clinic before the woman attends to have the sample taken may be helpful. Scheduling a longer appointment time may also be beneficial, so that the individual has more time to relax and become familiar with her surroundings and with the sample taker.
When the woman attends for a test, the sample taker should check for behavioural signs of compliance with the procedure. This is especially important when screening women for whom it may be difficult to ascertain their level of understanding or consent.

There are six behavioural signs to look for:

1. Is the woman relaxed and cooperative?
2. Is she able to keep still?
3. Is she willing to get undressed?
4. Is she willing to be positioned?
5. Is she willing to accept having the speculum passed?
6. Does she maintain awareness throughout?

Lack of co-operation by the woman, or distress in any way, must be recognised as the woman’s choice not to have the test. The woman should be offered another appointment if she needs more preparation and reassurance.

D7: Women with physical disabilities

Sample takers who work with women who are physically disabled should be confident and experienced in taking cervical samples. Some women’s physical disabilities may prevent them from achieving a position where the cervix can be visualised and a cervical sample taken. This may include women with severe arthritis or very severe obesity. The sample taker should consider:

- access to the venue (can an alternative be offered?)
- the height of the couch
- the woman’s physical limitations
- the possibility of a domiciliary visit
- the need for assistance
- seeking specialist advice if necessary

For paraplegic women, the sample taker may need to make special arrangements, for example with the local colposcopy service, to take a sample at a clinic where a hoist is available.

D8: Women who are not registered with a GP

If a woman is not registered with a GP, the sample taker should:

- give the woman a copy of the information leaflet in an appropriate format
- ensure the woman understands the purpose of the test
- make appropriate arrangements for the woman to receive her test result
• make appropriate arrangements for follow-up if the test result is abnormal
• explain to the woman that she may not receive invitation letters for future screening unless she registers with a GP

D9: Female to male transgender individuals (trans men)

A trans man who is registered with his GP as male, and who is aged between 25 and 64 and still has a cervix, is eligible for cervical screening. Individuals registered as male cannot currently be accommodated by the screening invitation and result notification system. However screening can be organised by GP practices or the team managing the gender reassignment process. It is important to ensure that there is a system in place for the result of a test to be communicated to the individual, and to ensure that any necessary follow-up tests, referrals or other actions are completed appropriately. A trans man registered as female, and who is aged 25 to 64 and still has a cervix, will continue to receive routine invitations for screening. (See also section A5.)

D10: Automatic ceasing from cervical screening for reasons of age

Automatic ceasing of a woman from the cervical screening programme happens:

• following the first negative test result after turning 60 if none of her last three adequate test results were abnormal and she would otherwise be on routine recall
• following the first non-response to a screening invitation after her 60th birthday if she has never attended for a test

This means that her name is permanently removed from the screening register and she is no longer sent invitations for cervical screening.

D11: Other circumstances for ceasing from cervical screening

A woman may only be permanently ceased from the cervical screening programme for one or more of the following reasons, if:

• she has no cervix (for example, women with a total hysterectomy, women with congenital absence of the cervix, or male to female transsexuals (trans women)
• she has had radiotherapy to the pelvic area for cancer of the cervix, bladder or rectum
• she has undergone a radical trachelectomy for cervical cancer
• she is over 65 with one or more abnormal results in her last three adequate tests but her GP or gynaecologist advises that she no longer requires screening
• she has asked to be ceased from the screening programme (informed choice)
In all other circumstances (including if the woman has withdrawn her consent before or during previous screening appointments), the woman is sent another invitation letter in three to five years’ time.

**D12: Women who ask to withdraw from the screening programme**

A woman or trans man can request that their name is removed from the screening register. No one else (such as a carer or a relative) can make this request unless a process is followed to clearly demonstrate that ceasing is in the individual’s best interests, and they are not able to make an informed choice themselves. Guidance on this can be found at: https://www.gov.uk/government/publications/cancer-screening-informed-consent

Examples of circumstances where a woman should continue to be invited unless she confirms that she wishes to withdraw from the screening programme include:

- women who have never had sex with a man
- women with a physical disability that would make taking a sample difficult
- women who have been cut/undergone FGM
- women with a learning disability
- women with a terminal illness (unless the GP judges that an invitation would be distressing)

Health professionals must ensure that women who express a wish to withdraw from screening have been provided with sufficient and accurate information to make an informed decision. This would include having received the NHS cervical screening programme leaflet which is sent out with all screening invitations. Women may be offered an appointment to discuss their decision to withdraw from the programme if they find this helpful.

