Guidelines for
Quality Assurance in
Cervical Screening

Third Edition

Quality assurance in programme operation
Chapter 2
Quality assurance in programme operation

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(September 2017)
2.1 Introduction

Programme operation includes:

- 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.

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 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.

2.2.1 Screening population and screening intervals

**Screening population**

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.

**Screening intervals**

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.
2.2.2 Identification and recording of screening population

The Health (Provision of Information) Act 1997 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.

**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.

**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 eligibility framework on the Cervical Screening Register.

**Quality requirement**

**Unique identification of women**

Each woman with a record on the Cervical Screening Register must be assigned a unique identifier number within the cervical screening programme.

**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 2-1**

**Eligible 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.

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Note: The number of eligible women on the CSR versus the number in the population statistics published by the Central Statistics Office (CSO).
Matching demographics

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 HlI number.

Note: Matching demographics are not subject to change in a woman’s lifetime and are in addition to the minimum demographics.

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.

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. Consent will be given at each screening event.
- Security and confidentiality of personal information.

Prevention of loss of data

Systems shall be in place for regular back-ups and secure storage of the personal health information and related data held by the programme.

2.2.3 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.
Invitation (call) of eligible women

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.

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Re-call of previously screened women

All previously screened women with re-call recommendations (routine or annual) should be issued a re-call letter at least 2 months in advance of the appropriate next test due date.

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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 or six 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.

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 within 3 months.

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Women who choose not to participate (opt off)

An opt-off 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 off.

Note: women who inform the programme in writing of their wish to opt-off 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.
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.

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.

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
10%
2%

2.2.4 Screening history of women

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.

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.

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.
Matching of screening events to the correct woman

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

99%

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.

Duplicates and merges

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

Target

0.5%

2.2.5 Registration of doctors and nurses for cervical screening

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.

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.
2.2.6 Communications with women

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

**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).

**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.

**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.

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

**Feedback from women**
The programme should provide suitable channels for women to provide feedback regarding all aspects of their experience with the screening programme. A process for recording and evaluating feedback must be in place.

Feedback channels should include telephone, email, post, website (initiated by women), surveys, forums and screening promotion reports (initiated by the programme).
2.2.7 Management recommendations and follow-up

**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.

**Programme communication with women following screening tests**
Letters should be issued to women advising them of the next recommended step in the screening programme within 3 working days following receipt of the screening test result from the laboratory.

**Programme response time**
Letters should be issued from the programme to women advising them of the next recommended step in the screening programme within 4 weeks from the date of their screening test.

**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 in the event of no evidence of subsequent recommended action.
**Standard 2-11**

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

Requests for follow-up action or information should be issued to women and to doctors within a maximum of 3 months of the due date where the recommended next step has not been notified to the programme.

**Target**

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.

**Standard 2-12**

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

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.

**Target**

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.
2.2.8 Quality assurance

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.

Review of quality standards
Quality assurance standards must be reviewed, updated and published at least once every 5 years.

Monitoring of service provision
Processes should be in place to measure and monitor 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.

Quality management system
Programme administration must operate a quality management system (QMS) that is certified by an approved external certification body at regular intervals, at least once every 3 years.

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.

Cervical cancer audit
A documented process must be in operation to log, categorise and review identified cases of invasive cervical cancer in order to contribute to quality improvement. Evidence should be available to demonstrate the operation of a cancer audit process, the outcomes, and the contribution to quality improvement actions.

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.
2.2.9 Programme reporting and evaluation

**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.

**Quality requirement**

**Programme key performance indicators (KPIs)**

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

Note 1: 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.

Appendix 1 provides notes about the programme KPIs.

Note 2: Key performance indicators (KPI) should be calculated after the programme is in operation for the least 5 years.

2.3 References

Guidelines for Quality Assurance in Cervical Screening

Second Edition

Cuid d’Fheidhmeannacht na Seirbhíse Sláinte. Part of the Health Service Executive.

CS/PUB/Q-6 Rev 2