The National Cancer Screening Service is part of the Health Service Executive. It encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.

Guidelines for Quality Assurance in Cervical Screening

Second Edition
Chapter 3
Quality assurance in primary care

3.1 Introduction
3.2 Non-primary care settings
3.3 Quality assurance requirements and standards in primary care
   3.3.1 Promoting awareness and benefits of cervical screening
   3.3.2 Promoting uptake and participation by women
   3.3.3 Promoting smearing skills
   3.3.4 Optimal environment for women within a structured practice setting
   3.3.5 Appropriate equipment and materials
   3.3.6 Pre-screening: preparation for the smear test
   3.3.7 Screening: undertaking the smear test
   3.3.8 Post-screening: after the smear test
   3.3.9 Management of smear test results
   3.3.10 Referral and follow-up of women
   3.3.11 Quality assurance monitoring

3.4 References
3.1 Introduction

Primary care plays a pivotal role in ensuring the overall success of CervicalCheck as it is where the vast majority of smear tests are carried out. The role of health professionals in providing a quality service in cervical screening to women is dynamic.

In addition to carrying out the smeartaking procedure and ensuring results are followed-up, health professionals in primary care play a vital role in the promotion of cervical screening and in the communication of key messages to support women's knowledge in this area.

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

These guidelines provide a framework to assist smeartakers to deliver a quality service. The quality requirements and standards mirror the woman's journey through the cervical screening process in primary care. They are important, achievable and take into account the evidence available at the time of statement. They address the most critical aspects in the screening pathway from a quality perspective.

Practices and clinics in primary care should 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).

3.2 Non-primary care settings

There will be circumstances where it may be appropriate to have screening undertaken in public gynaecology, colposcopy or sexually transmitted infection (STI)/genitourinary medicine (GUM) services. These services have their own clinical and organisational models and frameworks for service provision.

The quality assurance (QA) requirements and standards for primary care apply equally to all services supporting the CervicalCheck programme. They address the many facets of the smeartaking process including engaging with women, promoting the benefits of screening, smeartaking, management of results and the appropriate follow-up.

3.3 Quality assurance requirements and standards in primary care

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.
3.3.1. Promoting awareness and benefits of cervical screening

Primary care has a pivotal role in identifying and encouraging women to participate in regular screening. The Cervical Screening Register (CSR) information system is constantly updated to create records for women as they become eligible. As data on the CSR may not be complete or accurate, every effort must be made to identify and include all eligible women. Eligible women attending a practice or clinic should be included on the CSR.

**Quality requirement**

**Promoting awareness and benefits of cervical screening**

Practices and clinics should have current CervicalCheck signage on display and current CervicalCheck information leaflets available for women who attend.

**Quality requirement**

**Registration and eligibility of women**

Practices and clinics should ensure that an eligible woman is made aware of her options to register so that she is included on the CSR.

A letter of invitation is not required for a CervicalCheck smear test. The first CervicalCheck smear test will automatically register the woman. Practice staff should encourage a woman to self-register if she is not yet part of the CervicalCheck programme. Practice staff can register women with the programme if appropriate i.e. if she is not having a smear test on that day.

**Quality requirement**

**Understanding cervical screening programme operation**

All practice and clinic staff should be provided with updates in relation to the cervical screening programme and their role in supporting it.

Practice administration staff should ensure that information they give to women is accurate and in a format that is easily understood. A woman may choose a smeartaker in another practice. A woman may request a female smeartaker or choose to change smeartaker.

**Quality requirement**

**Addressing barriers to participation**

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

Recognition and identification of known barriers can help in increasing uptake. One of the recognised barriers to screening is lack of understanding about the smear test.
3.3.2. Promoting uptake and participation by women

The success of CervicalCheck depends on the uptake and ongoing participation of women in 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 (over 80%) attend for cervical screening.

**Standard 3-1**

**New women screened**

A proportion of the women screened should be eligible women who have not been previously screened. Achievable: 10% in a 12 month period. Min: 5% in a 12 month period.

**Note 1:** Smearakers should have an awareness of uptake of cervical screening in their practice.

**Note 2:** Where there is a recognised lack of uptake, specific measures shall be put in place to encourage women to attend for cervical screening.