**D13: Re-instatement to screening after a ceasing request**

If a woman changes her mind about withdrawing from the screening programme, she can ask for a new screening appointment at any time and will return to routine call and recall.

If a woman is aged over 65 and has not been screened since the age of 50, she is entitled to a new screening appointment if she requests one. We do not routinely recall women over 65.
Session E: Understanding the test results

E 1: Cytology results

The sample taker should understand:

- the possible test results
- the meaning of the results
- the reasons for repeating a sample

Inadequate test result
Cytology should be repeated where an initial LBC sample is inadequate. The repeat sample should not be taken less than three months after the previous test in order to allow for cell regeneration.

A laboratory will report a sample as inadequate if the sample taker has not completely visualised the cervix, or if they took the sample in an inappropriate manner (for example with a sampling device not approved by the NHSCSP). We refer a woman to colposcopy after three consecutive inadequate samples.

Negative
We classify adequate samples with no abnormal cells as negative. Women who receive a negative report can be safely returned to routine recall.

Borderline change in squamous or endocervical cells
If the laboratory reports borderline changes in either endocervical or squamous cells on a cytology sample, laboratories will perform a reflex HR-HPV test. Women who have borderline change of either type and who test positive for HR-HPV must be referred for colposcopy. Women who are HR-HPV negative are returned to normal recall.

Low-grade dyskaryosis
When the laboratory reports low-grade dyskaryosis on a cytology sample, laboratories will perform a reflex HR-HPV test. If the HR-HPV test is positive, the woman is referred for colposcopy. If the HR-HPV test is negative, the woman is returned to routine recall.

High-grade dyskaryosis (moderate)
We refer women for colposcopy after 1 test reported as high-grade dyskaryosis (moderate). A HR-HPV test is not performed.

High-grade dyskaryosis (severe)
We refer women for colposcopy after one test reported as high-grade dyskaryosis (severe).
Invasive squamous cell carcinoma
Women must be referred for colposcopy after one test reported as invasive squamous cell carcinoma. They colposcopy clinic should see them within two weeks of referral.

Glandular neoplasia
When the laboratory reports glandular neoplasia, the referral pathway depends on the source of the abnormal glandular cells.

Where the abnormal glandular cells probably originated from the endocervix, or the source is not specified, the woman must be referred for colposcopy. If a woman is not referred directly, the GP must make an urgent referral through the ‘two-week wait’ pathway.

In cases where the source of the abnormal glandular cells is likely to be the endometrium or another gynaecological site, we refer the woman to a gynaecology clinic. If a woman is not referred directly, the GP must make an urgent referral through the cancer wait times (CWT) ‘two-week wait’ pathway.

Referrals to gynaecology clinics are not part of the screening programme and should be managed according to local protocols.

Arrangements must be made to inform the woman of her diagnosis of non-cervical glandular neoplasia. The screening result letter advises that there is an abnormality and that the woman needs to make an appointment to see her GP as soon as possible. Sample takers should be aware of national protocols for the referral of women for colposcopy and guidelines for the clinical management of women.

If the trainer has appropriate training in cytology, they may present examples of cytological images in this session. The trainer may wish to use examples from their local laboratory.

E2: HPV testing

HPV triage and test of cure
The NHSCSP currently uses HPV testing for the triage of women with borderline or low-grade cytology abnormalities. It is also used following treatment for CIN.

HR-HPV triage protocol
Women whose cervical samples are reported as showing borderline changes (of squamous or endocervical type) or low-grade dyskaryosis are given a reflex HPV test.
Those who are HPV positive are referred to colposcopy. Those who are HR-HPV negative are returned to routine recall.

Women whose cervical sample is reported as high-grade dyskaryosis or worse are referred straight to colposcopy without an HPV test.

**HPV ‘test of cure’ protocol**

After treatment for cervical intraepithelial neoplasia (CIN) women are invited back six months after treatment for a repeat cervical sample in the community. A woman whose sample is reported as negative, borderline change (of squamous or endocervical type), or low-grade dyskaryosis, is given an HPV test. If the HPV test is negative, the woman is recalled for a screening test in three years (irrespective of age) and can be returned to routine recall if the subsequent test result is cytology negative.

