Standards for Quality Assurance in Cervical Screening Quality Assurance in Primary Care and Other Cervical Screening Settings

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CervicalCheck
An Clár Náisiúnta Scagthástála Cheirbheacs
The National Cervical Screening Programme

Contents

1 Introduction

Primary care plays a pivotal role in ensuring the overall success of the cervical screening programme as it is where the vast majority of cervical screening tests are carried out. CervicalCheck is committed to promoting equity of access for all people who require screening and sampletakers in the community are expected to uphold this commitment.

Cervical screening may also be undertaken in public gynaecology, colposcopy, infectious disease and sexual health services. The role of health professionals is to provide a quality assured service in cervical screening.

In addition to taking the test and ensuring results and recommendations are followed up, doctors, nurses and administrative staff play vital roles in supporting women to participate in the cervical screening programme. Health professionals are a key point of communication with women and as such have opportunities to provide information, answer questions and support women's understanding of the risks and benefits of cervical screening.

The overall aim of the process of care is to ensure that women receive a high-quality service in a sensitive, appropriate and timely manner with due regard to best practice, safety, comfort and dignity throughout the screening process.

This document provides a framework to assist sampletakers performing the test to deliver a quality assured service. The quality requirements and standards mirror the woman's journey through the cervical screening process and address the essential aspects of the screening pathway from a quality perspective. They are important, achievable and take into account the evidence available at the time of publication.

Services engaged in cervical screening are expected to meet the quality requirements and standards as set out below.

Please note, throughout this document, where we refer to 'women', we mean 'women, and anyone with a cervix'.

2 Quality assurance requirements and standards

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

Quality requirements are stated as a description. There are no targets associated with a requirement as service providers must fulfil the requirement.

Quality standards are stated as a description of an activity with a measurable level of performance, with an associated target for achievement, i.e. quantitative with criteria that are valid, reliable and feasible.

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards. Quality standards are those with a measurable level of performance and associated target for achievement. *Where no target is provided, these are considered quality requirements that the service provider must fulfil. These requirements are identified with a 'must' or 'will' statement.*

Quality requirements must be monitored on a continuous basis by practices and clinics and are assessed during training visits by the NSS.

2.1 Promoting awareness of cervical screening

Health professionals in primary care and other cervical screening settings have a pivotal role in identifying eligible women and encouraging them to participate in regular cervical screening. Staff must ensure that the information they give to women is accurate and in a format that is easily understood.

QR 3.01 Quality requirement

Promoting awareness of cervical screening

Services must have current CervicalCheck signage on display and have current CervicalCheck information leaflets available for women who attend.

QR 3.02 Quality requirement

Access and availability of learning and reference resources

Each practice and clinic must have access to, and be aware of, current versions of relevant learning and reference resources provided by CervicalCheck

Relevant learning and reference resources, at a minimum, include:

- Quality Assurance in Primary Care chapter of the current Standards for Quality Assurance in Cervical Screening
- *HPV Primary Screening: Eligibility Framework*
- Cervical screening results and recommendations table
- Online CervicalCheck learning resources available through the National Screening Service Learning Portal NSSresources and CervicalCheck website www.healthpromotion.ie.
- Information for women through the CervicalCheck website and promotional materials about cervical screening (including benefits and limitations, HPV, screening tests and results and colposcopy).

QR 3.03 Quality requirement

Understanding the benefits and limitations of cervical screening

All practice and clinic staff involved in cervical screening must understand both the benefits and the limitations of cervical screening and be able to apply such understanding in counseling women and promoting informed choice.

QR 3.04 Quality requirement

Eligibility

Services must ensure that eligible women including those who are not patients of their practice, are facilitated to have a free cervical screening test when they are due. Eligibility (which can be checked online) must be confirmed for each woman prior to taking a screening test*

*See appendix 1 *HPV Primary Screening: Eligibility Framework*

Note: A letter of invitation is not required for an eligible woman to have a CervicalCheck screening test. The first CervicalCheck screening test for an eligible woman will automatically register the woman with the programme. Women should be encouraged to register with the CervicalCheck programme and to check that their contact details are correct.

For continuity of care a woman can be recommended to attend a single practice for all their screening tests, but they do not need to be a registered patient of this practice.