**Note 3:** At all times, smearakers should be aware that any woman has the right to decline to participate in the CervicalCheck programme.

**Standard 3-2**

**Screening of the eligible population**

Women screened should be eligible for programme screening as defined by the CervicalCheck Eligibility Framework. Min: 100%

**Note:** Smearakers should ensure that women who are not patients at their practice are facilitated if they request a smear test.

**Standard 3-3**

**Adherence to recommended screening intervals**

Smear tests for previously screened women should not be carried out earlier than the recommended interval. Achievable: 100% Min: > 95%
3.3.3 Promoting smeartaking skills

<table>
<thead>
<tr>
<th>Standard 3-4</th>
<th>Qualifications and professional registration of smeartakers</th>
<th>Min: 100%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All smeartakers must be registered with the Irish Medical Council or An Bord Altranais.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Standard 3-5</th>
<th>Maintenance of registration</th>
<th>Min: 100%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All smeartakers must maintain their professional registration for the period of time that they are registered with CervicalCheck.</td>
<td></td>
</tr>
</tbody>
</table>

Quality requirement

Change of status

Smeartakers should advise the programme office of any change to their professional registration status. They should also advise the programme regarding any change of location, retirement or when ceasing to provide smeartaking services.

Quality requirement

Access and availability of learning and reference resources

Each practice and clinic should have current versions of relevant learning and reference resources available and accessible for all those engaged in cervical screening. Relevant learning and reference resources, at a minimum, include:

- CervicalCheck Guide for Smeartakers
- CervicalCheck Eligibility Framework
- CervicalCheck Cytology Terminology Table
- Health professionals section of the CervicalCheck website (www.cervicalcheck.ie)
- Online CervicalCheck learning resources (health professional section of the CervicalCheck website).
Quality requirement

**Appropriate training**

All cervical smears takers should be appropriately trained. It is the duty of the doctor with clinical responsibility to ensure that all smear takers who take smear tests in their practice or clinic are appropriately trained and competent. This is a dynamic requirement as competence is not static. Smear takers should endeavour to attend a CervicalCheck smear taker training course during the first three to five years following start of contract.

Quality requirement

**Clinical updates**

Smear takers should 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 online virtual learning facilities.

Quality requirement

**Supervision of new smear takers**

New smear takers starting out in practice should carry out smear tests according to a defined plan under the supervision of a clinically responsible doctor. A new smear taker is one who is starting out in practice, not having completed a CervicalCheck-recognised smear taker training programme. The doctor with clinical responsibility should agree a set number of smear tests to be performed by the new smear taker under supervision.

Standard 3-6

**Smear taking performance – unsatisfactory/inadequate rate**

In any defined period of time, the proportion of the total number of smear tests by an individual smear taker reported as unsatisfactory/inadequate should be within a defined proportion relative to the programme average rate in the period.

1.5 times of programme average rate for the period

**Note 1:** Information regarding smear taking performance is available from CervicalCheck.

**Note 2:** Where the unsatisfactory/inadequate rate is greater than the target, the individual smear taker concerned may need to undergo retraining.
3.3.4 Optimal environment for women within a structured practice setting

A suitable environment will help establish rapport, relax, and encourage women. Every effort should be made to ensure that the smeartaking environment contributes to the comfort of women. Smeartaking services should be provided in an environment that respects the privacy, dignity and autonomy of women.

- **Confidentiality**
  Confidentiality in relation to each woman and her personal information must be maintained throughout the cervical screening process.

- **Data protection**
  The storage, access and transfer of women's personal and health information must be compliant with the Data Protection Act 1988, Data Protection (Amendment) Act 2003 and any future revision or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive.

- **Practice records**
  Each practice or clinic should manage and maintain accurate records in a safe and secure environment.

- **Privacy and security**
  Smear tests must be carried out in a private and secure setting with respect to the woman's needs.

- **Room temperature**
  Smear tests must be provided in a comfortable environment where the room temperature is ambient.

- **Chaperone**
  A chaperone should be facilitated if the woman requires one. The chaperone or support person may be a relative or friend.

