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
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Foreword

The National Cancer Screening Service (NCSS) is part of the Health Service Executive (HSE) National Cancer Control Programme. The NCSS has significant experience in developing, implementing and delivering organised, population-based screening programmes.

The NCSS encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme. When all four programmes are fully implemented, over two million people in Ireland will be eligible for at least one screening programme.

CervicalCheck was introduced in September 2008. At time of publication, the programme had completed its first five year round of screening and provided over 1.65 million smear tests to more than 900,000 women of all ages. Among those women screened in the first four years, 13,117 had pre-cancerous abnormalities detected and 464 cancers were detected.

Cervical screening is a preventative health measure. The primary objective of cervical screening is to reduce the mortality from cervical cancer by detecting and treating changes in the cells of the cervix, before they become cancer.

CervicalCheck provides free regular smear tests to over 1.1 million eligible women aged 25-60 every three or five years (depending on age). Over time, a successful national cervical screening programme in Ireland has the potential to significantly reduce mortality rates in the screened population by as much as 80 per cent. CervicalCheck has a minimum target participation rate of 80 per cent of eligible women.

No screening test is 100 per cent accurate. The value of a population-based screening programme, such as CervicalCheck, is in the repeat nature of the test.

Some women will remain part of the CervicalCheck programme for 35 years and can have 11 or more smear tests during this time. It is essential that these women remain confident in the service that CervicalCheck provides. Quality assurance is at the heart of the programme and dictates every aspect of the screening journey.

The ‘Guidelines for Quality Assurance in Cervical Screening (second edition)’ is the result of a collaborative process encompassing the entire screening pathway – programme operation, primary care, cytopathology, HPV testing, colposcopy and histopathology. Rigorous adherence to, and continuous monitoring of the quality assurance requirements and standards outlined in this document are vital, and the cornerstone on which the programme is built.

Quality assurance is a continuous process. This document builds on the standards set in the first edition and reflects programme developments such as the introduction of HPV testing post-treatment at colposcopy.

We would like to thank all involved in developing these quality assurance requirements and standards for their time, expertise and commitment to delivering an internationally recognised cervical screening programme in Ireland. In particular, we thank the many thousands of women who have participated in, and supported the CervicalCheck programme since it commenced. Their continuing participation ensures the establishment of cervical screening as a routine feature of women's healthcare in Ireland and in essence, the programme's effectiveness.

Dr Susan O'Reilly
Director, National Cancer Control Programme

Ms Majella Byrne
Head of the National Cancer Screening Service
Preface

The National Cancer Screening Service (NCSS) Quality Assurance (QA) Committee for Cervical Screening was established to develop and monitor quality assurance as part of CervicalCheck – The National Cervical Screening Programme. The committee is responsible for reviewing international standards, recommending best practice, monitoring and evaluating achievement of the recommended standards and their adherence by service providers.

Regular cervical screening can reduce cervical cancer mortality. This is the goal of the CervicalCheck programme. While it is an ambitious goal, it is achievable. Quality assured screening, detection and treatment have ensured these women have been given the highest possible level of care. Continuing adherence to, and development of quality assured care will enable CervicalCheck to achieve its goal into the future.

This second edition of ‘Guidelines for Quality Assurance in Cervical Screening’ has been developed to support and measure the programme as it establishes itself as a vital and integral element of the healthcare landscape in Ireland.

A set of quality assurance requirements and standards are presented for each element of the programme. Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

There are over 1.1 million women aged 25-60 in Ireland who are eligible for the CervicalCheck programme. It is incumbent upon all involved in delivering the programme to adhere to the requirements and standards outlined.

Mr Simon Kelly

Chairperson of the NCSS Quality Assurance Committee for Cervical Screening
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Staff and representatives of service providers to CervicalCheck – including GP Practices, Cytopathology and HPV Testing Laboratories, Colposcopy Services and Histopathology Laboratories – who provided information, data and suggestions in support of the development and drafting of the second edition of the quality requirements and standards.
Chapter 1

Introduction

1.1 Cervical screening in Ireland
   1.1.1 Cervical cancer burden in Ireland
   1.1.2 Cervical screening
   1.1.3 Background to cervical screening in Ireland

1.2 CervicalCheck – The National Cervical Screening Programme
   1.2.1 Programme goals

1.3 Quality assurance

1.4 Quality assurance as part of the CervicalCheck programme
   1.4.1 Principles of the quality assurance framework
   1.4.2 Key quality requirements of the quality assurance framework
   1.4.3 Development of the CervicalCheck quality assurance requirements and standards
   1.4.4 Statement of the quality assurance requirements and standards
   1.4.5 Monitoring and evaluation

1.5 References
1.1  Cervical screening in Ireland

1.1.1 Cervical cancer burden in Ireland

The National Cancer Registry Ireland (NCRI) reports that between 2008 and 2010, on average there were 308 cases of cervical cancer per year and 88 recorded deaths in 2010. The median age at diagnosis was 44 years between 2008 and 2010 and median age at death was 58 in 2010.

1.1.2 Cervical screening

Screening is a means of detecting disease before it has developed to the point where it results in symptoms. It can allow detection of cancers at an early stage of invasiveness, or even before they become invasive.

Screening aims to improve survival, limit morbidity and to improve the quality of life of those who have developed cancer.

Screening is different from most other forms of healthcare and there is often uncertainty about its purpose. Screening does not diagnose illness; its purpose is risk reduction. It is not a guarantee of diagnosis and cure. Those who have a positive screening test require confirmatory diagnostic testing before definitive diagnoses can be established and appropriate treatment planned.

Cervical cancer screening is a preventative health measure as smear tests can detect early changes in the cells of the cervix. The earlier a change is found the easier it is to treat.

Cytological screening at the population level every three to five years can reduce cervical cancer mortality by up to 80 per cent (IARC, 2004). Such benefits can only be achieved if quality is optimal at every step in the screening process, from demographic information and invitation of the eligible population, to performance of the screening test and follow-up, and if necessary, treatment of women with screen-detected abnormalities.
### 1.1.3 Background to cervical screening in Ireland

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>Minister for Health made the decision to establish a national cervical screening programme.</td>
</tr>
<tr>
<td>2000</td>
<td>The Irish Cervical Screening Programme (ICSP) Phase One was established as a pilot cervical screening programme operating in the Mid West region.</td>
</tr>
<tr>
<td>2006</td>
<td>‘A Strategy for Cancer Control in Ireland 2006’ from the National Cancer Forum made recommendations in relation to the organisation, governance, quality assurance and accreditation of all aspects of cancer care. It examined prevention, screening, detection, treatment and management of cancer and advocated a comprehensive cancer control policy programme and cancer screening managed by one organisation.</td>
</tr>
<tr>
<td>2007</td>
<td>National Cancer Screening Service (NCSS) established by the Minister for Health and Children in January 2007, responsible for the governance of BreastCheck - The National Breast Screening Programme, and of the Irish Cervical Screening Programme (ICSP) Phase One.</td>
</tr>
<tr>
<td>2009</td>
<td>‘Guidelines for Quality Assurance in Cervical Screening 1st Edition’ published by the NCSS.</td>
</tr>
<tr>
<td>2010</td>
<td>NCSS subsumed into the Health Service Executive (HSE) within the National Cancer Control Programme (NCCP).</td>
</tr>
<tr>
<td>2013</td>
<td>CervicalCheck completed the first 5 years of operation on 31 August 2013.</td>
</tr>
</tbody>
</table>
1.2 CervicalCheck – The National Cervical Screening Programme

The National Cancer Screening Service (NCSS) is part of the HSE National Cancer Control Programme. It encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme. The NCSS is responsible for the governance of CervicalCheck.

CervicalCheck commenced on 1 September 2008. The programme offers free smear tests to eligible women aged 25-60 (more than 1.1 million women). The screening programme is based in primary care, with more than 4,500 doctors and nurses registered with the programme. CervicalCheck has 15 colposcopy services located throughout the country for investigation, diagnosis and treatment.

1.2.1 Programme goals

<table>
<thead>
<tr>
<th>Incidence</th>
<th>To reduce the incidence of cervical cancer among the screened population.</th>
<th>35% reduction*</th>
</tr>
</thead>
</table>

*To be calculated following the completion of two rounds of screening (10 years)

<table>
<thead>
<tr>
<th>Mortality</th>
<th>To reduce mortality from cervical cancer among the screened population.</th>
<th>50% reduction*</th>
</tr>
</thead>
</table>

*To be calculated following the completion of two rounds of screening (10 years)

The National Cancer Registry Ireland (NCRI) is the repository of cervical cancer data in Ireland, including statistics on cervical cancer mortality.

There are many factors that will impact on the interpretation of trends in mortality data including treatment advances, quality of death certification and cancer registration. Nonetheless the programme will strive over the long term towards a mortality reduction of 80 per cent.

In pursuit of the achievement of these goals, CervicalCheck has set a principal objective of achieving a significant level of coverage of the eligible population.

Coverage is defined as the proportion of unique women who have had at least one satisfactory smear test taken within the defined screening interval, expressed as a percentage of the total number of eligible women in the population.

A satisfactory smear test is one that is deemed adequate to be screened and where the sample is not damaged, broken or expired.

<table>
<thead>
<tr>
<th>Coverage of screening population</th>
<th>Women within the defined screening population should have at least one satisfactory smear test within a screening interval.</th>
<th>80%</th>
</tr>
</thead>
</table>

Coverage is included in the Key Performance Indicators (KPIs) (Appendix 1) for the programme, which are in line with the European guidelines for quality assurance in cervical cancer screening*.
1.3 Quality assurance

The CervicalCheck quality assurance (QA) framework adopts the principles and quality requirements set out for screening programmes in New Zealand. According to the QA framework developed by the New Zealand Ministry for Health, once a screening programme is established, quality assurance and quality improvement activities are essential for ensuring ongoing safety and effectiveness of the programme. Screening programme quality assurance and quality improvement activities occur at all points along the screening programme pathway.

The framework states the aims of quality assurance for a screening programme as:

- Reduce the risk of errors
- Set and reset standards
- Help professionals and organisations improve their performance
- Identify and manage errors effectively and sensitively.

Four dimensions of quality are considered key to fulfilling quality requirements.

<table>
<thead>
<tr>
<th>Equity and access*</th>
<th>The extent to which people are able to receive a service on the basis of need, mindful of factors such as socioeconomic factors, ethnicity, age, impairment or gender.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>The extent to which harm is kept to a minimum.</td>
</tr>
<tr>
<td>Efficiency</td>
<td>The extent to which a service gives the greatest possible benefit for the resources used.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>The extent to which a service achieves an expected and measurable benefit.</td>
</tr>
</tbody>
</table>

*The inclusion of equity and access clearly indicates that attention to the needs of groups with poorer access is an essential part of achieving high quality.

Quality assurance of the screening process requires a robust system of programme management and co-ordination, ensuring that all aspects of the service are performing adequately. Attention must be paid not only to communication and technical aspects but also to qualification of personnel, performance monitoring and audit, as well as evaluation of the impact of screening on the burden of the disease.

Population-based screening policy and organisation, conforming to evidence-based standards and procedures, provide the overall programme framework essential for the implementation of quality assurance; and are therefore crucial to the success of any cervical cancer screening programme.

All cervical screening programmes have false positive and false negative cytology results. The false positive rate and the false negative rate are universally related and measures to reduce one may increase the other. The challenge for those managing screening programmes and the quality assurance of screening is to strike a balance between the false positive rate and the false negative rate.

If the false negative rate is too high the effectiveness of the screening programme will be reduced. It will fail to detect and treat sufficient numbers of women with high grade abnormalities and the incidence of cervical cancer will be higher. If the false positive rate is too high the quality of the programme will be reduced. Large numbers of women will be made unnecessarily anxious and placed at risk from over-treatment by the screening programme.
1.4 Quality assurance as part of the CervicalCheck programme

The CervicalCheck quality assurance (QA) framework adopts the principles and quality requirements set out for screening programmes in New Zealand\(^6\). For quality-assured screening programmes, seven principles and seven quality requirements are set out.

1.4.1 Principles of the quality assurance framework

<table>
<thead>
<tr>
<th>Principle (Quality Requirement)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>People-centred</td>
<td>Screening programmes must be trusted by and serve the needs of individuals and communities by ensuring fair access for all eligible people, safety, effectiveness and efficiency. Individual requirements and community perspectives need to be considered when determining the balance of benefits and harms and the costs of screening programmes.</td>
</tr>
</tbody>
</table>
| Continuous improvement | A cycle of ongoing improvement is fostered through:  
  - Systems for individual and programme evaluation and feedback  
  - The development and updating of standards, policies and processes  
  - Ongoing measurement and analysis of processes and services to monitor safety and effectiveness  
  - Publication of the results of such monitoring, and their incorporation into further programme developments |
| Building the knowledge base | Individuals working within screening programmes are valued and supported to develop, maintain and improve their professional skills. Opportunities for sharing information and learning within and between screening programmes are fostered. |
| Accountability | Screening programmes clearly define roles and document processes as part of accountability expectations, which should be regularly reviewed and updated. |
| Bridging the expectation gap | Screening is not well understood by many professionals and the public, which results in a gap between public expectations of screening programmes and what they are able to deliver. Thus, screening programmes need to work to improve understanding of the principles of screening through the development and dissemination of understandable, evidence-based information about the benefits and limitations of screening. |
| Coherence throughout the programme | Screening programmes are planned, funded, delivered and monitored as population health programmes. Clear, evidence-based approaches are applied across the screening pathway irrespective of the condition being screened for or where they are delivered. Opportunities for learning within and between programmes will facilitate coherence. Quality management systems, including quality assurance activities and audit, should align with other health quality management systems wherever possible. Duplication is avoided through the sharing of information within a programme to minimise resource costs. Co-operative approaches with service providers are sought to minimise compliance costs while still obtaining assurances of quality. |
Partnership with programme staff, participants and service providers

Screening programmes require the effort of all stakeholders, particularly those involved in service provision to achieve the desired outcomes. It is important for all involved to have a sense of shared ownership of the screening programme quality goals.

### 1.4.2 Key quality requirements of the quality assurance framework

<table>
<thead>
<tr>
<th>Standard setting and monitoring</th>
<th>Standards are the backbone of quality management in screening programmes. A set of written, auditable standards relevant to the specific screening methods and policy should be developed and regularly reviewed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance management</td>
<td>Individual, team, organisation and programme performance should be monitored against agreed processes and outcome indicators through routine audits against programme standards. Specific programme activities should be formally evaluated.</td>
</tr>
<tr>
<td>Training and certification</td>
<td>Personnel employed within screening programmes should have relevant competencies. Minimum training levels required to perform specific activities within a screening programme should be specified. In addition, accreditation or certification to carry out specific screening activities may be required. Ongoing education is essential to maintaining and improving quality.</td>
</tr>
<tr>
<td>Effective information systems</td>
<td>Effective and efficient information systems are essential as both management tools for screening programmes and as the basis for evaluation and monitoring. Support participants to update their information on the Cervical Screening Register (CSR).</td>
</tr>
<tr>
<td>Appropriate resources</td>
<td>Resources for screening programmes, including diagnostic and treatment services, must be appropriate to provide safe, efficient, effective and equitable services for the eligible populations. Resources include personnel, workforce training and development, equipment and facilities. Screening programmes should not be initiated before adequate resources are secured to ensure quality requirements can be met.</td>
</tr>
<tr>
<td>Information and communications</td>
<td>Clear, evidence-based information should be widely available and effectively communicated to participants of the screening programme in appropriate formats. The information should be regularly updated. This should facilitate informed consent to the screening test and the full screening pathway, and include appropriate detail for healthcare professionals, other programme staff and people invited to screening. Information should include both benefits and limitations of screening and programme policies and should cater to the needs of different cultural groups.</td>
</tr>
<tr>
<td>Risk management</td>
<td>For population-based screening programmes, a quality assurance framework is a critical requirement and must be embedded in any programme from the outset. This should include risk management strategies to minimise the potential harmful effects of screening and follow-up.</td>
</tr>
</tbody>
</table>
1.4.3 Development of the CervicalCheck quality assurance requirements and standards

The National Cancer Screening Service (NCSS) established the Quality Assurance (QA) Committee for Cervical Screening in 2007. The primary function of the NCSS QA Committee is to advise the Head of the NCSS regarding quality assurance and standards for the national cervical screening programme.

The QA committee initially focused on developing quality assurance standards for the planned national cervical screening programme. Three technical subgroups were established, the Primary Care QA Subgroup, the Laboratory QA Subgroup and the Colposcopy and Gynae-Oncology QA Subgroup. The ‘Guidelines for Quality Assurance in Cervical Screening, ‘First Edition’, were approved and published in 2009.