QR 3.05 Quality requirement	**Understanding cervical screening programme operation** All practice and clinic staff (both clinical and administrative) who are involved in the cervical screening process have a duty to remain informed of programme policies either by attending clinical updates or partaking in e-learning modules.

2.2 Promoting uptake and participation

The success of CervicalCheck depends on the uptake and ongoing participation of women from the target population. The potential percentage reduction in cumulative incidence of and mortality from cervical cancer can only be achieved if a high proportion of the target population attends for cervical screening. CervicalCheck aims to achieve at least 80% coverage of the target population.

Equitable coverage is an important factor in ensuring screening does not widen health inequalities. Specific groups may require additional supports to attend for their screening test.

Examples of specific groups are detailed below:

- LGBT+ community: Every person who has a cervix and is within the screening age range is eligible for cervical screening regardless of their gender identity.
- Members of the Travelling community
- People with literacy difficulties
- Those for whom English is not their first language
- People with intellectual disabilities
- People with physical disabilities for whom the process of taking the test may be challenging
- People from areas of social deprivation where screening rates tend to be lower
- People from cultural backgrounds for whom an intimate exam can be challenging to their customs/ beliefs
- Previous trauma including sexual assault, childhood sexual abuse and female genital mutilation

Doctors, nurses and administrative staff must have an awareness of the uptake of cervical screening in their practice and take steps to promote uptake, especially amongst groups with low attendance rates, and hard to reach groups.

Note 1: HIV positive women are recommended to attend for annual screening with referral to colposcopy recommended after any HPV positive result.

Note 2: Pre- and post-organ transplant recipients are recommended to attend for annual screening with referral to colposcopy recommended after any HPV-positive result.

Note 3: Immunosuppressive therapy: A variety of immunosuppressant drugs increase the risk of non-clearance of high-risk (HR)-HPV and it is important that people taking immunosuppression medication engage with cervical screening when invited.

Note 4: Women exposed to Diethylstilbestrol (DES) in utero are at increased risk of clear cell cancer of the vagina. These women should have a colposcopy assessment in a specialist setting. Arrangements should be made for the follow-up of those individuals who have the stigmata of DES exposure (eg. double cervix, structural uterine anomalies). This is usually via annual colposcopy. Women who do not have stigmata of DES do not require more intensive screening and should be managed within the standard HPV screening algorithms. Daughters of those exposed to DES in utero are not at any increased risk of cervical or vaginal cancer and require routine screening only.

DES exposure is rare in Ireland and generally all women are managed in a single specialised clinic by suitably experienced clinicians. CervicalCheck recognises the DES clinic at the National Maternity Hospital, Dublin, as the appropriate location for the care of this group of women.

Standard 3-1	**Screening of eligible women** Women screened must be eligible to attend for programme screening. Eligibility is defined in the *HPV Primary Screening: Eligibility Framework*. Eligibility must be confirmed for each woman prior to taking a cervical screening test. *Note: The next test due date is available to women and to health professionals through a secure online check facility (www.hse.ie/cervicalcheck) and through the Information Service (Freephone – 1800 45 45 55) provided by CervicalCheck.*	**Target** Achievable 100% to meet sample acceptance criteria Min 98%

2.3 Qualifications and skills for cervical screening

QR 3.06 Quality requirement	**Qualifications and professional registration of sampletakers** All sampletakers undertaking cervical screening must be qualified and registered with the Irish Medical Council or the Nursing and Midwifery Board of Ireland (NMBI). Nurses or midwives must be registered on the General Nurse Division or Midwives Division of the Nursing and Midwifery Board of Ireland.
QR 3.07 Quality requirement	**Maintenance of professional registration** All sampletakers must maintain their professional registration for the period of time that they are registered with CervicalCheck.
QR 3.08 Quality requirement	**Registration to provide cervical screening** Clinically responsible doctors and sampletakers must register with CervicalCheck to provide cervical screening services and provide evidence that they have undertaken at minimum an introductory module through online learning that outlines the requirements and operation of the programme as part of their registration process. It is the responsibility of the contract holder to ensure that new sampletakers register with the programme. *Note: Sampletakers should register separately at each practice with each CRD where they provide cervical screening services.*