Those who are HPV positive are referred back to colposcopy. Women whose cytology is reported as high-grade dyskaryosis or worse are referred straight to colposcopy without an HPV test.

For the algorithm used in cervical screening triage and test of cure, refer to:


**HPV primary screening**

In February 2016 the UK NSC recommended HPV screening for adoption by the cervical screening programme as the primary screening test.

HPV primary screening means that the HR-HPV test is the first test performed on the cervical screening sample. Cytology then becomes the triage test, performed only when the HR-HPV test confirms HR-HPV to be present.

HR-HPV testing is performed on the sample taken for a cervical screening test. Where cytology triage is indicated, a slide is prepared and examined under the microscope for abnormal cells. This is carried out on the same sample, so there is no need for the woman to return for a second test. Both test results are issued as part of a single report. If a cytology result is included in the report, this is reflected in the management recommendation provided.

Women receiving a negative HR-HPV test result are returned to routine recall in three to five years dependant on age.
Women who test positive for HR-HPV will have a cytology test performed. Women with abnormal cytology (borderline changes or worse) are referred to colposcopy.

If the cytology test is normal, we advise women to return for a repeat test in 12 months. If the woman remains HPV positive/cytology normal at this 12 month repeat test, we advise a further repeat test in another 12 months’ time. At the next repeat test (24 months after the initial test) we will refer the woman to colposcopy if she remains HR-HPV positive (with no cytology performed), or return her to routine recall if she is HR-HPV negative.

For the algorithm used for HPV primary screening, refer to:
‘NHS Cervical Screening Programme Screening Human papillomavirus (HPV): primary screening protocol algorithm’ at:

Session F: Anatomy and physiology of the pelvic organs

F1: Structure and function of the female genitalia

It is essential that trainees are familiar with the structure and function of the female genitalia including the:

- vulva
- vagina
- pelvic floor
- cervix uteri
- body of the uterus
- fallopian tubes and ovaries

F2: The transformation zone

It is very important to understand the position of the cervix and the anatomy of the cervix and its cellular structure, with particular reference to the transformation zone and the squamocolumnar junction.

Trainers should draw attention to how age and pregnancy affect the position of the transformation zone and changes in cells. Refer to the cervical screening video resource at:
http://cpd.screening.nhs.uk/csp-videos

The video resource consists of four modules:
- Module 1: Anatomy of the cervix
- Module 2: Human papillomavirus replication and cell cycle dysfunction
Module 3: Cervical intraepithelial neoplasia
Module 4: Invasive carcinoma

Session G: Practical aspects and professional responsibilities of taking cervical samples

G1: Medico-legal considerations

All healthcare professionals have a duty to work within their professional boundaries. For cervical screening, this ensures that the woman receives a quality service delivered by competent individuals. The sample taker should understand:

- definitions of terminology
- consent to cervical screening
- the NMC code in relation to cervical screening
- indemnity and HCP responsibility
- the GP contract
- conduct relating to sharing patient information
- the importance of correct patient details
- incident reporting
- healthcare responsibilities around FGM

G2: Preparing the room

The environment for sample taking should be:

- warm
- well lit
- private
- comfortable
- as relaxing as possible

G3: Equipment for taking samples for LBC

Equipment should include:

- an adjustable height examination couch
- a good light source
- specula of different sizes, reusable or once-only use
- sterilisation facilities if reusable specula are used
• disposable non-latex gloves
• information leaflets for women
• a supply of Cervex-Brushes
• a supply of EndoCervex Brush
• a supply of fixative vials – ThinPrep or SurePath
• packaging for transporting LBC samples to the laboratory

G4: Checking the woman’s identity

At least three legible and correct patient demographics are required to identify a patient. This enables matching with any existing record on the pathology system. Ideally the NHS number should be used.

The minimum identifying requirements for carrying out cervical sampling are:

• the person’s full name including first name and surname
• the person’s date of birth
• ideally a fourth identifier such as NHS number or home address

G5: Providing information and answering questions

Sample takers should explain the purpose of cervical screening and what will happen at each step of the procedure. Every person attending screening should understand:

• the purpose of cervical screening and its limitations
• the purpose of the HPV test
• the meaning of a normal test result (low risk, not no risk)
• the meaning of a negative/positive HPV test
• the likelihood of an inadequate test (between 1% and 4%) and why this may occur
• the reasons for being referred following a test (normal or abnormal) which will include HPV result
• how and when test results are made available
• the importance of contacting the sample taker if no result has been received within two weeks
• the importance of always reporting any abnormal bleeding or discharge to her doctor

Sample takers should explain to the woman what they are going to do during the procedure, and what to expect. A woman who is having a test for the first time may need a more detailed explanation, including looking at the speculum and the sampling device. She needs to know she will have to remove her underwear and that the speculum will be inserted into her vagina.
Consent is demonstrated if the woman is willing to proceed with having screening. It is good practice to document that consent was gained for the procedure.