The standards were based on a woman’s journey as she moves through different parts of the cervical screening pathway. They were designed to support the service providers to the CervicalCheck programme and to provide a means to monitor and continually improve services. The standards covered every aspect of the screening pathway, from identification of the eligible population, through screening, diagnosis and treatment, to programme monitoring and evaluation.

Following publication of the first edition of the standards, the QA Committee for Cervical Screening was re-organised as a single-tier committee, comprising representatives from the clinical areas of the cervical screening pathway – primary care, cytopathology, colposcopy, histopathology – and from programme management and clinical direction.

Following the completion of the first five years of operation in August 2013, the QA committee determined that it was timely to review the ‘Guidelines for Quality Assurance in Cervical Screening’. The reasons for undertaking the review of the standards included:

- Feedback from stakeholders in relation to the first edition of standards
- The significant quantity of data that had been assembled, arising from the operation of the screening programme for over 5 years
- Monitoring outcomes of programme activity and performance
- Experience gained in the various components of programme delivery
- Developments in cervical screening, particularly in relation to the use of HPV testing technology.

1.4.4 Statement of the quality assurance requirements and standards

The quality assurance (QA) standards and requirements are grouped under the principal components of the cervical screening pathway – programme operation, primary care/smeartaking, cytopathology, HPV testing, colposcopy and histopathology.

The grouping permits service providers to readily assess the most relevant requirements for their roles within the screening programme. Care has been taken to address the links between the components in the pathway, including the quality of communications between components, to ensure that a woman’s care is effectively managed.

Where applicable, the QA standards and requirements draw upon the ‘European guidelines for quality assurance in cervical cancer screening’.

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.
Stakeholders are expected to be able to demonstrate how they fulfil quality requirements. The means of demonstration may include, as examples, certification, accreditation, external audit or self audit.

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.

The targets set are those judged to be achievable by service providers when operating effectively and efficiently. Where appropriate, a minimum level is also stated. Service providers should not fall below this level of outcome.

1.4.5 Monitoring and evaluation

Standards drive specific datasets that must be collected in order to monitor the performance of each element of the cervical screening programme. Data collection, analysis and programme reporting is primarily carried out by the Programme Evaluation Unit (PEU) of the NCSS.

Data is obtained from, among other sources:

- Cervical Screening Register (CSR)
- Databases for smearaker registration, training and education
- Activity and outcome reports and quality metrics from cytopathology laboratories
- Activity and outcome reports and quality metrics from colposcopy services
- Activity and outcome reports and quality metrics from histopathology laboratories
- Activity and transaction logs from the programme office and its quality management system (QMS).

Screening programme evaluation is distinguished from quality assurance and quality improvement activities. Evaluation involves monitoring and assessing the service delivery and outcomes of a screening programme, which may include assessing overall programme effectiveness, cost effectiveness and acceptability. Evaluation will determine whether the programme is actually delivering on its objectives. In contrast, quality improvement activities are concerned with maximising the likelihood that the day-to-day operation of the programme will deliver the expected outcomes.
1.5 References


Chapter 2
Quality assurance in programme operation

2.1 Introduction

2.2 Quality assurance requirements and standards
   2.2.1 Screening population and screening intervals
   2.2.2 Identification and recording of screening population
   2.2.3 Call, re-call process
   2.2.4 Screening history of women
   2.2.5 Registration of smeartakers
   2.2.6 Communications with women
   2.2.7 Management recommendations and follow-up
   2.2.8 Quality assurance monitoring
   2.2.9 Programme reporting and evaluation

2.3 References
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.

<table>
<thead>
<tr>
<th>Quality requirements</th>
<th>Quality standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>are stated as a description. There are no targets associated with a requirement as service providers must fulfil the requirement.</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

**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).

**Eligible population register**

The CSR must contain the minimum demographics for the eligible women within the population. 95% of Census Min: 90%

Note: The number of eligible women on the CSR versus the number published in the Central Statistics Office (CSO) census.
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.

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, Data Protection (Amendment) Act 2003 and any future revisions or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive.

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.

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 smearaker
- 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.

### Invitation (call) of eligible women

<table>
<thead>
<tr>
<th>Standard 2-4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>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.</strong></td>
</tr>
<tr>
<td><strong>100% within 1 year.</strong></td>
</tr>
<tr>
<td><strong>Min: 90%</strong></td>
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</tbody>
</table>

### Re-call of previously screened women

<table>
<thead>
<tr>
<th>Standard 2-5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>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.</strong></td>
</tr>
<tr>
<td><strong>100% at least 2 months in advance of due date.</strong></td>
</tr>
<tr>
<td><strong>Min: 90%</strong></td>
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</tbody>
</table>

**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.

### Reminders

<table>
<thead>
<tr>
<th>Standard 2-6</th>
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</thead>
<tbody>
<tr>
<td><strong>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.</strong></td>
</tr>
<tr>
<td><strong>100% within 3 months of first letter.</strong></td>
</tr>
<tr>
<td><strong>Min: 90%</strong></td>
</tr>
</tbody>
</table>
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.

100%

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.

< 10% of invitation or re-call letters returned.
< 2% of result and follow-up letters returned.

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.

---

**Standard 2-9**

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%

---

**Standard 2-10**

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

Quality requirement

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.

Quality requirement

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

Quality requirement

Commitment to women
The programme should develop and make publicly available its commitments to women through the publication of a Client Charter.

Quality requirement

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).

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.
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.
### Standard 2-12

**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% |

### Quality requirement

- **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.

### Standard 2-13

**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.

### Standard 2-14

**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

**Programme activity and outcomes**

A report of programme activity and outcomes should be prepared at regular intervals.  
Annually  
Min: 18 months

The ‘European guidelines for quality assurance in cervical cancer screening’\(^6\) 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.

**Programme key performance indicators (KPIs)**

KPIs for the cervical screening programme must be calculated and made available.  
Every 5 years.

2.3 References

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 smear taking 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 smear-taking 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 smear-takers 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 smear-taking process including engaging with women, promoting the benefits of screening, smear-taking, 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.

<table>
<thead>
<tr>
<th>Quality requirements</th>
<th>Quality standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>are stated as a description. There are no targets associated with a requirement as service providers must fulfil the requirement.</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Standard 3-1</th>
<th>New women screened</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Achievable:</strong> 10% in a 12 month period.</td>
<td></td>
</tr>
<tr>
<td><strong>Min:</strong> 5% in a 12 month period.</td>
<td></td>
</tr>
</tbody>
</table>

A proportion of the women screened should be eligible women who have not been previously screened.

**Note 1:** Smear-takers 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, smear-takers should be aware that any woman has the right to decline to participate in the CervicalCheck programme.

<table>
<thead>
<tr>
<th>Standard 3-2</th>
<th>Screening of the eligible population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Min:</strong> 100%</td>
<td></td>
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</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Standard 3-3</th>
<th>Adherence to recommended screening intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Achievable:</strong> 100%</td>
<td></td>
</tr>
<tr>
<td><strong>Min:</strong> &gt; 95%</td>
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</tbody>
</table>

Smear tests for previously screened women should not be carried out earlier than the recommended interval.
3.3.3 Promoting smeartaking skills

**Standard 3-4**

Qualifications and professional registration of smeartakers

All smeartakers must be registered with the Irish Medical Council or An Bord Altranais.

Min: 100%

**Standard 3-5**

Maintenance of registration

All smeartakers must maintain their professional registration for the period of time that they are registered with CervicalCheck.

Min: 100%

**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 Smeartakers¹
- CervicalCheck Eligibility Framework²
- CervicalCheck Cytology Terminology Table³
- 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 smear 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 taker 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.

**Quality requirement**

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

**Quality requirement**

**Data protection**
The storage, access and transfer of women's personal and health information must be compliant with the Data Protection Act 1988\(^4\), Data Protection (Amendment) Act 2003\(^5\) and any future revision or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive\(^6\).

**Quality requirement**

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

**Quality requirement**

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

**Quality requirement**

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

**Quality requirement**

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

**Quality requirement**

**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 Smear takers’. There should be advanced preparation of smear taking 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:** Specimen vials 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 smearsakers 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 smearsaker
The smearsaker should ensure that the woman is aware of her entitlement to choose her smearsaker 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 smearsaker. 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.
Quality requirement

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.

Standard 3-8
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.
**Standard 3-9**

**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%

**Standard 3-10**

**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%

**Standard 3-11**

**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.

**Standard 3-12**

**Minimum repeat interval**
There must be a minimum of 3 months between any 2 smear tests.

Achievable: 100%
Min: 99%

**Quality requirement**

**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 smeartaker 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 smeartaker’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. Smear takers 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 smaretaker within 28 working days from the smear test date and followed-up as appropriate.

A smear test result must be received by the smaretaker 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.

Smaretakers must access the most current information and documentation in relation to cytology results and management recommendations. Smaretakers need to check that the management recommendation associated with the cytology result is correct with regard to the woman's screening history. Smaretakers 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 smaretaker 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.

≥ 90% within 10 working days.

**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).

≥ 90% within 10 working days.

**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.
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

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).
Chapter 4
Quality assurance in cytopathology

4.1 Introduction

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4.1 References
4.1 Introduction

The quality of results issued by a cervical cytology laboratory depends on adequate sampling, handling, and staining of cytology samples, screening and interpretation of cytology slides and reporting of results. The objective of a quality assured laboratory service is to accurately identify those cervical cancer precursors likely to progress to invasive cancers (maximising the benefits of screening) and avoid the detection and unnecessary treatment of benign lesions that are not destined to become cancerous (minimising the potential harms associated with screening).

The cervical screening pathway involves three key stages:

- Smear taking, sample transport and receipt of sample in the laboratory (pre-analytical)
- Sample processing, screening and interpretation (analytical)
- Report generation, call, re-call protocols and patient management (post-analytical)

The quality requirements and standards for cytopathology laboratories providing services to CervicalCheck are set with regard to:

- The first edition of ‘Guidelines for Quality Assurance in Cervical Screening’
- European guidelines for quality assurance in cervical cancer screening
- The evolution of standards and guidelines in response to technological developments and research outcomes in other cervical screening programmes. Particular reference is given to revisions in the NHS CSP Publication No. 1 (revised 2012) and the BSCC ‘Code of Practice for Laboratories Participating in the UK Cervical Screening Programmes’ (2010)
- The activity and performance metrics for cytopathology collated since the commencement of CervicalCheck.

Compliance with the requirements and standards is measured and monitored by:

- Quality metrics reports by cytopathology laboratories.
- Analysis of data provided to the Cervical Screening Register (CSR) by cytopathology, colposcopy and histopathology services providers.
- Quality assurance site visits to laboratory providers.
- Monitoring and review of operational activity and performance data.
4.2 Quality requirements and standards in cytopathology

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.

4.2.1 Organisational requirements

**Accreditation**

The laboratory will have and maintain accreditation to ISO15189 standard or equivalent, certified and documented by an approved accreditation body. The scope of the laboratory accreditation must include cytopathology.

External accreditation at least once every 2 years.

Note: Laboratory accreditation covers facilities, staff qualifications, training and competencies, equipment, laboratory information systems and quality management systems.

**Capacity**

Individual cytopathology laboratory facilities will have the capacity to process a minimum cytology screening throughput.

Min: 25,000 samples per annum.

Achievable: 35,000 samples per annum.

**Data protection**

In relation to the provision of services to the National Cancer Screening Service (NCSS), all data protection requirements (storage, access, security, confidentiality and data transfer) should be compliant with the Data Protection Act 1988, the Data Protection (Amendment) Act 2003 and any future revisions or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive.

A Virtual Private Network (VPN) should be installed between the laboratory and the programme operations office for the secure exchange of electronic data.
Quality requirement

Health and safety compliance
The laboratory should be compliant with all national legal and statutory health & safety requirements.

Quality management system
The laboratory should have a quality management system (QMS) in place as required by their accreditation standard.
The laboratory should have a designated person responsible for quality management who will liaise with the NCSS to resolve any quality issues that may arise.
Any complaints in relation to the provision of the cytology services on behalf of NCSS will be notified to the NCSS.

Laboratory information management system (LIMS)
A computerised laboratory information management system (LIMS) should be installed and be in operation in the laboratory. The LIMS should be in a secure facility with adequate back-up arrangements, on- and off-site. Access to the LIMS should be by privilege-level access control. The LIMS should be capable of generating periodic quality metrics and audit returns to the NCSS.
In addition the LIMS should:
- Link multiple test results for the same patient
- Provide easy access to details about previous cervical cytology and histology of the patient
- Provide a mechanism for ascertaining and recording clinical outcome after cytology tests, including colposcopy findings, treatments, biopsies and reasons for biopsies not being taken
- Provide the data necessary for evaluation of the CervicalCheck programme.

Data capture
The LIMS should be capable of recording the data required by the NCSS (Cervical Screening Register (CSR) information system data entry standards demographic details\textsuperscript{a}) from the CervicalCheck Cervical Cytology Form\textsuperscript{a}.

Reporting
The LIMS should be capable of recording screening results including management recommendations. The LIMS should be capable of recording the identity of the reporting screeners and pathologists.
Format and timing of electronic data exchange with programme

The LIMS should be capable of extracting and transferring required data to the programme in the required format as per NCSS specifications (notification and result files). The laboratory should also receive information from the programme in specified formats and transfer it to its information systems (error and history/eligibility files).

The laboratory should have in place the capability to exchange electronic communications between staff members and programme staff through secure protocols (e.g. secure email).

Capability and format for electronic orders and results

It is desirable that laboratories should be capable of receiving orders electronically and issuing results electronically to and from ordering doctors or clinics, according to a specified messaging standard. Electronic laboratory order format is HL-7 based and conforms to the laboratory order message specifications of the Health Information and Quality Authority’s (HIQA) current GP Messaging Standard. HL-7 based orders and results use the Healthlink Message Broker System. The physical form for electronic orders includes a barcode, which laboratories should be able to scan and extract the included details for automatic import into their data entry system.

Segregation, identification and traceability of programme samples

All work carried out in relation to the provision of laboratory services to the NCSS should be clearly distinguishable from the work carried out for other clients of the laboratory, beginning with receipt of samples, throughout the screening and resulting processes, to reporting, later investigations and reviews, as well as storage and archiving.

Telephone support

Laboratories should provide Freephone telephone access (for calls made from Ireland) to laboratory staff during normal business hours (09.00-17.30 GMT each working day) for registered smeartakers and NCSS staff, for queries and follow-up.

Changes to service capacity, capability or conformance to quality assurance (QA) standards

Any changes that have or could have an impact on any aspect of the laboratory services, including laboratory accreditation status, processes, system procedures, analysis, and reporting should be agreed with the NCSS. Any changes must be advised in advance, in writing, to the NCSS.
Other laboratories
Laboratories should make relevant clinical information and follow-up data available to other laboratories providing services to CervicalCheck.

Health agencies and authorities
Laboratories engaged by CervicalCheck should comply with all requests for data or reports by Irish health agencies and authorities, including the Department of Health and the National Cancer Registry Ireland (NCRI).

4.2.2 Laboratory facilities
Cytopathology services should be provided in a dedicated laboratory area/facility. All areas should be well lit, well ventilated, quiet and spacious. Samples receipt, discrepancy handling, and data entry areas should be readily identifiable. The screening room, the sample preparation room and the secretarial room should be separate rooms. The specimen preparation area should be equipped with effective exhaust systems and approved biological safety cabinets where required.

There should be appropriate storage facilities for flammable and toxic chemicals as required by national and regional legal and statutory health and safety requirements. Chairs, desks and microscopes should be ergonomically designed.

High-quality binocular microscopes should be available for all screening staff. Microscopes should include 4x 10x 20x and 40x objectives and be capable of marking slides. A multi-headed microscope should be available for training purposes or discussion of difficult cases.

4.2.3 Staff qualifications
Scientific, medical and non-medical staff should be qualified for the positions they hold according to national requirements to practice.

The cytopathology laboratory should be led by a medically qualified consultant who works in that discipline on a regular basis. All cervical cytology samples that have been identified as abnormal or possibly abnormal should be examined and reported by a medically qualified consultant.

There should be a lead medical scientist or cytology manager who is responsible for the day-to-day management of the department with responsibility for supervision of non-medical staff. Roles and responsibilities should be defined and should be incorporated into the laboratory quality manual.
4.2.4 Specimen reception

Standard operating procedures should be in place for handling CervicalCheck samples.

