



National
Cancer
Screening
Service



Guidelines for Quality Assurance in Cervical Screening

First Edition

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Foreword

The primary objective of cervical screening is to reduce the incidence and mortality from cervical cancer by detecting cell changes before they become cancerous.

In Ireland there are on average 180 new cases of cervical cancer diagnosed per year. The average age at diagnosis is 46 years and the average age at death from cervical cancer is 56.

Over time, a successful national, quality assured cervical screening programme in Ireland has the potential to significantly reduce mortality rates in the screened population. In Finland, mortality rates have dropped by 80 per cent over the last four decades.

CervicalCheck – Ireland's first national cervical screening programme became available to over 1.1 million eligible women aged 25 to 60 on 1 September 2008. Free smear tests are provided in primary care settings to women aged 25 to 44 every three years and on receipt of two consecutive results with no abnormality detected, women aged 45 to 60 will be screened every five years.

GPs, practice nurses and medical practitioners nationwide are registered with the CervicalCheck programme and when invited by the Programme to attend a woman can choose to have a smear test with any registered smearer, in any location of her choice.

To achieve maximum public health benefit from a population-based cervical cancer screening programme, every aspect of the service delivered to women must be fully quality assured.

Quality assurance is the foundation on which a successful programme is built. From initial invitation, through screening and treatment every individual involved in every step of the screening process must adhere to the highest standards set by the Programme.

This manual is the result of a collaborative process undertaken between representatives of each step of the cervical screening process – Programme Administration, Primary Care, Cytopathology, Colposcopy and Histopathology.

The guidelines and standards developed were thoroughly evaluated and approved by an international panel of experts in the area of cervical screening.

No screening test is 100 per cent accurate, that is why we must ensure that the service delivered to women in Ireland is one in which they can have undoubted confidence.

I would like to thank all involved for committing both their time and expertise to developing a set of guidelines and standards that will ensure a screening service that operates in line with the highest international standards.



Mr Tony O'Brien,
Chief Executive Officer
National Cancer Screening Service

Preface

The primary objective of cervical screening is to reduce the incidence and mortality from cervical cancer. This can only be achieved by a fully comprehensive quality assurance programme applied to the entire organisation.

The effectiveness of the screening programme is measured by the degree to which it achieves its objectives. The quality of the programme is measured by the degree to which it conforms to pre-set standards of effective screening.

It is possible to define three different types of standards:

Excellent Standards

- Quality assurance is the continual pursuit of excellence. These are the standards to which the organisation aspires.

Minimum Acceptable Standards

- The standard below which no service should fall.

Achievable Standards

- Lie between the above two standards.

For CervicalCheck, some standards are likely to be unattainable at the present time as the screening programme is currently in its initial phase. It is practical to consider an incremental approach to benchmark objectives and associated standards.

The National Cancer Screening Service (NCSS) Quality Assurance (QA) Committee was established to review international standards, recommend best practice, monitor and evaluate achievement of the recommended standards; and monitor and support adherence by service providers. The QA Committee reports to the Chief Executive Officer of the National Cancer Screening Service Board who has overall responsibility for quality assurance in programmes of the National Cancer Screening Service.

Three specialty groups of the QA Committee, Primary Care Group, Laboratory Group and Colposcopy, Gynaecology Group, along with Programme Administration developed the corresponding chapters in this document.

The National Cancer Screening Service convened an international expert peer review of the proposed quality assurance standards for CervicalCheck in August 2009. This document represents a consensus view of those involved.

The Board of the National Cancer Screening Service was established by the Minister for Health and Children in January 2007. The establishment followed the launch of 'A Strategy for Cancer Control in Ireland 2006' which advocates a comprehensive cancer control policy programme in Ireland by the Cancer Control Forum and the Department of Health and Children. The Strategy set out recommendations regarding prevention, screening, detection, treatment and management of cancer in Ireland in coming years and recommended the establishment of a National Cancer Screening Service Board. Governance of BreastCheck – The National Breast Screening Programme and the former Irish Cervical Screening Programme (ICSP) Phase One was transferred to the Board of the NCSS on its establishment. The NCSS has been responsible for the establishment of CervicalCheck – The National Cervical Screening Programme.

On its establishment, Dr Sheelah Ryan, was appointed as Chairperson of the NCSS Board and Mr Tony O'Brien was appointed as Chief Executive Officer of the National Cancer Screening Service.



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1

Introduction

1.1 A Strategy for Cancer Control in Ireland

A Strategy for Cancer Control in Ireland 2006

The strategy was prepared by the National Cancer Forum and makes recommendations in relation to the organisation, governance, quality assurance and accreditation of all aspects of cancer care. The strategy examines prevention, screening, detection, treatment and management of cancer in Ireland and advocates a comprehensive cancer control policy programme. The vision set out in the strategy is that Ireland will have a system of cancer control which will reduce our cancer incidence, morbidity and mortality rates relative to other EU15 countries by 2015. Irish people will know and practice health-promoting and cancer-preventative behaviours and will have increased awareness of, and access to early cancer detection and screening. Ireland will have a network of equitably accessible state of the art cancer treatment facilities and will become an internationally recognised location for education and research into all aspects of cancer.

1.2 Definition of Screening

According to A Strategy for Cancer Control in Ireland 2006, 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.

1.3 Quality Assurance Framework Principles of Screening Programmes

The following principles apply:

People Centred

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 and community perspectives need to be considered when determining the balance of benefits and harms and the costs of screening programmes.

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 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 to achieve the desired outcomes. It is important for all involved to have a sense of shared ownership of the screening programme quality goals.

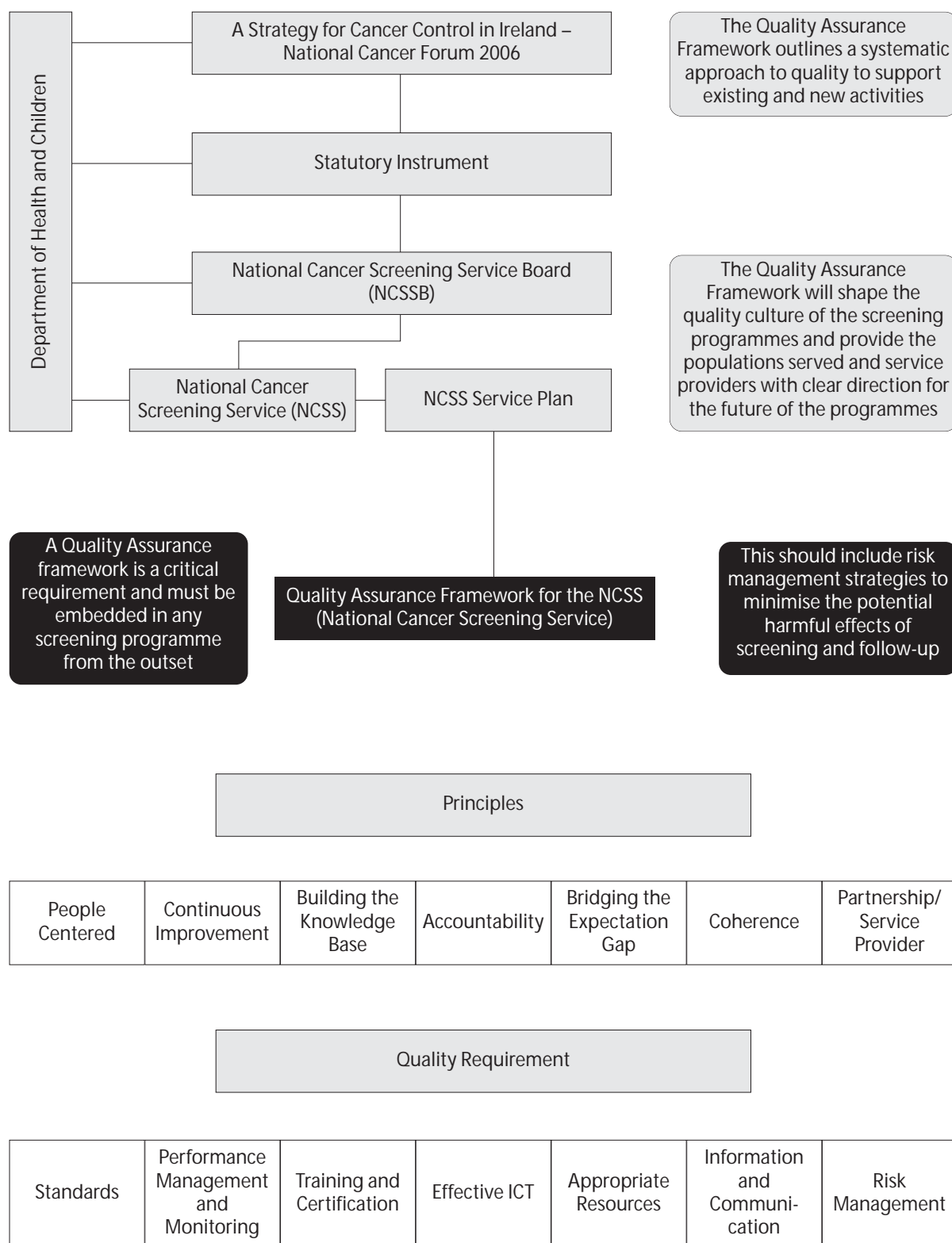


Figure 1: NCSS Quality Assurance Framework

1.4 Key Quality Requirements of Screening Programmes

The following key quality requirements apply:

Standard Setting and Monitoring

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.

Performance Management

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.

Training and Certification

Personnel employed within screening programmes should have relevant competencies. Minimum training levels that are 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.

Effective Information Systems

Effective and efficient information systems are essential as both management tools for screening programmes and as the basis for evaluation and monitoring.

Appropriate Resources

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.

Information and Communication

Clear, evidence-based information should be widely available and effectively communicated to participants of the screening programme. 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.

Risk Management

For population 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.

1.5 Quality Assurance and Screening Programmes

Once a screening programme is established, quality assurance and quality improvement activities are essential for ensuring ongoing safety and effectiveness of the programme¹.

Screening programme quality assurance and quality improvement activities occur at all points along the screening programme pathway¹.

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 outcomes¹.

When screening uptake is low, the relationship between benefit and harm, at any level of screening intensity, changes and it is possible for the harmful effects to be greater than the beneficial effects of screening. It is essential, therefore, not only to choose the right screening policy but also to be assured that the screening offered is of high quality¹.

Quality improvement activities in screening programmes should generate the information needed to confirm whether or not a programme is safe, effective and being delivered at a reasonable cost¹.

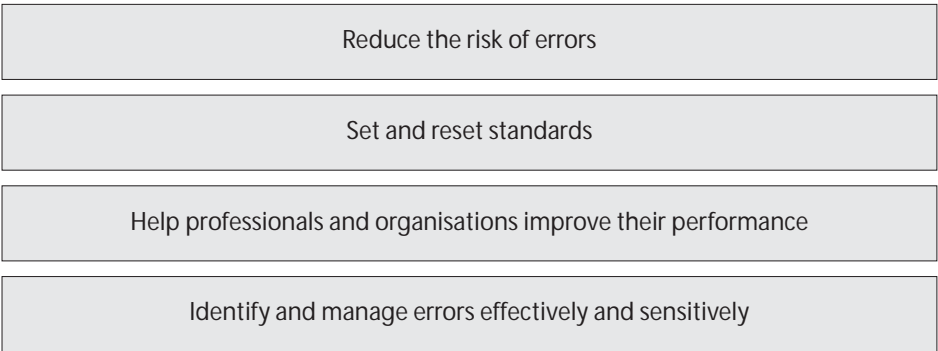


Figure 2: The Aim of Quality Assurance¹

1.6 Dimensions of Quality

Four dimensions of quality are considered key to fulfilling quality requirements. These are equity and access, safety, efficiency and effectiveness. The dimensions of quality in the approach are defined as:

- **Equity and Access:** 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
- **Safety:** The extent to which harm is kept to a minimum
- **Efficiency:** The extent to which a service gives the greatest possible benefit for the resources used
- **Effectiveness:** The extent to which a service achieves an expected and measurable benefit

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 quality¹.

1.7 Quality Assurance and Cervical Screening Programmes

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 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 abnormalities².

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 disease².

Population-based screening policy and organisation, conforming to evidence-based standards and procedures, provide the overall programmatic framework essential for the implementation of quality assurance; and are therefore crucial to the success of any cervical cancer screening programme².

All 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 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 too many cancers will develop. 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.

Poor quality screening is ineffective and may do more harm than good

Figure 3: Effect of Poor Quality Screening¹

1.8 Quality Assurance and CervicalCheck – The National Cervical Screening Programme

Following the establishment of the National Cancer Screening Service (NCSS) by the Minister for Health and Children in January 2007, governance of the Irish Cervical Screening Programme (ICSP) Phase One (when operational in the Midwest) was transferred to the Board of the National Cancer Screening Service. The establishment of the NCSS followed the publication of 'A Strategy for Cancer Control in Ireland' in 2006, which advocates a comprehensive cancer control policy programme in Ireland and cancer screening managed by one organisation.

The NCSS was responsible for the implementation of CervicalCheck – The National Cervical Screening Programme.

The National Cancer Screening Service Quality Assurance (QA) Committee was established in 2007 reflecting membership of the Chairs from the technical QA Subgroups (see Figure 4). The technical subgroups consist of the Primary Care QA Subgroup, the Laboratory QA Subgroup and the Colposcopy, Gynae-Oncology QA Subgroup. These subgroups are made up of experts in their particular area.

The NCSS QA Committee and associated technical QA Subgroups are responsible for developing and monitoring the QA standards for CervicalCheck. Standards must be measurable i.e. quantitative and the criteria chosen should be valid, reliable and feasible. The standards are based on the woman's journey as they move through different parts of the cervical screening pathway.

The primary function of the NCSS QA Committee is to advise the Chief Executive Officer (CEO) of the NCSS regarding standards and quality assurance for CervicalCheck, including protocols around cancer audit, and to satisfy itself that the management of the NCSS can ensure that the screening service is being managed to quality standards as agreed by the Board.

Standards drive specific datasets that must be collected in order to monitor the performance of each element of the cervical screening programme. The data collection and reporting will be primarily carried out by the Performance Evaluation Unit (PEU) which is part of the National Cancer Screening Service.

1.9 Standard Setting and Monitoring

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. Standards are chosen to define 'levels of goodness' and are set in different ways¹.

Where a new programme is being implemented, there is no data on which to set standards, and they have to be set on the basis of performance in research studies and programmes already established in other countries, combined with professional experience. Such standards should be modified when data is available¹.

Different levels of quality standards can be set including:

- The minimum acceptable standards below which no provider should fall
- The achievable standards that all providers can aim to attain

The former may be regarded as the safety standard and if a provider falls below that standard then an explanation should be sought urgently and remedial action must be considered. However, if no provider ever falls below the minimum standard it is probably not a challenging enough target. Standards are developed and evaluated with reference to the quality dimensions of equity and access, safety, efficiency and effectiveness¹.

The standards will support the service providers to the CervicalCheck programme and provide a means to monitor and continually improve services.

The standards that have been developed will cover every aspect of the screening pathway, from identification of the eligible population, through diagnosis and treatment of the condition being screened for, to programme monitoring and audit. Standards incorporate clear expectations regarding reducing inequalities.

The standards developed by the National Cancer Screening Service, Quality Assurance Committee are:

- Focused on clinical issues and include non-clinical factors that impact on the quality of care
- Written in simple language
- Based on evidence (recognising that levels and types of evidence will vary)
- Written to take account of other recognised standards and clinical guidelines
- Clear and measurable
- Developed by healthcare professionals
- Consulted on widely
- Regularly reviewed and revised to make sure they remain relevant and up-to-date

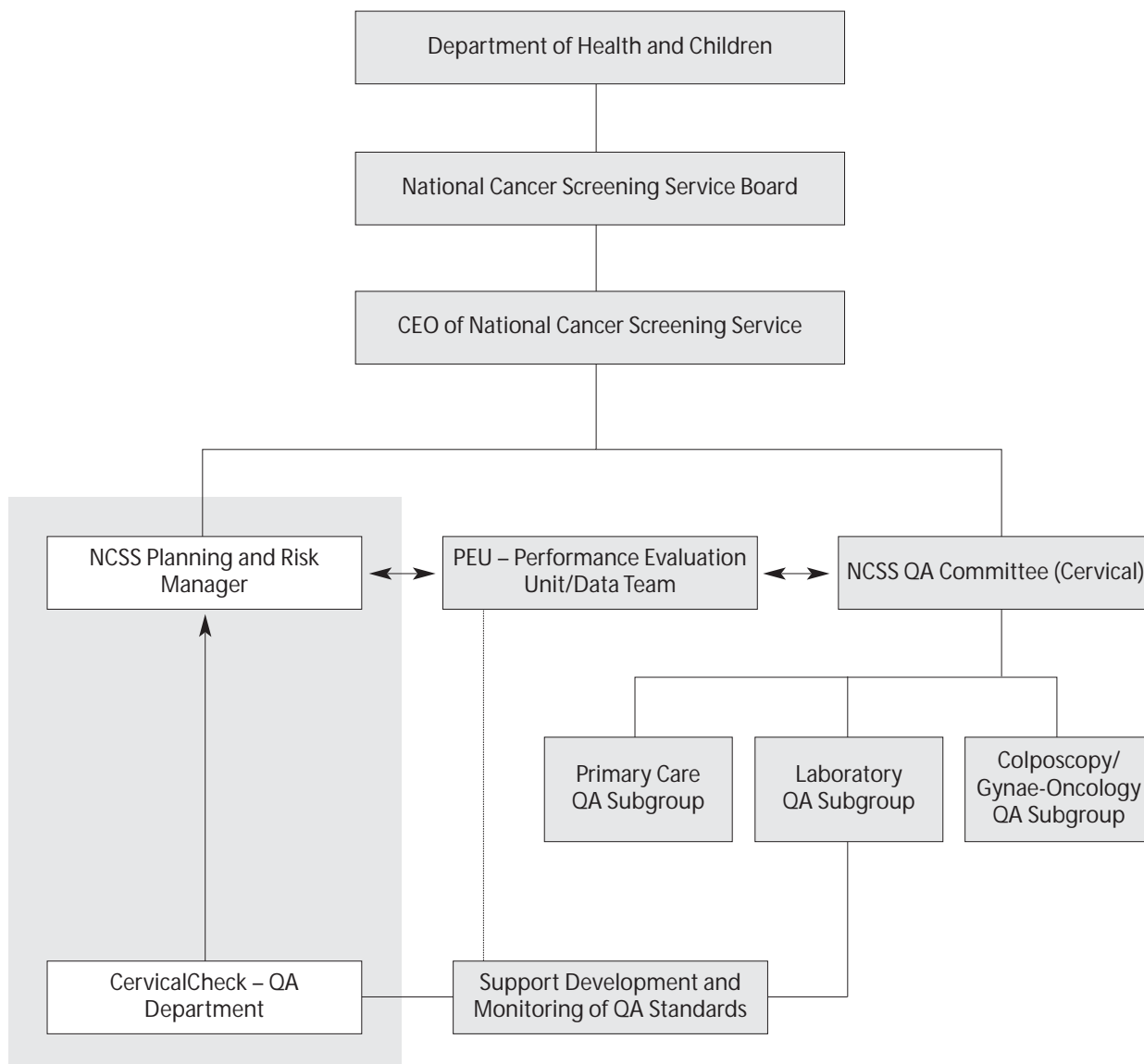


Figure 4: NCSS Quality Assurance – Organisation Chart

1.10 Background to Cervical Screening in Ireland

The Irish Cervical Screening Programme (ICSP) Phase One was in operation in Ireland from October 2000 to August 2008, providing women in the Midwest aged 25-60 with free smear tests.

Women aged 25-44 in the target screening population were invited for screening every three years and women aged 45-60 were invited every five years (after two consecutive results with no abnormality detected).

CervicalCheck – The National Cervical Screening Programme was introduced in Ireland on 1 September 2008.

Cervical 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.

The service providers for the Programme are primary care smertakers (in general practice, Well Woman Clinics, Women's Health and Family Planning Clinic settings), laboratory service providers, colposcopy service providers and primary treatment.

A central office based in Limerick manages the Cervical Screening Register (CSR) information system. The register is a list of eligible women in the screening region and is compiled from data sources and self registration. The CSR information system maintains the call and re-call system and manages the failsafe process. Failsafe is a process to ensure that a woman is not lost during the screening pathway. The computerised Clinical Result Register records women's cytology, colposcopy, cervical histology and hysterectomy status. This organised approach ensures that appropriate follow-up care is provided.

1.11 Cervical Cancer Burden in Ireland

The National Cancer Registry of Ireland reports that on average there are 180 cases of cervical cancer per year and 73 recorded deaths³. The average age at diagnosis is 46 years and 56 years at death.

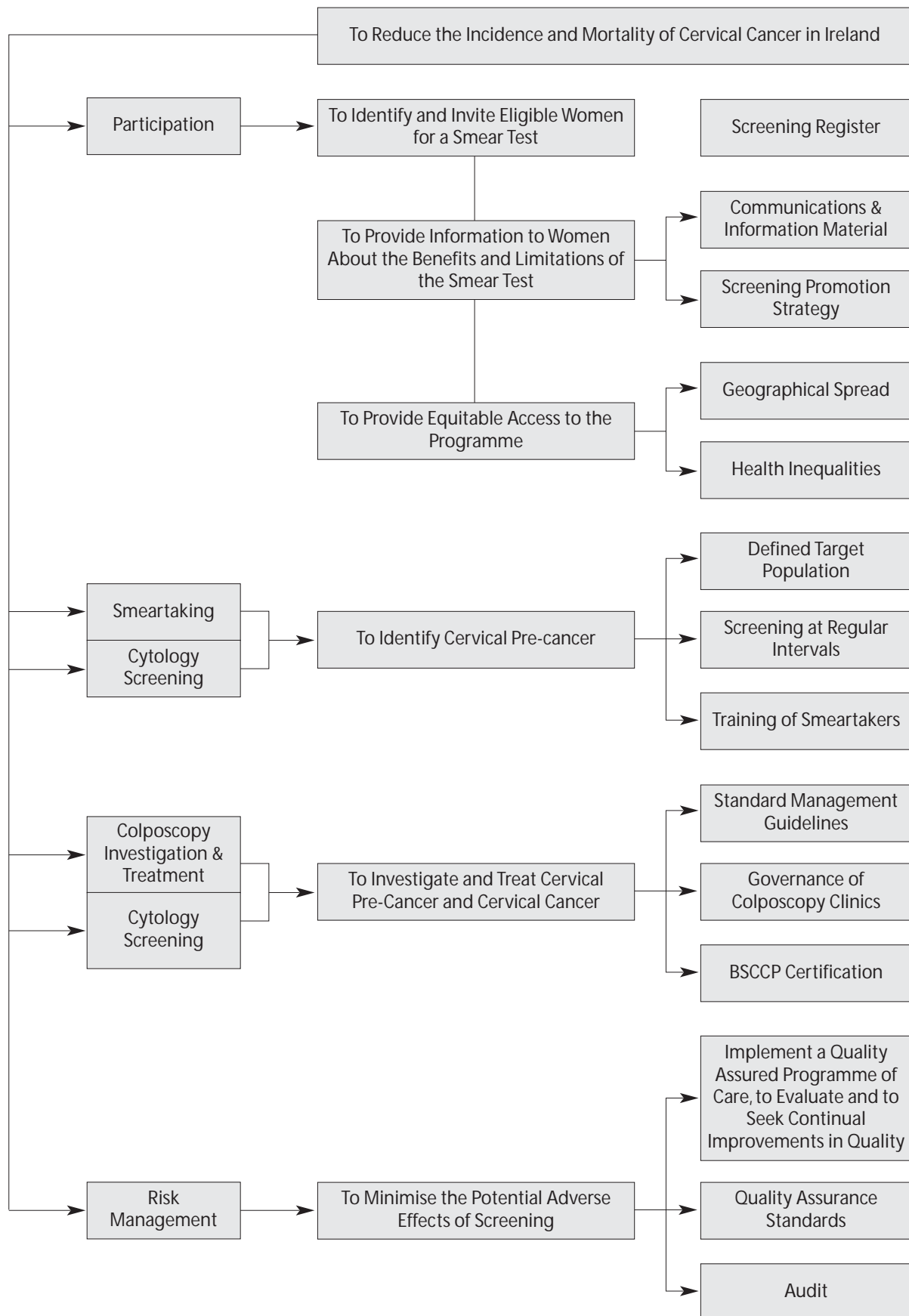



Figure 5: CervicalCheck Programme Objectives



WOMEN'S CHARTER

Screening commitment:

- CervicalCheck – The National Cervical Screening Programme offers a free complete quality assured programme of care
- You choose your smearer from a wide range of eligible service providers registered with the Programme
- You may change your preferred provider for subsequent Programme screening
- All Programme staff will respect your privacy, dignity, religion, race and cultural beliefs
- Your screening records will be treated in the strictest confidence
- You will always have the opportunity to make your views known and to have them taken into account
- Once you become known to the Programme you will be invited every three years for screening while you are aged 25 to 44 and every five years while you are aged 45 to 60
- Your smear test will be screened in an accredited quality assured laboratory
- Your result and any treatment recommendation will be provided to you and your nominated smearer by the Programme within four weeks.

We aim:

- To ensure pleasant and comfortable surroundings during screening.

If you require further treatment, we aim:

- To ensure that you will be offered an appointment at a quality assured colposcopy clinic (*within four weeks for high grade cell changes and within eight weeks for low grade cell changes*).

Tell us what you think:

- Your views are important to us in monitoring the effectiveness of our services and in identifying areas where we can improve
- You have a right to make your opinion known about the care you received
- If you feel we have not met the standards of this Charter, let us know by telling the people providing your care or in writing to the Programme
- We would also like to hear from you if you feel you have received a good service. It helps us to know that we are providing the right kind of service – one that satisfies you
- Finally, if you have any suggestions on how our service can be improved, we would be pleased to see whether we can adopt them to further improve the way we care for you.


Ways you can help us:


- Please make your appointment with a registered smearer on receipt of your invitation letter from the Programme
- Please bring your PPS number with you to your appointment
- Please read any information we send you
- Please try to be well informed about your health.

Let us know:

- If you change your address
- What you think – your views are important.

Freephone 1800 45 45 55
www.cervicalcheck.ie





**National
Cancer Screening
Service**

The National Cancer Screening Service encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme.