If a woman chooses not to proceed with screening, or is too distressed by the procedure, then this must be recognised as her valid choice not to have the test on this occasion. Another date for the test may be offered.

Some women may wish to have a chaperone irrespective of the sex of the sample taker. The offer of a chaperone should be made to the woman in accordance with local policies. If a chaperone is declined, this should be noted.

G6: Taking a clinical history

Questions should be asked about:

- the date of last menstrual period (LMP)
- any abnormal bleeding, ie intermenstrual, menorrhagia, post-coital, post-menopausal
- any unusual vaginal discharge
- contraceptive use
- use of HRT

Unless a woman seems unlikely to re-attend at a later date, a sample should not be taken:

- during menstruation
- less than 12 weeks postnatally
- less than 12 weeks after TOP and miscarriage
- if there is a discharge/infection present (the infection should be treated first)

Cervical screening should be avoided during pregnancy. We advise women to wait for three months after giving birth before being screened.

The screening test is not a diagnostic tool, and a normal test result could offer false reassurance. Women with symptoms of abnormal bleeding or persistent discharge, pelvic pain, bloating or urinary symptoms, should be referred for further investigation without waiting for the cytology result.

G7: Taking a screening history

The woman’s screening history should be checked, in particular:
- the date of her last test
- any abnormal test results

The sample taker must establish that a woman is eligible for a test (usually age 24.5 to 64 for routine tests) and that a test is now due (or overdue).

Some women outside the standard screening age range may be eligible for screening if:

- they have a routine recall date allocated as a result of a previous test
- they are under surveillance or follow-up as a result of a previous abnormality
- they did not respond to their last invitation and now wish to be tested

If the woman has had a previous abnormal result the sample taker should check:

- when
- where (laboratory)
- the type of result
- if there was any treatment
- what (if any) follow up was undertaken

**G8: Preparing the request form**

The following data items should be completed by the sample taker.

1. The woman’s surname, previous surnames, first names (check details, including spelling, with the woman)
2. A full postal address and postcode (check details, including spelling, with the woman)
3. Date of birth
4. NHS number
5. Name and address of sender if not GP
6. Name and address of GP
7. GP code
8. The woman’s hospital registration number (if applicable)
9. The source of the sample (type of organisation)
10. Date of this test
11. First day of last menstrual period
12. Condition if applicable (pregnant, postnatal, IUCD fitted, use of hormones)
13. Reason for the test
14. Any clinical information (completed after sample is taken)
15. Sample taker’s code.

It is essential to check the details recorded on the cytology request form and electronic record for accuracy.
G9: Choosing the appropriate speculum

All sample takers should have a range of specula available including very small, small, medium and large. This should include a long bladed narrow speculum such as the ‘Winterton’ speculum, to enable better visualisation of the cervix when the vagina is long or the cervix is lying posteriorly.

Examples should be available when discussing the choice of speculum. The quality of the equipment selected should be checked.

When using the speculum, the sample taker should:

- warm or cool under running water to reach body temperature for a metal speculum (make it clear to the woman what is being done)
- consider using a little water based lubricant (avoiding the tip of the speculum so as not to contaminate the cervix)
- gently insert the speculum side-on, directing it in a downward using gentle, unhurried movements
- open and close the speculum slightly or change the angle of insertion to bring the cervix into view
- note that a common error is failure to insert the speculum far enough into the vagina
- allow time after inserting the speculum to allow the woman to relax

During training, the trainer may use a model or video to demonstrate the correct procedure to insert the speculum.

G10: Appearance of the cervix

Once the speculum is inserted, sample takers need to:

- visualise the cervix
- assess the cervix
- interpret what is seen

The following appearances of the cervix should be familiar:

<table>
<thead>
<tr>
<th>Cervical epithelium</th>
<th>The cervical epithelium is of two kinds, the multi-layered squamous epithelium on the ectocervix that appears pale pink and the thinner columnar epithelium in the endocervix that appears red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical eversion</td>
<td>A wide area of columnar epithelium, also known as</td>
</tr>
</tbody>
</table>
‘ectropion’. The appearance is exaggerated further by opening the speculum. No treatment for cervical eversion is required unless symptomatic. If symptomatic, refer the individual to colposcopy.

