Chapter 2
Quality assurance in programme operation

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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
• 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. The standards are designed to be measurable 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\(^1\) 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.

**Creation of a register**

The programme shall establish and 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.

**Acquisition and update of demographic details**

Processes shall be in place to acquire, maintain and update the demographic details of eligible women on the CSR.

**Unique identification of women**

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

**Minimum demographics**

Each woman’s record on the CSR must contain forename, surname, date of birth, address and unique cervical screening programme identification (CSP ID).

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**Eligible population register**

The CSR must contain the minimum demographics for the eligible women within the population.

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<tr>
<th>Standard 2-1</th>
<th>Eligible population register</th>
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<td>The CSR must contain the minimum demographics for the eligible women within the population. 95% of Census Min: 90%</td>
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**Note:** The number of eligible women on the CSR versus the number published in the Central Statistics Office (CSO) census.
### Standard 2-2

**Matching demographics**

The demographic details for each woman should include at least one of the following elements: surname at birth, mother’s maiden name or PPS number.

Achievable: 95%  
Min: 90%

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

### Standard 2-3

**Data protection and confidentiality**

The programme (under the relevant Health Authority) shall be registered with the Data Protection Commissioner and comply with directives regarding the use and security of personal information, subject to the provisions of the Data Protection Act 1988\(^2\), Data Protection (Amendment) Act 2003\(^3\) and any future revisions or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive\(^4\).

Annual

**Note:** The acquisition and use of personal health information is for the purpose of implementing the cervical screening programme.

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 at the time of their initial smear test to allow CervicalCheck to hold and share their personal and screening data
- Security and confidentiality
- CervicalCheck will act to minimise the risk to women.

### Quality requirement

**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 a smear test with a registered smeartaker
- Re-call letters that invite previously screened women to attend for another smear test at defined intervals
- Letters following cytology 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 of women with abnormal cytology results.

### Standard 2-4

**Invitation (call) of eligible women**

Every eligible unscreened woman with a record on the CSR should be invited (called) within a reasonable period of having her record first created on the CSR.

- 100% within 1 year.
- Min: 90%

### Standard 2-5

**Re-call of previously screened women**

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

- 100% at least 2 months in advance of due date.
- Min: 90%

**Note:** For previously screened women, the re-call smear 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 cytology result. The programme must have a system to notify these women in advance of the re-call smear test due date. Women with a three month or six month repeat recommendation are not issued a letter. These women are excluded from the standard.

### Standard 2-6

**Reminders**

Women who do not respond to an invitation (call) or re-call letter by attending for a smear test within a specified period are sent at least one reminder letter.

- 100% within 3 months of first letter.
- Min: 90%
Women who choose not to participate

An opt-off process should be provided for women who choose not to participate in CervicalCheck. Women can opt-off directly or in some cases the medical practitioner may deem it appropriate to opt-off a woman.

Opt-off

CervicalCheck should not issue letters to women who choose to opt-off.

Note 1: 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 signing the consent form and having a smear test.

Note 2: A medical practitioner can opt-off a woman who is deemed not to require cervical screening e.g. they do not have the capacity to consent, it is not physically possible for the woman to have a smear test or the woman is terminally ill.

Accuracy of addresses for correspondence

Demographic details of women on the CSR should be accurate and updated as necessary.

Note: This is measured by the proportion of issued letters that are returned as undeliverable by the postal system. Follow-up letters include letters following smear test results and abnormal follow-up letters.

The limitations defined for this standard are:

- Some letters will never be returned
- Calls are received to the programme to change address
- Can only be calculated on a yearly basis as an indication.
2.2.4 Screening history of women

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

A woman's cervical screening history may include some or all of her cytology results, HPV test results, management recommendations, colposcopy attendances, procedures and discharges, and biopsy 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 her screening history on the CSR to be shared with third-party service providers including cytology 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 CSR 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 and HPV, colposcopy and histology results, notified to the programme must be matched to the correct woman's record on the CSR.