CS/PUB/CC-5 Rev 3

Figure 6: CervicalCheck Women's Charter

1.12 Reference List

- 1) Ministry of Health. Improving Quality: A Framework for Screening Programmes in New Zealand. Auckland: National Screening Unit; 2005
- 2) Arbyn M., Antilla A., Jordan J., Ronco G., Schenck U., Segan N., Wiener H.G., Herbert A., Daniel J., von Karsa L. (2008) European guidelines for quality assurance in cervical cancer screening [2nd Edition]. International Agency for Cancer Research and EU, Health & Consumer protection Directorate-General.
- 3) The Women's Health Council, National Cancer Registry Ireland. Women and Cancer in Ireland 1994-2001. Dublin; February 2006.

The background of the slide is an abstract composition of overlapping, semi-transparent geometric shapes in various shades of orange and yellow. These shapes create a sense of depth and movement, with some areas appearing brighter than others due to the layering.

2

Quality Assurance in Administration

2.1 CervicalCheck Programme Standards

The World Health Organisation International Agency for Research on Cancer confirms the efficacy of cervix cancer screening for women in reducing mortality¹.

Such benefits can only be achieved if quality is optimal at every step in the screening process, from information and invitation of the eligible target population to performance of the screening test and follow-up, and if necessary, treatment of women with screen detected abnormalities. Organised screening appears to be more effective and largely more cost-effective than opportunistic activity².

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 the 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 disease².

	Category	Description of Standard	Standard	Demonstration of Compliance
2.1.1	Incidence	To reduce the incidence of cervical cancer among the screened population	35%	CSR Information System Audit

Explanatory Note:

- To be calculated following the completion of two rounds of screening (10 years)
- The National Cancer Registry of Ireland (NCRI) was the repository of cervical cancer data prior to the commencement of CervicalCheck on 1 September 2008
- The staging of cancers detected in screening rounds is a marker of CervicalCheck's effectiveness

	Category	Description of Standard	Standard	Demonstration of Compliance
2.1.2	Mortality	To reduce mortality from cervical cancer among the screened population	50%	NCRI report

Explanatory Note:

- To be calculated following the completion of two rounds of screening (10 years)
- The NCRI compiles the data on cervical cancer mortality
- There are other 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 as has been achieved in Finland over the course of the last four decades

	Category	Description of Standard	Standard	Demonstration of Compliance
2.1.3	Coverage	Women aged 25-60 years should have cervical screening every 3-5 years	* Minimum $\geq 80\%$ Achievable $\geq 90\%$	* CSR Information System Audit

- * Coverage is defined as the number of unique women (nominator) 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 (denominator). A satisfactory smear test is one which is deemed adequate to be screened and where the slide is not damaged or broken.

	Category	Description of Standard	Standard	Demonstration of Compliance
2.1.4	Annual Reports	A CervicalCheck annual report must be published every year	Yes	Availability of annual report

	Category	Description of Standard	Standard	Demonstration of Compliance
2.1.5	Cancer Audit	A process must exist to facilitate cancer audit	Yes	Evidence of a process

Explanatory Note:

- This involves linking cervical screening data with National Cancer Registry of Ireland (NCRI) data. A comprehensive evaluation with a systematic audit process of the entire screening programme can be performed¹

	Category	Description of Standard	Standard	Demonstration of Compliance
2.1.6	Cervical Smear Test Results	CervicalCheck letters with the appropriate management recommendations should be received by women within 4 weeks of her smear test date	* Minimum $\geq 60\%$ Achievable $\geq 90\%$	CSR Information System Audit

- * In any defined period of time 60% or more of CervicalCheck letters with the appropriate management recommendation are posted to women within four weeks of the smear test date.

2.2 Quality Management Systems

	Category	Description of Standard	Standard	Demonstration of Compliance
2.2.1	Quality Policy	A Quality Policy Statement must exist for Programme Administration and must be reviewed in line with Programme policy changes	Yes	Documentary evidence
2.2.2	Quality Management System	Programme Administration must operate a Quality Management System (QMS) which is certified to an approved certification body	Yes	Documentary evidence of certification
2.2.3	Document Management	A Document Management System must be in use to control approval and revision updates of documents for communication and publication	Yes	Documentary evidence

Explanatory Note:

- Such documents will include but are not limited to policy documents, charters, information leaflets and forms for obtaining information from women and stakeholders, communications with women and stakeholders, publications and any other published documentation pertaining to CervicalCheck

	Category	Description of Standard	Standard	Demonstration of Compliance
2.2.4	Complaints	All CervicalCheck complaints must be managed through the Quality Management System (QMS) and an outcome recorded for each	Yes	Documentary evidence through the QMS

	Category	Description of Standard	Standard	Demonstration of Compliance
2.2.5	Complaint Response Time	CervicalCheck complaints should be closed out and a response sent to the complainant within 30 working days	*Minimum $\geq 60\%$ Achievable $\geq 90\%$	Quality metrics

- * In any defined period of time 60% or more of complaints are closed within 30 working days.

Explanatory Note:

- All feedback in addition to complaints directed to CervicalCheck and relevant service providers should be logged and reviewed by management on an ongoing basis to support continuous improvement

	Category	Description of Standard	Standard	Demonstration of Compliance
2.2.6	Non-Conformances	Non-Conformances must be managed through the QMS and an outcome recorded for each	Yes	Evidence through the QMS

	Category	Description of Standard	Standard	Demonstration of Compliance
2.2.7	Non-Conformance Response Times	Non-Conformances that are raised should be closed out within 30 working days	Minimum $\geq 60\%$ Achievable $\geq 90\%$	*Quality metrics

* In any defined period of time 60% or more of non-conformances are closed within 30 working days.

Explanatory Note:

- All non-conformances relating to CervicalCheck activities and relevant service providers should be logged and reviewed by management on an ongoing basis to support continuous improvement

2.3 Cervical Screening Register

The Cervical Screening Register (CSR) is a secure electronic database containing records of personal health information of women in the eligible population – aged 25 to 60 years – that supports the accurate identification and appropriate management of women throughout their participation in the Programme.

Each woman on the CSR is assigned a CervicalCheck identification number known as the Cervical Screening Programme ID (CSP ID). A woman's record includes her demographic details and details of her screening history communicated to the Programme – results of cervical smear tests, colposcopy procedures and biopsies taken in a colposcopy clinic, if any, and the results of histology examinations. The CSR provides a woman's screening history to service providers – cytology and histology laboratories, and colposcopy clinics.

The Health (Provision of Information) Act 1997 provides the legislative framework for the compilation of the Cervical Screening Register which has meant that data from the Department of Social and Family Affairs can be used to establish and update this register. A woman's demographic data may also be submitted directly by her to CervicalCheck. Data related to a woman's screening history is acquired only following signed and informed consent by the woman.

The CSR is used to control the issuing of Programme letters to women, including:

- Invitation (call) letters, to invite women to participate in the Programme by attending for a smear test with a registered cervical smearer
- Re-call letters, to invite previously screened women to attend for another smear test at defined intervals
- Letters informing women of management recommendations for the results of their smear tests
- Failsafe letters to women and their doctors to ensure follow-up of not normal cytology results

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 sign consent to empower CervicalCheck to hold their screening history data
- Security and confidentiality
- CervicalCheck will act to minimise the risk to women

2.3.1 Data Quality

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.1	Creation of the Cervical Screening Register (CSR)	Acquire and maintain demographic details for eligible women aged 25-60 years, recorded on the CSR	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	CSR Information System Audit

- * In any defined period of time the number of eligible women listed on the CSR (numerator) expressed as a percentage of relevant Central Statistics Office (CSO) census data (denominator).

Explanatory Note:

- Demographic details include name, address, date of birth, Personal Public Service Number (PPS No.), middle name, mother's maiden name, surname at birth and the woman's CSP ID

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.2	Unique Identifier Number	Each woman listed on the CSR should have a unique identifier number	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	CSR Information System Audit

- * In any point in time, 80% or more of women listed on CSR should have a unique identifier number.

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.3	Accuracy of Demographic Data	Call, re-call letters returned to CervicalCheck offices	* Minimum $\leq 25\%$ Achievable $\leq 10\%$	CSR Information System Audit

- * In any defined period of time 25% or less of call, re-call letters are returned.

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.4	Accuracy of Demographic Data	Failsafe letters returned to CervicalCheck office	* Minimum $\leq 5\%$ Achievable $\leq 2\%$	CSR Information System Audit

* In any defined period of time 5% or less of failsafe letters are returned.

Explanatory Note:

- Demographic details on the CSR should be accurate and updated as necessary. This is measured by the number of letters that are returned to CervicalCheck

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.5	Invitation (call) Process	Eligible women on the CSR are called over a 3 year maximum timeframe for smear tests	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	CSR Information System Audit

* In a three year time period 80% or more of eligible women on CSR are called.

Explanatory Note:

- Women should receive a call letter within three years of their name being placed on the register

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.6	Re-call Process	All screened women are re-called for screening at the appropriate interval	* Minimum $\geq 90\%$ Achievable $\geq 95\%$	CSR Information System Audit

* In a defined period of time 90% or more of eligible women on CSR are re-called.

Explanatory Note:

- The re-call smear test interval depends on the woman's age and the management recommendation associated with her previous cytology result

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.7	Reminder Process	Women who do not respond to a call or re-call invitation within a specified period are sent at least one reminder letter	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	CSR Information System Audit

* In a defined period of time 80% or more of eligible women who do not respond to an invitation are sent a reminder letter.

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.8	Opt-off Process	Woman who chooses to opt-off from CervicalCheck	* Minimum $\leq 10\%$ Achievable $\leq 5\%$	CSR Information System Audit

* In any defined period of time 10% or less of eligible women listed on CSR opt-off from CervicalCheck.

Explanatory Note:

- Women who inform CervicalCheck in writing of their wish to opt-off are not included in any future call, re-call process
- The aim is to provide women with the option, 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
- Screening history includes results of smear tests, colposcopy procedures and histology biopsy specimens

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.9	Matching of Clinical History	Clinical history details – cytology, colposcopy and histology – received to the CSR are matched to the correct woman's record	* Minimum $\geq 95\%$ Achievable $\geq 98\%$	CSR Information System Audit

* In any defined period of time 95% or more of eligible women listed on CSR are correctly matched to their clinical history details.

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.10	Issuing of Management Recommendations	All letters with the appropriate management recommendations will be sent to print within 4 days of receipt of the cytology cervical smear result	* Minimum $\geq 95\%$ Achievable $\geq 98\%$	CSR Information System Audit

* In any defined period of time 95% or more of letters concerning smear test results are sent to print within four working days.

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.11	Failsafe Process	Women with smear test results that are 'not normal' who do not attend for follow-up	* Minimum $\geq 95\%$ Achievable $\geq 98\%$	CSR Information System Audit

* In any defined period of time 95% or more of eligible women on CSR with smear test results that are 'not normal' attend for follow-up.

Explanatory Note:

- A process of failsafe is in place to ensure that all recommendations requiring repeat smear tests or referral to colposcopy are appropriately followed-up
- Failsafe is a process involving communications sent by CervicalCheck to the woman and the doctor with clinical responsibility when the woman does not attend for her recommended smear test (following an inadequate or 'not normal' result), colposcopy referral or post colposcopy smear tests
- The failsafe actions are designed to ensure that all reasonable steps are taken so that screening results have been communicated to a woman and/or her clinically responsible doctor and that she has been offered a repeat smear test or further investigation as appropriate

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.12	Data Protection and Confidentiality	The Programme will 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 and Data Protection (Amendment) Act 2003	Yes	Audit and documentation

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.13	Secure Transfer of Personal Health Information	All personal health information transferred between the CSR and third party service providers must use Virtual Private Network (VPN) or secure email systems and must be encrypted to an accepted standard or protocol	Yes	Audit and documentation

	Category	Description of Standard	Standard	Demonstration of Compliance
2.3.1.14	Prevention of Loss of Data	Systems are in place for regular backups and secure storage of the personal health information and related data held on the CSR	Yes	Audit and documentation

2.4 Cervical Smeartaking Process

	Category	Description of Standard	Standard	Demonstration of Compliance
2.4.1	Skills Development for Quality Smeartaking	CervicalCheck smearthakers will be provided with training opportunities – initial and update – by the Programme on an ongoing basis to foster and maintain quality cervical smearthaking	Yes	Audit and documentation

	Category	Description of Standard	Standard	Demonstration of Compliance
2.4.2	Access to Programme Smearthakers	CervicalCheck smearthakers are registered with the Programme and listings of registered smearthakers are maintained and made publicly available	Yes	Audit and documentation

	Category	Description of Standard	Standard	Demonstration of Compliance
2.4.3	Smeartaker Training Programme	Smeartaker training programmes should be recognised by a third level institution or professional body	Yes	Audit and documentation

	Category	Description of Standard	Standard	Demonstration of Compliance
2.4.4	Performance Indicator	Unsatisfactory or inadequate reporting rate	Outside the 90th percentile	CSR Information System Audit

2.5 Programme Communications

	Category	Description of Standard	Standard	Demonstration of Compliance
2.5.1	Quality of Communications to Women and Smeartakers	CervicalCheck-generated communications to women and smeartakers is reviewed on a periodic basis	Yes	Audit and documentation

	Category	Description of Standard	Standard	Demonstration of Compliance
2.5.2	Accuracy of Communications to Women	The correct letter and corresponding information leaflet must be sent to women	*Minimum $\geq 95\%$ Achievable $> 98\%$	Audit and documentation

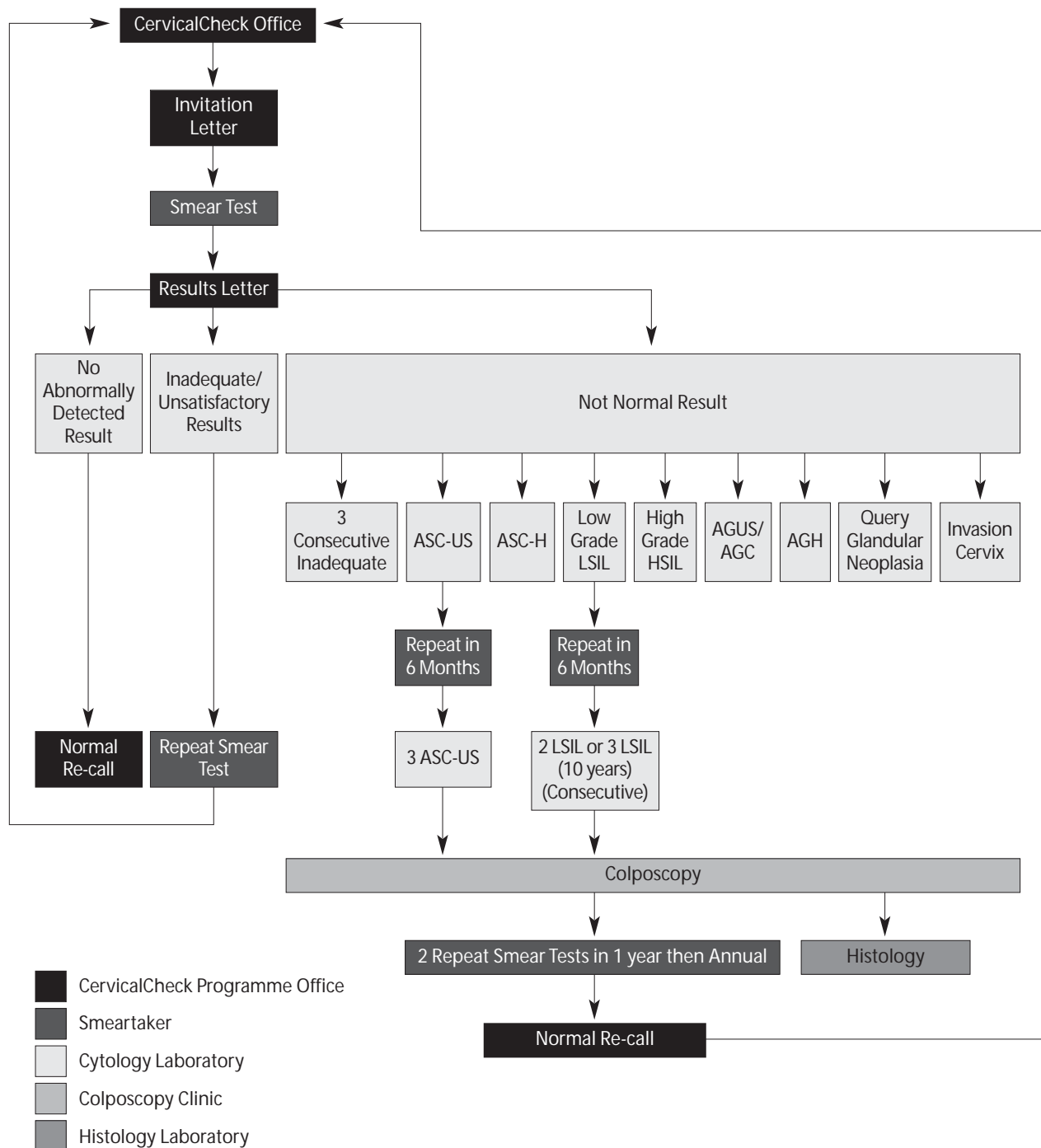
* In any defined period of time 95% or more of CervicalCheck communications (call, re-call and letters pertaining to smear test result) to women are complete and correct.

In any defined period the number of correct letters with the correct leaflets counted compared to the total letters and leaflets should exceed the minimum standard.

2.6 Reference List

- 1) Press release no. 151. IARC Cervix Cancer Screening Meeting Apr 20-27. 2004.
- 2) Arbyn M., Antilla A., Jordan J., Ronco G., Schenck U., Segan N., Wiener H.G., Herbert A., Daniel J., von Karsa L. (2008) European guidelines for quality assurance in cervical cancer screening [2nd Edition]. International Agency for Cancer Research and EU, Health & Consumer protection Directorate-General.

Appendix 1: CervicalCheck Programme Screening Process



The background of the slide is an abstract composition of overlapping, curved shapes in various shades of orange and yellow. The shapes create a sense of depth and movement, with some areas appearing lighter and more saturated than others. The overall effect is warm and modern.

3

Key Performance Indicators

3.1 Key Performance Indicators for CervicalCheck

The following reflects the European guidelines for quality assurance in cervical cancer screening, 2nd Edition 2008 (Chapters 2 and 7)¹.

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 consumption.

Screening Test Performance: Indicators include the referral rates for repeat cytology and for colposcopy, in addition to the positive predictive value 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.

3.2 Screening Intensity

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 women. 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.

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

3.2.1 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

N women in target population of catchment area actively served by programme

N women in target population of entire respective region or country

3.2.2 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

N women invited in defined period (3 or 5 years)

N resident women in target population

3.2.3 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

N women screened at least once in defined interval (3 or 5 years)

N resident women in target population

3.2.4 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

N invited women in a given period who were screened

N invited women in that period

3.2.5 Smear Test Consumption

- Include only screening smear tests (no repeat tests, e.g. after unsatisfactory smear tests or for follow-up) and 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

3.2.6 Incidence of Invasive Cancer in Unscreened and Underscreened Women in a Given Interval (3.5 of 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

N fully invasive cancers detected in women not screened in a given interval (3.5 or 5.5 years)

N person-years of women not screened in the same interval (3.5 or 5.5 years)

3.3 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 Cervical Intraepithelial Neoplasia (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 by 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 a priori 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 and 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.

3.3.1 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

N screen women with
cytological diagnosis

N screened women

3.3.2 Referral Rate for Repeat Cytology

- Calculate separately:
 - By cytology that resulted in recommendation to repeat
 - For initial and subsequent screening

N screened women advised to
repeat test at shorter than
regular interval

N screened women

3.3.3 Compliance with Referral for Repeat Cytology

- Calculate separately:
 - By cytology that resulted in recommendation to repeat
 - For initial and subsequent screening

N women screened following
recommendation for repeat
cytology

N women recommended for
repeat cytology

3.3.4 Referral Rate for Colposcopy

- Calculate separately by:
 - Cytology that resulted in referral to colposcopy
 - For initial and subsequent screening

N screened women referred for
colposcopy

N screened women

3.3.5 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

N screened women who had
colposcopy with histologically
confirmed CIN+

N screened women who had
colposcopy

3.3.6 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)

$$\text{a) } \frac{\text{N screened women not referred for colposcopy}}{\text{N screened women who had no histologically confirmed CIN+}}$$

$$\text{b) } \frac{\text{N screened women with normal screening test results}}{\text{N screened women who had no histologically confirmed CIN+}}$$

3.3.7 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

$$\frac{\text{N screened women with histologically confirmed CIN+}}{\text{N screened women}}$$

3.3.8 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

$$\frac{\text{N screened women with fully invasive cervical cancer detected within 3.5 (5.5) years of normal cytology}}{\text{N person-years of screened women for same period after normal cytology}}$$

3.4 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.

3.4.1 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

N new women attending colposcopy following referral from screening programme

N screened women referred for colposcopy from the screening programme

3.4.2 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
- Trachelectomy
- SWETZ
- Cold coagulation

N women with screen-detected CIN2 or CIN3 treated

N women with screen-detected CIN2 or CIN3 confirmed on histology

3.4.3 Proportion (%) of Women Total Hysterectomised following Screen-Detected Intraepithelial Lesions

- Calculate separately by histology (CIN1, CIN2, CIN3)
- Appropriateness of individual cases should be evaluated by peer review

N screened women with histological CIN total hysterectomised

N screened women with histological CIN

3.4.4 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 biopsys/Diagnostic biopsy
- Cryotherapy
- LLETZ
- Smear test
- Swabs
- Laser ablation
- Laser excision
- Radical hysterectomy
- Trachelectomy
- SWETZ
- Cold coagulation

N women with screen-detected CIN1 treated

N screened women with screen-detected CIN1 confirmed on histology

3.4.5 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

N cases of invasive cancer in screened women after abnormal cytology

N person-years of screened women after normal cytology

3.4.6 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, CGIN or AdenoCa 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

N screened and treated women with negative cytology after 6 months

N screened and treated women followed-up for at least 6 months

3.5 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 six (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.

3.6 Reference List

- 1) Arbyn M., Antilla A., Jordan J., Ronco G., Schenck U., Segan N., Wiener H.G., Herbert A., Daniel J., von Karsa L. (2008) European guidelines for quality assurance in cervical cancer screening [2nd Edition]. International Agency for Cancer Research and EU, Health & Consumer protection Directorate-General.

4

Quality Assurance in Primary Care

4.1 Introduction

Primary care plays a pivotal role in ensuring the overall success of CervicalCheck – The National Cervical Screening Programme as it is the first point of contact for women presenting for screening. General practice is the setting where the vast majority of smear tests are carried out. The role of health professionals in providing this service is complex. It involves carrying out the smearing procedure, and ensuring smear test results are followed-up. There is also an important role to play in encouraging the target population and improving the woman's knowledge about cervical screening.

These standards for quality assured primary care have been developed to provide a framework which will guide smear takers in primary care who provide this service for CervicalCheck. This document will provide a defined set of quality standards and best practice guidelines to ensure consistency in the services offered. The standards for quality assured primary care have been prepared to inform, enable and ensure that all the key components of a quality assured process are being addressed.

Identifying and highlighting standards assists each smear taker to make best practice and best quality care possible through practice audit, practice protocols and other methods.

Systematic methods were used in reference checking for an evidence based approach to detail the bibliography section. Health benefits and risks have been considered in formulating these standards.

4.2 Meeting the Needs of Women

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 given to safety, comfort and dignity throughout the screening process.

To allow women to make informed decisions about participation in screening, it is important that they have a sufficient understanding of cervical cancer and the risks and benefits of screening. Ensuring that women understand the purpose and procedures involved in cervical screening is an essential task for smear takers. The smear taker must ensure a quality clinical environment when undertaking smearing but also has a key role in communicating with the women so that issues of consent, confidentiality and information are clearly dealt with.

Among the guiding principles of the screening process are respect, openness and honesty. With a focus on addressing any fear or anxiety women may have and raising awareness about the Programme, the healthcare professional can promote women's active participation in screening.

Respect, Openness and Honesty

The Programme must be women centred at all times; women must feel that their best interests are maintained throughout the Programme. Women should expect and receive respect, openness and honesty throughout their participation in the screening programme. In so far as possible they should be fully involved in the process. Quality assurance is facilitated by a feedback process through CervicalCheck.

Communication

Good communication is a prerequisite for the success of the Programme. It may be written, verbal and non-verbal.

Fears and Anxieties

The screening programme should work to allay any anxieties, both medical and psychological, that women may have. Differences which may cause difficulties such as language, culture, education, and physical and intellectual disabilities should be recognised. Empathy and understanding will help to allay fears. Women should be encouraged to voice any fears or worries they may have to ensure the services offered meets their needs¹.

Screening Awareness and Promotion of Self-care

Women should have access to information about the screening programme. Communications and promotion will encourage active involvement by women in the process and increase the likelihood of their self-care.

The value of cervical screening is undeniable, effective cytological screening every three to five years can reduce cervical cancer mortality by up to 80 per cent². Aspects critical to the provision of quality assured screening programmes are that the screening test, the management of the test results and follow-up are performed competently. It is essential that the woman has a positive experience every time she attends for cervical screening.

4.3 Optimal Uptake of Screening in the Eligible Population

Definition: This section highlights the area within the cervical screening process where uptake can be increased and encouraged. Low uptake will compromise the overall success of the Programme¹.

Rationale: The primary aim of CervicalCheck – The National Cervical Screening Programme is to reduce incidence and mortality from cervical cancer in women aged 25 to 60.

The International Agency for Research on Cancer (IARC) confirms that organised cervical screening programmes are effective. With organised quality assurance of every key step of the entire process, it is estimated that an 80 per cent reduction in mortality could be achieved²⁻³. The potential percentage reduction in cumulative incidence can only be obtained if a high proportion of the population (over 80 per cent) comply with screening.

The CervicalCheck Cervical Screening Register (CSR) information system is constantly updated and maintained to include women as they become eligible.

- Primary care has a pivotal role in identifying and encouraging women to participate in regular screening to ensure that eligible women attending the practice/clinic are included in the register
- The practice population is those attending the practice/clinic for smear tests
- The CSR information system may not be complete hence every effort must be made to identify and include all eligible women

	Category	Description of Standard	Standard	Demonstration of Compliance
4.3.1	Age Profile to Start Cervical Screening	Women who are screened should be 25 years of age or over	* Minimum $\geq 70\%$ Achievable $\geq 80\%$	Practice audit

* In any defined period of time, 70% or more of all those screened at the practice/clinic are over the age of 25 years.

