



Standards for  
**Quality Assurance in  
Cervical Screening**  
Quality assurance in  
programme operation



An tSeirbhís Náisiúnta Scagthástála  
National Screening Service

**CervicalCheck**  
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS  
THE NATIONAL CERVICAL SCREENING PROGRAMME



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## Quality assurance in programme operation

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*(March 2020)*

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## 1.1 Introduction

Programme operation includes:

- Coverage standard, the definition of the screening population and of the recommended screening intervals
- Processes for the identification of eligible women
- The acquisition and update of the demographic details of eligible women
- An organised process of communication with eligible women
- The means of enabling access and participation by eligible women
- Acquiring and maintaining the screening history of eligible women over time
- Processes to ensure that women are followed-up based on management recommendations
- Reporting and performance monitoring
- Programme evaluation.

CervicalCheck requires quality assurance in programme operation as one element of the cervical screening pathway.

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

## 1.2 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 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.

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## 1.2.1 Screening population and screening intervals

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<b>Standard 1-1</b>	<b>Eligible Population Coverage</b> The number of eligible individuals screened in a defined period is maximised across all groups.	<b>Target</b> ≥ 80%
<b>QR1. Quality requirement</b>	<b>Screening Population</b> The programme shall make publicly available at all times the defined screening age range in operation together with definitions of any women outside of this age range that are deemed eligible for programme screening in specific circumstances.	
<b>QR2. Quality requirement</b>	<b>Screening Intervals</b> The programme shall make publicly available at all times the defined screening intervals, with the associated qualifying attributes (e.g. age, previously unscreened, post-colposcopy) that are in operation.	

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## 1.2.2 Identification and recording of screening population

The Health (Provision of Information) Act 1971<sup>1</sup> provides the legislative framework for the acquisition and retention of the demographic details of eligible women for the purposes of delivering an organised screening programme.

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<b>QR3. Quality requirement</b>	<b>Maintenance of a screening register</b> The programme must maintain a secure database (known as the Cervical Screening Register (CSR)) to contain individual records for each woman in the screening programme. The CSR is designed to support the accurate identification and appropriate management of women throughout their participation in the programme.
<b>QR4. Quality requirement</b>	<b>Acquisition and update of demographic details</b> Processes shall be in place to acquire, maintain and update the demographic details of women in the target population as defined by the eligibility framework for cervical screening on the Cervical Screening Register.
<b>QR5. Quality requirement</b>	<b>Unique identification of women</b> Each woman with a record on the Cervical Screening Register must be assigned a unique identifier number with the cervical screening programme (CSP ID).
<b>QR6. Quality requirement</b>	<b>Minimum demographics</b> Each woman's record on the Cervical Screening Register must contain forename, surname, date of birth, address and unique cervical screening programme identification (CSP ID).

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<b>Standard 1-2</b>	<p><b>Eligible population register</b></p> <p>The Cervical Screening Register must contain a record for the majority of eligible women within the target population as defined by the eligibility framework for cervical screening.</p> <p>Note: The number of eligible women on the CSR versus the number in the population statistics published by Central Statistics Office.</p>	<p><b>Target</b></p> <p>97%</p>
<b>Standard 1-3</b>	<p><b>Matching Demographics</b></p> <p>The matching demographic details for each woman must include at least one of the following unique identifiers: surname at birth, mother's maiden name, PPS number or IHI number.</p> <p>Note: Matching demographics are not subject to change in a woman's lifetime and are in addition to the minimum demographics.</p>	<p><b>Target</b></p> <p>99%</p>
<b>QR7. Quality requirement</b>	<p><b>Data protection and confidentiality</b></p> <p>The programme (under the relevant Health Authority) shall be registered with the Data Protection Commissioner and comply with the most recent national and European legislation regarding the use and security of personal information that is in force at any one time<sup>2</sup>.</p> <p>Note 1: The acquisition and use of personal health information is for the purpose of implementing the cervical screening programme.</p> <p>Note 2: The following principles guide the use of data held on the CSR:</p> <ul style="list-style-type: none"> <li>• One woman with one set of demographics</li> <li>• Personal health information belongs to the woman to whom it relates</li> <li>• Women give consent to allow CervicalCheck to hold and share their personal and screening data. Consent will be given at each screening event.</li> <li>• Security and confidentiality of personal information.</li> </ul>	
<b>QR8. Quality requirement</b>	<p><b>Prevention of loss of data</b></p> <p>Systems shall be in place for regular back-ups and secure storage of the personal health information and related data held by the programme.</p>	

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### 1.2.3 Call, re-call process

Call, re-call history: The Cervical Screening Register (CSR) will be capable of recording a woman's call, re-call history.