QR 3.09 Quality requirement	**Change of status** Sampletakers must advise the programme administration office regarding any change of location (practice or clinic) or if they wish to cease their registration. For contract holders the programme administration office must be advised a minimum of six weeks in advance of retirement or when ceasing to provide cervical screening services. Where a new clinically responsible doctor is taking over the practice, the contract must be in place prior to commencement of cervical screening samples. It is the responsibility of the contract holder (CRD) to ensure continuity of care by ensuring that all cervical screening results are managed prior to cessation of the service.
QR 3.10 Quality requirement	**Appropriate education and training** All sampletakers engaged in cervical screening should be appropriately trained by completing an accredited training programme. It is the duty of the clinically responsible doctor to ensure that all sampletakers in their service are appropriately educated and competent prior to commencement of sample taking. *Note: After completion of both theoretical and clinical components of the education programme, the CervicalCheck clinical trainer completes the clinical screening competency framework to certify clinical competency.*
QR 3.11 Quality requirement	GP practices and clinics must facilitate visits from CervicalCheck clinical trainers on request.
QR 3.12 Quality requirement	**Maintaining clinical competence through CPD** Sampletakers must participate in CervicalCheck clinical and programme updates at least once every three years. Clinical and programme updates may be delivered through face-to-face meetings (national, regional, continuing medical education (CME) or CervicalCheck-led) or through the National Screening Service learning portal (online).

2.4 Organisational Requirements

QR 3.13 Quality requirement	**Confidentiality** Providers must ensure that confidentiality in relation to each woman and her personal information is maintained throughout the cervical screening process.
QR 3.14 Quality requirement	**Data protection** The storage, access and transfer of women's personal and health information must be compliant with relevant national and European statutory requirements for data protection of personal information, including, but not limited to, GDPR.
QR 3.15 Quality requirement	**Practice records** Each practice or clinic must manage and maintain accurate records in a safe and secure environment.

2.5 Optimal environment

Practices must provide all personnel, equipment, facilities, materials, services and other resources necessary or appropriate to ensure a safe, environment that respects the privacy, dignity and autonomy of women.

QR 3.16 Quality requirement	**Privacy and security** Cervical screening tests must be carried out in a private and secure setting with respect to the woman's needs.
QR 3.17 Quality requirement	**Room temperature** Cervical screening tests must be carried out in a comfortable environment where the room temperature is suitable for the woman's comfort.
QR 3.18 Quality requirement	**Chaperone** A chaperone must be facilitated if the woman requires one. The chaperone or support person may be a relative or friend.

QR 3.19 Quality requirement	**Women with disabilities or additional needs** Sampletakers must facilitate eligible women with disabilities, to perform a screening test having due regard to the woman's ability to give informed consent and ensuring benefits versus harms have been considered. Doctors, nurses and associated staff must facilitate eligible women with adequate time and an environment that accommodates their requirements. In any instance where barriers to cervical screening are encountered in the primary care setting, a referral to colposcopy may be considered. Contact should be made with the colposcopy clinic in advance, to explain the barriers to primary care screening for the women being referred so as to allow assessment of the accommodations needed for the sampling to be performed.

2.6 Appropriate equipment and materials

There must be advanced preparation of equipment and consumables for the screening test. Preparation must ensure that consumables are within manufacturer's expiry date.

Note: Sample vial expiry date is in the format YY:MM:DD

QR 3.20 Quality requirement	**Examination couch** An examination couch with a disposable sheet/paper roll must be available. Consideration must be given to the use of a height-adjustable couch in order to assist women.	
Standard 3-2	**Consumables – cervical screening test kits and specula** Consumables in use for cervical screening must be within expiry dates. *Note: Sampletakers undertaking cervical screening must ensure that the sample vials used do not expire before reaching the laboratory or before being processed. Sample vials within six weeks of expiry should not be used. Note: Sample vial expiry date is in the format YY:MM:DD* *Sampletakers must ensure that a stock rotation system is in place to ensure oldest dated stock is used ahead of new orders.*	**Target** Achievable 100% to meet sample acceptance criteria Min 99%
QR 3.21 Quality requirement	**Infection control** The service must have infection control procedures in place. Cervical screening activity must adhere to these infection control procedures. Regular monitoring and review of infection control procedures must be in place to ensure their effectiveness.	

QR 3.22 Quality requirement

Single-use disposable specula

The use of single-use disposable specula is mandatory. Single-use disposable specula must be opened just prior to carrying out the test and must be properly disposed of in accordance with hazardous waste regulations.