Acceptance of samples

Laboratories should accept orders via postal delivery and electronic laboratory orders where applicable (followed by the receipt of the physical sample and form). For electronic orders the laboratory should be capable of extracting bar-coded information.

The laboratory should only accept programme samples from practices and clinics that are notified to the laboratory by CervicalCheck.

Only those samples accompanied by a CervicalCheck Cervical Cytology Form or Cervical Cytology and HPV Form should be accepted.

Indication of consent

Only those samples indicating either signed consent or prior consent by the woman should be accepted. All forms should be date-stamped upon receipt.

Matching of vials and forms

Sample vials should be matched to associated form prior to labelling. To ensure a robust ‘chain of custody’ cross-checking of a minimum of three and preferably four patient identifiers should be performed.

Discrepancy handling and resolution

A discrepancy handling and resolution process should be in place to manage all discrepancies with received CervicalCheck samples. A CervicalCheck guidance document is available.

Discrepancies with received samples should be recorded and the log should be made available to CervicalCheck. The format of the log must be approved by CervicalCheck. All supporting documentation and actions taken in discrepancy resolution should be recorded and traceable.

Vial and form tracking

After second person verification of correct correlation of the sample vial with the corresponding form, and acceptance of the sample and form for processing, both should be labelled with a laboratory-generated unique identification number.
4.2.5 Data entry and notification to CervicalCheck

Data capture
Data entry of the details recorded on CervicalCheck forms accompanying submitted sample vials should conform to CervicalCheck data capture requirements.

All relevant data recorded on the Cervical Cytology Form by the smeartaker should be entered onto the LIMS (Cervical Cytology/Cervical Cytology+ HPV/Cervical HPV Requests and Results).

A second-person verification of all relevant data entered from the form onto the computer system should be carried out and deemed to be correct before the sample is authorised for further processing.

Laboratory accession number
A unique permanent accession number must be assigned to each sample.

Note: The unique laboratory accession number for the sample must remain constant whether the sample is for cytology screening only, HPV testing only, or both cytology screening and HPV testing.

Assignment to ordering doctor or clinic
Samples should be assigned to the correct clinically responsible doctor or clinic (CervicalCheck Registered Smeartakers Types and Identification) as per the received form.

Access to received Cervical Cytology Forms
Copies of all submitted Cervical Cytology Forms, in electronic format and indexed by the laboratory accession number, will be made available promptly to CervicalCheck. 100% within 7 working days of acceptance.

Notification of sample receipt to programme
Samples, once received, will be notified promptly by electronic means to CervicalCheck. 95% within 48 hours of receipt of sample. Min: 80% by 17:00 GMT next working day.

Note 1: A tracking system or log should be in place to verify that the number of electronic notifications sent to CervicalCheck on any given day equals the number of samples entered onto the LIMS that day.

Note 2: A weekly reconciliation of files sent or received should be in place between CervicalCheck and the cytology laboratory.
Programme ineligible samples
Samples identified by CervicalCheck as ineligible for the screening programme should not be processed. Certain samples that are not to be processed may have to be reported. These include expired vials and samples that are not processed but a report is sent to both CervicalCheck and the requesting doctor. Ineligible samples may be required to be returned to the doctor or clinic.

4.2.6 Sample processing

Cytology technology
Liquid-based cytology (LBC) is mandatory. Liquid-based specimens must be processed according to the manufacturer’s instructions. Processors used to prepare slides must be maintained only by laboratory staff who have been trained by the manufacturers or individuals designated by the company.

Staining
Slides should be stained using the Papanicolau stain (original or modified). The samples should have a cover slip that covers all the cellular material. Internal technical quality assurance checks should be carried out routinely including quality of staining and quality of preparation. The results of these checks should be available for review and should specify individual machines if multiple machines are used. All laboratories should participate in a recognised technical external quality assurance (EQA) scheme.

Identification of case/slide
Standard operating procedures (SOPs) for handling samples should ensure a robust ‘chain of custody’ across the specimen pathway. These involve the cross-checking of a minimum of three and preferably four patient identifiers at each stage. Mandatory identifiers include surname and first initial of forename. Other identifiers include full forename, date of birth and cervical screening programme identification (CSP ID) number. Slide labels should include patient surname and forename or first initial of forename in addition to the barcode and accession number. Where the laboratory uses automated processors which read and transfer the unique laboratory accession number (barcode) onto the slide, it may not be necessary to include all three identifiers on the sample slide.
### 4.2.7 Proficiency and competency of staff

#### Quality requirement

**Pathologists**

All pathologists should participate in continuing professional development (CPD) relevant to their clinical practice. All consultant pathologists participating in CervicalCheck should participate in a recognised cervical cytopathology EQA scheme.

If there is an absence from work for a period exceeding six months then the individual should undertake a short period of retraining consisting of double screening a minimum of 150 cases with 95 per cent sensitivity for HSIL and have successfully participated in the most recent round of EQA slides/proficiency testing.

#### Standard 4-5

**Pathologist - proficiency**

To maintain a medical consultant’s diagnostic skill in cervical cytopathology, a minimum number of cases will be reviewed.

| Min: 750 cases per annum. |

#### Standard 4-6

**CPC/MDT meetings**

Pathologists reporting Irish workload will participate in regular CPC/MDT meetings.

| Min: 50% of meetings. Achievable: 90% of meetings. |

#### Quality requirement

**Lead medical scientist, cytology manager and supervisory scientific staff**

The lead medical scientist or cytology manager should be responsible for maintaining a high quality service.

Sufficient supervisory scientific staff should be available to provide satisfactory supervision for checking cervical samples, training, service development and quality control. Competence for the role should be ascertained before solo checking of cervical samples.

#### Standard 4-7

**Lead medical scientist, cytology manager, supervisory scientific staff**

If the role involves cervical screening then a minimum number of cases will be reviewed.

| 750-3,000 cases per annum depending on role. |
Cytology screening staff

Cytology screening staff can participate in the primary, double and rapid screening of cervical samples. They should only sign out cases which they deem to be negative or inadequate.

All screeners (including supervisory screening staff) should maintain their competence through participation in proficiency testing schemes, recognised cervical cytopathology EQA schemes and in-house training, as appropriate.

If there is an absence from work for a period exceeding three months then the individual should undertake a formal period of retraining. If absent for more than six months, then, external training may be required.

**Standard 4-8**

**Screener proficiency**

In order to maintain proficiency, a minimum number of smear tests per year must be screened per screener. Min: 3,000 cases per annum.

**Standard 4-9**

**Primary screening**

In order to maintain quality, accuracy and safety in the screening process, the maximum time spent on primary screening LBC smear test samples must not be exceeded. Max: 5 hours per day.

**Standard 4-10**

**All screening – maximum hours**

Screening should be limited within a 24-hour period. Max: 6 hours per day.

**Note 1:** The maximum screening hours includes both primary and rapid screening.

**Note 2:** Regular breaks will be provided to prevent screener fatigue.

**Standard 4-11**

**All screening – maximum numbers per annum**

Maximum primary screening numbers per screener per annum must not be exceeded. Max: 12,000 per annum.
Continuing education

There should be protocols and practices in operation to demonstrate a system of both internal and external continuing education for scientific and medical staff reporting CervicalCheck cases. Internal continuing education may comprise some or all of the following:

• Discussion of difficult/review cases between cytotechnologists, medical scientists and/or cytopathologists. Laboratories should have a multi-headed microscope for this purpose
• Provision of up-to-date cytology textbooks and/or electronic material for consultation in the cytopathology laboratory
• Access to one or more of the cytology journals.

External continuing education may comprise some or all of the following:

• Attending workshops and symposia
• Attendance at regular update courses
• Regional inter-laboratory slide review sessions
• Participation in proficiency testing
• Teaching cytotechnology students, pathology residents and fellows
• Independent study contributions to laboratory handbooks or work in committees of the relevant medical societies.

4.2.8 Microscopy

Access to a woman’s previous screening history

Prior to the assessment of the sample, the patient’s screening history will be retrieved from the local laboratory files and/or the CervicalCheck screening database and be made available to the scientific staff screening the sample. Within 48 hours of receipt of sample notification, CervicalCheck will transmit an electronic file or record containing all previous screening history for the woman known to the programme for samples that are to be processed by the laboratory.

Primary screen

All samples to be processed should receive a full manual primary screen, unless the cytology laboratory is notified by CervicalCheck that primary screening may utilise automated-assisted screening.

All the material on the slide must be examined. Screeners should overlap fields by at least 30 per cent. Screening should be carried out using a x10 objective, but in particularly crowded or difficult samples, it may be safer to slow down considerably or screen using a x20 objective.

Screeners should record their results independently on the LIMS.
**Rapid review/re-screen**

All samples other than those requiring reassessment should receive a manual rapid re-screen, or automated assisted re-screen as notified by the NCSS.

Manual rapid re-screen should take approximately 60-90 seconds and aims to cover a representative area of the cellular material.

Individuals should undergo basic training in the different skills and techniques involved in manual rapid screening and automated screening before they are permitted to carry it out.

Screening performance will be monitored.

**Internal quality control**

Accuracy of screening must be monitored and managed with approved protocols and procedures for defining and dealing with poor performance.

Internal quality control of cytology screening must be monitored by:

- Re-screening of slides initially judged during primary screening as negative or inadequate to detect false positives/negatives and to determine sensitivity and specificity rates
- Monitoring screening detection and reporting rates by measuring the percentages of the main types of cytological findings (high grade, low grade, inadequate, undetermined, negative) detected by individual screeners and cytopathologists, and in comparison with the laboratory as a whole, the programme and national standards
- Performance evaluations to identify those with deficiencies in knowledge and skills who would benefit from a more directed educational programme
- Correlation of cytology with clinical/histological outcomes
- Re-screening of samples from women with negative or low grade test results less than 3 or 5 years before diagnosis of invasive cancer
- Correlation of cytology with HPV testing for smear tests reported as ASCUS
- Monitoring and analysis of quality metrics as requested by CervicalCheck.
4.2.9 Results management

**Quality requirement**

**Cytology screening results – reporting**

Cytology patterns must be reported with the detail and the format specified by CervicalCheck.

**Quality requirement**

**Cytology terminology and assignment of management recommendations**

All cytology results must have a management recommendation accompanying the cytology pattern as a P and R code combination (Cervical Cytology Management Recommendations Explanatory Guide\(^1\) and Cytology Terminology Table\(^2\)).

**Note:** Where a combined cytology screen and HPV test is carried out, the management recommendation will be assigned using the appropriate cytology and HPV management recommendations table for follow-up of women post-treatment, or similar NCSS publication for other HPV test scenarios.

**Quality requirement**

**Management recommendations with respect to screening history**

The management recommendation should be correct for each cytology result with respect to the screening history of the woman.

The screening history of the woman provided by the smeartaker via the Cervical Cytology Form\(^3\) and by CervicalCheck from the CSR (where such history is available) must be referred to and taken into account during the results process, in order to assign the correct management recommendation.

CervicalCheck uses the management recommendation accompanying results to issue appropriate correspondence where appropriate to a woman advising her of her next recommended step in the screening programme.

**Quality requirement**

**Check of result and recommendation**

An independent check of the case result and management recommendation should be in place, prior to report authorisation, to minimise the risk of error.

**Quality requirement**

**Authorisation of results**

Every result must be appropriately authorised before release. Every report should be checked for inconsistencies before authorisation.

Depending on the national legal requirements under which the laboratory operates, the cytological reports may be signed (electronically or manually) either by cytotechnicians or the cytopathologist or medical scientist in charge.

Abnormal cytology results will only be reported by a pathologist.

Reports should identify the cytotechnologist or medical scientist and/or cytopathologist responsible for the conclusion and recommendation.
Result codes notification to programme
Results, once authorised and released, will be issued in summary format (P & R codes as soon as possible by electronic means to CervicalCheck).

Laboratory response time (turnaround time [TAT])
Cytology results must be authorised, released and transmitted to CervicalCheck within the target TAT from sample validation by the NCSS.

95% within 10 working days.

Note 1: If the target for turnaround (TAT) time cannot be achieved for any period exceeding three working days, CervicalCheck must be immediately informed. A plan to remove the delay must be provided within one week.

Note 2: No category of urgent smear test exists within the screening programme.

Adequacy of results reports
The contents of the results report to doctors and clinics must be in accordance with Cervical Cytology/Cervical Cytology+ HPV/Cervical HPV Requests and Results.

Results reports to ordering doctors and clinics
Results, once authorised and released, must be issued promptly to the ordering doctor or clinics.

99% to be received within 5 working days.

Note: The issuing of results should take account of the time taken for delivery of printed paper results (post or courier) to meet the target for receipt by the ordering doctor or clinic.

Delivery of results reports to ordering doctors or clinics
Results reports will be issued to the correct ordering doctor or clinic.

Documented processes are required to:
• Ensure that results are sent to the correct doctor
• Handle discrepancies between the number of samples/notifications received, the number of reports transmitted and the number of reports printed.
Results reports by electronic means
It is desirable that all results reports in addition to paper format be issued to ordering doctors/clinics and CervicalCheck in full electronic format via a nominated telecommunications pathway. The electronic format for results is HL-7 based and conforms to the laboratory result message specifications of HIQA’s GP Messaging Standard.[10]

Re-screening requests and amended reports
Laboratories will have procedures in place to manage and respond to requests for re-screening and amended management recommendations, and provide replacement reports to doctors/clinics where necessary. Amended results, once authorised and released, must adhere to the same standards and targets.

4.2.10 Storage and archiving
The laboratory must ensure adequate administration and secure archiving and disposal of Cervical Cytology Forms, samples, slides and written and/or computerised reports.

Administration, archiving and disposal procedures must comply with accreditation standards and national legislation, including that relating to confidentiality and data security of personal health information.

<table>
<thead>
<tr>
<th>Standard 4-14</th>
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<tbody>
<tr>
<td>Storage and archiving</td>
</tr>
<tr>
<td>Secure archiving of Cervical Cytology Forms, samples, slides and written and/or computerised reports is required for specific retention periods.</td>
</tr>
<tr>
<td>99% to be received within 5 working days.</td>
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<tr>
<td>Cervical Cytology Forms</td>
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<tr>
<td>Slides</td>
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<tr>
<td>Sample vials</td>
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<td>Reports</td>
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</table>

Note 1: Cervical Cytology Forms may be in paper format or in their electronic equivalent.

Note 2: All slides must be stored in conditions adequate for preservation.

Note 3: Records will be stored to allow prompt retrieval if required.

Access to materials
Laboratories are required to provide access to CervicalCheck to materials including slides and records on request.
4.2.11 Clinico-pathological conferences (CPC)/multi-disciplinary team (MDT) meetings

Support for CPC/MDT meetings
Cytology laboratories will provide facilities, participation and support for CPC/MDT meetings held in programme colposcopy services. Such support will include the following:

- Real-time correlation between histopathologist and cytopathologist with the provision of the original glass slides, if requested.
- The provision of a web-based digital slide viewing system for all CPC/MDT meetings, as required.

Cases discussed at CPC/MDT will include discrepancies between two or more of the diagnostic results (cytology/colposcopy impression/histology), glandular abnormalities and cancers. Discrepancies are defined as a difference of two or more grades of abnormality.

Participation in CPC/MDT meetings
The cytopathologist(s) (with or without other scientific staff members) will participate in CPC/MDT meetings. CPC/MDT meetings are convened by CervicalCheck colposcopy services. The locations, timing and frequency of CPC/MDT meetings may vary from time to time but reasonable notice should be provided by colposcopy services to the cytology laboratory. Cytology laboratories are encouraged to submit cases for discussion where of benefit.

Protocol for CPC/MDT meetings
Participation, including a signed record of personnel attending and operational decisions, must be recorded. Participants must be subject to national legislation relating to confidentiality and data security of personal health information.

Cytology laboratories are encouraged to incorporate CPC/MDT meetings into the internal continuing education of scientific staff.

Provision of slides
Cytology laboratories will retrieve and provide slides or digital images for cases notified for review at CPC/MDT meetings on request, within 10 working days.
4.2.12 Cancer review process

The CervicalCheck Cancer Review Process reviews notified cases of invasive cervical cancers. It operates as a feedback and learning process within quality assurance, contributing to potential continuous improvement measures.

Re-screening of smear tests

The cytology laboratory must review slides for women with a diagnosis of invasive cancer, as requested by the programme, and provide the results of these reviews to CervicalCheck.

Independent third-party review

Cytology laboratories will provide all case material as requested by CervicalCheck for cases identified as warranting independent third-party review by the CervicalCheck Cancer Review Process.

4.2.13 Quality assurance and continuous improvement

External quality assurance (EQA)

Laboratories will participate and show adequate performance in accredited (EQA) schemes for cytology screening and for technical quality.