Explanatory Note:

- Screening in women under 25 years of age is strongly discouraged as there are risks associated with over-treatment in this age group
- The incidence of cervical cancer in the under 25 age group is low and the prevalence of HPV after sexual activity starts is high. Screening in this age group would result in unnecessary attendances at colposcopy with the resultant possible negative consequences of increased anxiety and possible over-treatment with an increase in morbidity from the intervention. In addition, screening has not been shown to be effective at reducing the incidence of invasive cancer in women under the age of 20 or indeed under the age of 25⁴
- For exceptions, refer to 4.3.6, 4.3.7 and 4.3.8
- An exception may also be made if a woman is post-colposcopy and has been recommended for further screening
- A woman is eligible to start cervical screening (even if over 60 years) if she has not previously had a Programme smear test⁵

	Category	Description of Standard	Standard	Demonstration of Compliance
4.3.2	Age Profile to End Cervical Screening	Women should end their screening at 60 years of age following a 'no abnormality detected' (NAD) screening history	* Minimum $\geq 70\%$ Achievable $\geq 80\%$	Practice audit

* In any defined period of time 70% or more of all those screened at the practice/clinic are under the age of 60 years.

Explanatory Note:

- Women who follow screening recommendations and have 'no abnormality detected' (NAD) smear test results no longer require screening after the age of 60 years
- Screening in women over 60 years is not required following two NAD smear test results regardless of the age that screening commenced
- Women should continue to have smear tests if recommended beyond the age of 60 years

	Category	Description of Standard	Standard	Demonstration of Compliance
4.3.3	Recommended Intervals for Cervical Screening	Cervical screening guidelines and recommendations should be followed by smertakers. Screening smear tests are carried out on eligible women only	* Minimum $\geq 80\%$ Achievable $\geq 90\%$	Practice audit

- * In any defined period of time 80% or more of the total number of women screened at the practice/clinic are screened within the recommended intervals.

Explanatory Note:

- Cervical smear tests outside of the Programme guidelines are not eligible
- Women should be offered screening every three years from 25 years to 44 years and every five years (following two consecutive NAD results) from age 45 to 60 or as per recommendations
- There is no requirement for increased screening if the woman has a history of genital warts, is a cigarette smoker, is using the contraceptive pill or if the woman has an Intra Uterine Contraceptive Device (IUD)

Please Note:

- The screening programme is based in primary care. There will be circumstances where it may be appropriate to have screening undertaken in gynaecology, colposcopy and sexually transmitted infection (STI) clinics

4.3.4 Quality Issue: Adherence to Programme Recommendations by Women

The smertaker should ensure that women participating in the Programme should adhere to and complete their management recommendation.

- A management recommendation is based on the individual woman's cytology report and her clinical history
- A key role played by the smertaker is that of encouraging women to have regular smear tests in accordance with the screening recommendations
- This can be achieved by taking the initiative and raising the issue of smear tests with women
- A woman's eligibility for participation in the screening programme will be on average for 35 years. Ongoing participation and continuity should be encouraged

4.3.5 Quality Issue: Barriers to Screening

Smertakers should recognise and minimise barriers that may reduce a woman's participation in cervical screening so that any woman wishing to participate in cervical screening can avail of the service. One of the recognised barriers to screening is lack of understanding about the smear test.

- Primary care has a pivotal role in informing women that policy, standards, monitoring and evaluation are in place
- Other barriers to participation include gender of smertaker, accessibility, appointment times and other commitments
- Equality in access for screening is vital because in many screening programmes the population most at risk have least uptake of screening

- Specific measures should be put in place to promote health and encourage women to attend for cervical screening where there is a recognised lack of uptake
- It is recognised that certain areas have a poor uptake of screening e.g. disadvantaged areas, unemployment black spots, prisons and institutions
- It is recognised that language barriers in a multicultural society may impact on uptake
- At all times any woman should have the right to decline to be screened

	Category	Description of Standard	Standard	Demonstration of Compliance
4.3.6	HIV Positive Women	Women 20 years of age or over who are HIV positive should be offered screening yearly	* Minimum $\geq 80\%$ Achievable $\geq 90\%$	Practice audit

- * In any defined period of time 80% or more of women at the practice/clinic who are known HIV+ are offered annual screening.

Explanatory Note:

- Women who are HIV positive have difficulty clearing the HPV virus and are at increased risk of developing cervical cancer
- Recording of sensitive personal information such as HIV infection should be coded with the code 'CD4i'⁶

	Category	Description of Standard	Standard	Demonstration of Compliance
4.3.7	Women with Transplants	Women 20 years of age or over who have had organ transplants and are receiving immunosuppressant medications should be offered screening yearly	* Minimum $\geq 80\%$ Achievable $\geq 90\%$	Practice audit

- * In any defined period of time 80% or more of women with transplants at the practice/clinic are offered annual screening.

Explanatory Note:

- Patients with chronic kidney disease (CKD) and kidney transplants have demonstrated a greater excess cancer risk especially cervical cancer risk⁷⁻⁹
- Transplant status must also be recorded on the Cytology Referral Form

	Category	Description of Standard	Standard	Demonstration of Compliance
4.3.8	Renal Dialysis	Women undergoing regular renal dialysis should be offered screening yearly from the age of 20 years or over	* Minimum $\geq 80\%$ Achievable $\geq 90\%$	Practice audit

- * In any defined period of time 80% or more of women on renal dialysis at the practice/clinic are offered annual screening.

Explanatory Note:

- Women who are on dialysis are potentially at risk of cancer for many reasons, including: immunosuppressant medication, cytotoxic drugs, altered DNA repair, chronic infections, nutritional deficiencies and uraemic dysfunction¹⁰
- Renal dialysis status must also be recorded on the Cytology Referral Form

4.3.9 Quality Issue: Women on Immunosuppressant Medication (other than 4.3.6-4.3.8)

- Vigilant promotion according to the national programme screening intervals is necessary
- Immunosuppressant medications are used to treat many diseases like Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis, Inflammatory Bowel Disease
- Presently there is insufficient evidence to warrant a recommendation of increased frequency of cervical screening for the women highlighted above
- Primary care has an important role in ensuring that women with chronic disease are offered and encouraged to have regular cervical screening

4.4 Appropriate Training

Definition: This section highlights the areas within the cervical screening process where smertakers must be competent in all aspects of cervical screening in the primary care setting.

Rationale: The primary aim of CervicalCheck is to reduce incidence and mortality from cervical cancer¹¹⁻¹². To help achieve this aim all cervical smertakers should be appropriately trained. Therefore, it is the duty of the doctor with clinical responsibility to ensure that all smertakers who take smear tests in their practice/clinic are appropriately trained and are competent¹³.

Quality cervical smertaking training is central to an effective national screening programme. Training in cervical screening enables healthcare professionals to develop the appropriate knowledge, skills and attitudes essential in screening women for cervical cancer. Practitioners express the need to be formally trained in procedures such as inserting a speculum, and performing a smear test^{14,15}.

Training updates are also required to ensure practitioners involved in cervical screening continue to keep up with new knowledge and insight into the complex issues relating to screening^{16,17}.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.4.1	Professional Qualifications	Smertakers must be a medical doctor or a registered general nurse	* Minimum $\geq 95\%$ Achievable 100%	Documentation of qualifications

* Documentary evidence of qualifications recognised by An Bord Altranais/Irish Medical Council.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.4.2	Training in Cervical Screening	Smertakers should complete a CervicalCheck recognised smertaker training course during the first 3-5 years following registration	* Minimum $\geq 60\%$ Achievable $\geq 80\%$	Certificate

* Within three to five years of registration, 60% or more of the total number of smertakers in the practice/clinic partake in smertaker training.

Explanatory Note:

- The doctor with clinical responsibility should ensure that smertakers in their practice/clinic are appropriately trained
- The doctor with clinical responsibility should provide support and guidance to smertakers within the practice/clinic
- Inadequate training may have medico legal implications

	Category	Description of Standard	Standard	Demonstration of Compliance
4.4.3	Training in Cervical Screening	Smertakers should participate in CervicalCheck recognised accredited clinical update sessions on a 3 yearly interval	* Minimum $\geq 70\%$ Achievable $\geq 80\%$	Certificate

* Within three yearly intervals of actively taking smear tests, 70% or more of the total number of smertakers in the practice/clinic partake in CervicalCheck recognised accredited clinical update sessions.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.4.4	Training in Cervical Screening	Smear takers starting out in practice should carry out smear tests under supervision	* Minimum $\geq 95\%$ Achievable 100%	Practice records

- * In any defined period of time 95% or more of new smear takers starting out in practice perform a set number of smear tests under supervision.

Explanatory Note:

- 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

	Category	Description of Standard	Standard	Demonstration of Compliance
4.4.5	Performance Indicators	Unsatisfactory or inadequate reporting rate	* $\leq 2\%$	Cytology reports

- * In any defined period of time 2% or less of the total number of smear tests reported as unsatisfactory/inadequate for a smear taker.

Explanatory Note:

- CervicalCheck will provide smear takers with feedback on their smear test results
- Where the annual unsatisfactory or inadequate reporting rate is less than or equal to two per cent, then that individual may need to undergo retraining

4.4.6 Quality Issue: Administrative Personnel

- Administration personnel should be made aware of their roles and responsibilities in the smearing process
- Administration personnel should have access to training if required
- Administration personnel should be provided with updates in relation to their role in the cervical screening process
- Administrative staff need training to ensure that information they give to women is accurate, easily understood and takes culture into account¹⁸

4.5 Appropriate Equipment in an Appropriate Setting

Definition: This section highlights the high standard environment required when smearing.

Rationale: CervicalCheck will invite eligible women to attend for a smear test. It is important that women are satisfied with the service offered to them or they will not return for re-screening or follow-up tests. Some women find a smear test difficult. A suitable environment will help establish rapport, relax, and encourage women. Every effort should be made to ensure that the smearing environment contributes to the comfort of women. Smearing services should be provided in an environment that respects the dignity and autonomy of women.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.1	Privacy	Smearing activity must be provided in a private setting	Yes	Practice audit

Explanatory Note:

- The examination should take place in a room, where the consult cannot be observed or overheard while the woman is having the examination
- Blinds should be used where appropriate
- Screens should be used where appropriate
- Toilet facilities must be available and accessible

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.2	Secure Examination Room	Smearing activity must be provided in a secure setting	Yes	Practice audit

Explanatory Note:

- The examination should take place in a closed room that cannot be entered while the woman is having the examination

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.3	Room Temperature	Smearing activity must be provided at an ambient temperature i.e. 18°-21°C	Yes	Practice audit

Explanatory Note:

- The examination should take place in a closed room that cannot be entered while the woman is having the examination

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.4	Choice of Smeartaker	Women should be accommodated with a choice of smeartaker	Yes	Practice audit

Explanatory Note:

- Within the Programme there is a facility for choice of registered smeartaker
- Women may choose a female smeartaker
- Women have the choice to change smeartaker

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.5	Chaperone	A chaperone must be facilitated if the woman requires one	Yes	Practice audit

Explanatory Note:

- The smeartaker should consider their own requirement for a chaperone or support person
- The smeartaker should offer a chaperone or support person
- The support person may be a relative or a friend

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.6	Consumables	Smeartaking consumables are within expiry date	Yes	Practice audit

Explanatory Note:

- There should be advanced preparation of smeartaking equipment and consumables (including expiry date checks of vials and speculae)
- Appendix 1 provides a list of the necessary equipment

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.7	Examination Couch	An accessible examination couch must be available	Yes	Practice audit

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.8	Infection Control	Smear-taking activity must adhere to the infection control procedures of the practice/clinic	Yes	Practice audit

Explanatory Note:

- Regular monitoring and review of infection control procedures must be in place to ensure their effectiveness

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.9	Single Use Disposable Speculae	Single use disposable speculae should be disposed of as clinical waste	Yes	Practice audit

Explanatory Note:

- CervicalCheck recommends the use of single use disposable speculae
- Ensure single use only specula are opened just prior to smear-taking and never reused

	Category	Description of Standard	Standard	Demonstration of Compliance
4.5.10	Reusable Speculae	Reusable speculae must be decontaminated using either: <ul style="list-style-type: none"> Sterilisation preferred where practicable or High level disinfection (See Appendix 2) 	Yes	Practice audit

Explanatory Note:

- The use of inadequately decontaminated instruments and appliances during examination of the vagina and cervix may lead to the transmission of infection. Smear-takers must have appropriate infection control processes in place and follow EU sterilisation guidelines should they decide to use reusable speculae¹⁹⁻²⁴

4.5.11 Quality Issue: Women with Special Requirements – Physical or Intellectual Disability

- Smear takers should make every effort to provide women who have a physical or intellectual disability with adequate time and an environment that accommodates their requirements
- A pictorial information leaflet should be made available
- Wheelchair accessibility should be considered in the primary care setting
- Assistance to women with physical disabilities undergoing a smear test should be facilitated

4.6 Accurate Identification of Women

Definition: This section highlights the importance of attention to personal details at all stages in identifying and tracking women having smear tests. The smear taker must record the woman's demographic details on the Cervical Cytology Form for each smear test taken with current, accurate and complete information to ensure that the right woman is linked to the right result.

Rationale: There are two specific areas that relate to primary care:

- Cervical Cytology Form
- Practice Medical Records

4.6.1 Cervical Cytology Form

Accurate documentation is an integral component of a cervical screening programme. The proper medical management of the woman requires that the woman is uniquely identified. It is important to capture, record, and relay current demographic details accurately and legibly. Unique identification of the woman starts with the inclusion of all relevant information recorded on the Cervical Cytology Form.

There are risks associated with incomplete, inaccurate, and illegible demographic information:

- Woman matched to incorrect smear test result leading to errors in treatment
- Woman not receiving a result of the smear test and not receiving treatment
- Previous history not found, incorporated, matched and returned to the laboratory possibly resulting in an incorrect management recommendation
- CervicalCheck correspondence going to incorrect woman
- Woman having more than one record

CervicalCheck aims to create one record for each woman over her lifetime, which could potentially be over a 35 year period.

The demographic aspects of the Cervical Cytology Form should be completed at the time of the test in the presence of the woman for accuracy.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.6.1.1	Demographic Information Recording	Forename	* Minimum ≥80% Achievable ≥95%	Cervical Cytology Form
		Surname	* Minimum ≥80% Achievable ≥95%	
		Address	* Minimum ≥80% Achievable ≥95%	
		Date of birth	* Minimum ≥90% Achievable ≥95%	
		Surname at birth	* Minimum ≥70% Achievable ≥85%	
		Mother's maiden name	* Minimum ≥70% Achievable ≥85%	
		PPS Number	* Minimum ≥80% Achievable ≥95%	
		Telephone number (mobile or landline)	* Minimum ≥80% Achievable ≥95%	
		CSP ID	* Minimum ≥50% Achievable ≥75%	
		Middle name	* Minimum ≥50% Achievable ≥75%	

* In any defined period of time, for each demographic field, the number of forms with the field completed expressed as a percentage of the total number of forms.

Explanatory Note:

- The unique identifiers are forename, date of birth, surname at birth and mother's maiden name
- Where this information is incomplete the cytology laboratory may return the Cervical Cytology Form to the smearer
- The PPS Number is available from the:
 - CervicalCheck office
 - CervicalCheck invitation letter
 - PCRS Medical Card
 - Drugs Cost Subsidy Card
 - Social Welfare Office
- The CSP ID (Cervical Screening Personal Identification) number is created by the Cervical Screening Register and used within the CervicalCheck office

	Category	Description of Standard	Standard	Demonstration of Compliance
4.6.1.2	Consent	Indication of consent is required to participate in the screening programme	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	Cervical Cytology Form

* In any defined period of time 80% or more of forms will indicate consent.

Explanatory Note:

- The woman must sign the Cervical Cytology Form to take part in CervicalCheck. By signing the consent form the woman agrees to participate in the cervical screening programme. It is a legal requirement and allows the information about the woman to be transferred throughout the Programme and to the National Cancer Registry for statistical purposes
- Obtaining informed consent is the responsibility of the smearer who is taking the test
- Women may withdraw consent to participation in the screening programme by writing to the Programme
- If there is no indication of consent on the form the cytology laboratory will not forward the woman's details to the Programme office and the smearer will not get paid

	Category	Description of Standard	Standard	Demonstration of Compliance
4.6.1.3	Matched Samples and Referral Forms	Vials and forms must be accurately matched	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	Cervical Cytology Form

* In any defined period of time, 80% or more of vials and forms are correctly matched compared to the total number of smear tests.

Explanatory Note:

- To minimise any potential errors, the vial should only be opened immediately prior to use
- The vial and the form should be transported together in the same transport box
- Vials and forms that do not match will not be accepted for screening and may be returned to the smearer

	Category	Description of Standard	Standard	Demonstration of Compliance
4.6.1.4	Legible Information	The smearer must ensure that the Cervical Cytology Forms are legible and not returned by the laboratory	* Minimum $\leq 10\%$ Achievable $\leq 5\%$	Cervical Cytology Form

- * In any defined period of time, 10% or less of forms returned as illegible compared to the total number of forms completed.

Explanatory Note:

- Electronic form filling is strongly encouraged as it reduces transcription, documentation and data accuracy errors
- A ballpoint pen should be used in completing the forms by hand and block capitals used where requested on the form

	Category	Description of Standard	Standard	Demonstration of Compliance
4.6.1.5	Accurate Information	The smearer must ensure that the Cervical Cytology Forms are completed with current accurate information and not returned by the laboratory	* Minimum $\leq 20\%$ Achievable $\leq 10\%$	Cervical Cytology Form

- * In any defined period of time, 20% or less of forms returned as inaccurate compared to the total number of forms completed.

Explanatory Note:

- Cervical Cytology Forms must be completed with current information checked with the woman at the time of each smear test

4.6.2 Practice Medical Records

It is the responsibility of each practice/clinic to maintain accurate records in a safe, secure environment.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.6.2.1	Patient Medical Records at the Time of Smear taking	The smearer must ensure that smear tests taken are recorded in the correct woman's medical records	* Minimum $\geq 85\%$ Achievable $\geq 95\%$	Practice patient medical record

- * In any defined period of time 85% or more of smear tests are recorded in practice patient medical records.

Explanatory Note:

- The medical record should reflect the date of the smear test
- Computerised patient record keeping is strongly encouraged as records are easily stored, readily available and retrievable for future use
- All Data Protection issues (storage, access and data transfer) must be compliant with the Data Protection Act of 1988 and the Data Protection (Amendment) Act 2003

4.7 Communication with Women

Definition: The importance of clear communication with women having smear tests. All aspects of the cervical screening process must be explained to women.

Rationale: The cervical screening process should be explained to women. Women should have sufficient information and understanding to enable them to make an informed decision to have a smear test and to participate in the cervical screening programme.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.7.1	Confidentiality	Confidentiality in relation to each woman is maintained throughout the screening process	Yes	Practice protocol

Explanatory Note:

- Assurance of confidentiality is essential in ensuring a woman's confidence with the screening process
- Confidentiality around the cervical screening programme should be explained to the woman
- Women's Charter: 'Your screening records will be treated in the strictest confidence'²⁵

	Category	Description of Standard	Standard	Demonstration of Compliance
4.7.2	Consent to Participate in CervicalCheck	Smear taker informs the woman about the consent process	Yes	Practice audit

Explanatory Note:

- Women are given a copy of the Information Sheet for Women accompanying to the Cervical Cytology Form
- Consent is required for transfer of personal health information between service providers in the cervical screening pathway
- Consent is required and information surrounding consent is included on the information attached to the Cervical Cytology Form
- Informed consent includes the giving of all necessary information by the smear taker; this includes the benefits and limitations of cervical screening²⁶

4.7.3 Quality Issue: Communication throughout the Smear Test Procedure

- Smear taker informs the woman about the smear taking process
- The woman should be allowed the opportunity to ask questions
- It is essential that the woman remains informed throughout the procedure
- The woman has the right to ask the smear taker to stop at any time

	Category	Description of Standard	Standard	Demonstration of Compliance
4.7.4	Information Leaflets	Practices/clinics should have current CervicalCheck information leaflets available	Yes	Practice audit

4.7.5 Quality Issue: Women Should Have the Choice to Change Smear taker

- The smear taker must ensure that the woman is aware of her entitlement to choose her smear taker either within the practice/clinic or elsewhere in primary care

4.7.6 Quality Issue: Information Regarding Results

- Women should be informed of the protocol for receiving results
- Written or verbal communications in relation to the smear test result must be kept in the woman's records

4.8 Quality Smear taking

Definition: The cervix is visualised, assessed and effectively sampled. All relevant clinical information must be recorded on the Cervical Cytology Form.

Rationale: Effective cytological sampling is an integral component of a quality screening programme. Smear takers should have a clear understanding of effective sampling of the cervix. Accurate, current and complete information about the woman and her test must be recorded. Optimal time for a smear test is mid-menstrual cycle, between day seven and 15²⁷.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.8.1	Minimum Repeat Time	There must be a minimum of 3 months between any 2 smear tests	* Minimum ≥80% Achievable ≥90%	Cervical Cytology Form

- * In any defined period of time, 80% or more of smear tests are taken on an individual woman at an interval of at least three months.

4.8.2 Quality Issue: Locating the Cervix

- While every effort should be made to visualise the cervix, no more than three efforts should be considered
- At this point, the smearer should consider referral to another CervicalCheck registered smearer in either primary care (within or outside the practice/clinic) or the gynaecology setting as appropriate

	Category	Description of Standard	Standard	Demonstration of Compliance
4.8.3	Recording of Visualisation of the Cervix	The smearer must record visualisation of the cervix, where applicable, on the Cervical Cytology Form	Minimum $\geq 80\%$ Achievable $\geq 95\%$	* Cervical Cytology Form

- * In any defined period of time, for the 'Cervix Visualised' field on the Cervical Cytology Form, 80% or more of forms indicate that the cervix is visualised.

Explanatory Note:

- A smear test should not be taken if the cervix has not been visualised
- It is the smearer's responsibility to sample the correct site
- If a smear test cannot be taken because the cervix is not visualised the smearer may ask that the woman return on another day or may ask another smearer to perform the smear test within primary care
- Referral outside of primary care to public gynaecology outpatients clinic is facilitated by CervicalCheck
- Clinical features that raise suspicion of cervical cancer need urgent referral

4.8.4 Quality Issue: Sampling of the Cervix

- The smearer must ensure that all of the Transformation Zone is sampled using the technique advised by the manufacturing instructions of the sampling tool
- All samples must be in an optimal condition. Optimal condition of the sample includes adequate solution in vial, no contamination with other liquids, and that the cytologist should be able to use the contents of the vial to make a quality slide

4.8.5 Quality Issue: Relevant Clinical Details and Findings

- Relevant clinical details requested on the Cervical Cytology Form (e.g. LMP) must be completed
- The smearer must record the clinical condition of the cervix on the Cervical Cytology Form

	Category	Description of Standard	Standard	Demonstration of Compliance
4.8.6	Previous Smear Test History	Forms (other than that of the first screening smear test) must have previous smear test history completed	* Minimum $\geq 50\%$ Achievable $\geq 80\%$	Cervical Cytology Form

- * In any defined period of time, 50% or more of Cervical Cytology Forms (other than that of the first screening smear test) record the previous smear test history.

4.8.7 Quality Issue: Previous Treatment History

- Previous treatment history of the cervix, where relevant (and date of treatment), must be recorded on every Cervical Cytology Form
- Post-colposcopy recommendations for smear tests should be recorded
- Hysterectomy details (i.e. total/sub-total, benign or neoplastic reason) should be recorded on the Cervical Cytology Form if known

	Category	Description of Standard	Standard	Demonstration of Compliance
4.8.8	Abnormal Vaginal Bleeding	Women with abnormal vaginal bleeding should have a speculum examination	* Minimum $\geq 50\%$ Achievable $\geq 80\%$	Practice patient medical record

- * In any defined period of time, 50% or more of women who attend for a smear test with abnormal vaginal bleeding have a speculum examination.

Explanatory Note:

- Abnormal vaginal bleeding should be considered where there is intermenstrual bleeding, postcoital bleeding, postmenopausal bleeding and vaginal discharge
- Women persisting with unexplained vaginal bleeding should be referred for gynaecological examination and onward referral for colposcopy if cervical cancer is suspected

4.9 Prompt Dispatch of the Sample

Definition: A standard delivery system of the correct sample to the laboratory within the appropriate time.

Rationale: GPs should have clear information and guidelines to ensure that specimens arrive safely to the laboratory and within a specified time interval. Standard procedures are necessary to minimise the risk of lost, delayed or damaged samples. There may also be safety concerns for handlers.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.9.1	Sample Specimen Identification	Vials must at a minimum have forename, surname and date of birth as identifiers	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	Practice audit

- * In a defined period of time, 80% or more of vials are identifiable with forename, surname and date of birth.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.9.2	Matching Vial to Form	Return of unmatched vial or form	* Minimum $\leq 5\%$ Achievable $\leq 2\%$	Practice audit

* In any defined period of time, 5% or less of forms or vials should be returned as unmatched.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.9.3	Packaging of Samples	Vials and forms must be packaged in the transport containers provided	* Minimum $\leq 5\%$ Achievable $\leq 2\%$	Practice audit

Explanatory Note:

- Universal precautions should be employed for handling and packaging of all samples

	Category	Description of Standard	Standard	Demonstration of Compliance
4.9.4	Dispatch Times	Vials and forms must be dispatched within 5 working days of the test being taken	* Minimum $\geq 60\%$ Achievable $\geq 90\%$	Practice audit

* In any defined period of time, 60% or more of vials and forms are dispatched from the practice within five working days of taking the sample.

Explanatory Note:

- It is the responsibility of the smearer to dispatch/post samples
- To facilitate the delivery of a result to the woman within four weeks, it is important to dispatch the sample promptly

4.10 Review of Smear Test Results

Definition: This section highlights the importance of record management procedures in the practice or clinic.

Rationale: A smear test result must be received by the smearer for each sample sent to the laboratory. The result, including the management recommendation, must be matched to the correct woman^{13,16}. The smearer must understand the significance of the result and the recommendation for follow-up.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.10.1	Records	Smear tests taken must have a retrievable record in the practice/clinic	Yes	Practice patient medical record

	Category	Description of Standard	Standard	Demonstration of Compliance
4.10.2	Receipt of Results	Results received from the laboratory should be cross checked with smear tests taken	Yes	Practice records

	Category	Description of Standard	Standard	Demonstration of Compliance
4.10.3	Matching Results	Smear test results must be matched to the woman's medical record	* Minimum $\geq 90\%$ Achievable $\geq 95\%$	Practice patient medical record

* In any defined period of time, 90% or more of smear test results must be matched to the woman's medical record.