Note: There must be a range of speculum sizes available for use at the practice. These are provided by the programme and can be ordered directly from the supplier.

QR 3.23 Quality requirement

Clinical waste

Single-use disposable specula and cervix brushes must be disposed of as clinical waste.

2.7 Pre-screening: preparation for the screening test

QR 3.24 Quality requirement

Communication with the woman about cervical screening

All aspects of the cervical screening process must be clearly explained to the woman. This includes providing each woman (both new and returning women) with a copy of the Information Sheet for Women accompanying the Cervical Screening form. Aspects of the cervical screening process to be communicated include:

- When cervical screening is appropriate and not appropriate
- The cervical screening test(s) including the underpinning reasons for Primary HPV testing and reflex cytology
- High-risk human papillomavirus (hrHPV) and its role in cervical cancer
- The importance of regular screening and following screening recommendations
- The opt-out process if a woman does not wish to participate in screening
- How the CervicalCheck programme stores and shares screening data
- The benefits and the limitations of HPV cervical screening
- When and how results will be received
- The likelihood and meaning of a normal result
- What it means if further tests are required
- If results are abnormal, the options available, including an assessment of the risks, limitations, side effects and benefits of each option.

Note: The Information Sheet on Cervical Screening *is available in several languages and in Braille to assist sampletakers in explaining the cervical screening process and consent to participate. A pictorial leaflet is available for situations where language or literacy is an issue.*

QR 3.25 Quality requirement

Informed consent

Informed consent to participate in CervicalCheck must be obtained each time a woman attends for a screening test.

Note: Informed consent means that information must be provided in a way that is understandable to a woman and enables her to reach a decision on whether or not to participate in screening. It is also a legal requirement which allows the woman's information to be transferred between service providers in the cervical screening pathway including screening and diagnostic laboratories, colposcopy clinics and the National Cancer Registry Ireland, if appropriate. Obtaining the woman's informed consent is the responsibility of the sampletaker taking the test. The woman's consent must be recorded on the Cervical Screening form, directly by signature or by accepted witnessed indication, in line with best practice policy.

Note 1: Consent to participate in the cervical screening programme is not accepted from a third party e.g. third-party or health professional.

Note 2: At all times, health professionals should be aware that any woman has the right to decline to participate in the CervicalCheck programme. Women who do not wish to be part of CervicalCheck must be advised how to opt off the programme. Eligible women who opt off the programme can re-engage at any future date if they wish to do so up to their 66th birthday.

Note 3: The requirement for informed consent is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and international law and is documented in the HSE National Consent Policy.

QR 3.26 Quality requirement

Completion of the CervicalCheck Cervical Screening form and sample vial

The current revision of the CervicalCheck Cervical Screening form must be completed (paper or electronic order) at the time of taking a cervical screening test in the presence of the woman, who should verify the accuracy and completeness of her details. Particular care should be taken to ensure the correct details are retrieved from practice management systems for sisters, twins, mothers and daughters and clients with the same or very similar demographics.

Failure to use the correct revision of the screening form will result in the form being returned to the practice or clinic.

QR 3.27 Quality requirement

Identification of the woman - mandatory fields to maintain a robust 'chain of custody'

The sampletaker must record the current minimum demographic details of the woman at the time of the screening test and in the presence of the woman completely, accurately and legibly. The details must be recorded on the Cervical Screening form and the sample vial to ensure a robust chain of custody for the sample.

The mandatory demographic details on the form include:

Forename, surname, address and date of birth of the woman as well as sampletaker and contract holder (clinically responsible doctor), registered numbers, the date of the last monthly period, and sample site must be recorded.