<table>
<thead>
<tr>
<th>Laceration of the cervix</th>
<th>Associated with childbirth. Exposes more of the canal lined by columnar epithelium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-treatment for CIN</td>
<td>A central ‘rosette’ of reddened epithelium may be seen on the cervix, which is asymptomatic and does not bleed to the touch. This represents an old area of healing</td>
</tr>
</tbody>
</table>

Trainers may wish to refer to the ‘Cervix Chart for Sample Takers in Primary Care’ (NHSCSP Publication No 25). This chart is available to order on a one per room basis. For details, see: https://www.gov.uk/government/collections/population-screening-programmes-leaflets-and-how-to-order-them

G11: Sampling the transformation zone

The whole cervix must be visualised to obtain a satisfactory sample. Sample takers should note that:

- CIN can develop anywhere in the vaginally exposed columnar epithelium, so the whole transformation zone needs to be sampled
- the position of the transformation zone varies; the part of the transformation zone adjacent to the squamo-columnar junction (SCJ) is the most vulnerable to CIN
- if the SCJ is visible, the sample must include the whole circumference of the SCJ and the adjacent 1cm of squamous epithelium
- if the SCJ is in the endocervical canal and not visible, the sample must include cells from the canal in addition to the ectocervix
- they must visualise the cervix at the time that the sample is taken, and ensure that the whole of the transformation zone has been sampled. It is not possible for the laboratory to be certain that the full circumference of the cervix has been sampled by the cellularity or cell content of the sample (a sample taken from half of the cervix would look to the cytologist the same as one from the whole circumference)
- if an experienced sample taker is unable to visualise the cervix, the woman should be referred to a colposcopy clinic for investigation
- samples taken after treatment for glandular neoplasia, CIN2 or CIN3 are special cases, and sample takers should ensure that information about previous treatment is given on the test request form
G12: Nabothian follicles

These are mucus-retaining cysts formed as islands of columnar epithelium covered by squamous epithelium. They are usually small (about 5mm in diameter), but occasionally may enlarge to 1 to 1.5cm. The cervix may have a knobbly appearance if several cysts are present. No treatment is required, and a sample can be taken as normal.

G13: Polyps

Samples may be taken as long as the polyp does not interfere with a full 360 degree coverage. If in doubt, refer the woman to gynaecology and then sample after treatment (three months later).

Small ectocervical polyps where the base is visible and which are asymptomatic do not require referral for gynaecological opinion.

Large, symptomatic or endocervical polyps where the base is not visible should result in referral for a gynaecological opinion (although such polyps are usually benign).

G14: Bleeding on taking a sample

Bleeding on taking a sample is not uncommon, especially from the columnar epithelium. If the cervix bleeds with no clinical suspicion of malignancy, sample takers should assess the amount of bleeding and consider possible causes. The sample should be sent to the laboratory, but it should be explained to the woman that the sample may be inadequate (and the test may have to be repeated).

If bleeding is a repeated problem and causes repeated inadequate samples, or if the woman has post-coital bleeding, the sample taker should consider referral to a gynaecologist for further investigation.

G15: Clinical suspicion of malignancy

Cervical cancer is rare in the UK. Many regular sample takers will never see a single case. Signs of malignancy include:

- an enlarged cervix where the surface is irregular and friable, crumbling to the touch (gross example)
- large blood vessels which bleed freely when rubbed by the end of the speculum
- an offensive, watery discharge may also be present
If the cervix bleeds with clinical suspicion of malignancy, and a clinician considers the cervical appearance is suspicious of malignancy, the woman must be urgently referred to a gynaecologist through the cancer wait times (CWT) ‘two-week wait’ pathway. A sample should not be taken.

Cervical screening is a screening test, not a diagnostic tool. If a woman presents to her GP practice with cervical cancer symptoms, she should be referred to a gynaecologist.

In rare cases, a normal screening result may occur even though malignancy is present.

If the sample taker has any concerns about the woman’s health when the cervix is visualised, they should seek appropriate clinical advice.