Explanatory Note:

- It is recommended that a lead smearer takes responsibility for managing the results process within the practice/clinic
- Outstanding results must be identified if they have not been received by the smearer within 28 working days from the smear test date
- The woman's medical records must be updated with the smear test result and management recommendation

	Category	Description of Standard	Standard	Demonstration of Compliance
4.10.4	Informing Women of Results	Practices/clinics should have in place a consistent protocol regarding the provision of smear test results to women	Yes	Practice audit

Explanatory Note:

- The practice/clinic protocol should include clear direction on the person responsible for providing women with their results. All staff, including reception staff, should be aware and informed of this protocol
- The practice/clinic protocol should include clear direction on the provision of all results
- Women should be given the opportunity for an appointment for further discussion and provision of information. Best practice would suggest that the smearer provides results that are not normal in a face-to-face consultation
- Where the results are not normal, women should be given full details of the result and advised of the process of their management. Explanation should be clear and appropriate to the level of understanding of each woman

4.11 Follow-up of Smear Test Results and Appropriate Action

Definition: The importance of ensuring that all smear test result management recommendations are followed-up with the appropriate action taken.

Rationale: The procedure for when 'no abnormality detected' (NAD), 'inadequate' and results that are not normal are received by the practice, including information on the CervicalCheck failsafe process.

A person responsible for providing women with results may be identified within the practice/clinic. All staff, including reception staff, should be aware and informed of this protocol.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.11.1	System for Managing All Results	Practices/clinics have in place a consistent protocol regarding management of smear test results	Yes	Practice audit

Explanatory Note:

- Smeartakers must contact the laboratory if they have queries in relation to results or management recommendations
- Smeartakers must access the most current information and documentation in relation to cytology results and management recommendations
- Post colposcopy recommendations need to be followed-up. The woman's medical record should detail the post colposcopy care plan
- Women need to be encouraged to follow their post colposcopy care plan

	Category	Description of Standard	Standard	Demonstration of Compliance
4.11.2	CervicalCheck Failsafe Process	Failsafe requests are responded to in full within 10 working days	* Minimum $\geq 70\%$ Achievable $\geq 90\%$	Practice audit

* In a defined period of time, 70% or more of failsafe requests are responded to within 10 working days.

Explanatory Note:

- Failsafe is a written communication (a letter) sent by CervicalCheck to the woman and to the doctor with clinical responsibility in the primary care setting (a form) when the woman does not attend for:
 - Her recommended smear test (following an 'inadequate' or 'not normal' result)
 - Her colposcopy referral
 - Her post colposcopy cervical smear tests
- Failsafe actions refer to the CervicalCheck administrative procedures that come into effect if, for whatever reason, follow-up actions have not been taken. If follow-up actions fail, 'failsafe' will come into effect
- Smertakers should have information and guidelines on intended referral pathways and on the outcome of the referred patient
- The smertaker must make every reasonable effort (at least two recorded efforts) to ensure that the woman is contacted

4.12 Colposcopy Referral and Subsequent Management

Definition: The importance of appropriate management of women who need further evaluation following their smear test result.

Rationale: The doctor with clinical responsibility must ensure prompt referral to a colposcopy clinic on receipt of a recommendation from the cytology laboratory. All referral information about the woman and her smear test and history must be forwarded directly to the colposcopy clinic. Further communication regarding the referral should be facilitated with the colposcopy clinic where necessary.

The guidelines for referral are not to replace clinical judgment, and women deemed to require urgent assessment may need specific personal contact with the specialist colposcopy service.

Recommendations of the colposcopy clinic and/or gynaecologists following treatment should be adhered to.

	Category	Description of Standard	Standard	Demonstration of Compliance
4.12.1	Referral to Colposcopy	Women requiring referral to colposcopy clinics must be referred directly by the doctor with clinical responsibility within 5 working days	* Minimum $\geq 80\%$ Achievable $\geq 95\%$	Practice patient medical record

- * In a defined period of time, 80% or more of women with a laboratory recommendation of a referral to a colposcopy clinic are referred within 5 working days.

Explanatory Note:

- Referrals for colposcopy should be made through the standardised Colposcopy Referral Form with a copy of the relevant cytology result report attached
- Post colposcopy discharge recommendations must be adhered to at a minimum

	Category	Description of Standard	Standard	Demonstration of Compliance
4.12.2	Continuity of Care	During and following her attendance throughout primary care, the woman must have a doctor with clinical responsibility assigned to her care	Yes	Practice patient medical record

Explanatory Note:

- If the doctor with clinical responsibility in the primary care setting leaves the practice/clinic for whatever reason, he/she remains clinically responsible for women who have had smear tests at his/her former practice/clinic until subsequent arrangements are made
- If the doctor with clinical responsibility leaves the practice/clinic, women must be contacted to gain consent to make arrangements to transfer medical records to another doctor with clinical responsibility who has agreed to take over their management

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Appendix 1: Environment and Equipment

Category	Description of Standard
Hand Washing Facilities/ Chemical Cleaning Liquid	The smear taker's hands should be washed or chemically cleaned before and after any duty that involves close contact with the woman
Illumination	An adjustable halogen spotlight provides one of the better sources of illumination
Examination Couch	The examination couch should be placed in a position to allow easy vaginal examination with the woman in either the left lateral or dorsal position
Gloves	Vinyl or latex disposable gloves are recommended. Be aware that some women are allergic to latex rubber
Sheet, Blanket, Pillow	A disposable sheet, pillow and blanket cover should be used for patient comfort
Cervical Cytology Form	Use the CervicalCheck Cervical Cytology Form
Ballpoint Pen	Label the vial with a ballpoint pen or as directed
Speculum	At least 3 different sizes of bivalve vaginal speculae (Cusco's speculum) should be available - small, medium, and large. A very small speculum (virgin speculum) and a long-bladed narrow speculum may occasionally be needed
Sampler – Broom and Brush	The plastic broom is used in Liquid Based Cytology (LBC)
Liquid Based Cytology (LBC)	An endocervical brush should also be available
LBC Vial	A vial containing transport medium for Liquid Based Cytology
LBC Transport Boxes	Supplied by the LBC supplier
Waste Disposal Bags	Clinical waste needs to be disposed of with care, especially used disposable speculums and samplers
Patient Information Leaflets	Available from CervicalCheck

Appendix 2: Decontamination and Sterilisation

Quality Assurance Standard:

100 per cent of reusable speculum must be decontaminated using either:

- High level disinfection
- Sterilisation preferred where practicable

The use of 'single use devices' i.e. disposable should be used where:

- Re-usable devices are impossible/difficult to clean /sterilise
- Economic
- Practicable

Decontamination: Process is broken down into a) cleaning and b) disinfection or sterilisation. All instruments to be disinfected or sterilised must first be thoroughly cleaned to remove all organic matter (blood and tissue) and other residue. This must precede disinfection and sterilisation procedures as organic matter shields organisms from destruction and may inactivate some disinfectants.

Cleaning is the process that physically removes soiling including large numbers of micro-organisms and the organic material on which they thrive*.

Disinfection describes a process that eliminates many or all pathogenic micro organisms on inanimate objects, with the exception of bacterial spores*.

Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable micro organisms from an object, including spores. Sterility is an absolute condition – an item is either sterile or not sterile*.

HPV is a very stable hardy virus and therefore more difficulty is experienced in sterilising instruments adequately. It has been found that HPV is relatively resistant to ether and acids.

Background:

Decontamination practice is continually evolving and those with responsibility for decontamination need to ensure that they are kept aware of current developments. This includes not only changes in the nature of equipment etc. that may be available but also includes changes in requirements in the light of new information about transmittable disease.

Definition of an Invasive Device:

A device which in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. Medical devices directive (93/42/EEC) made law in Ireland 1993.

Classification of Infection Risk:

Appropriate level of decontamination will depend on the procedure for which the device is used.

Background on Classification:

In 1968 Earle Spaulding devised a classification for infection risk associated with the decontamination of RIMD (Reusable Invasive Medical Devices). Spaulding believed that instruments and equipment should be cleaned and reprocessed according to the level of risk associated with their intended use*. The 'Spaulding's' classification divides medical devices into Critical, Semi Critical or Non-Critical. The vaginal speculum fall under the semi critical classification whereby the 'device contacts intact mucous membrane but does not penetrate sterile tissue' and therefore the level of decontamination required is high level disinfection or sterilisation where practicable. The vagina and cervix is not a sterile area.

High level disinfection or sterilisation can be carried out at:

- LDU's (Local Decontamination units i.e. GP practices) or
- CDU's (Central Decontamination Units)

* Arbyn M., Antilla A., Jordan J., Ronco G., Schenck U., Segan N., Wiener H.G., Herbert A., Daniel J., von Karsa L. (2008) European guidelines for quality assurance in cervical cancer screening [2nd Edition]. International Agency for Cancer Research and EU, Health & Consumer protection Directorate-General.

Note: In addition, in compiling this Appendix, References 19-24 were considered.

5

Quality Assurance in Cytopathology

5.1 Introduction

The quality of 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 following is an overview of procedures recommended in Ireland to achieve a balance between best patient care, laboratory quality assurance and cost effectiveness.

The microscopic examination and interpretation of histological and cytological specimens is a subjective procedure, highly dependent on the quality of the sample, the skills and experience of the investigator and the time spent on examination of the cell/sample^{1,2,3}.

Inter- and intra-observer variation and the high variance in percentages of correct diagnoses described in the literature are a logical and predictable consequence of such a screening process^{4,5,6}.

The aim of optimal quality assurance is to provide the best possible patient care.

With respect to cervical screening, this means a balance between manageable control of costs and low false positive/negative test result rates.

Cervical screening can be conveniently divided into three key stages:

- Stage 1: Pre-analytical (smeartaking)
- Stage 2: Analytical (smear processing, screening and interpretation)
- Stage 3: Post-analytical (report generation, call, re-call protocols and patient management)

Beyond correct sampling of the cervix, the quality of the test depends on the subsequent steps: adequate handling and staining of the sample, screening and interpretation. This chapter therefore only deals with Stage 2 and 3 of the cervical screening process as described above.

Demonstration of compliance with standards will include site visit, inspection of all relevant documentation and audit of policies, procedures and records against the standards.

5.2 Organisational Standards

5.2.1: Facilities

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.1.1	Laboratory Areas and Buildings (general standards)	Cytopathology services should be provided in a dedicated laboratory area/facility	Yes	Physical inspection
		The cytopathology laboratory must comply with national, regional and Federal legal requirements		
		The laboratory must be located, constructed and equipped in such a way that all functions can be properly performed within agreed safety standards and comply with national, regional and Federal guidelines and legal requirements All areas should be well lit, well ventilated, quiet and spacious	Yes	Physical inspection
		The screening room, the sample preparation room and the secretarial room should be separate rooms	Yes	Physical inspection
		The specimen preparation area must be equipped with effective exhaust systems and approved biological safety cabinets, together with bench space and sinks	Yes	Physical inspection
		There must be storage cabinets for flammable and toxic chemicals and storage must be carried out in accordance with national, regional and Federal legal requirements	Yes	Physical inspection and records
		Cytotechnologists/medical scientists should have a comfortable ergonomically designed chair with back support and desk space to permit microscopic examination of slides and record keeping	Yes	Physical inspection and records
		Measures should be taken to prevent repetitive strain injuries and other injuries due to ergonomic problems	Yes	Visual inspection of relevant records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.1.2	Equipment for Preparation, Staining and Screening of Cytology Slides	For cervical screening cytology the Papanicolaou stain, (original or modified), is mandatory	Yes	Visual inspection of relevant records
		<p>The equipment required depends on whether staining is automated or manual</p> <p>Equipment used for the preparation of Liquid Based Cytology (LBC) smear tests and automated staining machines/systems and automated screening platforms should be serviced (in accordance with the manufacturer's specifications), including a check of its technical set up and documented service record</p> <p>Internal technical quality assurance (IQA) checks should be carried out routinely and the laboratory should partake in appropriate technical external quality assurance (EQA) schemes and the results should be made available for inspection</p> <p>After staining, cytological material should present well-stained chromatin, differential cytoplasmic counterstaining and cytoplasmic transparency</p>	Yes	Visual inspection of relevant records
5.2.1.3	Microscopes	<p>A high quality binocular microscope should be available for all screening staff and should be serviced (in accordance with the manufacturer's specifications), including a check of its technical set up that includes adequacy of the stage and objectives</p> <p>Details of equipment maintenance schedules and reports must be available for examination by the NCSS</p> <p>For conventional cytology, 4x, 10x and 40x objectives are essential</p> <p>4/5x objectives should be present to allow convenient marking of cells of interest</p> <p>For LBC 20x objectives are required</p>	Yes	Visual inspection of relevant records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.1.4	Record Systems (see also Information Technology Standards)	Screening personnel should enter their cytological results onto a computerised laboratory information management system (LIMS) to allow data management, report generation, audit and quality assessment	Yes	Visual inspection of relevant records
		The LIMS should be operational to recognised national, regional and Federal standards	Yes	Physical inspection and records
		The LIMS should be in a secure facility Access to the LIMS will be by privilege level access control	Yes	Physical inspection and records
		Data storage and data exchange should be in accordance with national, regional and Federal data protection legislation	Yes	Laboratory standard operating procedure
		In relation to provision of services to the NCSS, all data protection issues (storage, access and data transfer) must be compliant with Irish and European legislative instruments: the Data Protection Act 2003 ⁷ . EU Data Protection Directive 95/46/EC (and relevant amendments) ⁸	Yes	Laboratory standard operating procedure

5.2.2 Systems Management (handling and management of cervical smear samples)

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.2.1	Laboratory Preparation	<p>All laboratory processes should have a standard operating procedure (SOP) and be allocated to an appropriate member of staff</p> <p>All SOPs should be controlled documents</p> <p>All personnel should be familiar with health and safety guidelines and procedures in case of emergency</p> <p>The laboratory should comply with all health and safety guidelines and legislation</p>	Yes	Visual inspection of relevant documents
		When delivered, all specimens (slides or vials) should be accompanied by a Cervical Cytology Form having as a minimum, the patient's identification data, date of sampling, requesting physician and clinical information including the appearance of the cervix, method of contraception and stage of menstrual cycle (Appendix 1)	Yes	Laboratory standard operating procedure and records
		Any irregularities concerning the Cervical Cytology Form and/or the cytological specimen should be recorded and resolved if possible in communication with the person/s sending the test	Yes	Laboratory standard operating procedure and records
		After verification of correct correlation of the sample with the corresponding Cervical Cytology Form, both should be labelled with a unique identification number	100%	Laboratory standard operating procedures
		Prior to the assessment of the sample, the patient's screening history should be retrieved from the local laboratory files and/or the NCSS screening database and be made available to the cytotechnologist/ medical scientist	Yes	Laboratory standard operating procedures

	Category	Description of Standard	Standard	Demonstration of Compliance
		Liquid based specimens should be processed according to the manufacturer's instructions	Yes	Laboratory standard operating procedure and records
		The slides should be stained according to a standard Papanicolaou protocol (including control of staining)	Yes	Laboratory standard operating procedure
		The samples should have a cover slip that covers all the cellular material (usually 50 by 24 mm), and labelling should be checked before the slide is screened	Yes	Laboratory standard operating procedure
5.2.2.2	Assessment of the Sample: <ul style="list-style-type: none"> • Initial Assessment • Samples Qualifying for a Second Screening Assessment 			
5.2.2.2.1	Initial Assessment	Manual screening: Primary screening is performed by cytotechnologists/medical scientists	Yes	Laboratory standard operating procedure and records
		Slides should be placed on the mechanical stage holder of the microscope with the label always on the same side	Yes	Laboratory standard operating procedure
		In liquid based specimens, the entire area within the circle must be screened All microscopes used (manual or automated) must have a marking capability	Yes	Laboratory standard operating procedure

	Category	Description of Standard	Standard	Demonstration of Compliance
		Unusual and/or abnormal cells should be marked manually or computer-guided (if applicable)	Yes	Laboratory standard operating procedure and physical inspection
		Repeat samples should be compared with the sample on which the recommendation was given if available	Yes	Laboratory standard operating procedures
		<p>The results should be reported according to the NCSS national standard classification system</p> <p>A statement about the quality of the cervical sample should be included (adequacy and representation)</p> <p>In case of unsatisfactory samples, a repeat smear test should be advised</p>	Yes	Laboratory standard operating procedure and visual inspection of relevant reports
		<p>Conclusion and recommendations, including those for repeat smear tests and referral for gynaecological, colposcopic or histological examinations should be given in accordance with guidelines of the NCSS</p> <p>Use of the NCSS P&R codes in the NCSS Cytology Terminology Translation Table is mandatory (Appendix 3)</p>	Yes	Laboratory standard operating procedures
		Reports must show the identity of the cytotechnologist/medical scientist and/or cytopathologist responsible for the conclusion and recommendation	Yes	Laboratory standard operating procedure and visual inspection of reports
		<p>Automated screening: Automated-assisted screening aims to increase sensitivity and specificity, e.g. by finding small atypical cells, known to be very difficult to detect in manual screening⁹</p> <p>These include both squamous and glandular cells</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Screening performance should increase by the selection of possible atypical cells in images or in fields examined under the microscope</p> <p>By enhancing the effectiveness of slide processing, automation should allow more slides to be screened by the same number of staff, improving processivity and turnaround time</p> <p>There should be a move towards incorporation of automated screening into the existing manual screening procedure</p> <p>With current devices the intention is to replace the manual primary screening step</p> <p>With automated screening a computer-assisted screening platform scans each patient slide, prioritising areas of interest based on the DNA content of individual cells and cell clusters</p> <p>Therefore, when an experienced cytotechnologist/medical scientist reviews the slide on an automated microscope the areas of special interest are clearly marked for review</p> <p>A slide preparation is made from the LBC sample vial and the unique laboratory accession number recorded on the frosted end of the special slide required by the automated screening platform</p> <p>The slide is then stained with a modified PAP stain to enhance the demonstration of DNA content of the squamous cell nuclei</p> <p>The automated screening platform scans each slide and identifies 22 fields out of a possible 120 that contain cells of interest</p> <p>These fields may or may not contain abnormal cells</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>The slide contains fiducial marks to enable the automated scanner to mark electronically the location of any cells of interest on each slide and store those co-ordinates against the unique laboratory accession number</p> <p>The cytotechnologist/medical scientist reviews those 22 fields using an automated microscope and reports 'no intraepithelial lesion/no abnormal cells seen' if all fields are judged to be normal</p> <p>If the cytotechnologist/medical scientist judges cells in any field to be suspicious, or has concerns that the slide may have insufficient squamous material present for evaluation, the entire slide is reviewed either on the automated microscope or a conventional microscope, and the abnormal cell groups marked (either electronically or manually with marker) for further review by a pathologist</p> <p>All slides reviewed on the automated microscope as a primary screening step and reported as 'no intraepithelial lesions/no abnormal cells seen' should have a full manual rapid review performed on a conventional microscope as a quality control measure, i.e. a minimum 120 seconds screen of the complete cellular area of the slide either vertically or horizontally with minimal overlap of each row</p> <p>Exceptions to this are the cases described in 'Assessment of Sample'; samples qualifying for a second screening assessment, which require a full manual re-screen by a cytotechnician/medical scientist. (Cases of first normal cytology after abnormal cytology or histology, clinically suspect cases i.e. abnormal discharge, PMB, PCB, or suspicious cervix, samples from post menopausal women with atrophic changes, difficult to classify smears, and possibly inadequate samples)</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.2.2.2	Samples Qualifying for a Second Screening Assessment	<p>The following cases should be re-screened by a second cytoscreener/medical scientist:</p> <ul style="list-style-type: none"> • Samples with inadequate/unsatisfactory quality • Samples with any cellular abnormalities leading to a specific recommendation • Samples with previous recommendations for a repeat or reference for gynaecological, colposcopic and histological examinations <p>Other high-risk samples according to clinical information or patient history, including:</p> <ul style="list-style-type: none"> • First normal cytology after abnormal cytology or histology • Samples of clinical suspect cases (abnormal discharge, post menopausal bleeding, abnormal or suspicious cervix) • Negative samples prior to a sample classified as abnormal and initiating further clinical treatment (maximum 5 years) • Samples of post menopausal women with atrophic, difficult to classify, probably abnormal cells with an advice for a repeat sample after short term oestrogen treatment • Quality control related slides 	Yes	Laboratory standard operating procedures and records
		The procedures must be carried out according to NCSS standards and must be performed either by one cytotechnologist/medical scientist and/or one cytopathologist or two cytotechnologists/medical scientist	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.2.3	Workload Requirements (primary screening)	<p>A maximum workload in terms of number of slides per day to be screened should be established within the laboratory and should depend on the method of sample preparation (conventional cytology or liquid based)</p> <p>Additional work done by the cytotechnologist/ medical scientist including staining, quality control procedures and other activities should be taken into account</p> <p>A maximum official workload time limit of 6 hours per day (for all screening events)</p> <p>The cytotechnologist/medical scientist must screen:</p> <p>a) In order to maintain proficiency a minimum of 3,000 smear tests per year must be screened per cytoscreener /cytotechnologist¹⁰</p> <p>b) In order to maintain processivity, up to 12,000 LBC smear tests per annum can be screened¹¹. It is recommended that 6,000 primary screening smear tests and 6,000 QC smear tests should be examined (BSCC guidelines 2009: in preparation –personal communication)</p> <p>c) In order to maintain quality, accuracy and safety in the screening process, a maximum of 60-80 LBC smear tests per day must not be exceeded (BSCC guidelines 2009: in preparation - personal communication)</p> <p>It is advised:</p> <ul style="list-style-type: none"> • That continuous screening not exceed 2 hours without a break • That primary screening does not exceed 6 hours per day <p>A record of primary screening assessments of individual cytotechnologists/medical scientists and the final signed results should be kept and be retrievable for quality control purposes/audit/inspection</p>	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		A consultant cytopathologist should screen a minimum of 750 smear tests per year	Yes	Laboratory records
5.2.2.4	Archiving of Cervical Cytology Forms, Samples, Slides and Reports	<p>Laboratory staff are responsible for proper administration and archiving of Cervical Cytology Forms, samples and written and/or computerised reports</p> <p>Procedures must comply with national, regional and Federal legislation, including that relating to patients' data security</p>	Yes	Laboratory standard operating procedures and records
		Cervical Cytology Forms: Cervical cytology forms or their electronic equivalent should be stored for a minimum of 30 years ¹²	Yes	Laboratory standard operating procedures and records
		<p>Samples: All slides must be stored for a minimum of 10 years in conditions adequate for preservation</p> <p>This is important for patient management as well as quality control and audit</p> <p>Sample vials should be stored for 3 months</p>	Yes	Laboratory standard operating procedures records and Royal College of Pathologists guidelines
		<p>Reports: The storage of written or computerised screening reports is primarily dependent on national, regional and Federal regulations and must be in compliance with Irish/EU Data protection legislation and instruments</p> <p>It is recommended that the reports should be stored for a minimum of 30 years</p>	Yes	Laboratory standard operating procedures and records and Royal College of Pathologists guidelines

5.2.3 Recording of Results and Results Management

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.3.1	Recording of Results	<p>There must be an adequate record keeping system, preferably computerised</p> <p>It must be accurate and easily accessible to all laboratory personnel</p>	Yes	Laboratory standard operating procedures and records
		<p>The record system should include at least:</p> <ul style="list-style-type: none"> • Patient identification data (in accordance with NCSS minimum data set – Appendix 2) • Name and address of the laboratory • Laboratory unique accession number • Laboratory ID number • Date of smear test sampling • Date of receipt of the smear test in the laboratory • Date of NCSS validation <p>Indication for examination: screening, follow-up (history) or clinical indication</p> <p>Type of examination: cytological or virological</p> <p>The results of the laboratory examination in accordance with the current standard classification system, NCSS P&R codes and data format, including a judgment of the quality/adequacy of the preparation</p> <p>Advice for repeat sample or referral</p> <p>Date of the final report, and name of the person or persons who screened the sample and authorised the report</p>	Yes	Laboratory standard operating procedure and records
		<p>The European guidelines recommend that cytology results should be reported using a nationally agreed-upon terminology that is at least translatable into the Bethesda system¹³</p> <p>Thus all reports must be reported according to the NCSS Cytology Terminology Translation Table (Appendix 3)</p>	Yes	Laboratory standard operating procedure and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Further requirements are that the information system should:</p> <ul style="list-style-type: none"> • 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, biopsies, reasons for biopsies not being taken • Provide the data necessary for evaluation of the population screening program <p>All or a selection of the recorded data mentioned above must be forwarded to the NCSS, the National Cancer Registry, according to current directives by the NCSS, and be held at the screening centre for its own evaluation</p>	Yes	Laboratory standard operating procedures and records
5.2.3.2	Authorisation of Results	<p>Every report must be checked for inconsistencies before authorisation and may then be manually or electronically authorised</p> <p>Depending on national, regional and Federal legal requirements, the cytological reports may be signed (electronically or manually) either by cytotechnicians or cytopathologist/medical scientist in charge</p>	Yes	Laboratory standard operating procedures and records
5.2.3.3	Laboratory Response Time (turnaround time)	<p>All efforts should be directed to report eligible smear test results within 10 working days counted from specimen validation by the NCSS</p> <p>If the above-mentioned time limit cannot be met, the NCSS must be informed</p> <p>No category of urgent smear test exists within the screening programme</p>	<p>Minimum ≥80%</p> <p>Achievable ≥95%</p>	Laboratory standard operating procedures and records