QR 3.28 Quality requirement	**Unique identification of the woman** In addition to the mandatory fields outlined in QR 2.27, at least one unique identifier from the list below must be recorded on the Cervical Screening form to ensure accurate matching to the woman's record on the cervical screening register. At least one of the following unique identifiers must be recorded: • Personal Public Service (PPS) number • Cervical Screening Programme Identification number (CSP ID) • Surname at birth • Mother's maiden name *Note: The woman's PPS number and CSP ID are permanent unique identifiers. The woman's surname at birth and mother's maiden name, together with her date of birth, are also permanent identifiers. Permanent identifiers are identifiers that do not change during a woman's lifetime. They are essential in identifying a unique woman and in matching screening events to her record on the Cervical Screening Register. Particular care should be taken to ensure the correct details are retrieved from practice management systems for sisters / twins and mothers / daughter and clients with the same or very similar names.*	
Standard 3-3	**Matching of sample vials with associated cervical screening forms** Each sample vial and accompanying cervical screening form must contain matching demographics for the same woman. *Note: The detachable bar code label on the vial must be placed on the cervical screening form in addition to recording the surname, forename and date of birth on the vial.*	**Target** Achievable 100% to meet sample acceptance criteria Min 99%
Standard 3-4	**Quality of data – completeness, accuracy and legibility** Cervical screening forms and/ or vials being returned, rejected or queried (either by the laboratory or by the programme office) due to completeness, accuracy or legibility deficiencies must be kept to a minimum in line with Laboratory Acceptance Policy. *Note 1: Computer generated forms must be checked for completeness, accuracy and quality of data.* *Note 2: A black ballpoint pen must be used when completing the form by hand and block capitals must be used where requested on the form.*	**Target** Achievable 100% to meet sample acceptance criteria Min 95%

2.8 Screening: undertaking the cervical screening test

Effective sampling is an integral component of a quality screening programme.

QR 3.29 Quality requirement

Visualisation of the cervix

The cervix, where present, must be visualised, assessed and effectively sampled. Ticking the cervix box on the form indicates that this has occurred. A screening test must not be taken if the cervix has not been visualised. If the sample is taken from the vaginal vault, consult the *HPV Primary Screening: Eligibility Framework* which is available on the CervicalCheck website.

QR 3.30 Quality requirement

Condition of sample

All samples must be in an optimal condition. Optimal condition of the sample means that there is adequate solution in the vial, that there is no contamination with other liquids, and that the sealed vial is not broken, damaged or leaking.

QR 3.31 Quality requirement

Relevant clinical details and findings

All relevant clinical details relating to cervical screening must be recorded on the Cervical Screening form.

These include:

- the use of OCP/hormones/HRT
- presence of IUCD
- If post-menopausal
- Post-coital bleeding
- Sub-total hysterectomy
- Pre/post-Transplant
- If receiving dialysis
- HIV+
- Post-menopausal bleeding
- Total hysterectomy

Each sampletaker must be informed of the implications of each of the above clinical details for screening recommendations and inform the woman of these.

Note1: The programme will provide a record of the woman's CervicalCheck screening history to the laboratory that processes the test. However, the record will not include treatments carried out outside the programme. Post-colposcopy recommendations for follow-up screening tests should be recorded.

Note 2: Unexplained abnormal vaginal bleeding must be referred appropriately to gynaecology and not colposcopy. Ambulatory gynaecology clinics are available to manage these referrals.

2.9 Post-screening: after the cervical screening test

QR 3.32 Quality requirement

Woman's medical record

The sampletaker must ensure that screening tests taken are recorded in the correct woman's medical record. A new medical record must be established if one does not already exist. The medical record must record the date of the screening test and the screening test result. A record of written or verbal communications in relation to the cervical screening test result must be kept in the woman's record.

QR 3.33 Quality requirement

Advising the woman of the results process

The woman must be informed of how and when the result of her cervical screening test will be available. The programme's commitment to make results available within four weeks must be communicated to the woman. Counselling the woman about her results and next steps must be provided where required. The result of the screening test will be sent to the woman directly from the programme. Refer to CR 3.40

QR 3.34 Quality requirement

Sample identification

Sample vial labels must include the woman's forename, surname and date of birth as identifiers.

Standard 3-5

Dispatch of samples

Sample vials and their associated forms must be dispatched to the laboratory so that they are received by the laboratory within a maximum of 5 working days of the test being taken.

Note 1: It is important to dispatch the sample promptly in order to facilitate the programme commitment of a prompt result to the woman. A written record of the date the sample was sent from the practice should be maintained.

Note 2: It is the responsibility of the practice / clinic to dispatch or post samples. Women must never be requested to post the samples of their screening tests.