Achievable: 99%
Min: 97%

**Duplicates and merges**
There must be processes in place to identify women with more than one record on the CSR, and to merge the records to a single record.

< 1% of records at any one time.
Min: < 5%
2.2.5 Registration of smeartakers

Registration of health professionals as smeartakers

The programme should have a system of engaging qualified doctors and nurses in primary care settings as identified smeartakers for the screening programme.

Information about programme smeartakers

The programme should make the contact details and locations of registered smeartakers publicly available through appropriate channels to eligible women.

2.2.6. Communications with women

Commitment to women

The programme should develop and 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, including women with special requirements, to make informed choices in relation to their participation in the programme. Information materials for women will be reviewed to reflect policy changes and users’ needs on a periodic basis. 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 in appropriate locations, 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.
Registration and eligibility
The programme should provide the means for women to register, check if they are registered, update their registration details, and check their eligibility for a programme smear test through appropriate means, including telephone, email, post and website.

Women with special requirements
The programme should have an access officer and procedures in place to support access and participation by eligible women with special requirements. The programme will provide appropriate literature 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 will be provided.

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

Standard management recommendations
The programme should provide smear takers with reports (through designated laboratory services and colposcopy services) containing cytology results with associated management recommendations for the follow-up of women after smear tests.

Programme communication with women following smear tests
Letters should be issued to women advising them of the next recommended step in the screening programme as soon as possible following receipt of the cytology smear test result from the laboratory.

95% within 4 working days of receipt of the cytology result.
Min: 80%

Note: The woman’s next recommended step in the screening programme is based on the management recommendation accompanying her smear test result, or the discharge recommendation from colposcopy.
**Programme response time**

Letters should be issued from the programme to women advising them of the next recommended step in the screening programme within a timely period from the date of their smear test.

- 90% within 4 weeks.
- Min: 75%

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

A process should be in place to monitor women with abnormal smear 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.

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

Forms and letters should be issued in a timely manner to women and to clinically responsible doctors where the recommended next step in the screening programme has not been taken.

- 100% within 3 months of due date.
- Min: 90%

**Note 1:** The abnormal follow-up 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 smear test (following an inadequate or 'abnormal' result), her recommended referral to colposcopy or her recommended post-colposcopy discharge smear 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 smear test or further investigation as appropriate.

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

Women with abnormal smear test results should have either subsequent, appropriate action (smear test or colposcopy attendance) or follow-up information from a clinically responsible doctor recorded.

- Achievable: 98%
- Min: 95%

**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 monitoring

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

Standard 2-15
Review of quality standards
Quality assurance standards will be reviewed, updated and published at regular intervals. At least once every 5 years.

Monitoring of service provision
Processes should be in place to measure and monitor the overall programme performance and the performance of service providers against requirements and standards on an ongoing basis. Planning, corrective actions and preventive actions should be in place to address failures to meet quality requirements and standards, and service or contract requirements.

Standard 2-16
Quality management system
Programme administration should operate a quality management system (QMS) that is certified by an approved certification or accreditation body. External review annually and recertification every 3 years.

Note: The QMS must encompass a quality policy, 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 review
A documented process should be in operation to enable the recording and review of identified cases of invasive cervical cancer in order to contribute to quality improvement.

Standard 2-17
Cervical cancer review
Identified cases should be reviewed on an ongoing basis. Achievable: Quarterly. Min: At least once every 6 months.
2.2.9. Programme reporting and evaluation

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<th>Standard 2-18</th>
<th>Programme activity and outcomes</th>
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<td>A report of programme activity and outcomes should be prepared at regular intervals.</td>
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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 a list of the KPIs, grouped within these categories.

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<th>Standard 2-19</th>
<th>Programme key performance indicators (KPIs)</th>
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<td>KPIs for the cervical screening programme must be calculated and made available.</td>
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2.3 References

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