5.2.4 Quality Management

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.1	Internal Quality Management	The laboratory must have in place and have documentary evidence that a quality management system exists which will help to ensure optimal patient care and minimise the risk of liability claims	Yes	Quality Manual, laboratory standard operating procedures and records
5.2.4.1.1	Laboratory Quality Management	<p>The laboratory must designate a person who, in addition to daily work in cervical screening, is trained in collecting and managing documents, process descriptions and manuals, and is either a trained quality manager or has access to a quality manager</p> <p>A Quality Manual should be in place and subject to examination by the NCSS</p>	Yes	Quality Manual, laboratory standard operating procedures and job descriptions
		<p>General management documents should include:</p> <ul style="list-style-type: none"> • Overview of the screening laboratory • Description of personnel in the organisation (including levels of competence and responsibilities of each person, lines of communication and infrastructure) • Structure of management documents 	Yes	Laboratory standard operating procedures and records
		<p>The process network should include:</p> <ul style="list-style-type: none"> • Customer definition • Management processes • Core processes • Processes of improvement and resources 	Yes	Quality Manual and laboratory standard operating procedures
		<p>The detailed process description should include:</p> <ul style="list-style-type: none"> • Step-wise slide screening protocols • Description of personnel responsible for specific processes • Methods of detecting and minimising errors (e.g. checklists/IQA) 	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		All staff must be informed and trained in relation to any changes to protocols which should be reviewed every 2 years (as a minimum) and adjusted according to technology assessment and/or continuing medical/professional education of all personnel	Yes	Laboratory standard operating procedures and training records
5.2.4.1.2	Analytical Quality Management (cytopathology)	<p>Accuracy of screening must be monitored and managed with approved protocols/procedures for defining and dealing with poor performance</p> <p>Measurements of screening accuracy should also account for variations in accuracy of the final report, which must also be monitored</p> <p>Methods used for quality assessment should incorporate a process of continuous dialogue within the lab and improve individual screening accuracy</p>	Yes	Laboratory standard operating procedure and records
		<p>There are 3 main methodologies for internal quality control of cytology screening:</p> <ul style="list-style-type: none"> • Methods based on re-screening of slides • Methods based on monitoring screening detection and reporting rates • Methods based on correlation of cytology with clinical/histological outcome 	Yes	Laboratory standard operating procedure and records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.1.3	Internal Quality Control Based on Re-screening of Slides	<p>Multiple screening includes prospective and retrospective variants</p> <p>Internal quality control of cytology screening largely depends on re-screening slides initially screened as negative or inadequate</p> <p>Procedures must be designed to detect potential false negatives/false positives before final results are reported, in which case they have the potential to improve patient care as well as individual and laboratory accuracy</p> <p>Procedures must also be designed to monitor accuracy of screening, either by measuring sensitivity and specificity of screening against the final result or by monitoring detection rates of cytological abnormalities</p>	Yes	Laboratory standard operating procedures
		<p>The following re-screening procedures are proposed as contributing to the sensitivity of cytological screening or to general quality control:</p> <ul style="list-style-type: none"> • Rapid reviewing of smear tests initially reported as 'negative' or 'inadequate' • Rapid preview/pre-screening of all smear tests • Targeted re-screening of specific patient groups • Seeding abnormal cases into the screening pools • Seeding abnormal cases into the re-screening pools • Retrospective re-screening of negative cervical cytology specimens from patients with a current high grade abnormality (targeted reviewing) • Automated re-screening of smear tests initially reported as negative 	Yes	Laboratory standard operating procedures

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.1.4	Rapid Review (RR)	<p>Consists of re-screening quickly, for 120 seconds, all slides that are originally reported as within normal limits (negative) by manual screening in order to identify those that might contain missed abnormalities</p> <p>Suspect smear tests are subsequently fully checked by an experienced cytotechnologist/medical scientist or cytopathologist who determines the final report</p> <p>Some laboratories may choose to perform double screening as part of their internal quality control</p>	Yes	Laboratory standard operating procedures and records
5.2.4.1.5	Rapid Preview/ Pre-screening (RP)	RP is defined as partial microscopic inspection of a slide during a limited duration (120 seconds) before full routine examination	Yes	Laboratory standard operating procedures and records
5.2.4.1.6	Targeted Re-screening of Specific Patient Groups	<p>Selects smear tests from patients known to be at higher risk of having cytological abnormalities, and is done by a senior cytotechnologist/medical scientist or cytopathologist</p> <p>The smear tests selected for targeted re-screening may be those with:</p> <ul style="list-style-type: none"> • A history of abnormal bleeding/spotting, e.g. intermenstrual, post coital, post menopausal • A history of recurrent cervical/vaginal infections • Previous abnormal smear tests • An abnormal cervix appearance on colposcopy 	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.1.7	Automated Re-screening	<p>Automated-assisted screening aims to increase sensitivity and specificity, e.g. by finding small atypical cells, known to be very difficult to detect in manual screening</p> <p>These include both squamous and glandular cells</p> <p>Screening performance should increase by the selection of possible atypical cells in images or in fields examined under the microscope</p> <p>A slide preparation is made from the LBC sample vial and the unique laboratory accession number recorded on the frosted end of the special slide required by the automated screening platform</p> <p>The slide is then stained with a modified PAP stain to enhance the DNA content of the squamous cell nuclei</p> <p>The automated screening platform scans each slide and identifies 22 fields (22 fields of view: 22 FOVs) out of a possible 120 that contain cells of interest</p> <p>These fields may or may not contain abnormal cells</p> <p>The slide contains fiducial marks to enable the automated scanner to mark electronically the location of any cells of interest on each slide and store those co-ordinates against the unique laboratory accession number</p> <p>The cytotechnologist/medical scientist reviews those 22 fields using an automated microscope and reports 'no intraepithelial lesion/negative/'no abnormality detected' (NAD) if all fields are judged to be normal</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>If the cytotechnologist/medical scientist judges cells in any field to be suspicious, or has concerns that the slide may have insufficient squamous material present for evaluation, the entire slide is reviewed either on the automated microscope or a conventional microscope, and the abnormal cell groups marked (either electronically or manually with marker) for further review by a pathologist</p> <p>Exceptions to this are the cases described in 'Assessment of Sample' samples qualifying for a second screening assessment which require a full manual re-screen by a cytotechnician/medical scientist</p>		
5.2.4.2	Internal Quality Control Based on Screening Detection and Reporting Rates			
5.2.4.2.1	Monitoring Primary Screening Detection Rates	<p>Accuracy of primary screening must be monitored without formal slide review procedures by measuring the percentages of the main types of cytological findings (high grade, low grade, inadequate, undetermined, negative) detected by individual screeners in comparison with the laboratory as a whole and local or national standards</p> <p>This data must be supplied to the NCSS</p>	Yes	Laboratory standard operating procedures and records
5.2.4.2.2	Monitoring Pathologists' Reporting Rates	Pathologists' reporting rates for inadequate low grade, inadequate high grade and results must be made available to the NCSS	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.2.3	Internal Quality Control Based on Correlation with Clinical/ Histopathological Outcome	<p>Correlation of cytology with clinical outcome is mandatory</p> <p>Correlation data must be derived in co-operation with the NCSS</p>	Yes	Laboratory standard operating procedures and records
		<p>Cyto-clinical correlation: Contact with clinicians and access to cancer registry data is essential</p> <p>Cyto-histological correlation is a major tool in internal education for both cytology and histology</p> <p>The laboratory must have a clearly defined policy regarding the methods used for cyto-histological correlation</p> <p>The laboratory must compare all abnormal cytology reports with subsequent histopathology and determine the causes of any discrepancy</p> <p>The correlation process must be documented in the laboratory quality assurance programme</p> <p>Positive predictive value for high grade cytology provides a measure of accuracy of cytology reporting and must be provided to the NCSS</p>	Yes	Laboratory standard operating procedures, policy and records
		<p>Cyto-virological correlation: If HPV testing can be used as a triaging test for patients with diagnosis of atypical squamous cells of undetermined significance (ASC-US), correlation analysis must be provided to the NCSS</p>	Yes	Laboratory standard operating procedure and records
		<p>Audit of interval cancers: Re-screening of smear tests from patients with negative or low grade test results less than 3-5 years before the diagnosis of invasive cancer is mandatory</p>	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.2.4	Internal Continuing Education	<p>Discussion of difficult cases between cytotechnologists/medical scientists and/or cytopathologists is strongly advised</p> <p>There should be a supply of up-to-date cytology textbooks available for consultation in the cytopathology laboratory</p> <p>The laboratory should have a subscription or online access to one or more of the cytology journals</p> <p>Cytotechnologists/medical scientists and cytopathologists should participate in regular meetings on review cases</p> <p>Performance evaluations should be used to identify those with deficiencies in knowledge and skills who would benefit from a more directed educational programme</p>	Yes	Training records and laboratory records
5.2.4.3	External Quality Management			
5.2.4.3.1	External Continuing Education	<p>Ongoing education is a requirement for proficiency in cytology</p> <p>This requirement can be fulfilled by:</p> <ul style="list-style-type: none"> • Attending workshops and symposia • 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 	Yes	Inspection of relevant documentation in relation to continuing professional development, (CPD)

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.4.3.2	External Quality Control of Screening Skills	<p>Results of proficiency testing and continuing professional education must be made available to the NCSS</p> <p>Copies of results from the following bodies should be provided to the NCSS:</p> <ul style="list-style-type: none"> • The European Federation of Cytology Societies EFCS aptitude test (QUATE test)¹⁴ • Voluntary proficiency tests • External quality assurance via test cases • Test slide results 	Yes	Laboratory records
5.2.4.3.3	Accreditation	<p>The laboratory must be ISO 15189 compliant</p> <p>Evidence of compliance with ISO 15189 from the relevant competent accrediting authority must be provided to the NCSS</p> <p>Any change in accreditation status must be immediately notified to the NCSS</p>	Yes	Certification
5.2.4.4	Responsibilities for Quality Control			
		The laboratory manager is responsible for the quality system within the laboratory and is responsible for the approval of working guidelines and procedures in the laboratory providing services to the NCSS	Yes	Quality Manual and job descriptions

5.2.5 Information Technology

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.5.1	Infrastructure	A computerised laboratory information management system (LIMS) must be installed in the laboratory	Yes	Documentary evidence of system validation
		The system must be networked in an accessible form	Yes	Documentary evidence of system validation
		The LIMS should be interfaced with the NCSS CervicalCheck information management system (IMS)	Yes	Documentary evidence of system validation
5.2.5.2	Training	Training in the use of the LIMS should be available to all staff working on NCSS sourced material A training log for LIMS users working on NCSS smear tests must be made available to the NCSS	Yes	Documentary evidence of training and laboratory records
		Concurrent user licenses should be available to enable efficient data entry and retrieval	Yes	Documentary evidence of user licences
5.2.5.3	Utilisation	The LIMS should generate data pertinent to the NCSS based on requests and clinical material received from the NCSS	Yes	Relevant reports
		The LIMS should be used for specimen management of NCSS smear tests and reports	Yes	Laboratory standard operating procedures
		The LIMS should be used for data storage and back up of all relevant data pertinent to NCCS smear tests	Yes	Documentary evidence of system validation and relevant records
		The LIMS should be used to enter test results	100%	Laboratory standard operating procedures

5.2.5 Information Technology

	Category	Description of Standard	Standard	Demonstration of Compliance
		The LIMS should be used to enter follow-up and management plans	100%	Laboratory standard operating procedures
		The LIMS should be able to generate periodic mandatory audit returns to the NCSS	100%	Laboratory standard operating procedures and reports

5.2.6 Staffing and Organisation

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.6.1	Cyto-technologist/ Medical Scientist/Cervical Screening Technician	<p>Qualifications required for this post must be in keeping with national requirements to practice</p> <p>In cervical cancer screening the main task of cytotechnologists/medical scientists is the primary screening of cervical smear tests of women without specific symptoms</p> <p>To reach the goal of correctly identifying precursor lesions, administrative tasks, technical laboratory tasks, monitoring of follow-up results and activities related to quality assurance, and archiving slides and results are included in the working process of cytotechnologists/medical scientists</p> <p>Training should be provided for all procedures</p> <p>Participation in relevant quality control and assurance programmes is required</p>	Yes	Job descriptions and training records and Quality Manual

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Administrative tasks include contact with smertakers, general practitioners (GPs), gynaecologists, other laboratories and hospitals</p> <p>Cytotechnologists/medical scientists must respect patient confidentiality and must be trained in country-specific legal requirements</p> <p>The cytotechnologist/medical scientist must be able to undertake technical laboratory tasks including handling specimens, carrying out relevant laboratory techniques and adhering to health and safety procedures</p> <p>The cytotechnologist/medical scientist must participate in continuing education, feedback sessions and quality control programmes are mandatory for all cytotechnologists/medical scientists</p>	Yes	Job descriptions and training records and Quality Manual
5.2.6.2	Senior Cytotechnologist/ Medical Scientist	<p>Qualifications required for this post must be in keeping with national requirements to practice</p> <p>The senior cytotechnologist/medical scientist will be responsible for internal quality control of all steps within the screening process, including administration, staining and microscopic cytodiagnosis, and should be familiar with external quality protocols</p> <p>A minimum of 5 years experience in gynaecological cytology is required</p> <p>Participation in relevant quality control and assurance programmes is required</p>	Yes	Job descriptions and training records and CPD records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Specific tasks of the senior cytotechnologists/medical scientists will be:</p> <ul style="list-style-type: none"> • Daily management of the cytopathology laboratory, including personnel affairs and annual staff review • Direction of laboratory technicians in sample preparation • Assistance and supervision of lower-level cytotechnologists/medical scientists in the performance of analytical procedures and tests • Communication with the cytopathologist/medical scientist to whom they are responsible • Management of periodical circulation and discussion of special cases among cytotechnologists/medical scientists, and between cytotechnologists/medical scientists and cytopathologists • Regular forwarding of cytology reports to the NCSS and the National Cancer Registry Ireland (NCRI) according to current directives issued by the NCSS • Procurement and ongoing maintenance of equipment • Assistance in the maintenance of supplies, equipment, and instruments, and in the day-to-day function of the laboratory • Assistance of scientists in the same programme area • Oversee training of laboratory personnel 	Yes	Job descriptions and training records
5.2.6.3	Other Technical Laboratory Staff (Medical Laboratory Assistants)	<p>Technical laboratory personnel must be educated and experienced in accordance with their role</p> <p>Technical personnel must be able to:</p> <ul style="list-style-type: none"> • Handle relevant laboratory techniques according to guidelines and procedure descriptions • Adhere to health and safety procedures; and take part in specific quality control programmes 	Yes	Job descriptions and training records and CPD records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.6.4	Cytopathologist	<p>Qualifications required for this post must be in keeping with national requirements to practice</p> <p>The cytopathologist is responsible for the final assessment of cervical samples</p> <p>Specific tasks of the cytopathologist with respect to cervical cytology are:</p> <ul style="list-style-type: none"> • Assessment and authorisation of all cases referred to the clinician for further follow-up or treatment (see 'Assessment of the Sample' (5.2.2.2)) • Resolving discrepancies between the diagnoses of cytotechnologists/medical scientists, if those diagnoses would lead to differing recommendations to the requesting physician • Review and intra-laboratory discussion of cases showing serious discrepancy between the cytological and/or histological follow-up • Communication with gynaecologists and other sample takers with respect to specific cases • Communication and education of cytotechnologists/medical scientists with respect to difficult cases and cases with discrepant cytohistological results • Guidance and support for adequate (continuing) education of cytotechnologists/medical scientists and junior medical staff • Participation in quality assurance programmes including preparation of an annual report concerning the outcomes of the cytological and histological follow-up examinations • Participation in multidisciplinary team meetings (MDTs) • Participation in national cervical screening performance review initiatives by the NCSS 	Yes	Job descriptions and training records and continuing medical education (CME) records

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.6.5	Administrative Personnel	Secretarial and administrative employees: <ul style="list-style-type: none"> • Must be educated in relevant medical terminology • Must be able to work with current word processors and with automated database systems • Must respect patient confidentiality 	Yes	Job descriptions and training records
5.2.6.6	Final and Overall Responsibility	Final responsibility is contingent on national legal regulations and responsibility to the NCSS The pathologist in charge (certified for cytopathology) is responsible for the provision of cytology services to the NCSS	Yes	Job descriptions and training records

5.2.7 Governance

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.7.1	Governance	The cytopathology service should have meetings with the NCSS and participation in Clinico Pathological Conferences (CPC)/ Multidisciplinary Team (MDT) meetings	Yes	Attendance records and minutes of meetings
		Management reports including personnel attending and operational decisions need to be communicated to the NCSS	Yes	Minutes of meetings and reporting systems
		The service should have regular CPC meetings on a monthly basis	Yes	Attendance records and minutes of meetings

5.2.8 Administrative Standards

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.8.1	Turnaround Times (see also KPIs 5.2.9)	Turnaround time for cytology smear tests should be 10 days or less	Minimum ≥80% Achievable ≥95%	Cytology returns and LIMS audit returns of turnaround times
5.2.8.2	Smear Tests Regarded as Being Unsatisfactory / Inadequate	A quarterly unsatisfactory/inadequate rate must be calculated and provided to the NCSS from each participating laboratory	Yes	Cytology returns (Cyto1 form)
5.2.8.3	High Grade Pick-up Rates	A quarterly high grade pick-up rate report must be provided to the NCSS	Yes	Cytology returns (Cyto1 form)
5.2.8.4	Positive Predictive Value (PPV) Analysis	Quarterly compliance and correlation data between cytological diagnosis of high grade disease and histologically proven high grade CIN must be provided to the NCSS	Yes	Cytology returns (Cyto1 form)
5.2.8.5	Alterations to System Procedures, Analysis and Reporting	Any changes to system procedures, analysis, reporting or any aspect of the cervical screening cytology service provided to the NCSS must be agreed previously with the NCSS and any changes advised in writing to the NCSS	Yes	Reports to NCSS/documentated evidence of change process and validation

5.2.9 Key Performance Indicators for Cytopathology

The purpose of key performance indicators (KPIs):

1. Constantly analyse performance
2. Spot trends and variations
3. Complete annual returns
4. Cross reference data from multiple sources
5. Produce rapid analysis
6. Improve performance

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.9.1	Laboratory Turnaround Times	Turnaround time must be 10 working days from receipt of specimen to the authorisation of the report	Minimum $\geq 80\%$ Achievable $\geq 95\%$	Cytology returns (Cyto1 form)
5.2.9.2	Laboratory Sensitivity Data	Sensitivity data must be supplied to the NCSS on a quarterly basis and must include the following data: <ul style="list-style-type: none"> • Total number of samples • Number of high grade cases • Sensitivity analysis for high grade cases • Total number of missed cases high grade (high grade false negative rate) • Total numbers of cases with an abnormality • Sensitivity analysis for all abnormalities reported • Total number of missed cases for any abnormality (overall false negative rate) 	Yes	Cytology returns (Cyto1 form)

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.9.3	Laboratory Result Grade Profile	<p>Performance characteristics in relation to grade result profiles:</p> <p>Data must be returned to the NCSS on a quarterly basis in relation to:</p> <ul style="list-style-type: none"> • Total number of samples • Laboratory results grade (number of samples and %) for: <p>01 Inadequate/unsatisfactory</p> <p>02 Negative/NAD</p> <p>03 Borderline /ASC-US/ASC-H 04 Mild dyskaryosis/LSIL</p> <p>05 Moderate dyskaryosis/HSIL</p> <p>06 Severe dyskaryosis/HSIL</p> <p>07 Severe dyskaryosis/invasive carcinoma</p> <p>08 Borderline glandular abnormalities/atypical glandular cells of undetermined significance (AGUS)/AGC/AGH</p> <p>09 Glandular neoplasia/AIS</p> <p>10 Broken or damaged or rejected vials/specimens (see criteria below)</p>	Yes	Cytology returns (Cyto1 form)
5.2.9.4	Sensitivity Data for All Scientific Staff	<p>Data in relation to scientific staff sensitivity performance must be returned on a quarterly basis to the NCSS</p> <p>Data must include:</p> <ul style="list-style-type: none"> • The number of all records/cases • The number of laboratory result grades and primary screener result grades that have been completed/filled in • High grade sensitivity (reported as abnormal %) <p>Screener 1</p> <p>Screener 2</p> <p>Screener 3</p> <p>Screener 4</p> <p>etc.</p>	Yes	Records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> All abnormalities sensitivity (reported as abnormal %) <p> Screener 1 Screener 2 Screener 3 Screener 4 etc. </p> <p>The number of high grade cases reported</p> <p>Sensitivity table (for high grade) to include:</p> <p> a) Missed cases b) Cases reported as abnormal c) Total number of cases </p> <p>for:</p> <p> Screener 1 Screener 2 Screener 3 Screener 4 etc. </p> <p>(Expressed as whole numbers of cases and %)</p> <p>Sensitivity table (for all abnormalities) to include :</p> <p> a) Missed cases b) Cases reported as abnormal c) Total number of cases </p> <p>for:</p> <p> Screener 1 Screener 2 Screener 3 Screener 4 etc. </p> <p>(Expressed as whole numbers of cases and %)</p> <p>Laboratory result grade or primary screener result grade which have NOT been filled in/completed</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.9.5	Specificity for All Scientific Staff	<p>Data in relation to scientific staff specificity performance must be returned on a quarterly basis to the NCSS</p> <p>Data must include:</p> <ul style="list-style-type: none"> • The number of all records/cases • The number of laboratory result grades and primary screener result grades that have been completed/filled in • High grade specificity (reported as a %) <p>Screener 1 Screener 2 Screener 3 Screener 4 etc.</p> <ul style="list-style-type: none"> • All abnormalities specificity (reported as a %) <p>Screener 1 Screener 2 Screener 3 Screener 4 etc.</p> <p>The total number of smear tests screened</p> <p>Specificity table (for high grade) to include:</p> <p>a) False positive b) Specificity c) Total number of cases</p> <p>for:</p> <p>Screener 1 Screener 2 Screener 3 Screener 4 etc.</p> <p>(Expressed as whole numbers of cases and %)</p>	Yes	Records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Specificity table (for all abnormalities) to include :</p> <p>a) False positive</p> <p>b) Specificity</p> <p>c) Total number of cases</p> <p>for:</p> <p>Screeners 1</p> <p>Screeners 2</p> <p>Screeners 3</p> <p>Screeners 4</p> <p>etc.</p> <p>(Expressed as whole numbers of cases and %)</p> <p>Laboratory result grade or primary screener result grade which have NOT been filled in/completed</p>		
5.2.9.6	Cytopathologist Workload	<p>Data in relation to cytopathologist workload must be returned on a quarterly basis to the NCSS</p> <p>Data must include:</p> <ul style="list-style-type: none"> • The name of the cytopathologist (identified by initials) • Total number of samples reported • Total number of NCSS derived samples expressed as a total of all smear tests reported by that cytopathologist in the laboratory 	Yes	Cytology returns (Cyto1 form)
5.2.9.7	Reporting Grade Analysis	<p>On a quarterly basis the NCSS must be provided with data on the following (whole numeric and %):</p> <ul style="list-style-type: none"> • Unsatisfactory • Negative • Low grade • High grade • Glandular 	Yes	Cytology returns (Cyto1 form)

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.9.8	Histopathology/ Cytopathology Correlation	<p>On a quarterly basis, data must be supplied to the NCSS in relation to:</p> <ul style="list-style-type: none"> Correlation between histopathology and cytology in relation to: <ul style="list-style-type: none"> High grade smear tests Total biopsy number correlated Number of smear tests confirmed by histopathology Positive predictive value (PPV) for cytopathology Results of external quality assurance (EQA) scheme analysis Results of technical external quality assurance (TEQA) scheme analysis 	Yes	Cytology returns (Cyto1 form)

5.2.10 Communication

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.10.1	Other Laboratories	<p>The laboratory/ies should make relevant clinical information and follow-up data available to other laboratories taking part in CervicalCheck</p> <p>All communications are confidential</p>	Yes	Laboratory records
	General Practitioners (primary care), Gynaecologists and Other Smeartakers	<p>Smeartakers must provide the essential information using the standard cervical cytology form</p> <p>Gynaecologists should make relevant clinical information and follow-up data available to the laboratories taking part in CervicalCheck</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
5.2.10.2	Health Agencies and Authorities	<p>Cytological and histological records must be sent at regular intervals to the NCSS and/or cancer registry that is responsible for the monitoring of screening programmes</p> <p>This condition is mandatory and should include all records irrespective of indication for the examination, status of the woman, the smearer or the laboratory</p> <p>The laboratories should receive reports with the results of process and impact evaluation of screening from the NCSS</p>	Yes	Laboratory records and reports

5.3 Clinical Management Standards

Cytology terminology must include terms on the NCSS Cytology Terminology Translation Table (Appendix 3).

The table presents Bethesda terminology, BSCC terminology (1986), management recommendations and a glossary of terms¹⁵.

Management recommendations must be strictly adhered to in all cases.