- **Women with special requirements**
  Smearakers should aim to facilitate women with special requirements where possible, including those who have a physical or intellectual disability. Smearakers should aim to facilitate women who have a physical or intellectual disability with adequate time and an environment that accommodates their requirements. Wheelchair accessibility should be provided where feasible. An Access Officer is available to respond to access queries.
3.3.5 Appropriate equipment and materials

A list of the necessary equipment is provided in the CervicalCheck ‘Guide for SmearTakers’. There should be advanced preparation of smearTaking equipment and consumables. This must include expiry date checks of vials and speculae.

Examination couch

An examination couch should be available. Consideration should be given to the use of a height-adjustable couch in order to assist women with physical disabilities.

Consumables – smear test kits and speculae

Smeartaking consumables in use must be within expiry dates. 100%

Note: SmearTakers must ensure that the sample vials used do not expire before reaching the laboratory.

Single-use disposable speculae

CervicalCheck recommends the use of single-use disposable speculae. Single-use disposable specula should be opened just prior to smearTaking. There should be a range of speculum sizes available for use at the practice.

Reusable speculae

Reusable speculae must be decontaminated ensuring that EU Sterilisation Guidelines are followed.

Infection control

The practice or clinic should have infection control procedures in place. Smeartaking activity must adhere to these infection control procedures. Regular monitoring and review of infection control procedures must be in place to ensure their effectiveness.

Clinical waste

Single-use disposable speculae and cervix brushes shall be disposed of as clinical waste.
3.3.6. Pre-screening: Preparation for the smear test

Communication with the woman

All aspects of the cervical screening process should be clearly explained to the woman. This includes providing each woman (both new and returning women) with a copy of the Information Sheet for Women accompanying the Cervical Cytology Form. The Information Sheet for Women is available in several languages and in Braille to assist smear takers in explaining the cervical screening process and consent to participate. Pictorial leaflets are available for situations where language or literacy is an issue. Aspects of the cervical screening process to be communicated include:

- The smear test
- The importance of regular screening
- The accuracy and limitations of tests
- 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.

Choice of smear taker

The smear taker should ensure that the woman is aware of her entitlement to choose her smear taker within the practice.

Informed consent by the woman

The woman must give her informed consent to participate in CervicalCheck. A woman’s consent or indication of previous consent, by signature or by witnessed mark on the Cervical Cytology Form, is required to participate. Obtaining informed consent from a woman is the responsibility of the smear taker. Consent is a legal requirement which allows the information about the woman to be transferred between service providers in the cervical screening pathway and the National Cancer Registry Ireland.

Consent to participate can never be given by a third party. Women may withdraw consent to participate in the screening programme by writing to the programme. Women may choose not to be part of the CervicalCheck screening programme. Women who do not wish to be part of CervicalCheck should be facilitated to opt-off the programme.

When a woman is unable to provide informed consent for whatever reason and the medical practitioner deems her not to require cervical screening, she can be made inactive on the Cervical Screening Register (CSR). The woman will receive no further communication from the programme. This requires that an Opt-off by Medical Practitioner form is completed (download from www.cervicalcheck.ie) signed by the medical practitioner and forwarded to CervicalCheck.
Use of CervicalCheck Cervical Cytology Form

A CervicalCheck Cervical Cytology Form must be completed at the time of taking a smear test in the presence of the woman, to ensure accuracy.

Identification of the woman

The smeartaker is required to record and relay a woman’s current demographic details at the time of the smear test completely, accurately and legibly. Unique identification of the woman starts with the inclusion of all relevant details on the Cervical Cytology Form.

Minimum data requirements

The woman’s forename, surname, address and date of birth, along with the woman’s indication of consent and the identification of the clinically responsible doctor or clinic should be accurately recorded on the Cervical Cytology Form at the time of the smear test and in the presence of the woman.

Requirements for unique matching of individual women

Smeartakers must make every effort to obtain and accurately record as many elements as possible of the following:

- Woman’s personal public service (PPS) number
- Woman’s cervical screening programme identification number (CSP ID)
- Surname at birth
- Mother’s maiden name
- Middle name
- Telephone number.

The woman’s PPS number and CSP ID are unique permanent identifiers. The woman’s surname at birth and mother’s maiden name, together with her date of birth are 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 CSR.

Accurate matching of the woman

The Cervical Cytology Form should record sufficient, accurate details to enable accurate matching of the woman with her record on the CSR.