The CSR is used to control the issuing of programme letters, including:

- Invitation (call) letters that invite women to participate in the programme by attending for a screening test with a registered doctor or nurse.
- Re-call letters that invite previously screened women to attend for another screening test at defined intervals
- Letters following screening test results which advise women of their next recommended step in the screening programme
- Letters and forms to women and their doctors to ensure appropriate follow-up.

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<b>Standard 1-4</b>	<b>Invitation (call) of eligible women</b>	<b>Target</b>
	Every eligible unscreened woman with a record on the Cervical Screening Register should be invited (called) within a maximum 12 months of having her record first created on the register.	99%
<b>Standard 1-5</b>	<b>Re-call of previously screened women</b>	<b>Target</b>
	All previously screened women with re-call recommendations (routine or increased surveillance) should be issued a re-call letter at least two months in advance of the appropriate next test due date.  Note: For previously screened women, the re-call screening test interval is typically one year (increased surveillance), or three or five years (routine screening). This depends on the woman's age and the management recommendation associated with her previous test result. The programme must have a system to notify these women in advance of the re-call screening test due date. Women with a three month repeat test recommendation are not issued a letter in advance of the due date and are not included in the scope of this standard.	99%
<b>Standard 1-6</b>	<b>Reminders</b>	<b>Target</b>
	Women who do not respond to an invitation (call) or re-call letter by attending for a screening test within a specified period are sent at least one reminder letter within three months.	99%

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**QR9. Quality requirement**

**Women who choose not to participate (opt out)**

An opt-out process should be in place for women who choose not to participate in the cervical screening programme. CervicalCheck should not issue correspondence to women who choose to opt out.

Note: Women, who inform the programme in writing of their wish to opt-out should not be included in any future call, re-call process. The aim is to provide women with the option and to support women for whom screening is not appropriate, for whatever reason, to choose to withhold or withdraw consent from any future participation in the programme. Women can re-enter the programme at any stage by attending for a screening event and providing their consent.

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**Standard 1-7**

**Accuracy of contact details for correspondence**

Contact details of women on the Cervical Screening Register should be accurate and updated as necessary. The proportion of letters issued to women that are returned as undeliverable by the postal service should be maintained within low limits.

**Standard 1-7a**

The proportion of letters of invitation and re-call issued to women that are returned as undeliverable by the postal service should be maintained within a low limit.

**Target**  
10%

**Standard 1-7b**

The proportion of letters following results and letters to follow up (failsafe) issued to women that are returned as undeliverable by the postal service should be maintained within a low limit.

**Target**  
2%



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## 1.2.4 Screening history of women

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### QR10. Quality requirement

#### Record of screening history

The Cervical Screening Register (CSR) should be capable of recording a woman's cervical screening history.

A woman's cervical screening history includes but is not limited to call and re-call, cytology and HPV test results, management recommendations, colposcopy attendances, procedures, treatments and discharge recommendations, and histology results.

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### QR11. Quality requirement

#### Informed consent

Data related to a woman's screening history should only be acquired when the woman has provided her informed consent.

A woman's consent allows CervicalCheck to hold a woman's screening history on the Cervical Screening Register and to share it with third-party service providers including cytology, molecular pathology and histology laboratories and colposcopy services to inform decision-making regarding management of the woman's care. Informed consent should include explicit information about the benefits and limitations of screening.

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### QR12. Quality requirement

#### Transfer of personal health information

All personal health information transferred between the Cervical Screening Register and third-party service providers engaged to support programme delivery should use secure communications methods, and/or must be encrypted to an accepted standard or protocol. Secure electronic communications methods should include Virtual Private Networks (VPNs) and secure email.