Sample Checklist to be completed prior to sample dispatch:

- *All cervical screening forms completed fully (including contract holder's MCRN, as well as sampletaker's MCRN or NMBI) and on the current revision of the form*
- *Each form corresponds to a vial and the vial is fully labelled (surname, forename, and DOB)*
- *Vial label attached to the form*
- *Informed consent is recorded (either woman's signature or evidence of verbal consent provided)*
- *Sample vials are not within six weeks of manufacturer's expiry date. Note: sampletakers undertaking cervical screening must ensure that the sample vials used will not expire prior to processing*
- *Sample vials with less than six weeks left before expiry should not be used. Sample vial expiry date is in the format YY:MM:DD.*

Target

Achievable 95%

Min 90%

QR 3.35 Quality requirement	**Packaging of samples** All vials and forms must be packaged in the transport boxes appropriate for secure transport to the laboratory. The specific-purpose transport boxes provided by CervicalCheck must be used for transportation to the laboratory. Universal precautions must be employed for handling and packaging of all samples. A written record of the date the sample was sent from the practice should be maintained.

2.10 Management of cervical screening test results

The practice / clinic protocol must include clear directions on roles and responsibilities for obtaining results of screening tests and providing women with their results. All staff, including administrative staff, must be aware and informed of this protocol.

QR 3.36 Quality requirement	**Results management** While women receive personal notification of their cervical screening test result by letter from CervicalCheck, each practice must develop its own protocol for the provision and communication of screening test results. Women must be made aware of this process at the time of their cervical screening test consultation.
QR 3.37 Quality requirement	**Receipt and checking of cervical screening test results** The practice results management protocol must include the identification of overdue results (e.g. results outstanding after four weeks) and include steps on appropriate follow-up with the laboratory. A result must be received for each sample, and every result must be cross-checked against the original sample – a result for each sample, and a sample for each result.
QR 3.38 Quality requirement	**Matching cervical screening results to the correct woman's record** Cervical screening test results must be recorded in the correct woman's medical record. The woman's medical record must be updated with the cervical screening test result and management recommendation. *Note 1: Be particularly cautious with electronic results to ensure that they have been downloaded into the correct patient file.* *Note 2: Healthlink electronic results are available for a period of 30 days for download onto the practice management system. They are then archived.*
QR 3.39 Quality requirement	**Checking management recommendations** Management recommendations accompanying screening test results must be checked in relation to the woman's CervicalCheck screening history. *Note: Sampletakers must access the most current information and documentation in relation to screening test results and management recommendations. Sampletakers need to check that the management recommendation associated with the cervical screening test result is correct with regard to the woman's CervicalCheck screening history. Sampletakers must contact the laboratory if they have queries in relation to results or management recommendations.*

QR 3.40 Quality requirement

Communicating results and outcomes to women

While women receive personal notification of their cervical screening test result by letter from CervicalCheck, practices / clinics must have an appropriate system to communicate the screening test result or outcome to the woman concerned. Explanations should be clear and appropriate to the level of understanding of each individual. The sampletaker is responsible for providing women with their results. All staff, including administrative staff, must be aware and informed of the protocol for communicating results to women. Refer to QR 3.33.

When the screening test result is abnormal, the woman must be given full details of the result and advised of the next step in the process of their management.

2.11 Referral and follow-up

QR 3.41 Quality requirement

Follow-up of women

Sampletakers must ensure that reasonable efforts are made to follow-up screening test management recommendations. Appropriate action includes two recorded attempts to contact the woman, one of which is in writing.

QR 3.42 Quality requirement

Use of CervicalCheck Colposcopy Referral form

The CervicalCheck Colposcopy Referral form must be used when referring a woman to a CervicalCheck colposcopy service.

A copy of the complete screening test result report should accompany the colposcopy referral form. The completed referral must be sent to the colposcopy service directly.

Note: When a screening test result carries a 'refer to colposcopy' recommendation, CervicalCheck will send a partly pre-filled colposcopy referral form by post to assist a doctor to make a referral for the woman to a colposcopy service where an appointment will be provided. Practices must use these pre-filled forms, rather than using hand written or practice developed forms.

QR 3.43 Quality requirement

Referral to colposcopy

Women whose screening test result recommends referral to colposcopy must be referred directly by the clinically responsible doctor to a colposcopy service within 10 working days of receipt of the screening test result and recommendation.

Note 1: All referral information about the woman, her screening test result and relevant history must be forwarded directly to the colposcopy service. Refer to the note in QR 3.42 above in relation to partly pre-filled colposcopy referral forms which are sent to clinically responsible doctors to facilitate referral to colposcopy.

Note 2: Further communication with the colposcopy service regarding the referral must be facilitated when necessary.