Category of Diagnosis (Bethesda)	Category of Diagnosis (BSCC)	Clinical Management Recommendation	Standard	Demonstration of Compliance
Unsatisfactory/ Inadequate	Unsatisfactory/ inadequate	<p>Repeat smear test in 3 months</p> <p>Refer to colposcopy after 3 consecutive unsatisfactory smear tests</p> <p>Refer to colposcopy if first unsatisfactory/ inadequate after having treatment</p> <p>Refer to colposcopy if indicated by the cytopathologist (<i>refer for specialist gynaecological opinion</i>)</p> <p>Refer to colposcopy – any 3 smear test results that are not normal in 10 years</p>	Yes	Cytology returns (Cyto1 form) and records
Negative/NAD	Negative/NAD	<p>Routine re-call (every 3 years 25-44, and every 5 years 45-60)</p> <p>Regardless of age, women must have two negative/NAD results at 3 yearly intervals before going onto a 5 year screening interval</p> <p>Annual re-call (if HIV+/post organ transplant/on renal dialysis/post DES exposed) from aged 20</p> <p>If this is the first smear test following a result or treatment for ASC-US or LSIL – repeat in 6 months. A further 2 NAD smear tests are required at least 6 months apart (at 12 and 18 months) before the woman may return to routine re-call</p>	Yes	Cytology returns (Cyto1 form) and records

Category of Diagnosis (Bethesda)	Category of Diagnosis (BSCC)	Clinical Management Recommendation	Standard	Demonstration of Compliance
		<p>If this is the first smear test following a result or treatment for HSIL/AIS, repeat smear tests at 6 and 12 months and then annually for 9 years (10 years in total)</p> <p>For women on routine re-call for at least 10 years prior to hysterectomy and no CIN in the sample at hysterectomy, no vault cytology is required</p> <p>For women with less than 10 years routine re-call and no CIN at hysterectomy, a sample should be taken from the vaginal vault 6 months after surgery and there should be no further cytology follow-up if it is negative (NAD)</p> <p>For women with completely excised CIN at hysterectomy, a sample should be taken from the vaginal vault at 6, 12 and 18 months after surgery and there should be no further cytology follow-up if all are negative (NAD)</p> <p>For women with incomplete or uncertain excision of CIN, follow-up should be conducted as if the cervix were still in situ</p> <p>Refer to colposcopy opinion if suspicious cervix (a specialist gynaecological referral is optimal)</p>		

Category of Diagnosis (Bethesda)	Category of Diagnosis (BSCC)	Clinical Management Recommendation	Standard	Demonstration of Compliance
Atypical Squamous Cells of Undetermined Significance (ASC-US)	Borderline nuclear abnormality (BNA) squamous or HPV	<p>Repeat smear test in 6 months</p> <p>Refer to colposcopy if first smear test after having treatment for CIN</p> <p>Refer to colposcopy after 3 consecutive BNA (squamous), ASC-US</p> <p>Refer to colposcopy – any 3 smear test results that are not normal in 10 years</p> <p>Refer to colposcopy – if ASC-US within 3 smear tests of a LSIL smear event</p>	Yes	Cytology returns (Cyto1 form) and records
Atypical Squamous Cells, Favour Neoplastic Process (ASC-H)		Refer to colposcopy	Yes	Cytology returns (Cyto1 form) and records
Low Grade Squamous Intraepithelial Lesion (LSIL)	Mild dyskaryosis	<p>Repeat smear test in 6 months</p> <p>Refer to colposcopy after 2 consecutive mild dyskaryosis smears</p> <p>Refer to colposcopy – single mild dyskaryosis/LSIL after treatment in colposcopy and has not returned to routine re-call</p> <p>Refer to colposcopy – any 3 smear test results that are not normal in 10 years</p> <p>Refer to colposcopy on the first LSIL result in HIV+/post-organ transplant/on renal dialysis/post-DES exposed</p>	Yes	Cytology returns (Cyto1 form) and records

Category of Diagnosis (Bethesda)	Category of Diagnosis (BSCC)	Clinical Management Recommendation	Standard	Demonstration of Compliance
High Grade Squamous Intraepithelial Lesion (HSIL)	Moderate dyskaryosis	Refer to colposcopy	Yes	Cytology returns (Cyto1 form) and records
High Grade HSIL	Severe dyskaryosis	Refer to colposcopy	Yes	Cytology returns (Cyto1 form) and records
Query Squamous Cell Carcinoma	Query squamous cell carcinoma	Refer to colposcopy	Yes	Cytology returns (Cyto1 form) and records
Atypical Glandular Cells (AGC)/Atypical Glandular Cells, Favour Neoplastic Process (AGH)	Borderline nuclear abnormality (glandular)	Refer to colposcopy	Yes	Cytology returns (Cyto1 form) and records
Query Glandular Neoplasia/ Adenocarcinoma (AIS)	Query glandular intraepithelial neoplasia (GIN)/ AIS	Refer to colposcopy	Yes	Cytology returns (Cyto1 form) and records
Broken/Damaged/ Expired Vial (see criteria for sample rejection below)	Broken/ damaged/ expired vial	Repeat smear test in 3 months	Yes	Cytology returns (Cyto1 form) and records

Categories of Rejection	Rejection Categories	Actions Required	Standard	Demonstration of Compliance
Rejected Vials/Specimens	See 'Reject or Return to Smear taker' list below	Return to the sample originator	Yes	Record of samples rejected

Reject or Return to Smearmaker:

- Expired smear sample
- Expired vial
- No patient name on vial
- No patient name on Cervical Cytology Form
- No sample received – please submit sample vial
- No Cervical Cytology Form received
- Sample/form mismatch – (on surname and date of birth [DOB])
- Illegible form
- Illegible sample label
- Empty vial
- Programme ineligible sample
- Incorrect sample preservative in vial
- Form/sample fails minimum acceptance criteria
- No patient consent or indicator of consent

Check/Follow-up:

- Spelling/numerical mistakes on demographics
- Minor DOB mismatch
- No smearmaker ID

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Appendix 1: Cervical Cytology Form (sample)

Cervical Cytology Form		 CervicalCheck <small>THE NATIONAL CERVICAL SCREENING PROGRAMME</small>													
INCOMPLETE FORMS MAY BE RETURNED															
WOMAN'S DETAILS		DOCTOR / SMEARTAKER													
Personal Public Service Number: <table border="1" style="display: inline-table; width: 100px; height: 20px; vertical-align: middle;"></table>		Smearmaker Name: Address:													
CSP ID: <table border="1" style="display: inline-table; width: 100px; height: 20px; vertical-align: middle;"></table>		Smearmaker ID: <table border="1" style="display: inline-table; width: 100px; height: 20px; vertical-align: middle;"></table> <small>(derived from Medical Council or An Bord Altranais No.)</small>													
Date of Birth: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>		Telephone No.: <table border="1" style="display: inline-table; width: 150px; height: 20px; vertical-align: middle;"></table>													
Surname <i>Block capital letters to be used in filling out form</i> <table border="1" style="width: 100%; height: 20px;"></table>		Clinically Responsible Doctor ID or Clinic ID: <small>(derived from IMC No.)</small> <table border="1" style="width: 100%; height: 20px;"></table>													
First Name <table border="1" style="width: 100%; height: 20px;"></table>		PCRS / GMS No. <table border="1" style="width: 100%; height: 20px;"></table>													
Middle Name <table border="1" style="width: 100%; height: 20px;"></table>		Relevant Clinical Details: Date of Smear: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table> LMP: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table> Parity: _____ Please Tick: <input type="checkbox"/> Hormone / HRT <input type="checkbox"/> IUCD <input type="checkbox"/> Pregnant <input type="checkbox"/> Post Menopausal <input type="checkbox"/> Post Colposcopy Smear <input type="checkbox"/> Cervix Visualised													
Surname at Birth <table border="1" style="width: 100%; height: 20px;"></table>															
Mother's Maiden Name <table border="1" style="width: 100%; height: 20px;"></table>															
Postal Address for Correspondence <table border="1" style="width: 100%; height: 60px;"></table>															
Contact Telephone No. <table border="1" style="width: 100px; height: 20px;"></table>		Relevant Clinical Findings <table border="1" style="width: 100%; height: 40px;"></table>													
<div style="background-color: #333; color: white; padding: 2px;"> I have read and understood the information given to me I consent to take part in CervicalCheck </div> Previous Consent <input type="checkbox"/> Yes <input type="checkbox"/> No or Woman's Signature: <table border="1" style="width: 100%; height: 20px;"></table>		Previous Smear History <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Lab Name</th> <th>Lab No.</th> <th>Test Date</th> <th>Result</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>		Lab Name	Lab No.	Test Date	Result								
Lab Name	Lab No.	Test Date	Result												
<div style="background-color: #333; color: white; text-align: center; padding: 2px;">LABORATORY USE ONLY</div>		Previous Treatment History <table border="1" style="width: 100%; height: 40px;"></table>													
Date Received in Laboratory: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>		Management Recommended <table border="1" style="width: 100%; height: 80px;"></table>													
Accession Specimen Number: _____		1 ^o <table border="1" style="width: 100px; height: 20px;"></table> 2 ^o <table border="1" style="width: 100px; height: 20px;"></table>													
Barcode: _____		Path: <table border="1" style="width: 100%; height: 20px;"></table>													
TZ Cells Yes <input type="checkbox"/> No <input type="checkbox"/>		Date Reported: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>													
Final Report <table border="1" style="width: 100%; height: 60px;"></table>		Signature: <table border="1" style="display: inline-table; width: 60px; height: 20px; vertical-align: middle;"></table>													

Appendix 2: CervicalCheck Minimum Data Set

CervicalCheck Cervical Screening Register (CSR)

Minimum Data Set

(Use of the Minimum Data Set is critically important to the safety of the woman and to the quality assurance of CervicalCheck)

- Forename (variations can be used)
- Surname at birth
- DOB (variations)
- PPS Number (may have more than 1 but they are all linked on the CSR)
- Mother's maiden name
- Surname
- Address
- Middle name (useful)
- Phone number
- CSP ID

Note 1: The six elements of the demographic set highlighted text above will never change throughout a woman's life. Therefore, if all of these details are obtained and recorded for a woman it will mean that the woman will be correctly (uniquely) identified.

Note 2: The Personal Public Service Number (PPS No.) consists of nine characters, with the following components:

- The first seven characters are digits
- Character eight is a check character in the range A to W
- Character nine is either blank or contains a "W"

Note 3: The CSP ID is the Cervical Screening Programme identifier assigned to a woman upon entry into CervicalCheck. It is a unique number for each woman.

Appendix 3: Cytology Terminology Translation Table (sample)

Cytology Terminology Translation Table



Office Use	Berthod's Terminology	BSCC Terminology 1986	Office Use	Management Recommendation	Rationale / Recommendation
P1	Unsatisfactory/Inadequate	Unsatisfactory/Inadequate	R6 R7	3 month repeat Refer to colposcopy	Repeat in 3 months 3 consecutive unsatisfactory/discretion of pathologist (gynae referral optimal) First smear test following a treatment in colposcopy Any 3 smear test results that are not normal in the previous 10 years
P2	Negative/NAD (No Abnormality Detected)	Negative/NAD	R1 R2 R3 R4 R7	Exit programme 3/5 year recall 12 month repeat 6 month repeat Refer to colposcopy	No further screening required Routine recall Second and subsequent smear tests following a result/treatment for HSIL/AGC/AIS If HIV+/post organ transplant/DES exposed/renal dialysis Following a result/treatment for ASC-US or LSIL First smear test following a result/treatment for HSIL/AGC/AIS Following hysterectomy & Cervical intraepithelial Neoplasia (CIN) is completely excised i.e. three years routine recall and no CIN at hysterectomy If unknown cervix, a gynaecology referral is optimal
P3	ASC-US (Atypical Squamous Cells of Undetermined Significance)	Borderline Nuclear Abnormalities (BNA) (Squamous)	R4 R7	6 month repeat Refer to colposcopy	First ASC-US or no more than 2 consecutive smear tests showing ASCUS Second consecutive ASC-US smear test Previous LSIL (within 18 months) Any 3 smear test results that are not normal in the previous 10 years First smear test following a treatment for CIN
	ASC-H (cannot exclude High Grade)	BNA-H (cannot exclude High Grade)	R7	Refer to colposcopy	Refer to colposcopy
P4	LSIL (Low Grade Squamous Intraepithelial Lesion)	Mild Dyskaryosis	R1 R7	12 month repeat Refer to colposcopy	First LSIL smear test Second consecutive LSIL smear test If previously attended colposcopy and not yet returned to routine recall If HIV+/post organ transplant/DES exposed/renal dialysis Any 3 smear test results that are not normal in the previous 10 years
P5	HSIL (High Grade)	Moderate Dyskaryosis	R7	Refer to colposcopy	Refer to colposcopy
P6	HSIL (High Grade)	Severe Dyskaryosis	R7	Refer to colposcopy	Refer to colposcopy
P7	Query Squamous Cell Carcinoma	Query Squamous Cell Carcinoma	R7	Refer to colposcopy	Refer to colposcopy
P8	AGC/AIS (Atypical Glandular Cells/AIS)	Borderline Nuclear Abnormalities (Glandular)	R7	Refer to colposcopy	Refer to colposcopy
P9	Query Glandular Neoplasia /AIS/Adenocarcinoma	Query Glandular Neoplasia /AIS/Adenocarcinoma	R7	Refer to colposcopy	Refer to colposcopy
P10	Broken/Damaged/ Expired Vial	Broken or Damaged Vial	R6	3 month repeat	Repeat in 3 months

Glossary

Atypical Squamous Cells of Undetermined Significance (ASC-US)
Atypical Squamous Cells, Favour Neoplastic process (ASC-H)
Atypical Glandular Cells (AGC)

Atypical Glandular Cells, Favour Neoplastic process (AGH)
Adenocarcinoma in situ (AIS)
Borderline Nuclear Abnormalities High Grade (BNA-H)

Low Grade Squamous Intraepithelial Lesion (LSIL)
High Grade Squamous Intraepithelial Lesion (HSIL)

6

Quality Assurance in Colposcopy

6.1 Introduction

Cervical cytology screening programmes aim to reduce both the incidence of and mortality from cervical cancer by the detection and effective treatment of pre-invasive lesions. In countries where these programmes have been well organised, especially in Scandinavia^{1,2} and British Columbia³, a significant reduction in both the mortality and incidence of cervical cancer has resulted. More recently, improvements in the British NHS Cervical Screening Programme have resulted in a significant reduction in the incidence of invasive cancer of the cervix from 16 per 100,000 in 1986 to 9.3 per 100,000 in 1997. A similar reduction in the mortality of cervical cancer has resulted with the rate falling by seven per cent per year⁴. Cervical screening programmes achieve success through the use of three essential ingredients; coverage of more than 80 per cent of the defined population; close co-ordination between smertakers, colposcopy clinics, laboratories and the programme management; and integrated quality assurance at all levels of the programme.

In Ireland, CervicalCheck – The National Cervical Screening Programme was established in 2008 for women aged 25-60 years. The aim of the Programme is to provide a service in which women can have confidence. This is particularly important because CervicalCheck – The National Cervical Screening Programme will invite largely asymptomatic women aged 25-60 to participate in cervical screening.

Colposcopy services play a key role in the success of any 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 essential. There should be access to prompt diagnosis and effective treatment with adequate information and counselling available at all stages. 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 of the individual practitioners and adequately resourced, well organised administration.

Effective quality assurance measures protect practitioners through the promotion of good clinical practice and the provision of a framework against which to audit local practice. Clinical guidelines and standards of care provide clinicians with a standard of quality that encourages continuous improvement. Health service and Programme management can confirm that services are being provided by certified colposcopists in accredited colposcopy clinics with documented evidence of good clinical practice.

This chapter provides guidelines for the provision of a quality assured colposcopy service as part of the National Cervical Screening Programme. It is based on the model of care agreed between the NHS Cervical Screening Programme, British Society of Colposcopy and Cervical Pathology (BSCCP) and the Royal College of Obstetricians and Gynaecologists (RCOG)⁵.

6.2 Colposcopy Standards

6.2.1 Organisational Standards

6.2.1.1 Facilities

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.1.1	Access Area	Colposcopy service should be provided in a dedicated outpatient facility	100%	Visit
		There should be a dedicated waiting area for women	100%	Visit
		There should be a dedicated reception area for colposcopy	100%	Visit
		There should be clear signage from the hospital entrance to the colposcopy clinic	100%	Visit
6.2.1.1.2	Clinical Area	There should be a dedicated area for history taking and counselling which should ensure the privacy of the woman	100%	Visit
		There should be provision to enter the history onto the IT system in this clinical space	100%	Visit
		There should be adjacent toilet facilities for the woman	100%	Visit
		A separate recovery room/area should be available	100%	Visit
		There should be a private changing area for the woman	100%	Visit
6.2.1.1.3	Equipment	There should be an examination couch capable of postural adjustment	100%	Visit
		There should be at least one working colposcope which should be maintained in accordance with the hospital guidelines on the maintenance of medical equipment		

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.1.1	Access Area	The colposcope should be linked to a camera to enable image capture	Yes	Visit
		A monitor should be available to allow the woman to view the procedure	Yes	Visit
		Images should be captured using the colposcopy management software	Yes	Visit
		Resuscitation equipment should be available at the colposcopy clinic	Yes	Visit
		Clinical and nursing staff should be trained in the use of the resuscitation equipment	Yes	Training log
		A panic button should be accessible within the clinical room which provides communication with staff outside the clinical room	Yes	Visit
		There should be a computer connected to the hospital network in the clinical room to facilitate data entry of clinical information	Yes	Visit
6.2.1.1.4	Administrative Area	There should be dedicated office space to house the administrative support for the colposcopy service ensuring compliance with hospital health and safety guidelines	Yes	Visit
		There should be space for secure storage of the colposcopy clinical records of all current colposcopy patients within this administrative area	Yes	Visit
		There should be a provision to enter data into the colposcopy computerised management system from this administrative space	Yes	Visit
		Computer and printer hardware as well as dedicated telephone and fax facilities should be available in this administrative space	Yes	Visit

6.2.1.2 Systems Management

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.2.1	The Management of New Referrals	There should be a defined process for the management of new referrals according to standards for waiting times for new referrals	Yes	Clinic standard operating procedure
		There should be a defined process for informing women of the appointment by letters from the colposcopy management system	Yes	Clinic standard operating procedure
6.2.1.2.2	The Management of Women Who Default	There should be a defined process for the management of women who default from attendance at the colposcopy clinic	Yes	Clinic standard operating procedure
6.2.1.2.3	The Management of Specimens	There should be a defined process for tracking all specimens to ensure that all are delivered to the laboratory	Yes	Clinic standard operating procedure
6.2.1.2.4	The 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	Yes	Clinic standard operating procedure
		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	Yes	Clinic standard operating procedure
		The defined process for review of results should include a method of fast tracking results suggestive of invasive cancer	Yes	Clinic standard operating procedure
6.2.1.2.5	Communication of Results to the Woman (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	Yes	Clinic standard operating procedure

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.2.6	Audit and Systems Review	There should be a defined process whereby computerised failsafe checking procedures are performed on a monthly basis at least	Yes	Record of failsafe management
		The colposcopy team should meet to review quality assurance processes and identify any opportunities for improvement on at least a quarterly basis	Yes	Record of meetings/ minutes
		The colposcopy statistical returns should be generated on a quarterly basis and reviewed by the team	Yes	Record of meetings/ minutes
6.2.1.2.7	Documentation	The colposcopy service should have clinical and administration guidelines which have been agreed by both the colposcopy team and the hospital administration	Yes	Visit
6.2.1.2.8	Follow-up	There should be a defined process for ensuring that all patients have at least one follow-up smear test at the colposcopy clinic prior to discharge	Yes	Clinic standard operating procedure

6.2.1.3 Information Technology

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.3.1	Infrastructure	A computerised colposcopy management system should be installed at the colposcopy clinic	Yes	Visit
		This system should be networked in an accessible form from all areas in use by the team	Yes	Visit
		The colposcopy management system should be interfaced with the hospital patient administrative system	Yes	Visit
		The colposcopy management system should be interfaced with the hospital appointments system	Yes	Visit

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.3.2	Training	Training in the use of the colposcopy management system should be available	Yes	Training logs
		Adequate numbers of concurrent user licences should be available to enable efficient data entry by all necessary staff	Yes	Visit
6.2.1.2.3	Utilisation	The colposcopy service should generate appointment letters from the colposcopy management system	Yes	Visit
		The IT system should be used for specimen management using a defined report which lists specimens taken at each clinical session	Yes	Visit
		The IT system should be used to store image and video data	Yes	Visit
		The IT system should be used to enter the results of any tests	Yes	Visit
		The IT system should be used to enter follow-up and management plans	Yes	Visit
		The IT system should be used to generate result and management plan letters to both GPs and the woman	Yes	Visit
		The IT system should be used to check failsafe processes	Yes	Visit
		The IT system should generate quarterly mandatory audit returns	Yes	Visit

6.2.1.4 Staffing

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.4.1	Staffing	Colposcopy should be delivered by a defined team including medical, nursing and administrative staff	Yes	Visit
		Colposcopists should be trained and certified according to the British Society of Colposcopy and Cervical Pathology (BSCCP) and should appear as such on the BSCCP website	Yes	Visit
		There should be a lead colposcopist with a sessional commitment of one session per week	Yes	Visit
		There should be a full time dedicated nurse available to the service for each quota of 500 new colposcopy patients per year	Yes	Visit
		A clinical nursing care assistant should be available to facilitate cleaning and enhance the turnaround time between patients at the colposcopy clinic	Yes	Visit
		There should be full time dedicated administrative support available; one for each quota of 500 new colposcopy patients per year to provide administrative support to the service	Yes	Visit
		There should be a separate nurse led smear test clinic for the follow-up of treated and untreated patients	Yes	Visit

6.2.1.5 Governance

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.5.1	Governance	The service should have regular (at least quarterly) operational meetings between nursing, hospital administration/managers and colposcopists	Yes	Attendance records/minutes
		Management reports including numbers attending, waiting times and default rates should be reviewed at these operational meetings and appropriate corrective actions taken	Yes	Minutes
		The service should have clinico pathological meetings on a quarterly (minimum standard) or monthly (recommended) basis	Yes	Attendance records/minutes
		Colposcopy clinics should be scheduled in sessions of 3 hours to include a minimum of 10 appointment slots of 15 minutes to maximise throughput while minimising waiting times at the colposcopy service	Yes	Audit of waiting times/clinic lists

6.2.1.6 Administrative Standards

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.1.6.1	Waiting Times	Women referred to colposcopy should be offered an appointment within 8 weeks of referral	>90%	Colposcopy returns
		Women referred to colposcopy with a smear suggestive of CIN2 or CIN3 (HSIL, moderate or severe dyskaryosis) should be offered an appointment within 4 weeks of referral	>90%	Colposcopy returns
		Women referred to colposcopy with a clinical suspicion of invasive cancer should be offered an appointment within 2 weeks of referral	>90%	Colposcopy returns

	Category	Description of Standard	Standard	Demonstration of Compliance
		Women referred to colposcopy with a smear test suggestive of glandular neoplasia should be offered an appointment within 4 weeks of referral	>90%	Colposcopy returns
6.2.1.6.2	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	<15%	Colposcopy returns
6.2.1.6.3	Information	Women should be sent a personalised invitation to colposcopy within two weeks of receipt of the referral letter	>90%	Colposcopy returns
		Women should be sent clinic specific information on colposcopy in advance of the appointment	Yes	Process guidelines documented and in place
		Clinics which operate a 'see and treat' policy should send appropriate information regarding treatment to the patient in advance of the appointment	Yes	Process guidelines documented and in place
6.2.1.6.4	Communication of Results and Management Plans	Information on results of investigations should be communicated to the woman within 4 weeks of her attendance at the colposcopy clinic	>90%	Colposcopy returns
		Information on results of investigations should be communicated to the woman within 8 weeks of her attendance at the clinic	>95%	Colposcopy returns
		Information on results of investigations should be communicated to the referring doctor within 4 weeks of the woman's attendance at the clinic	>90%	Colposcopy returns
		Information on results of investigations should be communicated to the referring doctor within 8 weeks of the woman's attendance at the clinic	>95%	Colposcopy returns

6.2.2 Clinical Standards

6.2.2.1 Diagnosis

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.2.1.1	Positive Predictive Value	Compliance between colposcopic impression of high grade disease and histologically proven high grade CIN	>65%	Colposcopy returns
6.2.2.1.2	Biopsy	A biopsy should be performed in the presence of an atypical Transformation Zone	>95%	Colposcopy returns
		Reasons for not performing a biopsy e.g. pregnancy should be recorded	>95%	Colposcopy audit
		Women should have a biopsy performed before ablative or destructive treatment and the result should be available before the treatment is carried out	100%	Colposcopy returns
		An excisional biopsy should be performed in preference to a punch biopsy where the lesion extends into the endocervical canal and the upper limit is not seen (Type 3 TZ)	>95%	Colposcopy returns
		Biopsy specimens should be suitable for histological diagnosis	>95%	Colposcopy returns

6.2.2.2 Treatment

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.2.2.1	Who to Treat	Women with high grade CIN (CIN 2/3) or AIS confirmed on a diagnostic biopsy should have a treatment performed	>95%	Colposcopy returns

	Category	Description of Standard	Standard	Demonstration of Compliance
		Women who present with a high grade cytological abnormality and who have no colposcopic abnormality identified on a fully visible Transformation Zone should have the smear test reviewed by the cytopathologist and if high grade changes are confirmed an excisional treatment should be performed	>95%	Colposcopy returns
		Women who present with a high grade cytological abnormality and who have an unsatisfactory colposcopy should have an excisional treatment performed	>95%	Colposcopy returns
		Women with CIN1 or less diagnosed on a diagnostic biopsy and who are being managed conservatively by surveillance at the colposcopy clinic should be treated if there is a subsequent high grade cytological abnormality or if there is a low grade cytological abnormality which persists for 12-18 months	>95%	Colposcopy returns
6.2.2.2.2	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 ('see and treat')	>90%	Colposcopy returns
		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%	Colposcopy returns

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.2.2.3	General	Women who require treatment must be informed about the procedure and their written or verbal consent recorded	Yes	Process guidelines documented and in place
		Women who require treatment must have a prior colposcopic assessment	Yes	Process guidelines documented and in place
		All treatments must be recorded	Yes	Process guidelines documented and in place
		All treatments must be performed in suitably staffed and equipped clinics	Yes	Process guidelines documented and in place
		Women should have a histological diagnosis prior to ablative treatment	Yes	Process guidelines documented and in place
		The majority of women should have treatment performed as an outpatient under local anaesthesia	>80%	Colposcopy returns
6.2.2.2.4	Choice of Treatment	Ablative treatment is only suitable: <ul style="list-style-type: none"> • When the entire Transformation Zone is visualised • When there is no evidence of either glandular or invasive disease • When there is no discrepancy between the cytology and the biopsy 	Yes	Process guidelines documented and in place

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.2.2.5	Excision – Removal of the Specimen	The specimen should be excised as a single specimen to maximise the interpretation of margins	>80%	Process guidelines documented and in place
		Excision of ectocervical specimens should aim for a depth of at least 7 mm to overcome the potential for residual disease in the crypts	>95%	Colposcopy returns
6.2.2.2.6	Results	Women treated by excisional technique at first visit should have CIN on histology	> 90%	Colposcopy returns
		Women treated by excisional techniques should have CIN on histology	> 80%	Colposcopy returns
6.2.2.2.7	Repeat Excision	Women over the age of 50 years who have CIN3 or AIS at the endocervical margin should have a repeat excision performed to obtain clear margins if satisfactory cytology and colposcopy cannot be guaranteed	>95%	Process guidelines documented and in place
		Women treated by excision for suspected high grade disease (CIN 2/3 or AIS) and who have no significant abnormality on histology should have consideration of repeat excision following discussion at the colposcopy clinico pathological meeting	>95%	Process guidelines documented and in place

6.2.2.3 Follow-up after Treatment

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.2.3.1	Follow-up: Clinic	At least one follow-up smear test should be performed at the colposcopy clinic	>95%	Colposcopy returns
		The cytology result should be normal following treatment with no indication of persistent CIN	>90%	Colposcopy returns
		The cytology result should be negative (including endocervical cells) before the woman is discharged to primary care	>95%	Colposcopy returns
		Cytological follow-up is recommended for most women with particular attention given to sampling the endocervical canal	>90%	Colposcopy returns
		Follow-up should start at between 6 and 8 months following treatment	>90%	Process guidelines documented and in place
		Follow-up after a hysterectomy showing completely excised CIN should include 3 negative vault smear tests at 6 month intervals before discharge from CervicalCheck	>95%	Process guidelines documented and in place
		Follow-up after a hysterectomy showing incompletely excised CIN should continue as if the cervix were still in situ.	>95%	Process guidelines documented and in place
6.2.2.3.2	Follow-up: Primary Care	Women with high grade CIN (CIN2/3) or with adenocarcinoma in situ (AIS) on histology require 2 negative 6 monthly smear tests with annual negative smears for the subsequent 9 years before returning to routine screening	>95%	Screening programme audit
		Women treated with low grade disease (CIN1 or HPV changes only) require 3 negative smear tests at 6 monthly intervals. If all are negative, then the woman may be discharged to routine screening	>95%	Screening programme audit

6.2.3.4 Follow-up of Women Who Have Not Been Treated

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.3.4.1	Women Who Present With a High Grade Cytological Abnormality	If the colposcopy suggests low grade disease and conservative management is preferred, multiple biopsies should be performed	>95%	Colposcopy returns
		If the diagnostic biopsy confirms low grade disease (CIN1 or less) the colposcopy and smear test should be repeated in 6 months In the presence of a high grade cytological abnormality in the repeat smear test, a treatment should be performed	>95%	Colposcopy returns
		Women should only be discharged to routine screening following 2 negative smear tests 6 months apart combined with colposcopic evidence of normality	>95%	Colposcopy returns
		In the presence of persistent low grade cytological abnormality or persistent colposcopic abnormality a treatment should be performed	>95%	Colposcopy returns
6.2.3.4.2	Women Who Present With Low Grade Cytological Abnormality	If the colposcopy is satisfactory and normal, the smear test should be repeated	>95%	Colposcopy returns
		If the colposcopy is atypical, a biopsy should be performed. If diagnosis is low grade disease, conservative management with cytology surveillance should be adopted except in special circumstances (patient choice, risk of default)	>90%	Colposcopy returns
		If persistent abnormality at 18 months repeat colposcopy with possible treatment should be performed	>95%	Colposcopy returns
		The woman should be discharged from the colposcopy clinic following 2 consecutive negative smear tests 6 months apart	>95%	Colposcopy returns

	Category	Description of Standard	Standard	Demonstration of Compliance
6.2.3.4.3	Pregnant Women	Women who are pregnant should have a colposcopy performed, using the same criteria as for women who are not pregnant	>95%	Process guidelines documented and in place
		Biopsy and treatment is usually deferred until the postpartum period except where there is a suspicion of invasive disease	>95%	Process guidelines documented and in place
		If low grade disease is suspected at colposcopy a repeat colposcopy appointment should be made for the post partum period	>95%	Process guidelines documented and in place
		If high grade disease is suspected the colposcopy should be repeated at the end of the second trimester as well as the post partum period	>95%	Process guidelines documented and in place
		If there is a suspicion of invasive disease a biopsy must be performed immediately	>95%	Colposcopy returns

6.3 Organisational Guidance for Quality Assured Colposcopy Services

6.3.1 Quality Assurance in Colposcopy – General

Colposcopy is a diagnostic technique for identifying the probable site of any cytological abnormality^{6,7}. It is a subjective assessment which relies on pattern recognition to discriminate between normal and abnormal tissue as well as between grades of abnormality. Used on its own, it is not an exact science, with the possibility of underestimating and overestimating the degree of CIN⁸. It is however generally an effective means of obtaining a confirmatory biopsy and directing treatment⁹. On the other hand, colposcopy, particularly if combined with diathermy loop excision at the first visit for all women ('see and treat') may result in over treatment¹⁰ and can also cause psychological morbidity¹¹⁻¹³. Colposcopists should balance the resultant risks and benefits and should aim to deliver safe, efficient and cost effective services. The training and accreditation of colposcopists is crucial to ensure the development and maintenance of the necessary skills. In addition, evidence-based guidance should be implemented to ensure the delivery of high quality standardised care.