Achievable: 98%
Min: 95%

Note: Letters of invitation (call, re-call) to women contain her PPS number and CSP ID. Information on the PPS number or CSP ID can be found in the Guide for Smeartakers.
### Identification of the doctor

The clinically responsible doctor for each smear test should be completely and accurately identified on the Cervical Cytology Form.

Achievable: 100%  
Min: 98%

### Identification of the smeartaker

The smeartaker for each smear test should be completely and accurately identified on the Cervical Cytology Form.

Achievable: 99%  
Min: 95%

### Quality of data – completeness, accuracy and legibility

Submitted Cervical Cytology Forms should not be returned, rejected or queried by either the cytology laboratory or by the programme office due to completeness, accuracy or legibility deficiencies.

Achievable: < 1%  
Min: < 3%

**Note 1:** Computer generated forms should be checked for quality of data.

**Note 2:** A ballpoint pen should be used when completing the form by hand and block capitals should be used where requested on the form.

### 3.3.7 Screening: undertaking the smear test

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

### Minimum repeat interval

There must be a minimum of 3 months between any 2 smear tests.

Achievable: 100%  
Min: 99%

### Visualisation of the cervix

The cervix, where present, must be visualised, assessed and effectively sampled. A smear test should not be taken if the cervix has not been visualised. No more than three efforts should be undertaken to visualise the cervix.
Sampling and Transformation Zone (TZ)
The smearsaker should ensure that all of the TZ is sampled. TZ sampling should be
evident in at least 80 per cent of women under the age of 50. It is the smearsaker’s
responsibility to sample the correct site. Smear tests with no evidence of TZ
sampling are not reported as ‘inadequate’. However, the overall percentage of the
smear tests taken by an individual which contain no evidence of TZ sampling is a
useful indicator of overall smear quality. The optimal time for a smear test is mid-
menstrual cycle, between day seven and fifteen.

Condition of sample
All samples should 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.

Relevant clinical details and findings
All relevant clinical details (e.g. last menstrual period [LMP]) should be recorded on
the Cervical Cytology Form as appropriate.

Previous smear test history
Cervical Cytology Forms must have previous smear test history completed where
known, available and relevant. The programme will keep a record of the woman’s CervicalCheck smear test history which is available to the cytology laboratory.
Management recommendations from the cytology laboratory are based on all
available previous results. Smearakers must ensure that the smear test result
history is complete where appropriate e.g. three ASCUS results in 10 years.

Previous treatment history
Previous treatment history of the cervix, where relevant (and date of treatment),
must be recorded on every Cervical Cytology Form where known and available.
The programme will keep the woman’s CervicalCheck treatment history which is
available to the cytology laboratory. Post-colposcopy recommendations for follow-
up smear tests should be recorded.
3.3.8 Post-screening: after the smear test

**Woman’s medical record**

The smeartaker should ensure that smear tests taken are recorded in the correct woman’s medical record. A new medical record should be established if one does not already exist. The medical record should record the date of the smear test and the smear test result. Computerised patient record-keeping is strongly encouraged as records are easily stored, readily available and retrievable for future use. Written or verbal communications in relation to the smear test result must be kept in the woman’s record.

**Advising the woman of the results process**

The woman should be informed of how and when the result of her smear test will be available. The result of the smear test is sent to the smeartaker and CervicalCheck. CervicalCheck will send a letter about her result to the woman.

**Sample identification**

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

**Matching vial to form**

The sample vial must be accurately matched with the associated Cervical Cytology Form. The detachable bar code label on the vial must be placed on the Cervical Cytology Form in addition to recording the surname, forename and date of birth on the vial.

**Dispatch of samples**

Vials and their associated forms must be dispatched to the cytology laboratory promptly after the test is taken. Achievable: 95% within 5 working days. Min: 90%

**Note 1:** To facilitate the delivery of a result to the woman within four weeks, it is important to dispatch the sample promptly.

**Note 2:** It is the responsibility of the smeartaker to dispatch or post samples – women should never be requested to post their samples.

