



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 CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

Quality Assurance in Primary Care and Other Cervical Screening Settings

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2.1 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 by Practice Nurses. CervicalCheck is committed to promoting equity through addressing inequalities. Primary care and other cervical screening services are expected to uphold this commitment.

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

In addition to taking the test and ensuring results and recommendations are followed up, doctors, nurses and administrative staff play a vital role in supporting women in making a decision whether or not to have cervical screening. 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 screening.

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

These standards provide a framework to assist sampletakers 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 must be able to demonstrate how they meet the quality requirements and standards via self-audit. The programme can assist in assessing compliance with several of the stated standards and their associated targets by providing statistics derived from data on the Cervical Screening Register (CSR).

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

2.2 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 is no target 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.

2.2.1 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 screening. Staff must ensure that the information they give to women is accurate and in a format that is easily understood.

QR33. Quality requirement

Promoting awareness of cervical screening

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

QR34. Quality requirement

Understanding the benefits and limitations of cervical screening

All practice and clinic staff 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.

QR35. Quality requirement

Eligibility and registration of women

Services must ensure that eligible women are facilitated to have a free cervical screening test either by presenting for a test or by registering with the programme. This is so they are included on the Cervical Screening Register and can be invited to participate in cervical screening.

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. At all times, service staff must encourage and assist eligible women to register if they are not yet part of the CervicalCheck programme.

QR36. Quality requirement

Understanding cervical screening programme operation

All practice and clinic staff have a duty to remain informed of programme policies either by attending clinical updates or by completing e-learning modules.

QR37. Quality requirement

Addressing barriers to participation

Practice and clinic staff (clinical and administrative) must be aware of the barriers to participation in cervical screening for eligible women, and of the means to minimise them.

Note 1: Appreciation and understanding of known barriers can help in increasing uptake. One of the recognised barriers to screening is lack of understanding about the cervical screening test.

Note 2: Services must ensure eligible women who are not patients of their service are facilitated if they request a cervical screening test.

2.2.2 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 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. Achieving equitable coverage is an important factor in ensuring screening does not widen health inequalities.

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

Standard 2-1	Screening of eligible women	Target
	Women screened must be eligible for programme screening as defined by the HPV Primary Screening: Eligibility Framework / Reference Guide for GPs and Clinics ¹ .	100%
Standard 2-2	Equitable Coverage	Target
	Uptake of cervical screening must be equitable, with even distribution of uptake across all groups in society, for example, by ethnic groups, by disability and by areas of social deprivation.	80%
Standard 2-3	Adherence to recommended screening intervals	Target
	Cervical screening tests for previously screened women must not be carried out earlier than the recommended interval.	100%
	<i>Note: The next test due date for screened women is available to women and to health professionals through a secure online check facility and through the Information Service (Free phone) provided by CervicalCheck.</i>	

2.2.3 Qualifications and skills for cervical screening

QR38. 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, as appropriate.
QR39. Quality requirement	Maintenance of professional registration
	All sampletakers must maintain their professional registration for the period of time that they are registered with CervicalCheck.
QR40. Quality requirement	Registration to provide cervical screening
	Doctors and nurses who register with CervicalCheck to provide cervical screening services must undertake an introductory module through online learning that outlines the requirements and operation of the programme as part of their registration process.

QR41. Quality requirement**Change of status**

Doctors and nurses who are registered with the programme must advise the programme office of any change to their professional registration status. They must also advise the programme regarding any change of location, retirement or when ceasing to provide cervical screening services.

QR42. Quality requirement**Access and availability of learning and reference resources**

Each practice and clinic must have current versions of relevant learning and reference resources available and accessible to all those engaged in cervical screening.

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

- Relevant sections of the current Standards for Quality Assurance in Cervical Screening².
- CervicalCheck HPV Primary Screening: Eligibility Framework / Reference Guide for GPs and Clinics¹.
- CervicalCheck Cervical Screening Results and Recommendations [table](#)³.
- Online CervicalCheck learning resources available through the National Screening Service Learning Portal and CervicalCheck website.
- Information for women through the CervicalCheck website and promotional materials about cervical screening (including benefits and limitations, HPV, screening tests and results and colposcopy).