G16: Taking the sample

A high cellular yield is achieved with correct use of the brush:

1. Using the Cervex-Brush, insert the central bristles of the brush into the endocervical canal so that the shorter, outer bristles fully contact the ectocervix
2. Using pencil pressure, rotate the brush FIVE TIMES in a clockwise direction. In order to ensure good contact with the ectocervix, the plastic fronds of the brush are bevelled for CLOCKWISE rotation only.

G17: Taking an additional endocervical sample

The EndoCervex Brush should be used only in a very few circumstances. It should always be used in conjunction with a Cervex-Brush. Sample takers should consider taking a second sample using an endocervical brush only if:

- they have difficulty inserting the Cervex-Brush into the os, for example if the os is narrow or stenosed
- the woman is being followed up for previous borderline changes in endocervical cells
- the woman is being followed up for a previously treated endocervical glandular abnormality (usually when the woman has not had a hysterectomy or radiotherapy) when a previous sample was inadequate because of the absence of endocervical cells

Sample takers should take the EndoCervex Brush sample after the Cervex-Brush sample:
1. Insert the EndoCervex Brush gently into the os, with the lower bristles remaining visible, and rotate clockwise through one whole turn
2. Fix both samples in the same vial, and clearly note on the cytology request form the use of two sampling devices and the reason why

G18: If a wide ectropion is present

A Cervex-Brush should be used to collect the sample. If necessary, a second brush can be used by sweeping the transformation zone in accordance with the advice from the LBC equipment supplier. Fix both samples in the same vial, and note on the cytology request form.

G19: Fixing the sample

For both technologies ensure the vial has not passed its expiry date.

Fix the sample immediately, using the relevant instructions below.

**ThinPrep**
1. Rinse the brush into the fixative vial using a vigorous swirling motion
2. Push the brush into the bottom of the vial at least 10 times, forcing the bristles apart. Firm pressure is necessary or the cells will cling to the brush
3. Inspect the brush for any residual material and remove any remaining by passing the brush over the edge of the fixative vial
4. Ensure that the material reaches the liquid or it will not be preserved
5. Tighten the cap so that the torque line passes the torque line on the vial
6. Shake the vial if you wiped any material on the edge
7. Label the vial

**SurePath**
1. Remove the head of the brush from the stem and place into the vial of fixative
2. Screw the lid on the vial
3. Label the vial

If the laboratory requests a cyto brush sample, add it to the same vial in the same way as the brush sample (either rinsing in the vial or removing and adding the brush head)

**For both LBC technologies, it is essential that you place the sample in the vial at once in order to achieve immediate fixation. Do this before removing the speculum.**

G20: Removing the speculum
Withdraw the speculum gently, with the blades apart until the cervix is no longer within the blades. Allow the speculum to close and continue to withdraw it until it is fully removed.

G21: Ending the appointment

Allow the woman time to dress before going on to complete the screening appointment.

Check that:

- you have recorded woman’s name and date of birth on the vial
- you have completed the cytology request form, and the detail on the form and vial match and are correct

Explain to the woman how and when she will receive her test result, what the results may be, and what follow up may be relevant (if appropriate). Ensure that she understands that if she has any abnormal bleeding or discharge she should see her GP. She should also understand that she can return to the practice for further advice.

G22: Completing the request form

Complete the clinical data box by:

- indicating the type of specimen
- specifying if an additional sample (such as an endocervical sample) was taken
- providing any information on current signs and symptoms
- detailing any problems with sampling the cervix
- providing all clinical details, such as unusual bleeding
- noting any issues regarding the appearance of the cervix
- providing details of an additional sampler, if used

Also provide brief details of any significant history, including abnormal cytology (with slide number) and any previous diagnosis and treatment. This ensures that the laboratory has sufficient information to make an appropriate recommendation on the future management of the individual.

Check that all the relevant boxes are complete and legible. Sign the form, and provide the sample taker identification code (if used locally).

G23: Sending the sample
Send the sample and the request form to the laboratory, packed in accordance with local arrangements. Ensure vial lids are fitting correctly to prevent any leakage. This could result in the laboratory rejecting the sample. Samples should be sent as soon as possible in order to achieve the programme standard 14-day turnaround for results.

**G24: Documenting the procedure**

The details of the test should be recorded in the woman’s records using appropriate codes and templates. These should include:

- confirmation that the cervix was fully seen
- confirmation of sampling from the transformation zone
- the date the sample was taken
- the sample taker’s details

There are benefits in standardising documentation and terminology within a practice or clinic. Trainees should record their actions clearly and accurately and should use only recognised abbreviations. As a failsafe measure, each sample taker should keep a list of all samples sent, and correlate this with the results returned by the laboratory.