Note 3: Referral to colposcopy for clinical indications is outside the remit of the CervicalCheck programme, only those women who are suspicious for invasive cervical disease should be referred to colposcopy with referral remaining the correct pathway for other scenarios to gynaecology clinics or ambulatory gynaecology clinics.

2.12 Failsafe follow-up of abnormal results

Failsafe follow-up of abnormal results refers to the process that occurs when a recommended action for a woman following an abnormal screening test has not occurred or has not been notified to the programme within a defined period from the due date of the recommended action. The failsafe is added to the woman's screening history. Recommended actions may be a repeat test or attendance at colposcopy following an abnormal screening test, or a test following a discharge from colposcopy.

The programme will send a failsafe follow-up information request by letter to the clinically responsible doctor and to the woman.

QR 3.44 Quality requirement	**Failsafe follow-up of abnormal results (information requests)** The clinically responsible doctor must make best efforts to encourage women to follow recommended actions. Where this has not been possible, follow-up information must be recorded and returned to the programme (online or by post) on receipt of a failsafe follow-up letter. *Note 1: The sampletaker who took the screening test must contact the woman, when required, to obtain the necessary information for completion of the information request. Every reasonable effort (at least two recorded efforts, one in writing) must be made.*
Standard 3.6	The number of women where a recommended action has not occurred and no failsafe response has been completed must be kept to a minimum. **Target** 5%
QR 3.45 Quality requirement	**Continuity of care of a woman** During and following her cervical screening pathway, a woman must have a clinically responsible doctor assigned to her care. If the clinically responsible doctor leaves the service for whatever reason, the practice remains clinically responsible for women who have had their most recent cervical screening tests with this practice until alternative arrangements are made, if necessary.

2.13 Quality assurance

QR 3.46 Quality requirement	**Audit of invasive cervical cancers** To be updated when an implementation plan for the recommendations of the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population is agreed.
QR 3.47 Quality requirement	**Quality improvement and audit** While the National Screening Service does not currently audit primary healthcare services, or other cervical screening settings, it reserves the right to do so using these standards. The standards in this document can be used by providers and sampletakers to undertake a self-audit.
QR 3.48 Quality requirement	**Quality assurance and training visits** Practices shall accommodate on-site visits by CervicalCheck designated personnel for training and quality monitoring, audit and quality assurance purposes, providing access to personnel, resources, processes, documentation and results.

Appendix 1: HPV Primary Screening: Eligibility Framework* (sample)

HPV Primary Screening: Eligibility Framework

Please note, throughout this document, where we refer to 'women', we mean 'women, or people with a cervix'.

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

A. Women – standard eligible population i.e. women aged 25 to 65 years who have a cervical screening requirement			GP / Clinic Payment
Women aged 25 to 29 years:	Routine Screening:	Every 3 years for women with negative HPV test results.	Yes if interval observed
Women aged 30 to 65 years:	Routine Screening:	Every 5 years for women with negative HPV test results.	
Women aged 25 years or older:	12 month repeat:	1-year repeat following positive HPV test with triage negative (NAD cytology).	
	3 month repeat:	Unsatisfactory result or expired sample / vial	

B. Women – special circumstances		GP / Clinic Payment
Women: • post-colposcopy screening tests	• First screening test as per colposcopy discharge recommendation, thereafter as per screening test recommendation.	Yes if interval and criteria observed
Women: • post-total hysterectomy	• Women with no CIN at hysterectomy: no further screening is required. • Women with completely excised CIN at hysterectomy: follow up is undertaken by the treating clinician in line with colposcopy management protocols • If histology is unknown: No further programme screening following 1 (one) negative HPV test result.	
Women: • with HIV infection (coded 'CD4i')	• Women are eligible for programme screening from the time of their HIV diagnosis. • Cervical screening should be performed within one year of HIV diagnosis. • Annual screening for women with negative HPV test results. • After first positive HPV result, women will be referred to colposcopy.	If woman is under 25 or over 65 years GP/Clinic must seek payment from CervicalCheck 061 406500 admin@cervicalcheck.ie
Women: • with renal failure requiring dialysis • about to undergo renal transplant • post organ transplant • undergoing pre-organ transplant workup	• Screening test required at or shortly after diagnosis of renal failure. • Women about to undergo organ transplantation should have had a cervical screening test performed within 1 year. • Annual screening for women with negative HPV test results. • After first positive HPV result, women will be referred to colposcopy.	
Women: • Post pelvic radiotherapy for cervical, bladder, rectal and other pelvic cancers • Congenital absence of the cervix	• Cervical screening not recommended.	Not Applicable
Eligibility check Check woman's next test due date www.cervicalcheck.ie		