QR43. Quality requirement**Appropriate training (Developmental Requirement)**

All sampletakers engaged in cervical screening should be appropriately trained by completing an accredited evidence-based training programme. It is the duty of the doctor with clinical responsibility to ensure that all sampletakers in their service are appropriately trained and competent. Sampletakers should attend a CervicalCheck screening training course within one year following the start of the contract and must facilitate visits from CervicalCheck Clinical Trainers.

QR44. Quality requirement**Clinical updates**

Sampletakers must participate in a CervicalCheck clinical update at least once every three years. Clinical 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).

QR45. Quality requirement**Supervision of sampletakers new to cervical screening**

A sample taker new to cervical screening is determined as working in a service where cervical screening is carried out and, not having completed a CervicalCheck recognised cervical screening training programme. The doctor with clinical responsibility should supervise 20 cervical screening tests to be performed by the new sample taker under supervision.

2.2.4 Optimal environment for women

Cervical screening services must be provided in an environment that respects the privacy, dignity and autonomy of women. Every effort must be made to ensure that the cervical screening environment is acceptable to the women who use them.

QR46. Quality requirement

Confidentiality

Providers must ensure that confidentiality in relation to each woman and her personal information is maintained throughout the cervical screening process.

QR47. 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.⁴

QR48. Quality requirement

Practice records

Each service must manage and maintain accurate records in a safe and secure environment. Computer information on women should not be on view between consultations.

QR49. 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.

QR50. Quality requirement

Room temperature

Cervical screening tests must be carried out in a comfortable environment where the room temperature is ambient.

QR51. Quality requirement

Chaperone

A chaperone must be facilitated if the woman requires one. The chaperone or support person may be a relative or friend.

QR52. Quality requirement

Women with disabilities

Sampletakers must facilitate eligible women with disabilities, including those who have a physical or intellectual disability. Doctors, nurses and associated staff must facilitate eligible women with adequate time and an environment that accommodates their requirements. Wheelchair accessibility should be provided.

Note: The programme's Access Officer is available to assist with access queries.

2.2.5 Appropriate equipment and materials

There must be advanced preparation of equipment and consumables for the screening test. Details of the necessary equipment are available in programme publications for sampletakers engaged in cervical screening. Preparation must include checks on expiry and maintenance dates as appropriate.

QR53. 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 with physical disabilities.	
Standard 2-4	Consumables – cervical screening test kits and specula Consumables in use for cervical screening must be within expiry dates. <i>Note: Sampletakers undertaking cervical screening must ensure that the sample vials used do not expire before reaching the laboratory or before being processed. At least 14 days left on expiry but ideally one month.</i>	Target 100%
QR54. 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.	
QR55. 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 after (single) use. <i>Note: There must be a range of speculum sizes available for use at the practice.</i>	
QR56. Quality requirement	Clinical waste Single-use disposable specula and cervix brushes must be disposed of as clinical waste.	

2.2.6 Pre-screening: preparation for the screening test

QR57. Quality requirement

Communication with the woman

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 on cervical screening accompanying the Cervical Screening Form⁵. Aspects of the cervical screening process to be communicated include:

- The cervical screening test(s) including the underpinning reasons for primary HPV testing and reflex cytology
- HPV and its role in cervical cancer
- The importance of regular screening
- The accuracy and the limitations of 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.

QR58. Quality requirement

Choice of sample taker

The sample taker must ensure that the woman is aware of her entitlement to choose which sample taker she wishes to attend within the service.

QR59. Quality requirement

Determination of requirement for cervical screening

The sample taker must provide sufficient information for a woman to assess whether cervical screening is appropriate for her.

The healthcare professional must notify the programme if cervical screening is not recommended for a woman at this time and if this is unlikely to change in the future.

Note 1: A woman may opt out of the screening programme. A healthcare professional must notify the programme when screening is not recommended or when it is not appropriate or possible for the woman to do so.

Note 2: The record of a woman on the Cervical Screening Register (CSR) will be made inactive on receipt of a notification of 'cervical screening not advised' form from a healthcare professional. The woman will receive no further communication from the programme.

QR60. Quality requirement**Informed consent**

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

Note 1: Informed consent means that information must be provided in a way that is understandable to the 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 and to the National Cancer Registry Ireland, if appropriate. Obtaining the woman's informed consent is the responsibility of the sample taker taking the test. The woman's consent must be recorded on the Cervical Screening Form⁵, directly by signature or by accepted witnessed indication, in line with best practice policy⁶.

Note 2: Consent to participate or withdrawal from the cervical screening programme is not accepted from a third party e.g. parent or guardian, spouse (unless in line with assisted decision making policy).