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### Standard 1-8

#### Matching of screening events to the correct woman

#### Target

Screening event details including cytology, HPV, colposcopy and histology results, notified to the programme must be matched to the correct woman's record on the Cervical Screening Register.

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There must be processes in place to identify women with more than one record on the Cervical Screening Register, and to merge the records to a single record.

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### Standard 1-9

#### Duplicates and merges

#### Target

The proportion of duplicate records on the Cervical Screening Register at any one time must be maintained below a minimum level.

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## 1.2.5 Registration of doctors and nurses for cervical screening

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### QR13. Quality requirement

#### Registration of doctors and nurses for cervical screening

The programme should have a system of registering qualified doctors and nurses to provide screening to eligible women.

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### QR14. Quality requirement

#### Information about registered doctors and nurses

The programme should make the contact details and locations of doctors and nurses registered with CervicalCheck publicly available through appropriate channels.

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## 1.2.6 Communications with women

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### QR15. Quality requirement

#### Commitment to women

The programme must make publicly available its commitments to women through the publication of a client charter.

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### QR16. Quality requirement

#### User Involvement /Patient and Public Partnership

The programme will partner with service users in the design and review of any correspondence and materials.

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### QR17. Quality requirement

#### Provision of relevant information to women

The programme should develop and provide information in appropriate formats to facilitate women to make informed choices in relation to their participation in the programme. Information materials for women must be reviewed on a periodic basis to reflect policy changes and users' needs. Reviews will consider materials for appropriateness, accuracy and clarity of content, means of dissemination, and new information to be incorporated.

Channels for the provision of information may include advertisements, promotional materials, information leaflets, website and by direct contact (telephone, email, post).

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### QR18. Quality requirement

#### Appropriate correspondence to women

Information leaflets should accompany invitation (call) letters and letters following results to inform women about the screening programme and the recommended follow-up steps to be taken. The correct information leaflet should accompany invitation (call) letters and letters following results.

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**QR19. Quality requirement****Means of registration and checking eligibility**

The programme should provide the means for women to register, check if they are registered, update their registration details, and check when their next programme test is due through appropriate means, including telephone, email, post and website.

**QR20. Quality requirement****Women with disabilities**

The programme should have a designated access officer and procedures in place to support access and participation by eligible women with disabilities. The programme will provide appropriate information to support women with disabilities.

**QR21. Quality requirement****Feedback from women**

The programme will provide suitable channels for women to provide feedback regarding all aspects of their experience with the screening programme in line with Your Service, Your Say.<sup>3</sup> A process for recording and evaluating feedback must be in place.

Feedback channels should include telephone, email, post, website (initiated by women) and surveys.

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**1.2.7 Management recommendations and follow-up****QR22. Quality requirement****Standard management recommendations**

The programme must ensure that doctors are provided with management recommendations (through designated laboratory services and colposcopy services) containing the next step for the follow-up of women.

**Standard 1-10****Programme communication with women following screening tests****Target**

95%

The result of the screening test will be sent to the woman directly from the programme within three working days following receipt of the screening test result from the laboratory.

Note: The woman's next recommended step in the screening programme is based on the management recommendation accompanying her screening test result.

**Standard 1-11****Programme response time****Target**

90%

Letters should be issued from the programme to women advising them of the result and next recommended step in the screening programme within four weeks from the date of their screening test.

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**QR23. Quality requirement**

**Abnormal follow-up (failsafe) process**

A process should be in place to monitor women with abnormal screening test results and women who have been discharged post-colposcopy. The programme will communicate with the woman and doctors concerned where there is no evidence of action taken subsequent to a recommendation.

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**Standard 1-12**

**Abnormal follow-up (failsafe) communications**

**Target**

Requests for follow-up action or information should be issued to women and to doctors within a maximum of three months of the due date where the recommended next step has not been notified to the programme.

99%

Note 1: The abnormal follow-up (failsafe) process involves communications sent by the programme to the woman and to the doctor with clinical responsibility when the woman does not attend for her recommended repeat screening test (following an inadequate or 'abnormal' result), her recommended referral to colposcopy or her recommended post-colposcopy discharge screening test.

Note 2: The follow-up actions are designed to ensure that all reasonable steps are taken to ensure screening results have been communicated to a woman and her clinically responsible doctor and that she has been offered a repeat screening test or further investigation as appropriate.