Notes	GP / Clinic Payment
1. Women aged less than 25 years who have never had a cervical screening test or have had a previous negative test result.	Not eligible. No payment
2. Women not yet due a routine or surveillance screening test.	Not eligible. No payment
3. Women aged 65 years or older (with no requirement for increased surveillance)	Not eligible. No payment
4. Women aged under 25 years with previous (non-CervicalCheck) screening test result that is not normal requiring a repeat test.	Not eligible. No payment
5. Women over 25 with previous CervicalCheck normal result and subsequent non-CervicalCheck test requiring a repeat test.	Not eligible. No payment
6. Women over 25 to 65 years receiving long-term immuno-suppressant medication or attending DES clinic.	Standard HPV screening algorithm applies.

CS/SPP/PM-9 Rev 9

* Subject to change

Appendix 2: Cervical Screening results and recommendations table* (sample)

Cervical Screening results and recommendations table

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

HPV Test Result	Cytology Pattern (where applicable)	Code	Management Recommendation	Rationale/ Recommendation
Not Detected/ Negative	**N/A**	R1	Screening completed	• Woman is aged 61 or over at date of test • Discharged from colposcopy with a recommendation of no further screening • Woman is aged 64 or over at date of test and has been on annual surveillance for reason of renal dialysis / post-transplant or HIV positive.
		R3	1 year recall	• Renal dialysis • Pre / post-transplant • If HIV+ • If increased surveillance is indicated as per colposcopy discharge (see note 1 below)
		R2a	3 year recall	• If aged between 25 and 29 years with no requirement for, or completed increased surveillance • First test at completion of increased surveillance post colposcopy - Any age
		R2b	5 year recall	• If aged between 30 - 60 years at test date with no requirement for increased surveillance (women must attend for one test at 3 year interval before moving to 5 year recall on completion of increased surveillance post colposcopy).
Detected/ Positive	**P1 (Unsatisfactory)**	R6	3 month repeat	Repeat 3 months
		R7	Refer to colposcopy	• 3 consecutive unsatisfactory screening test results • Any 3 screening test results that are not normal in previous 10 years & woman has not had colposcopy.
	P2 (No abnormality detected)	R3	1 year recall	First HPV positive and cytology NAD, repeat screening test in 1 year (includes women on post colposcopy surveillance)
		R7	Refer to colposcopy	• Second consecutive HPV positive and cytology NAD taken in non-colposcopy setting. See note 2 below • If HIV+ • Renal dialysis • Pre / post-transplant
	P3a+ (ASCUS or worse)	R7	Refer to colposcopy	Any HPV positive result with abnormal cytology
Indeterminate HPV result	**N/A**	R6	3 month repeat	First or second indeterminate screening test result
		R7	Refer to colposcopy	3 consecutive indeterminate screening test results
				Any 3 screening test results that are not normal in previous 10 years & woman has not had colposcopy
Test not Processed	**N/A**	R6	3 month repeat	Repeat 3 months

NOTES:

1. Women discharged from colposcopy pre March 2020 for cytology screening who receive a HPV negative result do not require continued annual surveillance unless there is a history of invasive cervical cancer/CGIN/AIS/SMILE. Women discharged after March 2020 should attend for their recommended number of post colposcopy HPV tests.
2. Disregard intervening cytology only, indeterminate, unsatisfactory result.
3. Where cervix is suspicious for invasive disease, refer for urgent colposcopy, do not take screening test.
4. When current clinical details record Post Coital Bleeding (PCB)/intermenstrual bleeding (IMB)/ Post-Menopausal Bleeding (PMB) it is recommended to refer for gynaecological assessment.
5. **Where there is a cytology result:** If there are endometrial cells present out of cycle for a woman over 40 years it is recommended to refer for gynaecological assessment.
6. **Where there is a cytology result and a previous history of treatment for glandular abnormality:** Report as UNSAT if TZ cells are not present.

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CS/PUB/LAB-2 Rev. 12

* Subject to change

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