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

Contents

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
- Clinical and managerial leadership
- Reporting and performance monitoring
- Programme evaluation.
  - CervicalCheck requires quality assurance in programme operation as one element of the cervical screening pathway.

Note: cervical screening is for women and people with a cervix. 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 standards are those with a measurable level of performance and associated target for achievement. Where there is no target provided these are considered quality requirements that the service provider must fulfil. These requirements are identified with a 'must' or 'will' statement.

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.

2.1 Screening population and screening intervals

Standard 2-1	**All Coverage by Screening** The number of eligible individuals screened in a defined period is maximised across all age ranges. *Note: in this context eligibility is based on the fact that the woman is within the screening age range and has a cervix.* *Note: the 80% target is for overall coverage, not per age subgroup.*	**Target** ≥ 80%
Standard 2-2	Response to invitation (uptake): Proportion of invited individuals who attended for a test within six months of call or recall open date.	**Target** Achievable 60% Min 50%
Standard 2-3	To obtain high screening coverage, it is essential to reach the entire target population. All women in the target population must be invited every three to five years.	**Target** 33% per annum (age 25-29) 20% per annum (age 30+)
QR 2.01 Quality requirement	**Screening Information** The programme shall make publicly available, via a dedicated website for the public and healthcare professionals, social media platforms and other communications platforms (e.g. leaflets, newsletters, etc.) 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. • The defined screening intervals, with the associated qualifying attributes (e.g. age, previously unscreened, post-colposcopy) that are in operation. • Sufficient accessible information to enable the eligible population to make an informed choice when consenting to screening.	

2.2 Legal Basis for Identification and recording of the cervical screening population

The Health (Provision of Information) Act 1997 as amended by Section 184 of the Data Protection Act 2018 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. The primary source for the acquisition of the demographic details of eligible women for CervicalCheck is the Department of Social Protection. The Health Service Executive may, for the purposes of compiling and maintaining a record of the names, addresses, telephone numbers, e-mail addresses and dates of birth of persons who, for public health reasons, may be invited to participate in any cancer screening (including any breast, cervical or bowel cancer screening) programme operated by the Executive, request from any person the names, addresses, telephone numbers, e-mail addresses and dates of birth of persons held by, or in the possession of, that person.

QR 2.02 Quality requirement	**Maintenance of a screening register** 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.
QR 2.03 Quality requirement	**Acquisition and update of demographic details** 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.
QR 2.04 Quality requirement	**Unique identification of women** Each woman with a record on the Cervical Screening Register must be assigned a unique identifier number with the cervical screening programme (CSP ID).
QR 2.05 Quality requirement	**A daily deduplication process must be in place** *Note: A duplicate record is where the woman is recorded more than once on the CSR under different CSPID numbers. The proportion of duplicate records on the Cervical Screening Register at any one time must be minimised to as low a level as is achievable. 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.*
QR 2.06 Quality requirement	**Minimum demographics** 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).

Standard 2-4	**Completeness of population register** 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. *Note: In any defined period of time, the number of eligible people listed on the register (numerator) expressed as a percentage of relevant Central Statistics Office (CSO) census data (denominator).*	**Target** 95%
Standard 2-5	**Register Linkage – Unique Identifying Demographics** Each record on the CSR must include at least one of the following unique identifiers: surname at birth, mother's maiden name, PPS number. *Note: Unique demographics are not subject to change in a woman's lifetime and are in addition to the minimum demographics (surname, forename, DOB).*	**Target** 95%
Standard 2-6	**Matching of screening events to the correct woman** Any incidents of data entry/capture error must be kept to a minimum. 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.	**Target** <=5%
QR 2.07 Quality requirement	**Data protection and confidentiality** 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. This requirement extends to all external stakeholders contracted to provide services to CervicalCheck (Privacy Shield). Service providers who are outside of EU/EAA or from countries without an Adequacy Decision from the EU Commission, will be required to provide additional guarantees in terms of data privacy. *Note 1: The acquisition and use of personal health information is for the purpose of implementing the cervical screening programme.* *Note 2: The following principles guide the use of data held on the CSR:* • *One woman with one set of demographics* • *Personal health information belongs to the woman to whom it relates* • *Women give consent to allow CervicalCheck to hold and share their personal and screening data. Data is shared with the other health services that deliver the programme, including the doctor or nurse who takes your screening test, the laboratory, colposcopy clinics and the National Cancer Registry Ireland. Consent will be given at each screening event.*	

- *Security and confidentiality of personal information.*
- *Where a women chooses to opt-out and doesn't wish to be included in any future call, or re-call process, then under the Health Act 2018, the programme will continue to hold personal data on file, in line with HSE Record Retention Policy guidelines, as it processes data 'for reasons of public interest in the area of public health' (more information is available from www.hse.ie/eng/gdpr/)*
- *It is currently not possible to give partial consent to data sharing within the programme office - data processing in other settings, e.g. primary care and colposcopy clinics will be included in their consent process.*

QR 2.08 Quality requirement

Security and Prevention of loss of data

A secure file transfer protocol (SFTP) must be installed between the screening register and all external stakeholders for the secure exchange of electronic data.

The register will be in a secure facility with the provision for adequate back-up arrangements.

Access to the CSR will be by secure privilege level access control. There must be an audit log facility.

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 (failsafe).

QR 2.09 Quality requirement

Invitation (call) of eligible women

Every eligible unscreened woman with a record on the Cervical Screening Register should be invited (called) within a maximum of 13 weeks of having her record first created on the register.