The organisation of colposcopy services is of vital importance. The service should involve an integrated process delivered by a defined team which complies with the NCSS quality assurance standards. The component parts of this service include clinical expertise, staffing, facilities, systems management and governance. The team should be led by a lead colposcopist and include nursing, administrative and managerial representation.

The role of the lead colposcopist is to ensure good practice and compliance with protocols, in addition to ensuring accurate collection of data to enable audit and the production of colposcopy audit returns. The team should meet regularly (at least four times per year) to discuss clinic policy, any problems which have arisen and any potential obstacles to reaching targets and explore how they might be resolved.

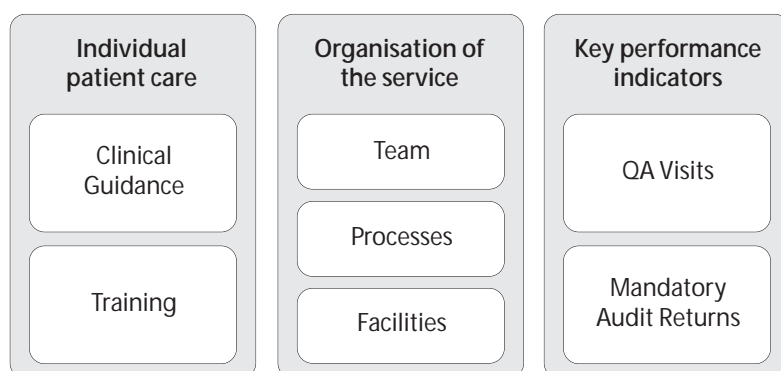


Figure 7: NCSS Approach to Quality Assured Colposcopy Services

The aim of the NCSS approach to quality assurance is to provide colposcopy services which are compliant with internationally agreed best practice. This will require input from all to ensure standards are uniformly high. The provision of mandatory colposcopy returns on a quarterly basis will inform this process. Each service should have a nominated co-ordinator who is responsible for ensuring that quality assurance targets are monitored and colposcopy audit returns are submitted in a timely fashion.

Organisational building blocks for quality assured colposcopy services include:

- Facilities
- Staffing
- Systems management
- Information technology (IT)

Quality assured colposcopy services should:

- Ensure timely and equitable access to colposcopy and treatment for women with abnormal cervical smear test results
- Communicate effectively with women to inform them about colposcopy and treatment including appointments, results of tests and planned intervention
- Ensure high quality diagnosis by certified colposcopists which includes satisfactory biopsy in the majority of cases
- Ensure adequate treatment in a timely fashion for women with a diagnosis of CIN; treatment should be delivered in the outpatient clinic in the majority of cases
- Establish a system for tracking tests and effectively managing the results, to ensure efficient communication of the diagnosis and treatment plan to the woman in a timely fashion
- Ensure that data management is such that clinical results can be easily accessed and checked using a designated computer programme. The production of regular audit reports facilitates comparison with national standards.
- Interact effectively with smertakers, laboratories and management of CervicalCheck to deliver a reduction in incidence and mortality of cervical cancer

6.3.2 Staffing of Colposcopy Services

The colposcopy team comprises:

- Lead colposcopist (BSCCP certified)
- Nursing staff
- Administrative support

6.3.2.1 The Colposcopy Secretarial and Clerical Team

Each colposcopy clinic should have dedicated secretarial support available to women. This support is essential as it provides the first point of contact between the woman and the colposcopy clinic and therefore will reflect the woman's first impressions of the service. Women who attend colposcopy clinics are often anxious and need to be put at their ease. It is essential that they are dealt with by courteous, friendly professionals. Effective communication skills as well as excellent organisational abilities are required.

Specific roles and responsibilities of the administration team should include:

- The management of new referrals, including the allocation of a timely appointment and communication of necessary information to the smertaker and the woman
- The management of women who do not attend and rescheduling cancelled appointments
- The generation of letters/documentation following the colposcopy visit and filing in the notes
- Efficient filing of results

- Inputting any results and management plans into the IT system
- Generation of results letters including communication of the plan and any subsequent appointments. The generation of failsafe reports to check the data and ensure that all results are managed appropriately as well as the production of required reports for colposcopy returns

6.3.2.2 The Nursing Staff

An experienced, committed nursing team is the cornerstone of any colposcopy service. The nursing team has to provide simultaneous support to both the colposcopist and the woman. It is essential that they have a thorough knowledge of the concepts of cervical screening and the colposcopy process. Equally important is the ability to put the woman at ease with a professional, calm and reassuring approach.

Specific roles of nursing staff should include:

- Greeting the woman in the waiting room and escorting her to the clinical area
- Taking the initial history, providing initial information, ensuring the woman meets the colposcopist and has an opportunity to ask questions before the procedure
- Ensuring the woman has privacy to change
- Ensuring the woman is comfortably placed on the colposcopy couch
- Checking and ensuring the colposcopist has the necessary equipment
- Supporting the woman during the procedure
- The management of specimens, ensuring correct labelling and completion of the relevant form
- Checking that the woman has no further questions and has adequately recovered before leaving the clinic

In addition clinic nurses have a vital role to play in nurse-led cytology surveillance at the clinic. There is a need for cytological follow-up at the colposcopy clinic for women following treatment as well as women undergoing surveillance for low grade abnormalities. Most of these women do not need colposcopy but can occupy vital colposcopy slots and risk causing congestion of the service. The establishment of nurse led cytology surveillance clinics greatly relieves these pressures.

6.3.2.3 The Colposcopists

Colposcopy should only be performed by certified colposcopists or trainee colposcopists under supervision. Traditionally most colposcopists were doctors but an increasing number of nurse colposcopists have now been trained. Excellent clinical and communications skills are required as well as the ability to work effectively within a team.

Training and Certification

The British Society for Colposcopy and Cervical Pathology (BSCCP) has an accredited training programme which is recognised by the Royal College of Obstetricians and Gynaecologists (RCOG). This training programme is available to both nurses and doctors and provides core knowledge, while enabling the development of necessary skills and professional attributes to attain defined competency in colposcopy. These competencies comprise administration and communication skills, in addition to colposcopic technical skills, practical procedures, pattern recognition and the ability to recognise both the normal and abnormal cervix. Continuous assessment during training is provided by a nominated trainer using standardised assessment tools and all trainees must pass a standardised Objective Structured Clinical Examination (OSCE) examination organised by the BSCCP. Complete information is available on the BSCCP website bsccp.org.uk and a link is provided on the CervicalCheck website.

Training in colposcopy

- BSCCP/RCOG training programme
 - Training log
 - Assessment tools
 - OSCE assessment
- CME and recertification
 - Three yearly cycle
 - Attendance at BSCCP annual meeting

Recertification

Certified colposcopists must recertify every three years. This involves an audit of six months, a minimum workload of 50 new patients per year (25 of whom should have an abnormal smear) and evidence of attendance at a BSCCP or other affiliated educational or scientific meeting.

6.3.2.4 Lead Colposcopist

Each colposcopy service must have a lead colposcopist whose role is to oversee the quality assurance aspects of the service and co-ordinate the completion and submission of colposcopy audit returns. It is recommended by the RCOG that the responsibility of lead colposcopists should be recognised by a sessional commitment of at least one three hour session per week. In addition this should be supported by at least one session of secretarial time to complete any tasks associated with this position.



Figure 8: Function of the Lead Colposcopist

Lead colposcopists should adopt the responsibility of devising appropriate written protocols for local use that will enable the service to work towards achieving quality assured standards as defined by the National Cancer Screening Service. After such protocols have been agreed and implemented, all those within the service under the direct management of the lead colposcopist should work within them.

The lead colposcopist is responsible for:

- Ensuring that written protocols are in place for the service and that these include recommended national guidelines
- Ensuring that the protocols are regularly reviewed so that the needs of the users of the service and the commissioners of the service are met. The lead colposcopists will be required to ensure that the defined quality assurance standards are being met
- Ensuring that the Minimum Data Set is collected
- Ensuring that regular audit of the service takes place to compare practice with local protocols and national targets
- Liaising with those responsible for providing the facilities to ensure that the service is adequately staffed by appropriately trained individuals (medical and non-medical) so that the service needs can be met in a timely manner
- Co-ordinating training and liaising with the BSCCP Certification and Training Committee as appropriate
- Facilitating the maintenance of continued accreditation of practicing colposcopists within the unit
- Informing hospital management about the need to ensure that procedures are in place to facilitate care and rapid communication with patients, other hospital departments, primary care agencies as well as cytopathology and histopathology services
- Convening regular multidisciplinary team meetings for case discussion and protocol review, including cytology and histology services
- Conducting regular dialogue with users, providers, and purchasers of care to ensure that service and development are both appropriate and meet the needs of the local population

Personal specification of lead colposcopist:

- BSCCP certified
- Commitment
- Organisational skills
- Training skills
- IT skills
- Team management skills

Assessment of Administrative Support

It is the responsibility of management to provide adequate space and facilities for colposcopy to be practised at the highest level. It is the responsibility of the lead colposcopist and the quality assurance visit assessors to identify deficiencies in infra-structural support and to make recommendations.

Assessment of Systems Management

The lead colposcopist is responsible for ensuring that the standards defined by the NCSS are being met. In addition the collection of data should be maintained to allow audits to be conducted against these standards. The data collected will serve as a means of comparing performance between colposcopy units and to ensure that services are running effectively. Regular visits encourage good practice and identify deficiencies before problems arise.

6.3.3 Facilities

Colposcopy services should be provided from dedicated outpatient facilities which have sufficient space to accommodate reception, waiting and clinical areas. In addition it should have adequate office space to house the administrative support as well as space for secure storage of current medical records.

The reception and waiting areas are the woman's first physical contact with the service and should be designed to provide a quiet and relaxing environment. There should be clear signage to the clinic which takes into consideration women with special needs.

6.3.3.1 Clinical Space

The clinical colposcopy facility should aim to deliver an empathic safe service which aims to maximise privacy and minimise any associated potential embarrassment to the woman. In addition, it should support an efficient and cost effective service to maximise capacity while maintaining high standards of quality¹⁴.

There should be at least one room which has all of the equipment necessary for the diagnosis and treatment of abnormalities. This area should include a private changing area. In addition there should be a dedicated separate area for history taking and counselling. Adequate toilet facilities should be provided.

More than one specialised colposcopy clinical room permits greater capacity and maximises use of specialist clinical staff. The availability of additional standard consultation rooms allows a more efficient service as well as providing a recovery or rest area for women. All rooms should have the necessary IT infrastructure for a networked colposcopy computerised management system.

6.3.3.2 Equipment

A specialised gynaecological examination couch is essential. An electrical mechanism should allow changes in height and angle to be easily achieved by the colposcopist. The colposcope should be well maintained and facilitate both white and green light examination. Changes in magnification and focus should be easily achieved.

An integrated camera attached to the colposcope should allow the option of simultaneous viewing of the examination by the woman on a monitor placed within her field of vision. This helps with communication of the findings and has been shown to reduce any anxiety the woman may experience. Image capture facilities constitute an integral part of colposcopy computerised management systems and are useful for both quality assurance and training.

A range of speculae and endocervical forceps should be available to facilitate adequate examination of the Transformation Zone (TZ), as well as a selection of biopsy forceps to ensure satisfactory sampling for histological diagnosis. All necessary equipment for outpatient treatment should be readily available and the staff should be familiar with its use. Adequate waste disposal facilities are mandatory. Staff should ensure that supplies of necessary equipment are available in stock and adequate storage space should be. Sterilisation of equipment should comply with local decontamination standards provided for this purpose. Resuscitation equipment must be available and staff must be familiar with its use.

Diagnostic equipment required:

- Image capture and electronic data storage system
- Biopsy forceps
- Caustic applicators
- Formalin specimen bottles
- Cytology solution and brushes (cervix and endocervical)
- Swabs (viral and bacterial)

Equipment required for treatment:

- Electrosurgical smoke evacuation system
- Diathermy plates (pads)
- Diathermy pencils
- Smoke filters
- Loop, ball and needle electrodes
- Local anaesthetic
- Dental syringes and needles
- Dissecting forceps

6.3.4 Systems Management

Colposcopy services should be delivered in an integrated fashion using a defined standard process to ensure access to high quality diagnosis and treatment. In addition to excellent clinical management systems, management processes are vital. In particular regarding the management of the following:

- New referrals
- Specimens
- Management of results
- Communication of the results and management plan
- Women who default

These processes require the involvement of all of the members of the colposcopy team who should meet on a regular basis to review their application and to identify and manage any problems.

6.3.4.1 Management of New Referrals

The time between being advised of a need for colposcopy and the date of the first appointment can be a very anxious period¹⁵ for women. Good practice demands that the woman be given information about colposcopy and details of their appointment as soon as possible. The accepted standard is two weeks from receipt of the referral letter. The referral letter should be sent directly to the clinic. It is the responsibility of the clinic to ensure that women are seen in the correct clinic within the recommended timeframe.

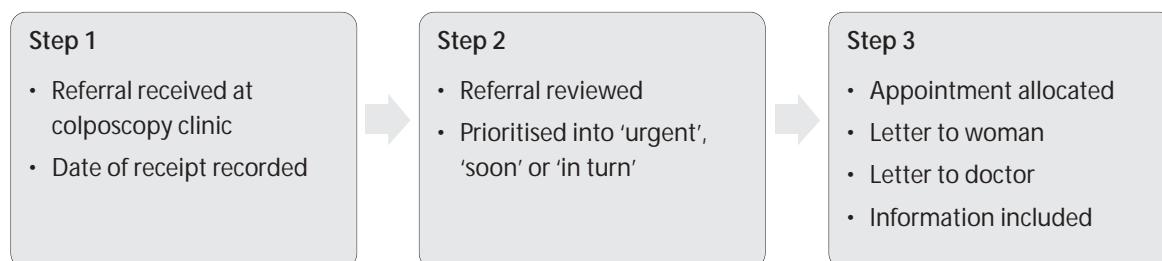


Figure 9: Process for the Management of New Referrals to Colposcopy

6.3.4.2 Process for Colposcopy Visit

The colposcopy visit includes a series of steps to ensure data is collected on the woman's details, history, clinical assessment and procedure. This data should be collected and entered in real time at the clinic to ensure accuracy and validity.

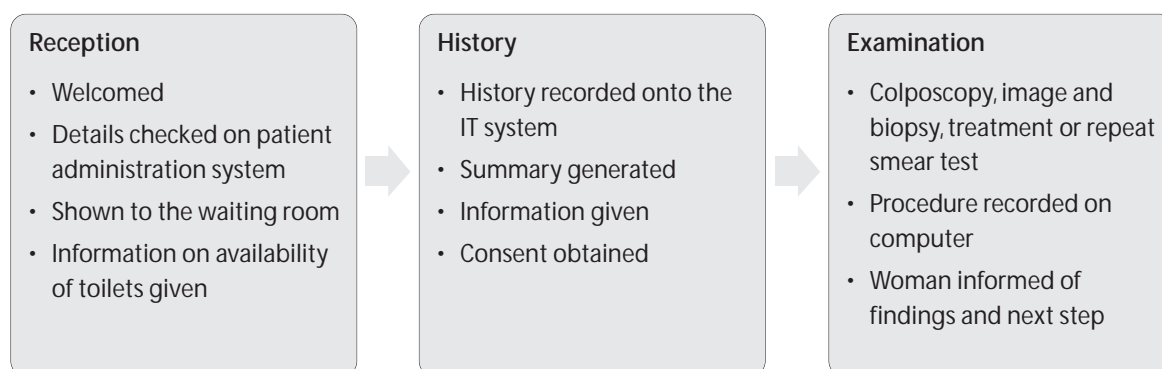


Figure 10: Process for Colposcopy Visit

6.3.4.3 Process Immediately Following the Colposcopy Visit

Following the colposcopy procedure, steps must be taken to communicate details of the procedure to the referring doctor as well as generating a computer generated summary for notes. It is crucial that all tests are labelled correctly and the relevant clinical details are entered onto the relevant forms. A log or list of specimens must be generated and checked before delivery to the laboratory for testing. The notes of any non attenders¹⁶ must be reviewed and new appointments made with supporting documentation and communication according to agreed local guidelines.

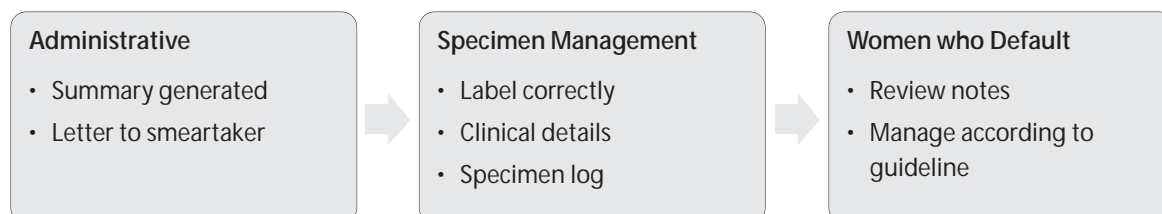


Figure 11: Process following Colposcopy Visit

6.3.4.4 Management of Results and Formulation of Management Plans

A seamless process should be implemented which ensures accurate and appropriate management of the results of any test. All results must be delivered in writing to both the woman and referring doctor. While the steps within this process involve input from more than one team member it is the responsibility of the colposcopist to ensure accuracy and compliance with clinical management guidelines.

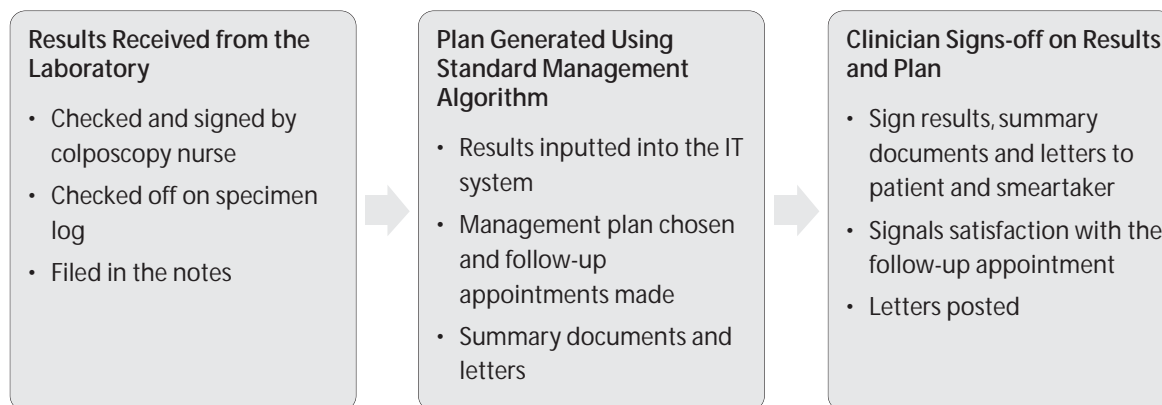


Figure 12: Process for the Management and Communication of Results

6.3.4.5 Failsafe Processes and Procedures

The steps outlined above demonstrate that colposcopy is a complex process. An error or omission at any level increases the risk of unrecognised persistent CIN and subsequent cancer. As part of the quality assurance programme there should be integrated failsafe processes and procedures. Any failure to register results or to communicate these to the woman could result in inappropriate management. Colposcopy management systems should have a series of failsafe mechanisms to identify these cases and to ensure correction. They should be run on a regular basis (at least once per month) and this should be annotated in the local administrative guidelines. In a colposcopy clinic, designated personnel have to be assigned to manage the failsafe lists on the IT systems.

6.3.4.6 Best Practice Standard Operating Procedures and Guidelines

The availability of evidence based best practice standard operating procedures and guidelines is important to reduce the possibility of significant variations in clinical practice between colposcopy clinics. This should include both administrative and clinical guidelines and should be reviewed on a regular basis to ensure they are up-to-date.

Evidence-based guidelines for colposcopy services encompass:

- Diagnosis
- Treatment
- Follow-up
- Administration

6.3.4.7 Regular Audit

Clinical audit is integral to maintaining quality, as it identifies opportunities for improvements and provides a mechanism for bringing them about^{17,18}. All colposcopy clinics have IT systems that allow access to reports for audit. Electronic linkage with the National Cervical Screening Programme will allow national audit to ensure consistent standards.

6.3.5 Multidisciplinary Team Meetings

6.3.5.1 Clinico Pathological Conferences (CPC)

It is well documented that best practice in terms of treatment planning and care for women is that provided by a multidisciplinary team (MDT). One of the team should adopt the role of co-ordinator to collate the relevant woman's details. The creation of IT solutions such as a dedicated MDT sub form within the colposcopy management system will serve to co-ordinate the work involved, and record the decisions made. A copy of the MDT report should go to all relevant clinicians including the general practitioner and referring doctor.

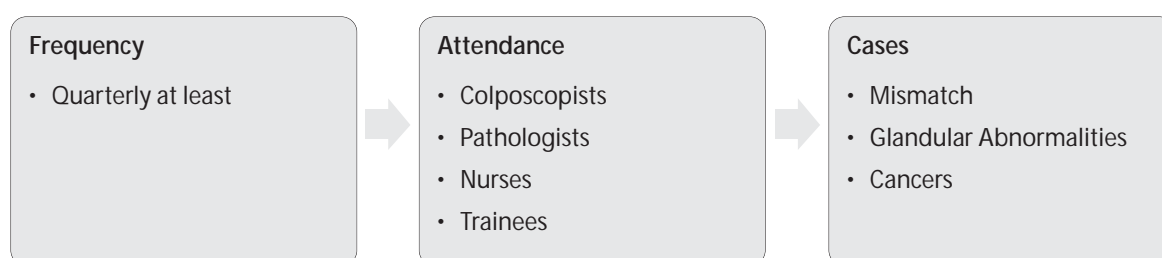


Figure 13: Multidisciplinary Team (MDT) Meetings

Interactions between cytology and pathology personnel with clinicians add greatly to diagnosis and patient management decisions. This may involve teleconferencing facilities. These meetings should take place on at least a quarterly basis.

6.3.5.2 Operational Meetings

The management of the colposcopy service requires regular operational meetings between:

- Colposcopists
- Clinic nursing staff
- Clinical administrative staff
- Information technology department
- Nursing administration
- Hospital administrator/manager

Issues to be discussed include anything which might impact on the achievement of quality assurance standards and might include staffing issues, IT issues, administrative issues and/or capacity and management of appointments. Minutes should be generated and communicated to all members of the team.

6.3.6 Information Technology

Function of colposcopy management systems:

- Collect and check data
- Manage appointments
- Audit failsafe procedures/processes
- Generate letters
- Manage special registers – microinvasive cancers, glandular lesions, incomplete excision, defaulters etc.

6.3.6.1 Collect Data

A colposcopy management system which collects the standard Minimum Data Set should be available in all colposcopy clinics. All staff (medical, nursing and administration) should have adequate training in the use of the system. A unique password system is necessary to prevent unauthorised access. The importance of systematic data entry should be emphasised in order to collect all relevant information. Standard information should be collected at each clinic throughout the country.

Each hospital should have the facility to store both image and video data. An agreed support system should be in place with the hospital IT team to provide support, allowing for prompt resolution of problems occurring with the IT system during clinic time. Data should be backed up on both a daily and weekly basis and stored off-site to ensure no loss of content in the event of fire or other unforeseen damage.

The IT system should have the necessary software to allow for cross reference and retrospective assessment to facilitate audit and research.

To facilitate easy collection of data for Clinico Pathological Conference (CPC) meetings, the IT system should be able to generate a summary document, with the ability to output all relevant data required for presentation to the meeting, and to capture proposed outcome. If necessary, appropriate letters should be created to inform the patient and GP of the consensus agreement.

