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.
Chapter 1
Introduction

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

| Coverage of screening population | Women within the defined screening population should have at least one satisfactory smear test within a screening interval. | 80% |

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. 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</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\(^6\).
1.5 References


Guidelines for Quality Assurance in Cervical Screening
Second Edition

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.