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**Standard 1-13**

**Abnormal follow-up (failsafe) outcomes**

**Target**

Women with abnormal screening test results should have either subsequent appropriate action (repeat screening test or colposcopy attendance notified to the programme) or recorded follow-up information from a clinically responsible doctor.

98%

Note: A 'lost-to-follow-up' report, identifying all women for whom no subsequent recommended actions have been notified should be prepared by the programme each year. There is a monthly failsafe process.

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## 1.2.8 Quality assurance

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### QR24. Quality requirement

#### Quality assurance standards

Quality assurance requirements and standards must be developed, maintained, published and made available to all service providers and stakeholders for all aspects of the cervical screening pathway.

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### QR25. Quality requirement

#### Review of quality standards

Quality assurance standards must be reviewed, updated and published at least once every three years.

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### QR26. Quality requirement

#### Monitoring of service provision

Processes should be in place to measure, monitor and publish overall programme performance and the performance of service providers against quality requirements and standards on an ongoing basis. Planning, corrective actions, preventive actions and risk assessment should be in place to address failures to meet quality requirements and standards, and service or contract requirements. Service improvement plans with providers should have clear timescales for actions and escalation arrangements.

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### QR27. Quality requirement

#### Quality management system

Programme administration must operate a quality management system (QMS).

Note: The quality management system (QMS) must encompass a quality policy, a quality manual, control of documents and control of records. The QMS must also incorporate procedures for handling complaints, non-conformances with service providers, feedback from women and stakeholders and management of measures for continuous improvement.

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### QR28. Quality requirement

#### Cervical cancer audit

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.

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### QR29. Quality requirement

#### Risk management

A process for identifying programme risks, recording risks, risk controls and risk assessment should be in place in order to contribute to quality improvement of the screening programme. Evidence should be available to describe the identified risks and their assessment and how risk management contributes to quality improvement actions.

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### QR30. Quality requirement

#### Incident Management

The programme will comply with the HSE Incident Management Framework for identifying incidents, recording incidents and managing incidents across the whole screening pathway.

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## 1.2.9 Programme reporting and evaluation

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### QR31. Quality requirement

#### Programme activity and outcomes

A report of annual programme activity and outcomes must be prepared and published. The report should be published within 15 months of the end of the year being reported.

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### QR32. Quality requirement

#### Programme key performance indicators (KPIs)

Relevant key performance indicators (KPIs) for the cervical screening programme must be calculated and made available.

Note: The European Guidelines for Quality Assurance in Cervical Cancer Screening describe the key performance indicators (KPIs) for a cervical screening programme.<sup>5</sup>

KPIs provide an indirect evaluation of the impact of the screening programme and act by monitoring the screening process. They enable the programme to identify and respond to potential problems at an early stage. The indicators also examine aspects of the programme that in addition to influencing the impact of the programme, address the human and financial costs of screening. Three distinct groups of indicators are used:

- Screening intensity
  - Screening test performance
  - Diagnostic assessment.
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## 1.3 References

1. Amendment of section 1 of Health (Provision of Information) Act 1997 contained within Data Protection Act 2018 <http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf>
2. Relevant national and European legislation regarding the use and security of personal information includes: Data Protection Act 1988, Data Protection (Amendment) Act 2003, EU Directive 95/46/EC <http://www.irishstatutebook.ie/eli/2003/act/6/enacted/en/pdf>
  - The Data Protection Directive 1995, EU Directive 2002/58/EC - Directive on privacy and electronic communications, General Data Protection Regulation (GDPR) (effective from 25 May 2018).
3. Health Service Executive (2017), Your Service, Your Say <https://www.hse.ie/eng/about/qavd/complaints/ysysguidance/ysys2017.pdf>
4. Health Service Executive (2018), Incident Management Framework <https://www.hse.ie/eng/about/qavd/incident-management/hse-2018-incident-management-framework-guidance-patient-staff-stories.pdf>
5. European Guidelines for Quality Assurance in Cervical Cancer Screening. 2nd edition. European Commission. 2008 and European Guidelines for Quality Assurance in Cervical Cancer Screening – Supplements to the 2nd edition. European Commission. 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2826099/>