Note 3: Women who do not wish to be part of CervicalCheck must be advised how to opt out of the programme using CervicalCheck's Opt-Out form. Eligible women who opt out of the programme can re-engage at any future date if they wish to do so.

QR61. Quality requirement**Use of CervicalCheck Cervical Screening Form**

A CervicalCheck Cervical Screening Form⁵ must be completed at the time of taking a cervical screening test in the presence of the woman, to ensure accuracy and completeness.

QR62. Quality requirement**Identification of the woman - minimum details**

The sample taker 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 minimum demographic details comprise the woman's forename, surname, address and date of birth.

QR63. Quality requirement**Unique identification of the woman**

In addition to the minimum demographic details, at least one unique identifier for the woman must be recorded on the Cervical Screening Form.

At least one of the following must be recorded:

- Personal Public Service (PPS) number
- Cervical Screening Programme Identification number (CSP ID)
- Individual Health Identifier (IHI)
- Surname at birth
- Mother's maiden name.

Note: The woman's PPS number, CSP ID and IHI 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 therefore of particular importance in identifying a unique woman and in matching screening events to her record on the Cervical Screening Register.

Standard 2-5	<p>Accurate matching of the woman</p> <p>The Cervical Screening Form must record sufficient, accurate details to uniquely identify the woman and enable accurate matching with her record on the Cervical Screening Register in line with good laboratory practice.</p>	<p>Target</p> <p>100%</p>
Standard 2-6	<p>Identification of the doctor</p> <p>The doctor with clinical responsibility for the screening test must be completely and accurately identified on the Cervical Screening Form in line with good laboratory practice.</p>	<p>Target</p> <p>100%</p>
Standard 2-7	<p>Identification of the sample taker who takes the cervical screening test</p> <p>The sample taker who takes the screening test must be completely and accurately identified on the Cervical Screening Form in line with good laboratory practice.</p>	<p>Target</p> <p>100%</p>
Standard 2-8	<p>Quality of data – completeness, accuracy and legibility</p> <p>Cervical Screening Forms 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 good laboratory practice.</p> <p><i>Note 1: Computer generated forms must be checked for accuracy and quality of data.</i></p> <p><i>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.</i></p>	<p>Target</p> <p><2%</p>

2.2.7 Screening: undertaking the cervical screening test

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

Standard 2-9	Minimum repeat interval	Target
QR64. Quality requirement	Visualisation of the cervix The cervix, where present, must be visualised, assessed and effectively sampled. A screening test must not be taken if the cervix has not been visualised.	100%
QR65. 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.	
QR66. Quality requirement	Relevant clinical details and findings All relevant clinical details relating to cervical screening (e.g. last menstrual period [LMP]) must be recorded on the Cervical Screening Form.	
QR67. Quality requirement	Previous cervical screening history Previous cervical screening history, where known, available and relevant, must be recorded on the Cervical Screening Form. <i>Note: The programme will provide a record of the woman's CervicalCheck cervical screening history to the laboratory that processes the test. However, this record will not include tests carried out outside the programme. Management recommendations from the laboratory are based on all available previous results.</i>	
QR68. Quality requirement	Previous treatment history Previous treatment history of the cervix, where known, available and relevant (including dates of treatment), must be recorded on the Cervical Screening Form. <i>Note: The programme will provide a record of the woman's CervicalCheck treatment 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 must be recorded.</i>	

2.2.8 Post-screening: after the cervical screening test

QR69. Quality requirement

Woman's medical record

The sample taker 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.

QR70. 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. The result of the screening test will be sent to the woman directly from the programme.

QR71. Quality requirement

Sample identification

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

Standard 2-10

Matching of sample vials and screening forms

Target

Each sample vial and accompanying Cervical Screening Form must be accurately matched for the same woman.

100%

Note: The detachable barcode 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.

Standard 2-11

Dispatch of samples

Target

Sample vials and their associated forms must be dispatched to the laboratory within a maximum of five working days of the test being taken.

99%

Note 1: It is important to dispatch the sample promptly in order to facilitate the programme commitment of a prompt result to the woman (4 weeks).

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

QR72. 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 must be used for transportation to the laboratory. Universal precautions must be employed for handling and packaging of all samples.

2.2.9 Management of cervical screening test results

The service 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.