Quality metrics

A complete and accurate report containing prescribed quality metrics will be provided at regular intervals to CervicalCheck. Complete data at least quarterly, to be received by CervicalCheck within one month of quarter-end.

The quality metrics collected during internal quality control procedures are used for monitoring, assessment, reporting, review and feedback purposes.

The quality metrics required are detailed in the current version of the CervicalCheck Cyto1. The metrics should be readily available from the laboratories internal quality control processes. They include metrics for both the laboratory and for individual screeners and cytopathologists.
Quality requirement

**Identification of individuals**
The identifier assigned to each individual screener and cytopathologist will be the same for different metrics of the report and over successive reporting periods.

Quality requirement

**CervicalCheck workload**
Laboratories will have the ability to separate CervicalCheck workload from other workloads for statistical and monitoring purposes.

Quality requirement

**Quality metrics improvement**
Laboratories will undertake appropriate and timely measures to address performance issues that impact upon quality metrics and cause values outside of laboratory, national and/or international norms.

Individual screeners whose percentile rates are outside national percentile ranges may be required to cease working on CervicalCheck specimens until evidence exists that their reporting profiles are within acceptable parameters. Evidence of retraining may be sought by CervicalCheck.

Quality requirement

**Quality assurance visits**
Cytology laboratories will accommodate on-site visits by NCSS-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.
4.3 References


8. CervicalCheck Cervical Screening Register (CSR) information system data entry standards demographic details (CS/PUB/REG-2).

9. CervicalCheck Cervical Cytology Form (CS/F/LAB-2).


11. CervicalCheck Combined Cytology and HPV Form (CS/F/LAB-14)


17. CervicalCheck Guidance for CPC/MDT meetings for colposcopy services - planning successful collaboration for web-based interactive meetings between colposcopy, histopathology and cytology (CS/PUB/CLP-2).

18. Pathology Laboratories cervical cytology and outcome of gynaecological referrals (Cyto 1 Report) (CS-F-LAB-10).
Chapter 5
Quality assurance in HPV testing

5.1 Introduction

5.2 Quality requirements and standards
   5.2.1 Organisational requirements
   5.2.2 Laboratory facilities
   5.2.3 Staff qualifications
   5.2.4 Specimen reception
   5.2.5 Data entry and notification to CervicalCheck
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   5.2.7 Proficiency and competency of staff
   5.2.8 Results management
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   5.2.10 Quality assurance and continuous improvement

5.3 References
5.1 Introduction

The role of persisting high risk human papilloma virus (HR-HPV) infection among women with cervical intraepithelial neoplasia (CIN) and cervical cancer is now clearly established.

HPV testing post colposcopy treatment was introduced into the cervical screening programme in 2012.

The reported negative predictive value of HR-HPV testing for CIN is over 99 per cent, therefore women who are negative for HR-HPV post-treatment are at very low risk of residual disease and may be discharged to routine re-call. By employing HPV testing post colposcopy treatment, approximately 80 per cent of treated women avoid having to undergo annual smear tests. HPV testing may be employed in other scenarios in due course. These include ASCUS triage which will allow women who receive a cytology result of ASCUS but are HPV negative and therefore at low risk to be returned to routine re-call. Those who are ASCUS on cytology and HPV positive can be followed-up at colposcopy services as appropriate. HPV testing may also be employed for the management of difficult cases in colposcopy.

HPV testing for CervicalCheck is carried out on the residual fluid remaining in the Thinprep® vial post-processing for cytology screening. As both tests are carried out on the same sample, the programme requires the cytology laboratory to inform it when a HPV test has been ordered or authorised. The same laboratory accession number is required for a combined cytology and HPV sample. For this reason, many of the requirements below are also outlined in Chapter 4.

HPV testing may be carried out in the cytology laboratory, a microbiological lab or a dedicated molecular testing laboratory. Regardless of the location of the testing environment, there are a number of quality requirements and standards that must be in place to ensure accurate and reliable results. The requirements are essential elements in the organisation, management and interface of a laboratory operating within a cervical screening programme. The standards are the metrics for specific elements of the performance of a laboratory. The statement of each standard is accompanied by both an achievable and a minimum target.

The quality requirements and standards for laboratories providing HPV testing services to CervicalCheck are set with regard to the evolution of standards and guidelines in response to technological developments and research outcomes in other cervical screening programmes, with particular reference to revisions in the NHS ‘CSP Publication No. 1’ (revised 2012)¹ and the NHS ‘HPV Triage and Test of Cure: Implementation Guidance’² document.

Compliance with the requirements and standards is measured and monitored by:

- Quality metrics reports by laboratories
- Analysis of data provided to the Cervical Screening Register (CSR) by cytopathology, colposcopy and histology services providers
- Quality assurance site visits to laboratory providers
- Monitoring and review of operational activity and performance.
5.2 Quality 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.

Several of the quality requirements and standards set out below may be simultaneously fulfilled if HPV testing is carried out by a cytopathology laboratory providing services to the screening programme.

### 5.2.1 Organisational requirements

<table>
<thead>
<tr>
<th>Quality requirement</th>
<th>Accreditation</th>
<th>Data protection</th>
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<tbody>
<tr>
<td><strong>Standard 5-1</strong></td>
<td>The laboratory will have and maintain accreditation to ISO15189 standard or equivalent, certified and documented by an approved accreditation body. The scope of the laboratory accreditation must include HPV testing.</td>
<td>The storage, access and transfer of women’s personal and health information shall be compliant with the Data Protection Act 1988 and the Data Protection (Amendment Act) 2003 and any future revisions or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive.</td>
</tr>
</tbody>
</table>

**Note:** Laboratory accreditation covers facilities, staff qualifications, training and competencies, equipment, laboratory information systems, and quality management systems.

**Quality requirement**

**Health and safety compliance**

The laboratory shall be compliant with all national legal and statutory health and safety requirements. The Clinical and Laboratory Standards Institute (CLSI) document ‘MM3-A2-Molecular Diagnostics Methods for Infectious Diseases; Approved Guideline-Second Edition’ is the reference document recommended.
Quality management system (QMS)
The laboratory shall have a quality management system (QMS) in place as required by their accreditation standard. The laboratory shall have a designated person responsible for quality management who will liaise with CervicalCheck to resolve any quality issues that may arise.

Any complaints in relation to the service shall be notified to the NCSS.

Security of electronic data exchange with programme
A Virtual Private Network (VPN) shall be installed between the laboratory and the programme operations office for the secure exchange of electronic data.

Laboratory information management system (LIMS)
A computerised laboratory information management system (LIMS) will be installed and be in operation in the laboratory.

The LIMS will be in a secure facility with adequate backup arrangements, on- and off-site. Access to the LIMS will be by privilege-level access control. The LIMS will be capable of generating periodic quality metrics and audit returns to CervicalCheck.

Data capture
The LIMS will be capable of recording the data required by CervicalCheck (Cervical Screening Register information system data entry standards demographic details) from the sample and Cervical Cytology Form or Cervical Cytology and HPV Form.

Format and timing of electronic data exchange with the programme
The LIMS will be capable of extracting and transferring required data to the programme in the required format as per CervicalCheck specifications (notification and result files). The laboratory will also receive information from the programme in specified formats and transfer it to its information systems (error and history/eligibility files).

The laboratory will have in place the capability to exchange electronic communications between staff members and programme staff through secure protocols (e.g. secure email).

Reporting
The LIMS will be capable of recording test results including combined cytology and HPV management recommendations. The LIMS will be capable of recording the identity of the person authorising the HPV report.
Capability and format for electronic orders and results

It is desirable that laboratories are capable of receiving orders electronically and issuing results electronically to and from ordering doctors or clinics, according to a specified messaging standard. Electronic laboratory order format is HL-7 based and conforms to the Laboratory order message specifications of the Health Information and Quality Authority (HIQA) current GP Messaging Standard\(^1\). HL-7 based orders and results use Healthlink’s Message Broker System. The physical form for electronic orders includes a barcode, which laboratories shall be able to scan and extract the included details for automatic import into their data entry system.

In addition the laboratory information system (LIMS) should:

- Link multiple test results for the same patient
- Provide easy access to details of previous cervical cytology and histology of the patient
- Provide a mechanism for ascertaining and recording clinical outcome after cytology tests, including colposcopy findings, biopsies and reasons for biopsies not being taken
- Provide the data necessary for evaluation of the cervical screening programme.

Changes to service capacity, capability or conformance to quality assurance standards

Any changes that impact on or could have an impact on any aspect of laboratory services, including laboratory accreditation status, processes, system procedures, analysis, and reporting will be agreed with CervicalCheck. Any changes will be advised in advance in writing to CervicalCheck.

Other laboratories

Laboratory/ies will make relevant clinical information and follow-up data available to other laboratories providing services to CervicalCheck.

Health agencies and authorities

Laboratories engaged by CervicalCheck will comply with all requests for data or reports by Irish health agencies and authorities, including the Department of Health and the National Cancer Registry Ireland (NCRI).
5.2.2 Laboratory facilities

HPV testing services will be provided in a dedicated laboratory area or facility. All areas will be clean, well lit and well ventilated. There will be appropriate storage facilities for flammable and toxic chemicals as required by national legal and statutory health and safety requirements.

5.2.3 Staff qualifications

Scientific, medical and non-medical staff will be qualified for the positions they hold according to national requirements to practice.

The laboratory carrying out HPV testing will be led by, or have access to a medically qualified consultant who works in that discipline on a regular basis. This is to facilitate high-quality testing and support the effective management of more challenging cases.

There will be a lead medical scientist or manager who is responsible for the day-to-day management of the department and has responsibility for supervision of non-medical staff.

Roles and responsibilities will be defined and should be incorporated into the laboratory quality manual.

5.2.4 Specimen reception

Standard operating procedures (SOPs) will be in place for handling CervicalCheck samples. Laboratories will accept orders via postal delivery and via electronic laboratory orders where applicable (followed by the receipt of the physical sample and form). For electronic orders the laboratory will be capable of extracting bar-coded information.

The laboratory will only accept programme samples from doctors or clinics that are notified to the laboratory by CervicalCheck. Only those samples accompanied by the programme's Cervical Cytology Form\(^9\) or Cervical Cytology and HPV Form\(^10\) will be accepted. Only those samples indicating either signed consent or prior consent by the woman will be accepted.

All forms will be date-stamped upon receipt.

Sample vials will be matched to the accompanying forms prior to labelling. To ensure a robust 'chain of custody' cross-checking of a minimum of three and preferably four patient identifiers will be performed. If the testing procedure requires initial aliquoting from the LBC vial then a second person verification should be in place to ensure a robust 'chain of custody'.

A discrepancy handling and resolution process will be in place to manage all discrepancies with CervicalCheck samples received. A CervicalCheck guidance document ‘Cervical smear samples laboratory – samples receipt. Discrepancy handling and resolution guidance’\(^{12}\) is available for laboratories contracted by the programme. Discrepancies with received samples will be recorded and the log will be made available to CervicalCheck. The format of the log will be approved by CervicalCheck.

Samples returned to ordering doctors or clinics will be traceable.

After verification of correct correlation of the sample vial with the corresponding form, and acceptance of the sample and form for processing, both will be labelled with a unique identification number (laboratory accession number).

The unique laboratory accession number for the sample must remain the same whether the sample is for cytology screening only, for HPV testing only, or for both cytology screening and HPV testing.
5.2.5 Data entry and notification to CervicalCheck

Data entry of the details recorded on the forms accompanying submitted sample vials will conform to CervicalCheck data capture requirements.

All relevant data recorded on the form by the smeartaker will be entered into the LIMS (refer to Cervical Cytology/Cervical Cytology + HPV/Cervical HPV Requests and Results).

Samples will be assigned to the correct clinically responsible doctor or clinic (Registered Smeartakers – Types and Identification).

**Standard 5-2**

**Access to received HPV test order forms**

Copies of all submitted HPV test order forms (HPV test only or combined cytology and HPV test orders), in electronic format and indexed by the laboratory accession number, shall be made available promptly to CervicalCheck.

100%, within 7 working days of acceptance.

**Standard 5-3**

**Notification of sample receipt to programme**

Samples, once accessioned, must be notified promptly by electronic means to CervicalCheck.

95% within 48 hours of receipt of sample.
Min: 80% by 17:00 GMT next working day.

**Note:** A tracking system or log will be in place to verify that the number of electronic notifications sent to CervicalCheck on any given day equals the number of samples entered onto the LIMS that day. A weekly reconciliation of files sent and received will be in place between CervicalCheck and the laboratory.

**Quality requirement**

**Programme ineligible samples**

Samples identified by CervicalCheck as ineligible for the screening programme will not be processed. Certain samples that are not to be processed may have to be reported. These include expired vials and samples that are not processed but a report is sent to both CervicalCheck and the requesting doctor. Ineligible samples may be required to be returned to the ordering doctor or clinic.
5.2.6 Sample processing

The HPV test used will be chosen from those considered acceptable for use within the CervicalCheck programme and agreed by contract.

Analysers will be installed by the manufacturer’s personnel. The installation will be in an appropriate environment to ensure accuracy and validity of results and to prevent contamination.

Periodic maintenance will be carried out by trained individuals as specified in the manufacturer’s user manual. A log of maintenance will be maintained.

The laboratory must verify that instrument, analyser, and reagent performance meets the published specifications. Appropriate personal protective equipment and handling techniques will be employed to prevent contamination of samples.

Reagents must be within expiry date. Reagents and samples will be stored according to specified storage conditions. Only those reagents or consumables specified by the manufacturer will be in use.

Processing of samples will be carried out according to instrument user manuals and assay specific package inserts.

All laboratories providing HPV testing will include positive and negative internal quality control (IQC) samples as well as all required kit controls in every run. The quality of the analytical runs may be monitored using additional quality assurance (QA) guidelines such as the Westgard rules $^{15}$.

Sample ‘chain of custody’

Handling procedures will ensure a robust ‘chain of custody’ across all phases of the analysis, including specimen receipt, nucleic acid extraction, nucleic acid quantification, hybridisation/amplification, detection, documentation and storage. An audit trail will be in place for sample processing.

5.2.7 Proficiency and competency of staff

Laboratory staff implementing HR-HPV technology will have relevant experience in interpreting and troubleshooting molecular technologies. They will have appropriate training to include sample handling, analysis, quality control and health and safety.

Continuing education

There will be protocols and practices in operation to demonstrate a system of both internal and external continuing education for scientific and medical staff reporting CervicalCheck cases.
5.2.8 Results management

For diagnostic purposes, results will be assessed in conjunction with the patient’s medical history, clinical examination, and other findings. There will be a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

**Reporting HPV test results**

HPV result codes will be reported with the detail and the format specified by CervicalCheck. Generally, the details required include: HPV test methodology, HPV test result, subtypes tested and reference range.

**Assignment of management recommendations**

All cytology results will take the HPV test result into consideration and have a management recommendation accompanying the cytology pattern as a P and R code combination according to ‘Cervical Cytology Management Recommendations Explanatory Guide’\(^\text{16}\) and ‘Cytology Terminology Table’\(^\text{17}\) as appropriate.

*Note:* Where a combined cytology screen and HPV test is carried out, the management recommendation will be assigned using Cytology and HPV Recommendations Table for follow-up of women post-treatment, or similar CervicalCheck publication for other HPV test scenarios.

**Management recommendations with respect to screening history**

Management recommendation will be correct for each result with respect to the screening history of the woman.

The screening history of the woman provided by the smeartaker via the Cervical Cytology Form\(^\text{9}\) or Cervical Cytology and HPV Form\(^\text{10}\) and CervicalCheck from the CSR (where such history is available) must be referred to and taken into account during the results process. This will ensure the correct management recommendation is assigned.

CervicalCheck uses the management recommendation accompanying results to issue appropriate correspondence to a woman advising her of her next recommended step in the screening programme.

**Check of result and recommendation**

An independent check of the case result and management code will be in place, prior to report authorisation, to minimise the risk of error.

**Authorisation of results**

Every result will be appropriately authorised before release. Every report will be checked for inconsistencies before authorisation. Reports will identify the cytotechnologist or medical scientist and/or cytopathologist responsible for the conclusion and recommendation.
Quality requirement

**Result codes notification to programme**
Results, once authorised and released, will be issued in the agreed summary format as soon as possible by electronic means to CervicalCheck.

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**Laboratory response time (turnaround time [TAT])**

| Cytology results must be authorised, released and transmitted to CervicalCheck within the target turnaround time from sample validation by the programme. | 95% within 10 working days. |

*Note:* If the target for turnaround time (TAT) cannot be achieved for any period exceeding three working days, CervicalCheck will be immediately informed and a plan to remove the delay must be provided within one week.