Standard 2.10	**Re-call of previously screened women** All previously screened women with re-call recommendations (routine or increased surveillance) should be issued a re-call letter at a specified period in advance of the appropriate next test due date. *Note: 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 requirement.*	
QR 2.11 Quality requirement	**Reminders** 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 in advance of the appropriate next test due date.	
Standard 2-7	**Women on the Cervical Screening Register screened for the first time** A proportion of the women screened should be eligible women who have not been previously screened.	**Target** Achievable: 10% in a 12 month period. Min: 5% in a 12 month period.
QR 2.12 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 as they will be made permanently inactive on CSR.* *Women can re-enter the programme at any stage by attending for a screening event and providing their consent. Where a woman chooses to opt-out, then under the Health Act 2018, the programme will continue to hold personal data on file, in line with HSE Record Retention Policy guidelines, as it processes data 'for reasons of public interest in the area of public health' (more information is available from www.hse.ie/eng/gdpr/)* *It is currently not possible to give partial consent to data sharing within the programme office - data processing in other settings, e.g. primary care and colposcopy clinics, will be included in their consent process.*	

Standard 2-8a	**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. ** accuracy of the data is dependent on the quality of the data received to the register.*	
Standard 2-8b	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 2-8c	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%
QR 2.13 Quality requirement	**Bespoke communications and exception process** While automated systems should be used, there are occasions where bespoke letters are required to manage particular incidents or while awaiting changes to the CSR. There must be a process in place to identify women who received bespoke letters instead of system letters or had automated communications stopped. The audit trail or event log should record the reason for same. Bespoke letters should be uploaded onto the document imaging management system (DIMS).	

2.4 Screening history of women

QR 2.14 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; HPV and cytology test results; management recommendations; colposcopy attendances; procedures; treatments and discharge recommendations; and histology results.

QR 2.15 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. Programme literature should provide sufficient, accessible information to enable the eligible population to make an informed choice when consenting to screening and record consent in an auditable manner. This pertains to the woman's ongoing screening record unless she chooses to opt out.

Note: The CervicalCheck consent process records that the woman understands the benefits and limitations of screening and gives consent to CervicalCheck to hold and share her screening history as outlined above. CervicalCheck consent does not include consent to have the test taken, this is implied by the person's attendance.

QR 2.16 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 secure file transfer protocols (SFTP), Virtual Private Networks (VPNs) and secure email.

Personal information should never be transferred by a non-secure method.

2.5 Registration of registered medical practitioners and Qualified Persons for cervical screening

QR 2.17 Quality requirement

Registration of medical practitioners for cervical screening

The programme should have a system of registering qualified medical practitioners to provide screening to eligible women who satisfy the following:

(a) who is listed on the Contractor Details and Acceptance form

(b) whose Irish Medical Council registration is not under suspension pursuant to Section 60 or 71(e) of the Act of 2007

(c) who has not had conditions attached to her registration by the Irish Medical Council pursuant to Section 71(c) of the Act of 2007 (including restrictions on the practice of medicine that may be engaged in by the practitioner)

(d) who does not hold any contract with the HSE that is under suspension or has been terminated by the HSE forcause

(e) who has not had a Contract for the Provision of the Cervical Screening Service terminated by the HSE

Note: specific requirements around training and education can be found in the primary care chapter.

QR 2.18 Quality requirement

Information about registered medical practitioners

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

2.6 Communications with women

QR 2.19 Quality requirement

Commitment to women

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

QR 2.20 Quality requirement

User Involvement / Patient and Public Partnership (PPP)

The programme will partner with service users in the design and review of any correspondence and materials through the NSS PPP Strategy and Guidelines. Where possible there should be PPP participation on programme committees, e.g. QA Committee. The HPV programme's annual report will contain a dedicated section outlining the participation of PPPs within the programme.

QR 2.21 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 as needed, and at least every three years, with changes and updates made as required 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).
QR 2.22 Quality requirement	A process must be in place to assist women with additional information needs (e.g. provision of leaflets in different languages or formats such as braille).
QR 2.23 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.
QR 2.24 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.
QR 2.25 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 or additional needs.
QR 2.26 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. A process for recording and evaluating feedback must be in place. Feedback channels should include telephone, email, post, website (initiated by women) and surveys.

2.7 Management recommendations and follow-up

Standard 2-9	**Programme communication with women following screening tests** 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.*	**Target** 95%
Standard 2-10	**Programme response time** 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.	**Target** 90%
QR 2.27 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.	
QR 2.28 Quality requirement	**Abnormal follow-up (failsafe) communications** Requests for follow-up action or information should be issued to women and to doctors in advance of the due date where the recommended next step has not been notified to the programme. *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.* *Note 3: 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.*	

2.8 Quality assurance

QR 2.29 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.
QR 2.30 Quality requirement	**Review of quality standards** Quality assurance standards must be reviewed, updated, and published at least once every three years.
QR 2.31 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.
QR 2.32 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.*
QR 2.33 Quality requirement	**Cervical cancer audit** A standard operating procedure (SOP) for patient-requested reviews of interval cervical cancers must be developed, based on the recommendation of the Expert Reference Group on Clinical Audit of Interval Cancer in the Screened Population.
QR 2.34 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 and in line with HSE's Risk Management and NSS Quality Assurance Framework. Evidence should be available to describe the identified risks and their assessment and how risk management contributes to quality improvement actions.
QR 2.35 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.

QR 2.36 Quality requirement	**Internal Audit** There must be a schedule of internal quality audits performed and reported on an annual basis. Internal Quality Audits are frequently undertaken as part of a scheduled audit programme. Where an Internal Quality Audit schedule is developed at the commencement of the year, it is good governance for it to be reviewed and approved by the relevant Quality Assurance committee. Internal quality audits may also be one-off audits that occur as a result of a specific identified area of risk / complexity. (HIQA, 2017) Internal quality audits must be approved prior to undertaking the audit.

2.9 Programme reporting and evaluation

QR 2.37 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.
QR 2.38 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. 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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