QR73. Quality requirement

Results management

Services must have in place a protocol regarding the management of screening test results. Women must be made aware of this process.

QR74. Quality requirement

Receipt and checking of cervical screening test results

Outstanding results must be identified if they have not been received within 21 working days from the cervical screening test date and followed-up with the laboratory as appropriate.

A screening test result must be received for each sample sent to the laboratory. Results received from the laboratory must be cross-checked against screening tests taken.

QR75. 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.

QR76. Quality requirement

Checking management recommendations

Management recommendations accompanying screening test results must be checked in relation to the woman's 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 result is correct with regard to the woman's screening history. Sampletakers must contact the laboratory if they have queries in relation to results or management recommendations.

QR77. Quality requirement

Communicating results and outcomes to women

Services must have an appropriate system to communicate every screening test result or outcome to the woman concerned. The sample taker is responsible for counseling women with abnormal results. All staff, including administrative staff, must be aware and informed of the protocol for communicating results to women.

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.

Explanations must be clear and appropriate to the level of understanding of each woman.

2.2.10 Referral and follow-up of women

QR78. Quality requirement

Follow-up of women

Sampletakers must ensure that reasonable efforts are made to follow-up screening test management recommendations ensuring that appropriate action is taken.

QR79. Quality requirement

Use of CervicalCheck Colposcopy Referral Form

The CervicalCheck Colposcopy Referral Form⁷ must be used when referring a woman to a CervicalCheck colposcopy service.

A copy of the relevant screening test result report must 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 form⁸ to assist a doctor to make a referral for the woman to a colposcopy service where an appointment will be provided.

Standard 2-12

Referral to colposcopy

Target

Women whose screening test result carries a referral to colposcopy recommendation must be referred directly by the doctor with clinical responsibility to a colposcopy service within 10 working days of receipt of the screening test result.

99%

Note 1: All referral information about the woman, her screening test result and relevant history must be forwarded directly to the colposcopy service.

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

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 to add 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 follow-up (failsafe) information request by letter to the clinically responsible doctor.

Standard 2-13	Failsafe follow-up of abnormal results (information requests)	Target
	<p>The doctor with clinical responsibility must determine, record and return requested follow-up information to the programme (online or by post) within 10 working days of receipt of the request (by letter).</p> <p><i>Note 1: The sample taker 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) must be made.</i></p>	99%

QR80. Quality requirement	<p>Continuity of care of a woman</p> <p>During and following her cervical screening pathway, a woman must have a doctor with clinical responsibility assigned to her care. If the doctor with clinical responsibility leaves the service for whatever reason, the practice remains clinically responsible for women who have had cervical screening tests until alternative arrangements are made if necessary.</p>
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2.2.11 Quality assurance

QR81. Quality requirement	<p>Cancer audit process</p> <p>Placeholder standard: To be updated once the Expert Reference Group on Clinical Audit of Interval Cancer in the Screened Population, publish its report and recommendations.</p>
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QR82. Quality requirement	<p>Quality monitoring – three year audit cycle</p> <p>The service must conduct a three yearly audit of its cervical screening activity with respect to compliance with the ‘Standards for Quality Assurance in Cervical Screening’².</p> <p>Clinically responsible doctors must instigate at intervals of three years (not more than five years). The audit scope and outcomes must be recorded and resulting planned actions must be documented and implemented.</p>
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2.3 References

1. HPV Primary Screening: Eligibility Framework / Reference Guide for GPs and Clinics (CS/SPP/PM-9).
2. Standards for Quality Assurance in Cervical Screening.
3. Cervical Screening Results and Recommendations Table (CS/PUB/LAB-2).
4. Amendment of Section 1 of Health (Provision of Information) Act 1997 contained within Data Protection Act 2018.
5. CervicalCheck Cervical Screening Form (CS/F/LAB-2).
6. Health Service Executive (Quality and Patient Safety Division). National Consent Policy (QPSD-D-026-1.2. V.1.2). 2017 (August). ISBN: 978-1-906218-63-8. Available at: <http://www.hse.ie/eng/about/Who/QID/Other-Quality-Improvement-Programmes/Consent/National-Consent-Policy-August-2017.pdf>
7. CervicalCheck Colposcopy Referral Form (CS/F/CLP-6 (online version))
8. CervicalCheck Doctor Referral to Colposcopy (CS/F/REG-46 (partially completed form sent by post to the doctor with clinical responsibility).