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**Adequacy of results reports**

The contents of the results report to ordering doctors and clinics must be in accordance with the guidelines outlined in Cervical cytology/Cervical Cytology + HPV/Cervical HPV Requests and Results.

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**Results reports to ordering doctors or clinics**

| Results, once authorised and released, must be issued promptly to the ordering doctor or clinic. | 99% to be received within 5 working days. |

*Note:* The issuing of results must take account of the time taken for delivery of printed paper results (post or courier) to meet the target for receipt by the ordering doctor or clinic.

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**Delivery of results reports to ordering doctors or clinics**

Results reports will be issued to the correct ordering doctor or clinic. Documented processes are required to ensure that results are sent to the correct doctor and to handle discrepancies between the number of samples received and the number of reports transmitted.

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**Results reports by electronic means**

It is desirable that all results reports in addition to paper format be issued to ordering doctors or clinics and CervicalCheck in full electronic format via a nominated telecommunications pathway. The electronic format for results is HL-7 based and conforms to the laboratory result message specifications of HIQA’s GP Messaging Standard.
5.2.9 Storage and archiving

The laboratory will ensure adequate administration and secure archiving and disposal of forms, samples, waste products and reports. Records will be stored to allow prompt retrieval if required.

Administration, archiving and disposal procedures will comply with accreditation standards and national legislation, including those relating to confidentiality and data security of personal health information.

Access to materials

Laboratories are required to provide CervicalCheck access to materials including logs and records, on request.

5.2.10 Quality assurance and continuous improvement

External quality assurance (EQA)

All laboratories providing HPV testing will participate, and show adequate performance, in an accredited external quality assurance (EQA) scheme. EQA samples will be analysed within the routine laboratory workload, by personnel who routinely test patient samples, using the same primary methods as for patient samples.

Quality metrics

A complete and accurate report containing prescribed quality metrics must be provided at regular intervals to CervicalCheck.

Complete data at least quarterly, within one month of end of period.

Note: The quality metrics collected during internal quality control procedures are used for monitoring, assessment, reporting, review and feedback purposes.

The quality metrics required are detailed in the current version of the ‘HPV 1 Report’. They include measures, which should be readily available from the laboratories internal quality control processes. Laboratories will have the ability to separate CervicalCheck workload from other workload(s) for statistical and monitoring purposes.

Quality metrics improvement

Laboratories will undertake appropriate and timely measures to address performance issues that impact upon quality metrics and cause values outside of laboratory, national and/or international norms. EQA results will be evaluated on an ongoing basis, with prompt corrective action taken for unacceptable results.
Quality assurance visits

Laboratories will accommodate on-site visits by NCSS-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.

5.3 References


8. CervicalCheck Cervical Screening Register (CSR) information system data entry standards demographic details (CS/PUB/REG-2).

9. CervicalCheck Cervical Cytology Form (CS/F/LAB-2).

10. CervicalCheck combined cytology and HPV form (CS/F/LAB-14).


17. CervicalCheck cytology terminology table (CS/PUB/LAB-2).

18. Pathology laboratories HPV testing HPV 1 Report (CS/F/LAB-15).
Chapter 6

Quality assurance in colposcopy

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   6.2.2 Governance
   6.2.3 Staff
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6.3 Clinical requirements and standards in colposcopy
   6.3.1 Diagnosis
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   6.3.6 Clinico-pathological conferences (CPC)/Multi-disciplinary team (MDT) meetings
   6.3.7 CervicalCheck cancer review process
   6.3.8 Quality assurance and continuous improvement

6.4 References
6.1 Introduction

Colposcopy services play a key role in the success of any cervical screening programme by ensuring optimal management of women with detected smear test abnormalities. In particular, colposcopy services must ensure accurate diagnosis and effective treatment. Quality assurance for colposcopy services is therefore essential. Interventions must reduce the risk of cancer in these women while minimising the risk of any significant physical and psychosocial impact. The quality of any colposcopy service is reliant on the skill and judgement of the individual practitioners as well as adequately resourced, well organised administration.

This chapter provides requirements and standards for the provision of quality assured colposcopy services. It is based on the model of care agreed between the National Health Service Cervical Screening Programme, British Society of Colposcopy and Cervical Pathology (BSCCP) and the Royal College of Obstetricians and Gynaecologists (RCOG).

This edition of requirements and standards for colposcopy services operating within the CervicalCheck programme have been based on the following references:

- The first edition of the NCSS ‘Guidelines for quality assurance in cervical screening’.
- European guidelines for quality assurance in cervical cancer screening. 
- The evolution of standards and guidelines in response to technological developments and research outcomes in other cervical screening programmes.
- The supplementary document - Organisational and Clinical Guidance for Colposcopy Services.
- The activity and performance of colposcopy services collated since the commencement of CervicalCheck.

Tools for monitoring compliance with the requirements and standards include:

- Service standard operating procedures/process guidelines documented and in place.
- Service record of failsafe management.
- Local register of BSCCP certified colposcopists and trainers including BSCCP identities updated six monthly.
- Training logs.
- Attendance records, minutes of multi-disciplinary clinico-pathological meetings.
- Minutes of MDT operational meetings.
- Audit of waiting times/clinic schedules.
- Colposcopy monthly returns and extracts of colposcopy information.
- Analysis of data provided to the Cervical Screening Register (CSR) by cytopathology, colposcopy and histopathology services providers.
- Quality assurance visits.
6.2 Organisational requirements and standards in colposcopy

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.

6.2.1 Facilities

**Access area**
The colposcopy service should be provided in a dedicated outpatient facility, with a dedicated reception area and a dedicated waiting area for women. There should be clear signage from the hospital entrance to the colposcopy clinic.

**Clinical area**
There should be a dedicated area for history taking and counselling which should ensure the privacy of the woman. There should be provision to enter the history onto the IT system in this clinical space. There should be adjacent toilet facilities for the woman. A separate recovery room/area should be available. There should be a private changing area for the woman.

**Equipment**
There should be an examination couch capable of postural adjustment. There should be at least one working colposcope which should be maintained in accordance with the hospital guidelines on the maintenance of medical equipment. The colposcope should be linked to a camera to enable image capture. A monitor should be available to allow the woman to view the procedure. Images should be captured using the colposcopy management software. Resuscitation equipment should be available at the colposcopy clinic. Clinical and nursing staff should be trained in the use of the resuscitation equipment. A panic button should be accessible within the clinical room which provides communication with staff outside the clinical room. There should be a computer connected to the hospital network in the clinical room to facilitate data entry of clinical information.
6.2.2 Governance

Quality requirement

Governance

The service should have regular (at least quarterly) operational meetings between nursing, hospital administration/managers and colposcopists. Management reports including numbers attending, waiting times and default rates should be reviewed at these operational meetings and appropriate corrective actions taken.

The service should have clinico-pathological meetings on at least a monthly basis to enable efficient decision making and timely discussion of challenging cases.

Colposcopy clinics should be scheduled in sessions of 3 hours to accommodate appointment slots of 20 minutes (30 minutes if a trainee is present) per room to maximise throughput while minimising waiting times at the colposcopy service.

6.2.3 Staff

Quality requirement

Staff

Colposcopy should be delivered by a defined team including medical, nursing and administrative staff. Colposcopists should be trained and certified by a recognised certification and recertification body such as the British Society of Colposcopy and Cervical Pathology (BSCCP) and should appear as such on the list of certified colposcopists of the certification body. A local register of certified colposcopists and trainers should be maintained at each service and updated on a six monthly basis.

Quality requirement

Lead colposcopist

There should be a lead colposcopist with a sessional commitment of one session per week to oversee continuous quality improvement and to troubleshoot any clinical or administration issues.

There should be adequate dedicated nursing staff available to the service as agreed in the memorandum of understanding for each service. A clinical nursing care assistant should be available to facilitate cleaning and enhance the turnaround time between patients at the colposcopy clinic. There should be enough dedicated administrative support available as agreed in the memorandum of understanding to provide administrative support to the service. There should be a separate nurse-led cytology and HPV clinic for the follow-up of both treated and untreated patients.
6.2.4 Information technology

**Infrastructure**
A computerised colposcopy management system should be installed at the colposcopy clinic. This system should be networked in an accessible form from all areas in use by the team. The colposcopy management system should be interfaced with the hospital patient administrative system and the hospital appointments system.

Adequate numbers of concurrent user licences should be available to enable efficient data entry by all necessary staff.

**Training**
Training in the use of the colposcopy management system should be available.

**Utilisation**
The colposcopy service should generate appointment letters from the colposcopy management system. The IT system should be used for specimen management using a defined report which lists specimens taken at each clinical session. The IT system should be used to store image and video data. The IT system should be used to enter the results of any tests. The IT system should be used to enter follow-up and management plans. The IT system should be used to generate result and management plan letters to both GPs and the woman. The IT system should be used to check failsafe processes. The IT system should generate quarterly mandatory audit returns.

**Update records to CervicalCheck**
All updates to records of women consented to participate in CervicalCheck should be transmitted to the CSR on a daily basis.

Controls should be in place to ensure that mandatory fields cannot be overwritten in the colposcopy computer systems. All mandatory fields must be complete to allow the transfer of files and updates to the CSR.

**Error files**
Error files that are returned from the CervicalCheck CSR should be checked on a regular basis using the broker log. All error files sent by the CSR should be actioned in a timely fashion and corrected updates resent to the CSR.
6.2.5 Systems management

Management of new referrals

There should be a defined process for the management of new referrals. There should be a defined process for informing women of the appointment by letters from the colposcopy management system. Services should use the facilitated referral process and inform the programme via a “red flag alert” if it is unable to process appointments within these timeframes and needs the programme to redirect new referrals to other services.

Standard 6-1

Waiting times

Women referred to colposcopy should be offered a timely appointment following receipt of referral.

- Women with a clinical suspicion of invasive cancer or adenocarcinoma in situ within 2 weeks.
- Women with a smear test suggestive of CIN2 or CIN3 (HSIL) within 4 weeks.
- All other women within 8 weeks.

Management of women who default

There should be a defined process for the management of women who default from attendance at the colposcopy clinic.

Standard 6-2

Women who default

The percentage of women who do not attend and who do not notify the colposcopy service should be maintained at a low level to maximise the efficiency of the colposcopy service and to avoid the loss of women to follow-up.

< 10%

Management of specimens

There should be a defined process for tracking all specimens to ensure that all are correctly delivered to the laboratory in a timely fashion (within one week).

Management of test results

There should be a defined process for tracking all test results to ensure that all are received by the colposcopy service. There should be a defined process for the review of the result in conjunction with the medical record to decide the most appropriate course of action based on the results. The defined process for review of results should include a method of fast tracking results suggestive of invasive cancer.
Provision of information
All women should be sent clinic-specific information on colposcopy in advance of appointments. Clinics which operate a ‘select and treat’ policy should send appropriate information regarding treatment to the patient in advance of the appointment.

Information to women
Women should be sent a personalised invitation to colposcopy in advance of attendance. > 90% within 2 weeks of receipt of the referral

Communication of results to the woman and to the referring doctor (negative and abnormal)
There should be a defined process to ensure that all test results and management plans are communicated to both the woman and the referring doctor.

Communication of results and management plans
Information on results of investigations should be communicated to the woman and to the referring doctor in a timely manner. > 90% within 4 weeks of the woman’s attendance

Audit and systems review
There should be a defined process whereby computerised failsafe checking procedures are performed on a monthly basis at least. The colposcopy team should meet to review quality assurance processes and identify any opportunities for improvement on at least a quarterly basis. The colposcopy statistical returns should be generated on a quarterly basis and reviewed by the team.

Documentation
The colposcopy service should have clinical and administration guidelines and procedures which have been agreed by both the colposcopy team and the hospital administration.

Follow-up
There should be a defined process for ensuring that all patients referred with abnormal cytology should have at least one follow-up smear test at the colposcopy clinic prior to discharge.
6.2.6 Data quality

Electronic updates from colposcopy to the CSR are really important in updating the woman’s record and ensuring the correct follow-up. Services should make sure that data capture is accurate and complete to enable correct transfer of the information.

**Data capture – demographics**

Every woman’s record sent to the CSR must contain the following demographic details to allow the CervicalCheck programme to uniquely identify and accurately match the woman on the CSR.

- **Minimum Demographics:** Every woman’s record sent to the CSR must contain at a minimum, the forename, surname, date of birth and address to uniquely identify the woman.
- **Additional Demographics:** In addition to the minimum demographics each record should include as many of the following elements where available: surname at birth, mother’s maiden name, PPS number, CSPID, Colposcopy Reference Number and Telephone Number.

**Confirmation of demographic details**

Women’s demographic details should be confirmed at each attendance and patients reminded to inform the clinic of change of address whilst attending. The computer record should be updated to reflect same.

**Notification of colposcopy procedures/outcomes to CSR**

Every colposcopy update sent to the CSR should contain the following information:

a) For those who fail to attend the colposcopy appointment, the appointment status must be updated with one of the following scenarios:
   - Cancelled
   - DNA (Did Not Attend).

b) For those who do attend the colposcopy appointment, all of the following should be updated:
   - Appointment Status
   - Procedure
   - Examiner Identification
   - Outcome.

**Smear taking - Data Recording**

When carrying out smear tests in colposcopy the Cervical Cytology Form should record sufficient, accurate details to enable accurate matching of the woman with her records on the CSR.
### 6.3 Clinical requirements and standards in colposcopy

#### 6.3.1 Diagnosis

<table>
<thead>
<tr>
<th>Standard 6-5</th>
<th>Positive predictive value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance between colposcopic impression of high grade disease and histologically proven high grade CIN.</td>
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<table>
<thead>
<tr>
<th>Standard 6-6a</th>
<th>Biopsy</th>
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<tbody>
<tr>
<td></td>
<td>A biopsy should be performed in the presence of an abnormal Transformation Zone (TZ).</td>
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<table>
<thead>
<tr>
<th>Standard 6-6b</th>
<th>Biopsy</th>
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<tbody>
<tr>
<td></td>
<td>Reasons for not performing a biopsy in the presence of an abnormal TZ at the first visit e.g. pregnancy should be recorded.</td>
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<thead>
<tr>
<th>Standard 6-6c</th>
<th>Biopsy</th>
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<tbody>
<tr>
<td></td>
<td>Women should have a biopsy performed before ablative or destructive treatment and the result should be available before the treatment is carried out.</td>
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</table>

<table>
<thead>
<tr>
<th>Standard 6-6d</th>
<th>Biopsy</th>
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<tbody>
<tr>
<td></td>
<td>Where a lesion extends into the endocervical canal and the upper limit is not seen (Type 3 TZ), an excisional biopsy should be performed in preference to a punch biopsy.</td>
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<table>
<thead>
<tr>
<th>Standard 6-6e</th>
<th>Biopsy</th>
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<tbody>
<tr>
<td></td>
<td>Biopsy specimens should be suitable for histological diagnosis.</td>
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### 6.3.2 Treatment

<table>
<thead>
<tr>
<th>Standard 6-7a</th>
<th>Who to treat</th>
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<tbody>
<tr>
<td></td>
<td>Women with high grade CIN (CIN 2/3) or AIS confirmed on a diagnostic biopsy should have a treatment performed.</td>
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<tr>
<td></td>
<td>Exceptions would include pregnancy. If conservative management for a high grade lesion is being considered this should be discussed at CPC meeting.</td>
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<td></td>
<td>&gt;90%</td>
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<thead>
<tr>
<th>Standard 6-7b</th>
<th>Who to treat</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Women who present with a high grade cytological abnormality and who have no colposcopic abnormality identified on a fully visible Transformation Zone including examination of the vagina should have the smear test reviewed by the cytopathologist at a CPC meeting and if high grade changes are confirmed an excisional treatment should be performed.</td>
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<tr>
<td></td>
<td>&gt;90%</td>
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<table>
<thead>
<tr>
<th>Standard 6-7c</th>
<th>Who to treat</th>
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<tbody>
<tr>
<td></td>
<td>Women who present with a high grade cytological abnormality and who have an inadequate colposcopy (Type 3 TZ) should have an excisional treatment performed.</td>
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<td></td>
<td>&gt;90%</td>
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<table>
<thead>
<tr>
<th>Standard 6-7d</th>
<th>Who to treat</th>
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<tbody>
<tr>
<td></td>
<td>Women referred with high grade cytology and who have CIN1 or less diagnosed on a diagnostic biopsy should be managed carefully and should be treated if there is a subsequent cytological abnormality (LSIL at least) or if is there is a positive high risk HPV infection at 12 months. Where serious disparity between colposcopy and cytology exists and treatment is not otherwise indicated then the case should be discussed at the CPC meeting.</td>
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<td></td>
<td>&gt;95%</td>
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</table>
**Standard 6-8a**

**When to treat**

Treatment at the first visit to colposcopy should be considered for women who present with a high grade cytological abnormality and who have suspected high grade disease at colposcopy (‘select and treat’). These women should have appropriate pre-visit information regarding the possibility of treatment.