**G25: Disposing of equipment and waste**

Dispose of equipment and waste safely in accordance with local protocols.

**G26: Infection control**

Sample takers should follow local protocols for infection control.

**G27: Auditing the test results**

Sample takers should keep a record of their individual rates of inadequate tests and abnormal test results. If either is significantly out of line with the rates reported by the local laboratory, seek advice from a trainer, a gynaecologist, and/or the laboratory.
Training sessions: further reading and resources

Session A


HPV vaccination programme: https://www.gov.uk/government/collections/immunisation


UK NSC recommendations: cervical cancer consultation regarding screening age in the UK: legacy.screening.nhs.uk/cervicalcancer-qa#fileid13111
Session B


Bosch, FX, Iftner T. *The Aetiology of Cervical Cancer*. NHS Cancer Screening Programmes (NHSCSP Publication No 22), 2005:

http://digital.nhs.uk/catalogue/PUB18932

National Cancer Intelligence Network (NCIN):
ncin.org.uk/cancer_type_and_topic_specific_work/cancer_type_specific_work/gynaecological_cancer/gynaecological_cancer_hub/resources/cervical_cancer#keyfacts

Cancer statistics for health professionals: Cancer Research UK. Accessed February 2016:
http://www.cancerresearchuk.org/health-professional/cancer-statistics

*Colposcopy and Programme Management*. NHS Cancer Screening Programmes, (NHSCSP Publication No 20), 2016:


*Liquid Based Cytology and National Policy*. NHS Cancer Screening Programmes, 2005:

Link to abstract: http://www.ncbi.nlm.nih.gov/pubmed/15262102

Guidance for the training of cervical sample takers

Link to full text: http://researchonline.lshtm.ac.uk/4328/1/FullReport-hta13510.pdf

Session C

Colposcopy and Programme Management. NHS Cancer Screening Programmes, (NHSCSP Publication No 20):

Service specification No.25 NHS Cervical Screening Programme
Public health national service specifications:
https://www.england.nhs.uk/commissioning/pub-hlth-res/

Guidelines on Failsafe Actions for the Follow Up of Cervical Cytology Reports. NHS Cancer Screening Programmes, 2004 (NHSCSP Publication No 21):

Session D

Ceasing Women from the NHS Cervical Screening Programme. NHS Cancer Screening Programmes, 2004 (NHSCSP Good Practice Guide No 1):

Consent to Cancer Screening. NHS Cancer Screening Programmes

An Easy Guide to Cervical Screening (picture leaflet for women with learning disabilities). NHS Cancer Screening Programmes, 2006:

https://www.booksbeyondwords.co.uk

Session E

Achievable standards, benchmarks for reporting, and criteria for evaluating cervical cytopathology 3rd Edition (NHSCSP Publication No 1), 2013:

NHS Cervical Screening Programme: Colposcopy and Programme Management. NHS Cancer Screening Programmes (NHSCSP Publication No 20, 3rd Edition), 2016:

Liquid Based Cytology and National Policy. NHS Cancer Screening Programmes, 2005:

Session G

Cervix Chart for Sample Takers in Primary Care. NHS Cancer Screening Programmes (NHSCSP Publication No 25). Paper copies only available. Ordering details at:

Product based information provided by suppliers:
Manufacturer websites:
www.hologic.com
www.sourcebioscience.com
www.roversmedicaldevices.com

NHS CSP Publications

NHS Cervical Screening Programmes publications and guidance for professionals – see:

PHE information leaflets for the NHS Cervical Screening programme – see:

*Cervical screening – helping you decide* (leaflet sent with all cervical screening invitations):

*HPV testing - information for women*

*NHS Cervical Screening – having a colposcopy* (leaflet sent to all women referred for colposcopy after an abnormal cervical screening result):

Cervical screening for lesbian and bisexual women:

*An easy guide to cervical screening.* A leaflet about cervical screening by and for women with learning disabilities:
Personal record book

Sample takers should have a personal training record, including attendance at taught courses, supervised practice, visits to cytology laboratories and colposcopy clinics and update training.

Appendices A to F are a guide to what should be included when designing a personal record book. Training mentors may like to agree an action plan with the trainee before the trainee takes unsupervised samples.