**Packaging of samples**

All vials and forms must be packaged in the transport boxes appropriate for secure transport to the cytology laboratory. CervicalCheck recommends that the vials and forms should be packed for transportation in the boxes provided by the programme. Universal precautions should be employed for handling and packaging of all samples.
3.3.9 Management of smear test results

The practice or clinic protocol should include clear directions on roles and responsibilities for obtaining results of smear tests and providing women with their results. All staff, including reception staff, should be aware and informed of this protocol.

**Results management**
Practices and clinics should have in place a consistent system regarding the management of smear test results. Women should be made aware of this process.

**Receipt and checking of cytology results**
Outstanding results must be identified if they have not been received by the smeartaker within 28 working days from the smear test date and followed-up as appropriate.

A smear test result must be received by the smeartaker for each sample sent to the cytology laboratory. Results received from the cytology laboratory should be cross-checked with smear tests taken.

**Matching cytology results**
Smear test results should be recorded in the correct woman’s medical record. The woman’s medical record must be updated with the smear test result and management recommendation.

**Checking management recommendations**
Management recommendations accompanying cytology results should be checked in relation to the woman’s screening history.

Smeartakers must access the most current information and documentation in relation to cytology results and management recommendations. Smeartakers need to check that the management recommendation associated with the cytology result is correct with regard to the woman’s screening history. Smeartakers must contact the cytology laboratory if they have queries in relation to results or management recommendations.

**Communicating results and outcomes to women**
Practices and clinics should have an appropriate system to communicate every smear test result or outcome to the woman concerned. A smeartaker is responsible for providing women with their result. All staff, including reception staff, should be aware and informed of the protocol for communicating results to women.

When the cytology result is abnormal, the woman should be given full details of the result and advised of the next step in the process of their management. Explanations should be clear and appropriate to the level of understanding of each woman.
3.3.10 Referral and follow-up of women

**Follow-up of women**
Smeartakers should ensure that reasonable effort is made to follow-up smear test management recommendations ensuring that the appropriate action is taken.

**CervicalCheck Colposcopy Referral Form**
The CervicalCheck Colposcopy Referral Form should be used when referring a woman to colposcopy services.
A copy of the relevant cytology result report should accompany the Colposcopy Referral Form which should be sent to the colposcopy service directly.

**Standard 3-14**
Referral to colposcopy
Women whose cytology result carries a referral to colposcopy recommendation must be referred directly by the doctor with clinical responsibility to a colposcopy service promptly upon receipt of the cytology result.

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

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

**Standard 3-15**
Follow-up of abnormal results (information requests)
Doctors should complete, sign and return follow-up information requests to CervicalCheck (online or by post) promptly upon receipt of the request (by letter).

**Note 1:** CervicalCheck will send an abnormal follow-up (failsafe) information request to the clinically responsible doctor.

**Note 2:** Failsafe follow-up of abnormal results refers to the CervicalCheck procedure that is triggered when a recommended action for a woman following an abnormal smear test result has not occurred (or if the programme has not been informed).

**Note 3:** Smeartakers 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) should be made to contact the woman.
Quality requirement

Continuity of care of a woman

During and following her cervical screening pathway in primary care, a woman should have a doctor with clinical responsibility assigned to her care. If the doctor with clinical responsibility in the primary care setting leaves the practice or clinic for whatever reason, he or she remains clinically responsible for women who have had smear tests at his or her former practice or clinic until alternative arrangements are made.

3.3.11 Quality assurance monitoring

Quality requirement

Periodic review

The practice or clinic should conduct a periodic review of its cervical screening activity and a review of compliance to CervicalCheck ‘Guidelines for Quality Assurance in Cervical Screening’.

Clinically responsible doctors should review their cervical screening activity and their practice or clinic’s compliance to the ‘Guidelines for Quality Assurance in Cervical Screening’ at periodic intervals (suggested once every 3-5 years). The audit scope and outcomes should be recorded and planned actions should be documented and implemented.

3.4 References

2. CervicalCheck Eligibility for Cervical Screening Framework (CS/SPP/PM-9).
3. CervicalCheck Cytology Terminology Table (CS/PUB/LAB-2).
7. HSE Standards and Recommended Practices for Decontamination of Reusable Invasive Medical Devices (RIMD), Version 2.1; 2011.
8. CervicalCheck Cervical Cytology Form (CS/F/LAB-2).
The National Cancer Screening Service is part of the Health Service Executive. It encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.