>80%

---

**Standard 6-8b**

**When to treat**

Treatment at the first visit to colposcopy should not be performed on women who present with low grade cytological change (even if there is a colposcopic suspicion of high grade disease) except in special circumstances.

<10%

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**Quality requirement**

**Pre-treatment**

All women who require treatment must be informed about the procedure and their written or verbal consent recorded. Women who require treatment must have a prior colposcopic assessment and all treatments must be recorded. Treatments must be performed in suitably staffed and equipped clinics.

---

**Standard 6-9**

The majority of women should have treatment performed as an outpatient under local anaesthesia.

≥90%
Choice of treatment: Ablative treatment is only suitable when:

- The entire Transformation Zone is visualised
- There is no evidence of either glandular or invasive disease
- There is no discrepancy between the cytology and the biopsy
- There has not been a previous treatment.

### Standard 6-10a

**Excision – Removal of the Specimen**

The specimen should usually be excised as a single specimen to maximise the interpretation of margins.  

> 90%

### Standard 6-10b

**Excision – Removal of the Specimen**

Excision of ectocervical specimens should aim for a thickness of at least 7 mm and not greater than 12 mm thickness to overcome the potential for residual disease in the crypts.  

> 95%

### Standard 6-11a

**Results**

Women treated by excisional technique at first visit should have CIN on histology.  

> 90%

### Standard 6-11b

**Results**

Women treated by excisional techniques should have CIN on histology.  

> 85%

### Standard 6-12a

**Repeat excision**

Women over the age of 50 years who have CIN3 at the endocervical margin and all women with AIS at a margin should have a repeat excision performed to obtain clear margins if satisfactory cytology and colposcopy cannot be guaranteed.  

> 90%
Repeat excision

Women treated by excision for suspected high grade disease (CIN 2/3 or AIS) and who have no significant abnormality on histology should be discussed at the colposcopy CPC meeting before repeat colposcopy including examination of the vagina and consideration of a repeat excision.  

> 90%

6.3.3 Follow-up after treatment

Follow-up after treatment

At least two follow-up smear and HPV tests should be performed at the colposcopy clinic within the first 18 to 24 months.  

>90%

Follow-up after treatment

The diagnosis of residual or recurrent CIN within twenty-four months of treatment should be very low.  

<5%

Follow-up after treatment

The results of the smear test and HPV tests on two separate occasions one year apart at colposcopy should facilitate discharge of the women to routine screening in the majority of cases.  

>80%

Follow-up after treatment

Follow-up should start between 6 and 8 months following treatment.  

>90%

Follow-up after treatment

Follow-up after a hysterectomy showing completely excised CIN should include 2 negative vault smear and HPV tests at 12-month intervals at colposcopy before discharge from CervicalCheck.  

>95%
### Follow-up after treatment

#### Standard 6-13f

Follow-up after a hysterectomy showing incompletely excised CIN should continue as if the cervix were still in situ. & >95%

#### Standard 6-14a

Women with persistent high risk HPV infection at eighteen months post treatment require annual smears for the subsequent 10 years before returning to routine screening. & >95%

#### Standard 6-14b

Women who are HPV negative 18 months post treatment and who have a smear test which is normal or shows ASCUS should be discharged to routine screening. & >95%

### 6.3.4 Follow-up of women who have not been treated

#### Standard 6-15

Women who present with high grade cytological abnormality

If the colposcopy suggests low grade disease and conservative management is preferred, multiple biopsies should be performed. & >95%

#### Standard 6-16a

Women who present with low grade cytological abnormality

If the colposcopy is satisfactory and normal, a smear and HPV test should be repeated in twelve months. & >95%
**Women who present with low grade cytological abnormality**

If the colposcopy is atypical, a biopsy should be performed. If diagnosis is CIN 1 or less a smear and HPV test should be repeated in twelve months, except in special circumstances (patient choice, risk of default).

**Standard 6-16b**

>90%

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**Women who present with low grade cytological abnormality**

If persistent abnormality or HPV positive for high risk HPV at 12 months repeat colposcopy with possible treatment should be performed.

**Standard 6-16c**

>90%

---

**Women who present with low grade cytological abnormality**

The woman should be discharged from the colposcopy clinic for routine screening if the HPV test is negative for High risk HPV and if the smear test is reported as ASCUS or normal.

**Standard 6-16d**

>90%

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**Pregnant women**

Women who are pregnant should have a colposcopy performed, using the same criteria as for women who are not pregnant.

**Standard 6-17a**

>95%

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**Pregnant women**

Biopsy and treatment is usually deferred until the postpartum period except where there is a suspicion of invasive disease.

**Standard 6-17b**

>80%

---

**Pregnant women**

If low grade CIN is suspected at colposcopy a repeat colposcopy appointment should be made for the post partum period.

**Standard 6-17c**

>95%
Pregnant women
If high grade CIN is suspected the colposcopy should be repeated at the end of the second trimester as well as the post partum period.  >95%

Pregnant women
If there is a suspicion of invasive disease a biopsy must be performed. This biopsy should be a wedge or small loop biopsy and not a punch biopsy.  100%

6.3.5 Discharges from colposcopy

Discharge recommendations
Discharge recommendations should be selected based on the table provided in the colposcopy guidance document. For non standard cases, the number of annual smear tests required post colposcopy before discharge to routine screening is determined by the treating clinician and will be followed by the programme laboratory.

Discharge correspondence
A process should exist to ensure that the discharge recommendation (post colposcopy screening requirements) sent to the CSR reflects the discharge recommendation on the discharge letter to the referring doctor.

Communication to referring doctor
All communication from the colposcopy service in relation to diagnosis/treatment and discharge of a woman must be sent to the referring GP or referring Clinic (WWC/FPC/Gynaecology/STI).

This is required so that the CervicalCheck programme office can ensure which doctor to send a failsafe letter to in the event of non compliance. A copy of the correspondence should only be sent to the woman’s own GP (if they are not the referring doctor) at her request and with her consent.
6.3.6 Clinico-pathological conferences (CPC)/Multi-disciplinary team (MDT) meetings

Participation in CPC/MDT meetings
All of the colposcopists should be invited to monthly clinico-pathological meetings organised by the service and should attend a minimum of 50 per cent. Histopathology and cytopathology representation is essential.

Protocol for CPC/MDT meetings
Participation, including a signed record of personnel attending and operational decisions, shall be recorded. Participants must be subject to national legislation relating to confidentiality, professional registration and data security of personal health information. The outcome of the discussions and any management plans should be inputted into the patient medical record. The protocol should be consistent with the provisions of Guidance for CPC/MDT Meetings for colposcopy services.

6.3.7 CervicalCheck cancer review process
The CervicalCheck cancer review process reviews notified cases of invasive cervical cancers. It operates as a feedback and learning process within quality assurance, contributing to potential continuous improvement measures.

Notification
The colposcopy should notify the details of women with a diagnosis of invasive cancer to the programme.

Review of cases
All cancers should be reviewed at both the colposcopy and oncology multi-disciplinary meetings. In addition, further reviews may be requested by CervicalCheck, and in some cases services will be asked to provide case material for cases identified as warranting independent third-party review in line with the cancer review process.
6.3.8 Quality assurance and continuous improvement

<table>
<thead>
<tr>
<th>Standard 6-18</th>
<th>Quality metrics</th>
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<tbody>
<tr>
<td></td>
<td>A complete and accurate report containing prescribed quality metrics shall be provided at regular intervals to CervicalCheck.</td>
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<tr>
<th>Quality metrics improvement</th>
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<tr>
<td>Colposcopy services will undertake appropriate and timely measures to address performance issues that impact upon quality metrics and cause values outside of national norms.</td>
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<tr>
<th>Quality assurance visits</th>
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<tbody>
<tr>
<td>Colposcopy services shall accommodate on-site visits by CervicalCheck-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.</td>
</tr>
</tbody>
</table>

6.4 References

2. CervicalCheck Organisational and clinical guidance for colposcopy services (CS/PUB/CLP-7).
3. Colposcopy service CPC/MDT meeting attendance log (CS/F/CLP-7).
4. CervicalCheck Guidance for CPC/MDT meetings for colposcopy services - planning successful collaboration for web-based interactive meetings between colposcopy, histopathology and cytology (CS/PUB/CLP-2).
5. CervicalCheck Cervical Cytology Form (CS/F/LAB-2).
6. Process for the review of incident cases of cervical cancer following the introduction of a national cervical screening programme (CS/PUB/PM-10).
7. National Cancer Screening Service quality assurance protocol for systematic review visit to colposcopy service.
Chapter 7
Quality assurance in histopathology

7.1 Introduction

7.2 Quality requirements and standards
7.2.1 Organisational requirements
7.2.2 Laboratory facilities
7.2.3 Staff qualifications
7.2.4 Specimen reception
7.2.5 Data entry and notification to CervicalCheck
7.2.6 Assessment of the sample (cut-up)
7.2.7 Sample processing
7.2.8 Sample embedding
7.2.9 Sample sectioning
7.2.10 Slide staining
7.2.11 Proficiency and competency of staff
7.2.12 Microscopy and reporting of results
7.2.13 Archiving
7.2.14 Clinico-pathological conference (CPC)/multi-disciplinary team (MDT) meetings
7.2.15 CervicalCheck cancer review process
7.2.16 Quality assurance and continuous improvement

7.3 References
7.1 Introduction

Cervical cytology currently represents the primary screening method. Colposcopy locates the most abnormal areas of the cervix. Histopathology provides the final diagnosis of cervical neoplasia, forming the basis for which treatment is planned.

In addition, histopathology:

- Serves as the ‘gold standard’ for quality control of cytology and colposcopy
- Is the source of diagnostic data stored at the National Cancer Registry Ireland (NCRI) and used for evaluation of screening programmes
- Is required to diagnose the degree of abnormality in women with persistent low grade abnormalities including HPV lesions, as well as high grade lesions (squamous and glandular)
- May also diagnose either glandular abnormalities or high grade CIN, adenocarcinoma-in-situ (AIS), or invasive cancer.

As in cytopathology, the sample pathway for histopathology can be subdivided into three key stages:

1. Sample taking, sample transport and receipt of sample in the laboratory (pre-analytical)
   The accuracy of the histopathological diagnosis of tissue specimens depends on adequate quality samples, obtained by colposcopically directed punch biopsies (with endocervical curettage, if necessary) or excision of the Transformation Zone (TZ) or conisation.

2. Sample processing and interpretation (analytical)
   Accurate histopathological diagnosis further depends on appropriate macroscopic description, technical processing, microscopic interpretation and quality management correlating cytological and histological diagnosis.

3. Report generation (post-analytical)
   It is important to recognise that the interpretative reports provided in histopathology and cytopathology are the opinion of the reporting pathologists. There is therefore a subjective element in the content of any report. Some diagnoses require the combined input of a colposcopist, cytologist and histopathologist. There are a variety of reasons why clinical appearances, cytology, biopsy and excision results may appear discrepant. Multi-disciplinary team (MDT) meetings can often resolve perceived discrepancies. If a colposcopist is unsure of the significance or meaning of a report or feels that a report is incorrect, they should contact the issuing laboratory or reporting pathologist. Histopathologists should remain abreast of current and emerging interpretation guidelines.\(^1\,2,3\).

The quality requirements and standards for histopathology laboratories providing services to CervicalCheck are set with regard to:

- NCSS Guidelines for Quality Assurance in Cervical Screening (first edition)
- ‘Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology - Faculty of Pathology, Royal College of Physicians in Ireland’\(^1\)
- Standards and guidelines, revised in response to technological developments and research outcomes, in other cervical screening programmes, with particular reference to histopathology reporting (NHS CSP\(^2\), Royal College of Pathology\(^3\))
- The activity and performance metrics for histopathology collated since the commencement of CervicalCheck.
Compliance with the requirements and standards is measured and monitored by:

- Quality metrics reports by histopathology laboratories
- Analysis of data provided to the Cervical Screening Register (CSR) by cytopathology, colposcopy and histology service providers
- Quality assurance site visits to laboratory service providers
- Monitoring and review of operational activity and performance.

7.2 Quality 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.

7.2.1 Organisational requirements

**Standard 7-1**

**Accreditation**

The laboratory must have and maintain accreditation to ISO15189 standard or equivalent, certified and documented by an approved accreditation body. The scope of the laboratory accreditation must include histopathology.

External accreditation at least once every 2 years.

**Note:** Laboratory accreditation covers facilities, staff qualifications, training and competencies, equipment, laboratory information systems, and quality management systems.

**Data protection**

All data protection issues (storage, access, security, confidentiality and data transfer) will be compliant with Irish and European legislative instruments: the Data Protection Act 1988, the Data Protection (Amendment) Act 2003 and any future revisions or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive.

Laboratories must have facilities, systems and procedures to ensure the secure exchange of personal health information and confidential data. These provisions must apply equally to data held in paper and in computer formats. A Virtual Private Network (VPN) must be installed between the laboratory or hospital and the programme operations office for the secure exchange of electronic data.
Health and safety compliance

The laboratory will be compliant with all national legal and statutory health and safety requirements.

Quality management system (QMS)

The laboratory will have a quality management system (QMS) in place as required by their accreditation standard. The laboratory should have a designated person responsible for quality management who will liaise with CervicalCheck to resolve any quality issues that may arise.

Any complaints in relation to the histopathology service within the screening programme will be notified to CervicalCheck.

Laboratory information management system (LIMS)

- **General:** An appropriate laboratory information management system (LIMS) will be installed and be in operation in the laboratory. The LIMS will be in a secure facility with the provision for adequate back-up arrangements. Access to the LIMS will be by privilege-level access control. The LIMS will be capable of generating periodic quality metrics and audit returns to the NCSS. Ideally, there should be an electronic linkage to CervicalCheck to ensure prompt retrieval of results.

- **Data capture:** The LIMS will be capable of recording the minimum dataset from the sample and request form.

- **Reporting:** The LIMS will be capable of recording test results including the identity of the reporting pathologist(s). The LIMS will be capable of recording and storing SNOMED codes for results.

- In addition the laboratory information system will:
  - Link multiple test results for the same patient
  - Provide easy access to details about previous cervical histology of the patient
  - Provide the data necessary for evaluation of the CervicalCheck programme.

Changes to service capacity, capability or conformance to quality assurance (QA) standards

Any changes that have or could have an impact on any aspect of the laboratory services, including laboratory accreditation status, processes, system procedures, analysis, and reporting should be advised in advance to CervicalCheck.

Health agencies and authorities

Laboratories will comply with all requests for data or reports by Irish health agencies and authorities, including the Department of Health and the National Cancer Registry Ireland (NCRI).
7.2.2 Laboratory facilities

All laboratories will provide appropriate facilities. These will include appropriate areas for sample reception, cut-up, processing, reporting, typing and authorisation.

7.2.3 Staff qualifications

Scientific, medical and non-medical staff will be qualified for the positions they hold according to national requirements to practice. All equipment will be maintained and used only by laboratory staff that are competent to carry out such tasks.

The histopathology laboratory will be led by a medically qualified consultant who works in that discipline on a regular basis. All samples will be reported by a medically qualified consultant.

There will be a lead medical scientist who is responsible for the day-to-day management of the department and who has responsibility for supervision of non-medical staff.

7.2.4 Specimen reception

Standard operating procedures (SOPs) will be in place for handling CervicalCheck samples.

For the purposes of data capture, samples originating from CervicalCheck colposcopy services must be segregated from samples from other sources. This may be via the programme’s Cervical Histology Form (where applicable) or by an accredited laboratory form where the origin of a sample is clearly identifiable. The issue of consent by the woman should be incorporated into the processes for sample data capture and data exchange.

All cervical histology forms will be date-stamped upon receipt.

All histopathological specimens must be received in either 10 per cent buffered formalin or as fresh samples and in an appropriate specimen container.

Sample containers will be matched to forms prior to labelling. Cross-checking of a minimum of three patient identifiers will be performed to ensure correct identification.

A discrepancy handling and resolution process will be in place to manage all discrepancies with CervicalCheck samples received.