A  Summary of training
B  Theoretical course
C  Record of practical training
D  Continuous audit of 20 consecutive samples
E  Final clinical assessment
F  Update training
Appendix A: Summary of training

<table>
<thead>
<tr>
<th>Name</th>
<th>Current role</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commencement of training (date)</th>
<th>Completion of theoretical course (date)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visit to cytology laboratory (if attended) or media tour undertaken</th>
<th>Date</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature of cytologist in charge

<table>
<thead>
<tr>
<th>Visit to colposcopy clinic</th>
<th>Date</th>
<th>Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature of colposcopist in charge

<table>
<thead>
<tr>
<th>Completion of practical training</th>
<th>Date</th>
<th>Signature of supervisor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Completion of training**

This is to certify that______________________________________________________________

has satisfactorily completed training and is competent in taking samples for cervical cytology.

Signature of trainee: ___________________________________________________________  
Signature of trainer: ___________________________________________________________  
Date: _______________________________________________________________________  

Appendix B: Theoretical course

Subjects covered Study method (for example distance learning, course attendance)

A The NHS Cervical Screening Programme

B The background to cervical screening

C Organisation of the NHSCSP

D Equal access to cervical screening

E Knowledge of the local screening programme

F Anatomy and physiology of the pelvic organs

G Practical aspects & professional responsibilities

Comments


Completion of theoretical course(s)

Date: 

Signature of trainee: 

Signature of trainer: 

## Appendix C: Record of practical training

*(Complete 1 sheet for each sample taken)*

<table>
<thead>
<tr>
<th>Trainee name</th>
<th>Sample number</th>
<th>Sample date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trainee role</td>
<td>Observation □</td>
<td>Supervised □</td>
</tr>
</tbody>
</table>

### Client details

<table>
<thead>
<tr>
<th>Code</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of last test</td>
<td>Date of LMP</td>
</tr>
</tbody>
</table>

### Screening history

<table>
<thead>
<tr>
<th>Reason for this test</th>
<th>Routine call □</th>
<th>Routine recall □</th>
<th>Previous abnormal □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opportunistic □</td>
<td>Follow up after treatment □</td>
<td>Previous inadequate □</td>
<td></td>
</tr>
<tr>
<td>Other □</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Taking the sample

<table>
<thead>
<tr>
<th>Appearance of cervix</th>
<th>LBC SurePath □</th>
<th>LBC ThinPrep □</th>
</tr>
</thead>
</table>

### Any unusual vaginal discharge

### Sampler used

### Transformation zone seen?

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>SCJ seen?</th>
<th>Yes/No</th>
</tr>
</thead>
</table>

### Reflection on the practical training session

#### Trainee’s comments

#### Supervisor’s comments (supervised samples only)

### Test result

<table>
<thead>
<tr>
<th>Date received</th>
<th>Follow-up action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine recall □</td>
<td>Early recall □</td>
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### Comments
Record of practical training cont.
Audit of Initial 20 consecutive samples

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Name of Trainee: ___________________________________________
Appendix D: Continuous self-evaluation audit of 20 Consecutive samples

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Appendix E: Final clinical assessment

**Welcoming the woman Satisfactory**

- Appropriate environment for sample taking
- Giving information and answering questions in relation to Cervical Screening and HPV
- Checking of screening request details
- Taking a history

**Visualising the cervix**

- Positioning the woman
- Choice of speculum
- Inserting the speculum
- Assessing the cervix

**Taking the sample**

- Sampling the cervix
- Transferring to LBC vial
- Removing the speculum

**Ending the consultation**

- Explaining how and when results are received and what they mean
- Completing the Request Form
- Completing the woman’s records

**Infection control and disposal of waste**

- 

**Trainee comments**

______________________________________________________________

______________________________________________________________

Signature of trainee __________________________ Date ______________

**Comments by mentor (formative feedback)**

______________________________________________________________

______________________________________________________________

This trainee has demonstrated competence and satisfactorily completed assessment:

Signature of mentor __________________________ Date ______________
Appendix F: Update training

Date______________________________

Venue (if face to face training attended) ________________________________

E Learning module undertaken ________________________________

Subjects covered

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Comments by sample taker

____________________________________________________________________
____________________________________________________________________

Current inadequate rate______________________________

Current positive pick-up rate ________________________________

Signature of sample taker ________________________________