After verification of correct correlation of the sample vial with the corresponding Cervical Histology Form, and acceptance of the sample and form for processing, both will be labeled with a unique identification number which is generated by the LIMS. The sample will be labeled on the top and side of the specimen container.

7.2.5 Data entry and notification to CervicalCheck

Relevant clinical details recorded on the Cervical Histology Form will be recorded. Notification and result files should be sent to CervicalCheck on a regular basis. A periodic reconciliation of files sent and received should be in place between CervicalCheck and the laboratory.
7.2.6 Assessment of the sample (cut-up)

The cut-up of the histopathological specimens will be performed either by a laboratory scientist, pathologist or anatomic pathology technician. The RCPPath Dataset for Histological Reporting of Cervical Neoplasia can be used to guide cut-up procedures.

Specimen description and sampling will be done in such a way as to facilitate microscopic reporting (and pathological staging). As margin involvement may be associated with persistent or recurrent disease, every effort will be made to identify whether margins are involved or are free of disease. Laboratories may use different means (including inking, where required) when assessing margins.

**Sample ‘chain of custody’**

Handling procedures will ensure a robust ‘chain of custody’ across the specimen pathway. These involve the cross-checking of a minimum of three patient identifiers at each stage, to typically include name, hospital number and accession number.

Slide labels will include patient surname in addition to the accession number.

**Cervical biopsy (not otherwise specified), wedge biopsy and cervical punch biopsy**

Careful handling of specimens is recommended to prevent surface trauma and disruption or loss of surface epithelium.

All tissue will be embedded in such a way as to minimise any loss of tissue during processing. Macroscopic description should include measurements and number of fragments.

**Endocervical curettage**

The aggregated size (in three dimensions) of the sample is recorded. All tissue will be embedded in such a way as to minimise any loss of tissue during processing.

**Cervical cone biopsy and cervical loop biopsy/large loop excision of the Transformation Zone (LLETZ), needle excision of the Transformation Zone (NETZ), straight wire excision of the Transformation Zone (SWETZ) and Cone**

Macroscopic description should include measurements in three dimensions. Care may be needed to ensure that the correct cut face is placed face down in the cassette.

These specimens will be blocked in their entirety. Cassettes will be separately identified, with a block designation to indicate their origin, if required.
**Trachelectomy**

Macroscopic description will include measurements in three dimensions. Bearing in mind that margin involvement will influence further treatment, sampling will be directed in such a way as to indentify the final surgical margin on microscopy (where possible). Inking may be considered.

In radical trachelectomy, the vaginal and parametrial margin should be sampled in such a way as to allow a microscopic description of differential margin status.

**Lymph nodes**

Where submitted, a gross description will take place with any pertinent macroscopic description. All identified lymph nodes will be submitted for microscopic examination.

**Uterus**

Macroscopic description including measurements in three dimensions will be entered into the LIMS (via electronic or manual dictation system).

The resection margins will be identified appropriately (e.g. vaginal, radial resection margin of cervix, parametrium etc.).

Macroscopic description will include a description of any lesion (with measurement).

In the case of radical hysterectomy, any resected lymph nodes must be described, measured and counted (and designated according to the anatomical site from which they have been removed).

Specimen dissection and block selection will be carried out in accordance with an agreed standard. Templates exist to guide specimen dissection and sampling and can be used where necessary e.g. the RCPath Dataset for Histological Reporting of Cervical Neoplasia (3rd edition) April 2011.

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### 7.2.7 Sample processing

Appropriate and standardised procedures will be in place for specimen processing. Quality management systems will surround these procedures.

### 7.2.8 Sample embedding

Dedicated facilities will be provided for sample embedding and a record will be kept of any tissue that does not survive the tissue processing schedule.
7.2.9 Sample sectioning

Appropriate procedures will be in place for sample sectioning. Health and safety procedures will be followed at all times to prevent cuts from microtome blades.

**Quality requirement**

**Cervical biopsy (not otherwise specified) and cervical punch biopsy**

In general, it is recommended that three levels of such biopsies are cut.

**Quality requirement**

**Cervical cone biopsy and cervical loop biopsy/large loop excision of the transformation zone (LLETZ), needle excision of the transformation zone (NETZ), straight wire excision of the transformation zone (SWETZ) and Cone/cervical wedge biopsy/endocervical curettage (ECC)/uterus**

A single level from each block may be likely to suffice initially, but further levels may be required by the pathologist.

7.2.10 Slide staining

Appropriate procedures should be in place for slide staining. Typically this will be Haematoxylin and Eosin. Special stains and immunohistochemical stains will be employed as required by the pathologist. Stains, reagents and protocols will be prepared and used according to manufacturer’s instructions with appropriate regard to both positive and negative control slides.

Internal technical quality assurance checks will be carried out routinely including quality of staining and quality of preparation.

7.2.11 Proficiency and competency of staff

**Quality requirement**

**All staff**

All staff will be competent to carry out their roles. Competency will be maintained by regular training and education. Training and competency records should be retained and available for review.

**Quality requirement**

**Pathologists**

All pathologists will participate in continuing medical education (CME) as required by Part 11 of the Medical Practitioners Act 2007 – Maintenance of Professional Competence."
Lead medical scientist, manager, supervisory scientific staff

The lead medical scientist will be responsible for maintaining a high quality service. Sufficient supervisory scientific staff will be available to provide satisfactory supervision for the training, service development and quality control of staff.

Internal quality control

Microscopic diagnosis is crucially dependent on quality control.

Methods used for quality assessment will incorporate a process of continuous dialogue within the laboratory and improve individual histopathology reporting accuracy.

Internal quality control of reporting can be monitored by a variety of methods and could include:

- Performance evaluations
- Periodic audit of histopathology outcomes
- Monitoring of non-conformities
- MDT review of slides
- Monitoring histopathology detection and reporting rates
- Correlation of cytology with clinical/histological outcome.

Pathologists will participate in regular clinico-pathological conferences (CPC)/multi-disciplinary team (MDT) meetings\textsuperscript{10}.

Continuing education

Continuing education will be facilitated with evidence of internal and external educational activities.

7.2.12 Microscopy and reporting of results

The reporting of the histopathological specimens will be performed by a pathologist. The relevant RCPath Dataset (currently Histological Reporting of Cervical Neoplasia (3rd edition)\textsuperscript{11} can be used as a reporting guide.

All histopathology reports must be authorised by a consultant pathologist (electronic and/or manual).

All histopathological results must be entered onto a computerised system (laboratory information management system [LIMS]) to allow quality assessment. Amended reports and supplementary reports will be auditable.

Reports will record the origin of the specimen, identify the tissue components that are present, provide a macroscopic description and microscopic diagnosis along with the identity of the reporting pathologist.
The microscopic diagnosis will record all grades of squamous and/or glandular intra-epithelial neoplasia, and invasive lesions.

The distribution of a lesion will note if an orientated specimen has been submitted.

Any invasive lesions are classified and graded according to national protocols and guidelines.

Where an excision procedure has been undertaken, any microscopic report will attempt to indicate whether or not the squamous or glandular lesion has been completely excised.

In the case of radical trachelectomy, this will include the vaginal and parametrial margins. In the case of radical hysterectomy, the report will contain specific comment on resected lymph nodes, including site designation, number (in total) and number involved by tumour (if applicable).

Features that impair interpretation will be recorded.

Other significant pathologic features, such as significant inflammatory changes will be recorded.

When a biopsy fails to reveal the source of the abnormal cells in a smear test, it is important to differentiate between a biopsy that is technically adequate but fails to identify a lesion, and a biopsy that is technically inadequate.

All reports will be coded (typically using standardised SNOMED nomenclature) to allow data collection.

**Quality requirement**

**Authorisation of results**

Every result will be appropriately authorised before release. Every report should be checked for inconsistencies before authorisation.

**Quality requirement**

**Recording of results**

Results details will include at least:

- Patient identification data
- Name and address of the laboratory
- Name of requesting physician
- Laboratory ID number
- Date of specimen procurement (specimen date)
- Date of arrival of the specimen in the laboratory
- Sample type
- Anatomical site of origin
- Relevant clinical details
- The results of the laboratory examination in accordance with the current standard classification system and data format, including a judgment of the quality and adequacy of the histopathological slide (if necessary), date of authorisation of the final report, and name of pathologist who has evaluated the sample.
**Standard 7-2**

**Turnaround time (TAT):**

Time between date of reporting results of the specimen from date of specimen arrival within the laboratory.

- Small specimens: At least 80% within 10 days.
- Large specimens: At least 80% within 14 days.

> 90% within 4 weeks of the woman’s attendance.

**Note:** Biopsies are performed on small specimens (<3 blocks). LLETZ, cone, trachelectomy, hysterectomy are performed on large specimens.

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**Standard 7-3**

**Results reports**

Results, once authorised and released, must be issued promptly to the ordering doctor or clinic. 100% to be received within 5 days of report being authorised.

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**Quality requirement**

**Delivery of results reports to ordering doctors or clinics**

Results reports will be issued to the correct ordering doctor or clinic. The laboratory will ensure that an appropriate delivery mechanism (for reports) is in place.

---

**Quality requirement**

**Review requests and amended reports**

Laboratories will have procedures in place to manage and respond to requests for second opinions and to issue amended or addendum reports as necessary. Additional or amended reports, once authorised and released, must adhere to the same standards and targets.
7.2.13 Archiving

Administration, archiving and disposal procedures will comply with accreditation standards and national and regional legislation, including that relating to confidentiality and data security of personal health information and disposal of hazardous medical waste or chemicals.

<table>
<thead>
<tr>
<th>Storage and archiving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secure archiving of cervical histology forms, blocks, slides and written and/or computerised reports is required for specific retention periods.</td>
</tr>
<tr>
<td>100% to be received within 5 days of report being authorised.</td>
</tr>
</tbody>
</table>

Cervical histology forms or their electronic equivalent

| Specimens | Until authorisation. |
| Blocks, Slides, Reports | 30 years |

**Note 1:** Cervical histology forms may be in paper format or in their electronic equivalent, as per local accredited practice.

**Note 2:** All slides/blocks will be stored in conditions adequate for preservation.

**Note 3:** Records will be stored to allow prompt retrieval if required.

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### Specimens retained and for disposal

Logs of specimens retained and for disposal will be maintained. Samples will not be disposed of prior to final report authorisation by the pathologist. Retention of specimens will comply with relevant legislation.

### Access to materials

Laboratories are required to provide CervicalCheck access to materials including slides and records on request.
7.2.14 Clinico-pathological conferences (CPC)/multi-disciplinary team (MDT) meetings

There are a wide variety of reasons for cases to be included in CPC/MDT meetings\(^{10}\). Cases discussed may include perceived discrepancies between cytology, histology and clinical appearances.

**Participation in CPC/MDT meetings**

Histopathologists (with or without other scientific staff members) are integral participants in CPC/MDT meetings\(^{10}\).

CPC/MDT meetings are convened by and organised by programme colposcopy services. The locations, timing and frequency of CPC/MDT meetings may vary from time to time but reasonable notice will be provided by the colposcopy service to the laboratory. While clinical teams are primarily responsible for case selection, laboratories are encouraged to submit cases for discussion. CPC/MDT meetings and cases require preparation.

**Protocol for CPC/MDT meetings**

Participation, including a signed record of personnel attending and operational decisions, will be recorded by a person nominated by the programme. Participants must be subject to confidentiality and data protection requirements\(^{5,6,10}\).

Laboratories are encouraged to incorporate CPC/MDT meetings into the internal continuing education of scientific staff within the laboratory.

**Case selection**

To ensure the efficient running of CPC/MDT meetings, cases will be appropriately selected by the colposcopist responsible for the patient. Clinicians should be aware of any relevant clinical history and should have a clear understanding about the reason for CPC/MDT discussion.
7.2.15 CervicalCheck cancer review process

The CervicalCheck Cancer Review Process\(^1\) reviews notified cases of invasive cervical cancers. It operates as a feedback and learning process within quality assurance, contributing to potential continuous improvement measures. This may lead to a request from CervicalCheck for any diagnostic material to be reviewed internally or externally.

**Review of histology slides**

The laboratory will review slides for women with a diagnosis of invasive cancer where such is requested by the programme or treating clinician and issue the results of these reviews to the programme.

**Independent third-party review**

Laboratories will provide all case material where requested for cases identified as warranting independent third-party review by the process for cervical cancer review.

7.2.16 Quality assurance and continuous improvement

**External quality assurance (EQA)**

Laboratories will participate, and show adequate performance, in accredited external quality assurance (EQA) schemes for histopathology and for technical quality.

**Quality metrics**

A complete and accurate report containing prescribed quality metrics will be provided at regular intervals to CervicalCheck.

Complete data at least quarterly, to be received by CervicalCheck within 1 month of quarter-end.
The quality metrics collected during internal quality control procedures are used to:

- Continuously analyse performance
- Spot trends and variations
- Complete annual returns
- Cross-reference data from multiple sources
- Produce rapid analysis
- Improve performance.

The quality metrics required are detailed in the current version of the CervicalCheck ‘Histo 1 Report’. They include measures which should be readily available from the laboratories internal quality control processes and are based on the QA metrics specified in the Faculty of Pathology Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology.

The quality metrics include, among others, details of:

- Workload
- Consultations
- Correlation of frozen section diagnosis with final diagnosis (if service requested)
- Cytological/histological correlation and follow-up (where available)
- Retrospective review
- CPC/MDT meetings
- External quality assurance (EQA)
- Turnaround times (TATs).

Laboratories will have the ability to separate CervicalCheck workload from other workload(s) for statistical and monitoring purposes.

The identifier assigned to an individual pathologist will be the same for different sections of the report and over successive reporting periods.

**Quality metrics improvement**

Laboratories will undertake appropriate and timely measures to address performance issues that impact on quality metrics and resulting values outside of laboratory, national and/or international norms.

Individuals identified as poorly performing may be required to be removed from working on CervicalCheck specimens until evidence exists that their proficiency in reporting is back in line. Evidence of retraining may be sought by the NCSS.

**Quality assurance visits**

Laboratories will accommodate on-site visits by NCSS-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.
7.3 References

1. Faculty of Pathology, Royal College of Physicians in Ireland (July 2011). Guidelines for the implementation of a National Quality Assurance Programme in Histopathology – Version 5.0.


8. CervicalCheck Cervical Histology Form (CS/F/LAB-1 Rev 3).


10. CervicalCheck Guidance for CPC/MDT meetings for colposcopy services - planning successful collaboration for web-based interactive meetings between colposcopy, histopathology and cytology.


13. Process for the review of incident cases of cervical cancer following the introduction of a national cervical screening programme (CS/PUB/PM-10).

Appendix 1

Key performance indicators (KPIs)

1. Introduction
2. Programme extension
3. Screening test performance
4. Diagnostic assessment and treatment
5. Definition of performance parameters in cervical cancer screening
6. References
1 Introduction

The following reflects the ‘European Guidelines for Quality Assurance in Cervical Cancer Screening’, Second Edition 2008 (Chapters 2 and 7).

Key performance indicators (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 can be identified:

• Screening intensity
  The proportion of the target population actually screened within the recommended interval is the main determinant of the success of a screening programme. If the screening interval is too frequent it increases financial and human costs with only marginal gain in the reduction of incidence and mortality. The duration of the recommended screening interval must be taken account of when monitoring and evaluating screening intensity. Indicators include programme extension, compliance with invitation, coverage and smear test consumption.

• Screening test performance
  Indicators include the referral rates for repeat cytology and for colposcopy, in addition to the positive predictive value (PPV) of referral for colposcopy, the specificity of the screening test and the rate of detection of histologically confirmed CIN.

• Diagnostic assessment of treatment
  Indicators include compliance to referral and repeat cytology and for colposcopy. The treatment of high-grade lesions is also an essential performance indicator. The proportion of women who undergo hysterectomy for CIN acts as an indicator of severe over-treatment.

Coverage is the most important factor that contributes to the success of a screening programme, i.e. the proportion of women in the target population actually screened at least once during the recommended interval by the screening programme, which is three or five years depending on the age of the woman. In order to measure coverage directly, computerised registration of all cytology and the ability to link the findings of each woman individually must be in place. Tests performed outside the organised programme can be a problem in relation to the completeness of the registration. In these cases, information obtained from informal surveys can be useful. Coverage should be calculated for the entire target age group as defined by CervicalCheck and in addition stratified by the five-year age group. To obtain high screening coverage, it is essential to reach the entire target population. The aim is that all women in the target population must be invited every three or five years, i.e. about one-third or one-fifth of the target population per year.

Compliance with invitation provides a parameter of the effectiveness of sending invitations and in addition it is a measure of the perceived quality of the programme. When examining compliance with invitation, whether extensive opportunistic screening is occurring must be taken into account, as this parameter is less relevant. Organised screening programmes, as opposed to opportunistic screening have achieved a greater reduction in the incidence of cervical cancer.

Appendix 1 – Key performance indicators (KPIs)
Calculation of test consumption is also required in a screening programme. If there is an excess of smear tests per screened women in comparison to what the programme recommends, this is inefficient. A reliable measure of test consumption requires complete registration of smear tests, as underestimates can result from incompleteness of registration. This particularly applies with smear tests taken outside the programme. This information may be obtained from other sources.

A measure of the burden of disease from lack of coverage can be obtained by examining the incidence of invasive cervical cancer in women:

- Unscreened and underscreened
- Never screened
- Screened at intervals longer than recommended by the programme.

2. Programme extension

Programme extension should be calculated regionally and nationally. If an entire region or country is actively served by a screening programme or programmes, then the programme extension in that region or country is 100 per cent.

2.1 Coverage of the target population by invitation

- Length of period corresponds to interval between two negative smear tests recommended by screening programme policy.
- Stratification by five-year age groups is recommended.
- For short-term monitoring, also calculate separately for women invited in the most recent calendar year in which screening was performed.
- For interpretation, take into account whether all women are invited or only a subset.
2.2 Coverage of the target population by smear tests

- Calculate separately for subgroups of women defined by:
  - Invitational status
  - Personally invited
  - Not personally invited
  - Unknown
- Programme status, i.e. smear test performed:
  - Within organised programme
  - Outside organised programme
  - Unknown
- Stratification by five-year age groups is also recommended.
- Also calculate separately with eligible women as denominator.

2.3 Compliance to invitation

- Consider women invited in a given period and those among them screened.
- A cut-off date of six months after the end of the respective period is recommended for determining whether a woman was screened in response to the invitation.
- If a different cut-off procedure is used, this should be specified.

2.4 Smear test activity

Include only screening smear tests (no repeat tests, e.g. after unsatisfactory smear tests or for follow-up). Count one test per ‘screening episode’.

A) N screening tests in 3 (5) years in the target population
- N women in the target population screened in the same period

B) Distribution of screened women by number of screening smears in the same period

Appendix 1 – Key performance indicators (KPIs)
2.5 Incidence of invasive cancer in unscreened and underscreened women in a given interval (3.5 or 5.5 years)

- Include only fully invasive cancer cases and person-years of the women not attending screening at the regular interval, i.e. women not screened in the previous 3.5 (5.5) years.
- Link screening registry and cancer registry data and calculate incidence age-adjusted, and by age group, based on the entire female population in the age groups eligible to attend screening.
- Analyse by cancer morphology (squamous vs. non-squamous)
- Calculate separately (with appropriate denominators):
  - Women never screened.
  - Women previously screened, but interval to last screening test >3.5 (5.5) years.
  - Women never invited.
  - Invited versus not invited in respective round.

3. Screening test performance

The rate of referral for repeat cytology and colposcopy are measures of economic cost and in addition a measure of the burden on women (anxiety and time consumption). These parameters must therefore be kept as low as possible. These rates depend on the sensitivity and specificity of the screening test, the prevalence of the disease and local protocols. Because the prevalence of disease is higher in the initial screening episodes than subsequent ones, they should be calculated separately for women at the different screening episodes. The rates should also be broken down by category of the cytological abnormality that dictated the referral initially. The referral rate for unsatisfactory smear tests provides a figure that reflects the proportion of smear tests resulting from poor quality smearing.

The positive predictive value (PPV) of referral for colposcopy for the confirmation of histologically high grade CIN is calculated based on the actual number of women having colposcopies. This indicator shows the number of colposcopies that must be performed to find one lesion requiring treatment. This number is the reciprocal of the PPV. The overall PPV for all women referred for colposcopy is dependent on local procedures for referral and therefore should be computed by cytological category and for the various grades of CIN. As with the other referral rates, PPV is dependent on specificity and disease prevalence. Therefore it must also be calculated separately for women attending initial and subsequent screening episodes.

Because the PPV varies with prevalence of disease, test specificity should be computed. This will in addition, facilitate comparison of performance between different screening programmes. Specificity cannot be calculated directly from screening programme data, the following formula can be used for the calculation:

\[
\frac{\text{Number of women with negative test results}}{\text{Number of women screened} - \text{number of women with confirmed CIN}}
\]
The detection rate (DR) of CIN (especially CIN2/3), depends on the number of lesions that are present in the screened population (disease prevalence) and how many of them are actually detected (cross sectional sensitivity). Since the prevalence of disease varies geographically and is apriori unknown, it is difficult to use the DR as an indicator of sensitivity. In addition, the DR also depends on the criteria of interpretation of histology, which are subject to variation. Nevertheless, DR should be monitored and compared between European screening programmes. This will provide a tool for recognising variation in quality and for developing the descriptive epidemiology of CIN within Europe, providing information for further study to improve control of cervical cancer.

There is no easily interpretable indicator of screening sensitivity that can be collected in a screening monitoring system. It is therefore essential to link screening registry and cancer registry data. Although it is difficult to obtain comparable data, comparison of the incidence of cancers which are detected in women after having findings of normal cytology, to the expected incidence in the absence of screening provides an estimate of test sensitivity for invasive lesions. Information on cervical cancer incidence among unscreened women can be taken into account, if adjustments for selection bias in relation to screening attendance or non-attendance are calculated. Correspondingly, estimates of screening episode sensitivity may be obtained from inclusion of all screened women in the follow-up of cervical cancers. When considering programme sensitivity, women invited, but not screened, must be taken into account. Previous smear tests of women with screen-detected cancer should also be reviewed (combined with those of other women who did not develop cancer in order to avoid over-interpretation).

The distribution of the interval to reporting i.e. time between smearing and result communication should be monitored. Reporting delays, which are not extreme, should not influence screening effectiveness. However, such delay can affect women’s perception of the quality of service, which in turn may affect participation in the programme and increases anxiety.

3.1 Distribution of screened women by the results of cytology
Calculate overall and separately for subgroups of women:
- For the regular screening interval and shorter time periods.
- Attending initial or subsequent screening.

3.2 Referral rate for repeat cytology
Calculate separately:
- By cytology that resulted in recommendation to repeat.
- For initial and subsequent screening.

3.3 Compliance with referral for repeat cytology
Calculate separately:
- By cytology that resulted in recommendation to repeat.
- For initial and subsequent screening.
3.4 Referral rate for colposcopy
Calculate separately:
- Cytology that resulted in referral to colposcopy.
- For initial and subsequent screening.

3.5 Positive predictive value of referral for colposcopy
If the number of women for whom colposcopy was performed is not known, estimate using number of women referred for colposcopy.
Calculate overall and separately by:
- Cytology (ASC-US+, LSIL+, HSIL+).
- Histology (CIN1+, CIN2+, CIN3+, invasive Ca).
- Initial and subsequent screening.

3.6 Test specificity
Calculate overall, and separately by:
- Cytology (<ASC-US, <LSIL, <HSIL).
- Histology (CIN1+, CIN2+, CIN3+, Invasive Ca).
- Initial and subsequent screening.

Test specificity cannot be computed from routine screening and follow-up data, because the true denominator is unknown. Nevertheless, either formula a) or b) on the right may be used to approximate specificity.
Normal test results refer to ‘negative for intraepithelial lesions/no abnormal cells’ (i.e. results not leading to referral for follow-up or confirmation).

3.7 Detection rate by histological diagnosis
Calculate separately:
- By histology (CIN1+, CIN2+, CIN3+, Invasive Ca).
- For the regular screening interval and shorter time periods.
- For initial and subsequent screening.
3.8 Cancer incidence after normal cytology

Normal cytology refers to cases recommended for re-screening at the regular interval. Count only fully invasive cancers among the women who had a normal screening cytology in the previous 3.5 (5.5) years.

Analyse by:

- Interval from index cytology.
- Cancer morphology (squamous vs. non-squamous).
- Cytology should be reviewed mixed with that of other women not developing cancer.

4. Diagnostic assessment and treatment

The success of a screening programme is reliant on diagnostic assessment being actually performed when required. Measuring compliance with referral for colposcopy requires systematic and complete registration of colposcopies. When a record is not available in the colposcopy register, the patient or her doctor should be contacted to obtain information on whether the colposcopy was performed or as a reminder for the need for examination. Compliance with colposcopy should be calculated for each category of cytology that was the initial reason for referral (more severe cytology the greater the relevance). In addition compliance should be monitored for different screening time intervals.

Another condition essential to screening effectiveness is actual delivery of requisite treatment, particularly for histologically confirmed CIN2 and CIN3.

Another important target of a screening programme is the avoidance of over-treatment. The proportion of women with pre-invasive lesions who undergo hysterectomy is a major indicator of unnecessary treatment, although some hysterectomies result from co-existing pathology. Peer review should be carried out to verify the appropriateness of treatment of such cases. It should be taken into account that relevant differences in the proportion of women with CIN who undergo hysterectomy suggest that local practice is the main cause of such differences.

The absence of SIL (or of high-risk HPV infection) can be routinely monitored at six monthly follow-up of treated women. This parameter should be included as an indicator of short-term quality of treatment.

The incidence of cervical cancer in women which was not detected by screening, although the cytology results were abnormal (i.e. after abnormal cytology), serves as a direct summary indicator of failure associated with diagnostic assessment and treatment. Various reasons for failure can be identified. For example, cervical cancer arising in women who did not comply with referral for colposcopy could represent a failure in the communication process or a lack of attendance compliance for follow-up. Cases that arise in women who had colposcopy, but without detection of CIN, represent failure in diagnostic accuracy, etc. To calculate this parameter, the screening history of each case of cervical cancer should be reviewed, and those cases should be excluded in which cancer was detected as a result of screening.

The above parameters apply under the assumption that cytology is used as the primary screening test, which is what is currently recommended. However, most of the present parameters can also be applied, with only minor changes, to different screening methods (e.g. HPV DNA testing). Depending on which screening test and screening policy that is employed, the values of some parameters (e.g. DR, PPV or specificity) may be expected to change.
4.1 Compliance with referral to colposcopy

Calculate separately by:

• Different intervals after referral (three months/six months).
• Cytology that resulted in referral.
• This measure examines the relationship between the numbers referred to colposcopy and the numbers who actually attended. It also only deals with new referrals from the programme. The denominator is the number of women referred to colposcopy from the programme (CSR) and the numerator should be the number of new patients attending colposcopy who came via the programme.

4.2 Treatment of high grade intraepithelial lesions

Note: Treatment includes the following and may take place at any visit in the episode:

• Cone biopsy
• Punch biopsy/diagnostic biopsy
• Cryotherapy
• LLETZ
• Smear test
• Swabs
• Laser ablation
• Laser excision
• Radical hysterectomy
• Tracehleectomy
• SWETZ
• Cold coagulation

4.3 Proportion (%) of women with total hysterectomy following-on screen-detected intraepithelial lesions

Calculate separately by histology (CIN1, CIN2, CIN3). Appropriateness of individual cases should be evaluated by peer review.
4.4 Proportion (%) of women treated for CIN1

Appropriateness of individual cases should be evaluated by peer review.

Note: Treatment includes the following and may take place at any visit in the episode:

- Cone biopsy
- Punch biopsy/diagnostic biopsy
- Cryotherapy
- LLETZ
- Smear test
- Swabs
- Laser ablation
- Laser excision
- Radical hysterectomy
- Trachelectomy
- SWETZ
- Cold coagulation

4.5 Incidence of invasive cancer after abnormal cytology

- Include screened women:
  - Without colposcopy carried out, despite existing indication.
  - With colposcopy carried out, but no CIN detected.
  - With CIN detected, but not treated.
  - Treated.
  - In diagnostic or post-treatment follow-up.
- Calculate overall and separately for each of above subgroups.
- Include only fully invasive cancers.
- Exclude cases detected as a result of screening.
4.6 Proportion of women with cytology negative for SIL, six months after treatment

Note: Treatment includes the following and may take place at any visit in the episode:

- Cone biopsy
- Punch biopsy/diagnostic biopsy
- Cryotherapy
- LLETZ
- Smear test
- Swabs
- Laser ablation
- Laser excision
- Radical hysterectomy
- Trachelectomy
- SWETZ
- Cold coagulation
- Include women treated for CIN2, CIN3, CIN or AIS in situ followed at least six months after treatment (denominator).
- Include women negative for HR-HPV (numerator), if this test is used for follow-up.
- Follow-up protocols – at least one smear test is carried out in colposcopy six months after a treatment (colposcopy procedure). For the purposes of audit, the measure is taken at eight months.
5. Definition of performance parameters in cervical cancer screening

The specific instructions are indicated below.

For calculations for a given period of time, such as the recommended screening interval (three or five years), the dates on which the period starts and ends, and the performance for determining the target population should be recorded. For calculations based on the size of the target population, use the average over the given time period.

Note that parameters 6 (incidence of invasive cancer in unscreened women), 14 (cancer incidence after normal cytology) and 19 (incidence of invasive cancer after abnormal cytology) require linkage with cancer registry data/histological data. The follow-up periods recommended for calculation of cervical cancer incidence are six months longer than the recommended screening interval of the respective programme (3.5 or 5.5 years). The purpose of adding one half-year to the screening interval is to include screen-detected cancer at the next screening episode. Calculations based on longer follow-up periods are also recommended.

7. References

Appendix 2
Revision history
## All chapters

<table>
<thead>
<tr>
<th>Details</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Original</td>
<td>December 2009</td>
</tr>
<tr>
<td>2 Restate a number of standards (those requiring ‘Yes’ or having to meet ‘100%’ to reach target) as requirements. The number of standards is apparently reduced, but is actually a restatement of many standards as requirements. Update references. Former references that are no longer cited are to be transferred to a separate bibliography.</td>
<td>October 2013</td>
</tr>
</tbody>
</table>

## Chapter 1 Introduction

| 2 National Cancer Registry Ireland (NCRI) statistics on cervical cancer burden in Ireland updated. | October 2013 |
| Revised background to cervical screening in Ireland, reduced historical development of standards to a note. |               |
| Re-ordered description and contents of quality assurance in (cervical) screening programmes. |               |
| Added note on CervicalCheck operation to date. |               |
| Moved goals of the programme from Chapter 2, and added objective regarding coverage. |               |
| Removed Women’s Charter (now referenced). |               |
| Added narrative about the statement of the quality requirements and standards and about monitoring and measurement. |               |

## Chapter 2 Quality assurance in programme operation

| 2 Re-order sequence of requirements and standards to better mirror a woman’s engagement with the programme, from initial identification through eligibility, invitation, access and participation, and follow-up. Standards: a) clarify description where necessary; b) specify achievable and minimum targets where appropriate. | October 2013 |

## Chapter 3 Quality assurance in primary care

<p>| 2 Remove guidance and best practice notes and replace with reference to ‘Guide for Smear takers’ where these are covered in that publication. Re-order to mirror a woman’s pathway in primary care. Add standards in the areas of promotion and awareness; uptake and participation (previously unscreened women); sampling, condition of sample and recording clinical details and previous treatment history; checking management recommendations accompanying cytology results; and follow-up of women. | October 2013 |</p>
<table>
<thead>
<tr>
<th>Chapter 4 Quality assurance in cytopathology</th>
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| 2   | • Remove process descriptions and replace with references where these are covered in external publications.  
     | • Restated certain requirements and standards for improved clarity.  
     | • Revised targets for certain standards based upon review and evidence. |
|     | October 2013 |

<table>
<thead>
<tr>
<th>Chapter 5 Quality assurance in HPV testing</th>
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<th>Chapter 6 Quality assurance in colposcopy</th>
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| 2   | • Removed descriptive sections related to organisational and clinical guidance for the operation of a colposcopy service (for separate publication).  
     | • Restatement of certain requirements and standards for greater clarity.  
     | • Revisions to certain targets based upon programme data collected and analysed.  
     | • Additional/revised requirements and standards re. diagnosis, treatment and follow-up of women (treated and untreated) to reflect use of HPV testing and new management protocols in colposcopy services.  
     | • Additional/revised requirements and standards re. data exchange with screening programme, and discharges from colposcopy. |
|     | October 2013 |

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<thead>
<tr>
<th>Chapter 7 Quality assurance in histopathology</th>
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| 2   | • Removed descriptive sections related to the internal operation of a histopathology laboratory.  
     | • Restated certain requirements and standards for improved clarity.  
     | • Revised targets for certain standards based upon updated knowledge and experience. |
|     | October 2013 |

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<th>Appendix 1 Key performance indicators</th>
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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.