There should be an ability to create a six monthly audit for each colposcopist to facilitate re-accreditation with the BSCCP.

6.3.6.2 Management of Appointments

The IT system should be linked to the main hospital administration system to facilitate automatic pick-up of demographic data and appointment schedules. In the absence of a hospital administration system the colposcopy management system should have a 'stand alone' appointment facility.

6.3.6.3 Audit Failsafe Procedures and Processes

The colposcopy IT system should have the ability to automatically create mandatory returns for quarterly audit. To ensure correct data collection, the system should have failsafe procedures in place to guarantee data entry is correct and up-to-date. This data should be checked on a regular basis and by a dedicated individual. There should be an ability to create alerts for certain approved categories e.g. untreated CIN 3.

6.3.6.4 Generation of Letters

Standard letters should be prepared for all potential outcomes. All relevant correspondence to the patient should be stored in the colposcopy system. Letters should reflect local agreed guidelines for patient and GP information and follow-up. There should be an ability to create new letters and edit existing ones. Standard letters should be updated regularly to ensure information is current and relevant.

6.3.6.5 Special Registers

Microinvasive Cancer

There should be an ability to create an annual summary document of all patients diagnosed with microinvasive or invasive cancer. This document should also capture the treatment or referral plans¹⁹.

Glandular Abnormalities

Women who have been treated conservatively for glandular lesions have an increased risk of recurrence and need close follow-up²⁰. A summary document of these women and their follow-up treatment plan would be an advantage and would ensure adequate and appropriate follow-up.

Incomplete Excision

Incomplete excision has shown to increase the risk of recurrence²¹⁻²³. While repeat treatment is not recommended in women under 50¹⁴ the ability to check and audit the number of women with incomplete margins would be an advantage.

Default

Each colposcopy clinic should have local written guidelines on management of women who default on their appointment²⁴. A register of these women could identify patterns of causes or reasons for default.

6.3.6.6 External Links

The provision of an infrastructure which facilitates links between colposcopy services will greatly assist the provision of quality assurance. The establishment of national forums for colposcopists, nurses in colposcopy and administrative staff in colposcopy should allow interaction and exchange of ideas.

6.4 Clinical Guidance for Quality Assured Colposcopy Services

6.4.1 Risk Management and Colposcopy Services

There are risks associated with the delivery of colposcopy services. These include direct risks to the woman as well as indirect reputational risks to colposcopists, hospitals, health authorities and the Programme as a result of an identified problem. The direct risks to the woman include the risk of unrecognised persistent high grade CIN and potential of malignant transformation to cervical cancer as well as the risk of physical and psychological harm as a result of the colposcopic management.

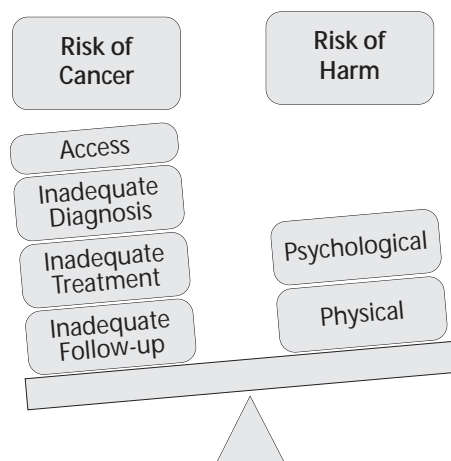


Figure 14: Colposcopy Services; the Balance of Risks

6.4.1.1 The Risk of Persistent High Grade Disease and Subsequent Cancer

Not all cervical cancers can be prevented by a national cervical screening programme, irrespective of clinical excellence and well organised services. Similarly it is impossible to abolish completely the risk of covert persistent pre-cancer with subsequent development of cancer at colposcopy. It is imperative however to define carefully the risks within the colposcopy service and to ensure the implementation of strategies to minimise those risks. These strategies should be reviewed on an ongoing basis with to ensure correlation with contemporaneous best practice.

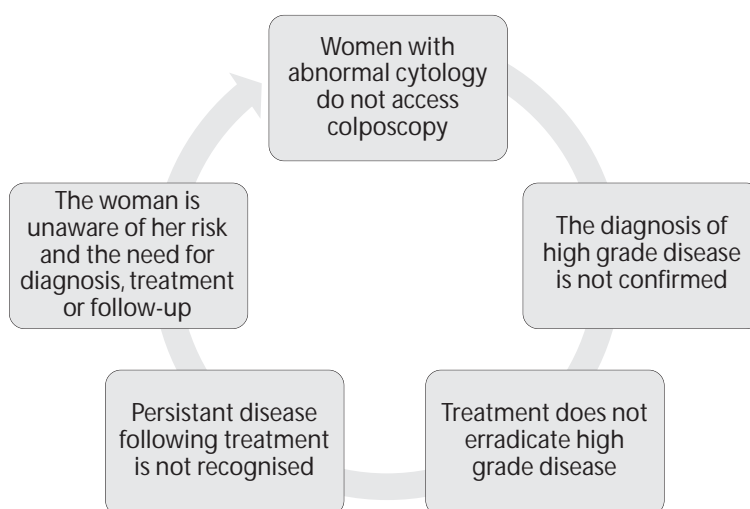


Figure 15: Risks of Persistent Disease and Subsequent Cancer in Women with Abnormal Cytology

6.4.1.1.1 Strategies to Reduce the Risk of Unrecognised Persistent Disease

Ensure women with abnormal cytology access colposcopy

- Women should have access to colposcopy within agreed timeframes
- There should be effective strategies for the management of women who default
- There should be effective strategies for communication and management of new referrals

Ensure that high grade CIN is diagnosed

- Colposcopists should be trained and certified by the BSCCP
- In the presence of any atypia, the colposcopic diagnosis should be confirmed by directed biopsy even for suspected low grade disease
- Excisional biopsy should be considered for women with a significant endocervical component or for women with suspected glandular disease
- Particular attention should be given to cases of unexplained high grade cytological abnormality or cases of discrepancy between cytology, colposcopy and histology

Ensure high grade CIN is treated effectively

- All women with CIN 2/3 should be treated
- When ablative treatment is considered, there should be strict adherence to the selection criteria
- Excisional treatments should provide a specimen in one piece and of sufficient depth to ensure negative margins

Ensure persistent disease following treatment is recognised

- All women should have at least one normal follow-up smear test at the colposcopy clinic before discharge
- Systems should be in place to inform CervicalCheck of increased need for surveillance of treated women

Ensure the woman is aware of her risk and the need for diagnosis, treatment and follow-up

- Appointment should be scheduled to ensure adequate time for counselling by the colposcopist
- Telephone enquiries should be facilitated by ensuring access to women of a colposcopy helpline during office hours
- The results of all tests performed at colposcopy may be communicated in writing to women within the agreed timeframes

6.4.1.2 Risks Associated With Colposcopy Procedures

The colposcopy procedures for diagnosis and treatment are associated with intrinsic risks which must be balanced against the overall benefits to the women. These negative effects include the psychological impact of colposcopy as well as the physical effects of the treatment.

6.4.1.2.1 The Psychological Impact of Colposcopy

Women with an abnormal smear test who need to attend colposcopy have been shown to experience a high level of anxiety and psychosocial problems²⁵. The levels of psychological distress are transient²⁶ and reduce significantly following colposcopy^{27,28}. Strategies to address the informational needs of women prior to colposcopy²⁹ reduce the psychological impact and may improve compliance reducing the numbers of women who default. These include the provision of information leaflets, pre-colposcopy discussions with a trained colposcopy nurse³⁰⁻³⁵

Strategies to reduce the psychological risks associated with colposcopy

- Information
 - Information on colposcopy should be sent in advance of the appointment
 - Information on 'see and treat' should be included
- The colposcopy visit
 - Women should be able to have a friend present if they wish
 - Permission should be sought prior to colposcopy if any additional staff are present
 - Counselling should be an integral part of colposcopy
- Results
 - Information with regard to visit and results of investigations should be communicated to the patient within four weeks

6.4.1.2.2 Physical Effects of Colposcopy Treatment

Cervical intraepithelial neoplasia (CIN) is mostly treated conservatively as an outpatient using local anaesthesia³⁶⁻⁵². These procedures involve either the ablation or excision of abnormal tissue and immediate problems include haemorrhage and infection⁵³. Later sequelae including cervical stenosis or incompetence can negatively affect fertility and future pregnancies and are related to the volume of tissue excised⁵⁴⁻⁵⁶. While these problems are relatively uncommon, it must be borne in mind that these women are young and asymptomatic and the preservation of reproductive function is crucial. Any unnecessary or excessive treatment should therefore be avoided.

The impact of treatment on future pregnancies has been the subject of a recent meta-analysis⁵⁷. The authors found that all excisional procedures to treat cervical intraepithelial neoplasia with an increased risk of preterm labour and low birth weight but without apparent neonatal morbidity. While there may be other confounding socio demographic factors for these findings^{58,59}, the authors advised caution in the treatment of young women with mild cervical abnormalities⁶⁰. This seems sensible particularly when repeated treatments might be required.

Strategies to reduce the risk of colposcopic treatment

- Location
 - The majority of women should have treatment performed as an outpatient under local anaesthesia without the need for admission to hospital
- Training
 - Colposcopists should complete the treatment module of the BSCCP training programme and be certified as Treatment Colposcopists

- Selection
 - Treatment at the first visit to colposcopy 'see and treat' should be reserved for women with suspected high grade disease on both cytology and colposcopy
 - CIN should be present in over 90 per cent of histology specimens

6.4.2 Referral Guidance

6.4.2.1 Referral on the Basis of an Abnormal Smear Test

Colposcopy services should be managed effectively to make optimal use of available capacity and should be targeted at women at risk of high grade CIN. Appointments should be allocated and prioritised according to the presenting abnormality. Every effort should be made to facilitate an appointment within the recommended time; to delay risk of default⁶¹ as well as unnecessary anxiety for women^{62,63}

Urgent – target 90% seen within 2 weeks of referral	<ul style="list-style-type: none"> • Suspected invasive cancer
Soon – target 90% seen within 4 weeks of referral	<ul style="list-style-type: none"> • Severe dyskaryosis • Moderate dyskaryosis • Borderline – high grade cannot be ruled out • Suspected glandular abnormalities
In turn – target 90% to be seen within 8 weeks of referral	<ul style="list-style-type: none"> • Recurrent mild dyskaryosis* • Recurrent smear tests showing borderline abnormalities* • Low grade abnormalities following treatment • Recurrent inadequate smear tests

* include following previous colposcopy treatment

Figure 16: Referral to Colposcopy According to BSCC Terminology

6.4.2.1.1 Terminology and Cytological Classification

The verbal communication between the cytologists and clinicians of the degree of abnormality within cervical cells and the clinical potential of these changes is an important component of the cervical screening process. The original Papanicolaou⁶⁴ numerical classification has been reviewed and replaced by systems which use alternative terminology to provide a more meaningful result^{65,66}. Regional variations evolved describing the changes in different ways using different words. While this served to improve communication locally it was difficult to compare the results from different centres⁶⁷ and it undermined quality assurance initiatives⁶⁸.

In Britain during the 1980s a new system of cytological classification was introduced as a result of a working party of the British Society of Cytologists in an attempt to improve the quality assurance of cytological diagnosis^{69,70} as well as the standardisation of colposcopy referral practices^{71,72}. This involved the categorisation according to the degree of nuclear abnormality (dyskaryosis).

In the US in 1991 the Bethesda Classification was introduced which uses a different terminology of squamous intraepithelial epithelial lesions (SIL).

These are divided into:

- **Low grade SIL (LSIL)** which includes HPV-associated cellular changes, mild dyskaryosis
- **High grade SIL (HSIL)** which includes moderate dyskaryosis, severe dyskaryosis, carcinoma in situ
- **Squamous cell carcinoma**^{73,74}

The rationale for grouping was based on the similarity of these two lesions, which makes them difficult to separate in a consistent and reliable fashion⁷³. Cytological changes in squamous cells which are not normal and do not fulfil the criteria for SIL are classed as atypical. In a review of Bethesda in 2001, this category was subdivided into ASC-US ('atypical squamous cells of undetermined significance') and ASC-H ('atypical squamous cells of undetermined significance but high grade changes cannot be out ruled')⁷⁵⁻⁷⁸. This terminology has proven acceptable to cytologists and clinicians alike and has been rapidly adopted as the standard in many countries⁷⁹⁻⁸².

In Britain the BSCC terminology was reviewed and changes have been made which narrow the gaps between the two systems. These changes have included renewed definition of mild dyskaryosis to include koilocytotic change (similar to LSIL)⁸³ as well as more recently reclassification of borderline nuclear abnormality to include a category of borderline query high grade (similar to ASC-H)⁸⁴. These changes make it easier to make comparisons between countries in Europe⁸⁵ while facilitating the rights of each country to adopt the system that suits individual screening programmes^{86,87}.

Urgent – target 90% seen within two weeks of referral	<ul style="list-style-type: none"> • Suspected invasive cancer
Soon – target 90% seen within 4 weeks of referral	<ul style="list-style-type: none"> • HSIL • ASC-H • Suspected glandular abnormalities
In turn – target 90% to be seen within 8 weeks of referral	<ul style="list-style-type: none"> • Recurrent LSIL • Recurrent smear tests showing ASC-US • Low grade abnormalities following treatment* • Recurrent inadequate smear tests

* Includes ASC-US

Figure 17: Referral to Colposcopy According to Bethesda System

6.4.2.1.2 Evidence for Referral Guidance

6.4.2.1.2.1 High Grade Squamous Abnormalities

The aim of cervical screening is to reduce the incidence of cervical cancer through the detection and treatment of cervical pre-cancer. It is therefore generally accepted that women with high grade abnormalities should be referred for a colposcopic assessment and biopsy as most of these women have CIN3 and require to be treated⁸⁸.

Women should be referred for colposcopy after one smear test reporting **possible invasive cancer**; as many as 56 per cent of these will have invasive cancer⁸⁹. Women should be referred for colposcopy after one smear test reporting **severe dyskaryosis**; between 80-90 per cent of these women will have concurrent high grade CIN2 or 3⁹⁰. Women should be referred for colposcopy after one smear test reporting **moderate dyskaryosis**; between 70-75 per cent of these women will have CIN⁹¹. Using the Bethesda System, 90 per cent of women presenting with HSIL had histologically proven high grade CIN⁹².

6.4.2.1.2.2 Low Grade Squamous Abnormalities

Mild dysplasia (LSIL) is present in between 2-3 per cent of all cervical smear tests⁹³. The management is controversial because while many women have trivial changes which will regress spontaneously, a significant proportion will have CIN3 which requires treatment^{94,95}.

Any approach should be effective in reducing the risk of cervical carcinoma and should involve the appropriate use of resources. Two alternative management policies exist. The traditional policy of cytological surveillance is based on the belief that a majority of these abnormalities will revert to normal over time and referral to colposcopy is reserved for women with persistently abnormal cytology or those who develop severe changes^{96,97}. Although retrospective studies of well organised programmes suggest that women who are successfully followed-up do not have an increased risk of cervical cancer if a biopsy is performed when cytological changes persist⁹⁷, some women default from surveillance and these women are definitely at an increased risk of invasive cancer⁹⁷. Women with a smear test showing mild dyskaryosis (LSIL) should have a repeat smear test (at a six monthly interval) with referral for colposcopy following a second LSIL result as a minimum standard^{98,99}. Where capacity allows an alternative strategy of immediate referral facilitates earlier diagnosis of high grade CIN and reduces the opportunity for default¹⁰⁰⁻¹⁰².

6.4.2.1.2.3 Borderline/ASC-US

More than two million US women receive an equivocal cervical cytological diagnosis (atypical squamous cells of undetermined significance [ASC-US]) each year. In Britain where the BSCC terminology is used the equivalent abnormality is known as 'borderline nuclear abnormalities' (BNA). Comparisons of outcomes for these two categories may as a result differ but the underlying principles for management are the same. Only a minority of these women have high grade CIN and in many cases these abnormalities represent a self-limiting viral infection with the HPV virus. Women with koilocytosis were followed over a period of 21 months – only 1.2 per cent had CIN3 and 16 per cent had any degree of CIN^{103,104}. While the risk of CIN after a single smear test showing borderline cells is low, women with persistent borderline change have an increased risk of developing CIN over time¹⁰⁵⁻¹⁰⁷ and careful follow-up was therefore advised.

The authors of the large American multicentre ALTS study suggested that testing for high risk HPV DNA was a viable option in the management of women with ASC-US¹⁰⁸. The longitudinal results from a similar British study (TOMBOLA) study¹⁰⁹ involving repeated testing are awaited and as yet the role of HPV testing in the optimal management of women with ASC-US smear test reports has yet to be determined. Women should be referred for colposcopy after three smear tests reporting borderline nuclear change in squamous cells or if three smear tests in 10 years have been abnormal.

6.4.2.1.2.4 ASC-H

The 2001 Bethesda conference split the category of ASC-US into ASC-H (atypical squamous cells where HSIL cannot be ruled out) and ASC-US (atypical squamous cells of undetermined significance)¹¹⁰. The current consensus guidelines published by the ASCCP recommend immediate colposcopy for women with ASC-H¹¹¹.

Factors in deciding the management of women with low grade cytological abnormalities:

- Early diagnosis
- Colposcopy resources
- Anxiety and risk of unnecessary treatment
- Risk of default

6.4.2.1.2.5 Glandular Abnormalities

Cytological abnormalities can reflect pre-cancerous change in the glands of the cervix called adenocarcinoma in situ (AIS). These abnormalities are less common than their squamous counterparts and are difficult to detect and treat. Women should be referred for colposcopy after one smear test reporting **glandular neoplasia** because a high prevalence of both invasive cancer (40-45%) as well as concomitant CIN in up to 50 per cent of cases in this group of women¹¹²⁻¹¹⁷. Women should be referred for colposcopy after one smear test reporting **borderline nuclear change in endocervical cells** because these women have increased rates of malignant (4-16%) and pre-invasive disease (17-40%)¹¹⁸⁻¹²¹.

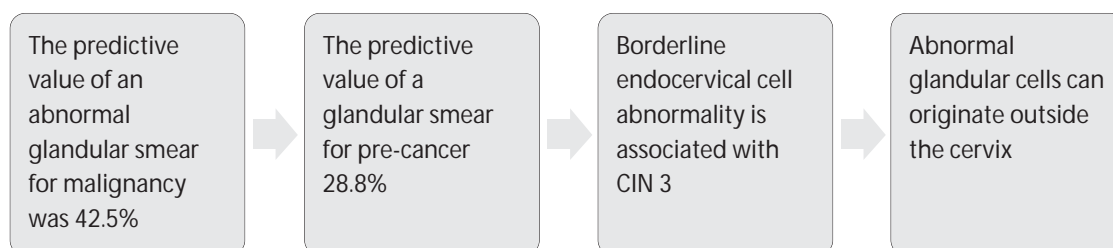


Figure 18: Key Information Regarding Glandular Abnormalities²⁰

6.4.2.1.2.6 Cytological Abnormalities Following Treatment

Women with previous treatment for CIN represent a high risk group with a risk of abnormality which is five times that of women with a normal smear test history¹²². In addition, the finding of an abnormal smear test and the diagnosis of what is often referred to as 'pre-cancer' can be a source of considerable anxiety with particular implications for future fertility, childbearing capacity and sexual function. Women who develop recurrent abnormalities following treatment are likely to be more anxious about any smear test result that is not normal. These anxieties stem from the finding of abnormal cells that are perceived as 'cancer cells'¹²³.

While little doubt exists that referral to colposcopy is stressful¹²⁴, it is clear that in the absence of colposcopy, women can be anxious at the idea of having a smear test that is not being attended to¹²⁵. The benefits of immediate colposcopy are early diagnosis, reassurance as to the absence of cancer, prompt treatment and a return to normal cytology. Women should be referred for colposcopy if they develop any grade abnormality on a smear test following treatment for CIN¹²⁶⁻¹²⁹ as these women are at an increased risk of developing cancer and early intervention will provide more reassurance.

6.4.2.1.2.7 Other Cytological Indications

Women should be referred for colposcopy after three consecutive inadequate smears tests¹³⁰⁻¹³² to provide reassurance and to rule out existing cancer.

6.4.2.2 Referral to Colposcopy for Other Indications

It is common for women with indications other than an abnormal smear test to be referred for colposcopy. The objective for the management of these women is the exclusion of invasive cancer as well as the management of symptoms.

- Clinically suspicious cervix
 - Women with a clinically suspicious cervix should be seen within four weeks of referral
 - Triage at the gynaecology clinic can reduce the pressure on colposcopy capacity
- Abnormal vaginal bleeding
 - Women with abnormal vaginal bleeding should have a speculum examination before referral for assessment within four weeks
 - Women under 35 with post coital bleeding should be tested for a Chlamydia infection

Suspicious lesions of the cervix are usually red, soft and fleshy or red, hard and irregular. It is important to do a speculum examination on women with intermenstrual bleeding or women with continuous 'non-stop' periods. The fact that a smear test cannot be performed in these circumstances should not preclude a prompt speculum examination. The presence of a symptomatic discharge should lead to a speculum examination and a high vaginal swab.

Cervical features not regarded as suspicious:

- Benign swellings
 - Nabothian cysts
 - Warts
 - Polyps
- Cervical ectropians
 - Physiological change in cervix
- Women with post treatment rosette
 - Red ring around internal os
- Bleeding at the time of a cervical smear test
 - Without other features

6.4.3 Diagnosis at Colposcopy

6.4.3.1 Introduction

Colposcopy plays an important role in the evaluation of women with suspected cervical abnormalities. It allows the identification of the site of the abnormality as well as an estimation of the grade of abnormality including the presence or absence of features suggestive of invasive cancer. As a procedure used alone however, it has diagnostic limitations with documented lack of correlation between the colposcopic and histological diagnosis, lack of reproducibility as well as difficulties in assuring the optimum site and quality of any biopsies¹³³.

Quality assurance and training are essential in maximising the opportunity for accurate diagnosis. To understand these limitations it is necessary to understand the anatomy and pathophysiology of the cervix as well as the changes that occur during the course of a woman's life.

6.4.3.2 Anatomical Considerations

The cervix is made up of two distinct types of tissue or epithelium; squamous and glandular. Where these two epithelia meet is an important anatomical landmark known as the Squamocolumnar Junction (SCJ). The location of this SCJ is not constant but changes with the changes which occur in the volume of the cervix in response to hormonal stimulation. Thus during the reproductive years, the SCJ is located on the outer or ectocervix and following menopause it retreats to the endocervical canal making it difficult to detect. The region between the original SCJ and the new SCJ is known as the Transformation Zone (TZ).

The TZ is the area where the majority of pre-cancerous changes are detected and the ability to recognise it is the crucial first step to colposcopic diagnosis. A recent classification of TZ types has been introduced to help colposcopists to document its location.

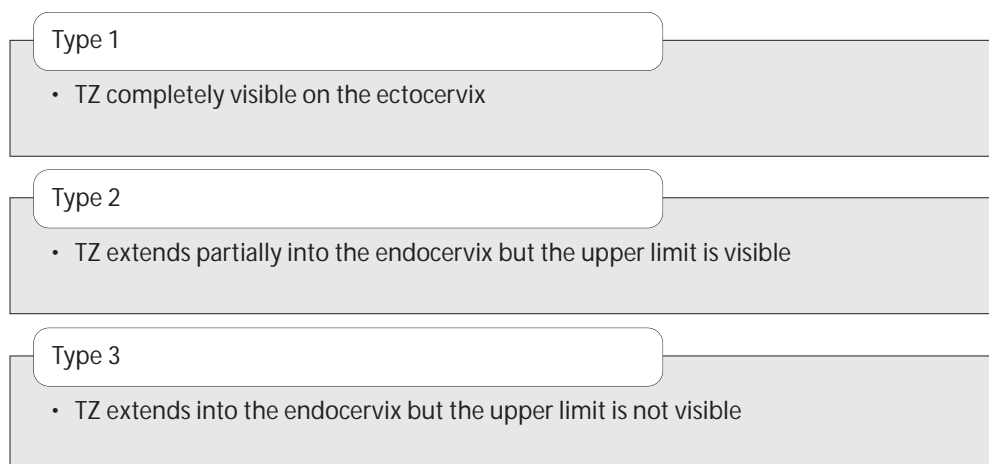


Figure 19: International Federation for Cervical Pathology and Colposcopy (IFCPC) Classification of the Transformation Zone (TZ) ¹³⁴

6.4.3.3 Colposcopy Process

Dilute acetic acid is applied to the cervix under direct vision and the diagnosis made based using a process of pattern recognition. This solution interacts with the cells protein structure and abnormal tissue shows up as a white area known as an atypical TZ. The intensity of the colour change as well as the sharpness of the margins help discriminate between grades of abnormality as does the rapidity with which the changes evolve and disappear.

A process of new blood vessel formation often accompanies high grade CIN on the cervix. These give rise to patterns which are distinguishable as punctuation on blood vessels which look like a series of red dots) and mosaicism (a cobblestone or 'crazy paving' type of appearance). In the presence of invasive disease this process becomes more chaotic with the appearance of abnormal blood vessels. These have a curly or spiral shape in contrast to the tree-like root and branch type normal vasculature which occurs in response to infection. The appearance of these vessels can be enhanced by the application of a green filter which excludes red light. Finally the location of the TZ can be checked using the application of Lugol's iodine. This stains mature squamous epithelium a dark brown colour while the immature epithelium stains an orange colour.

The colposcopists use pattern recognition to discriminate between normal, low grade and high grade disease¹³⁵. Clear documentation is vital and must include a description of the atypical features identified, the location of the TZ and SCJ and a colposcopic impression. Cervical imaging using either digital photography or videocolposcopy has been shown to represent what is seen at colposcopy and is useful for patient care as well as for teaching and audit^{136,137}.

Prerequisites for high quality diagnosis at colposcopy:

- Documentation
- Biopsy rate
- Clinico pathological review

6.4.3.4 Limitations of Colposcopic Assessment

The accuracy of colposcopic diagnosis as a single modality has been questioned. A systematic review of colposcopy demonstrated sensitivity and specificity levels for discrimination between high and low grades of CIN to be 96 per cent and 48 per cent respectively¹³⁸. The performance of colposcopy increases with the severity of the lesion¹³⁹, with the number of quadrants of the cervix involved¹⁴⁰ and with the level of experience of the colposcopist¹⁴¹. It is therefore recommended as good practice to perform a biopsy to confirm the diagnosis where possible.

6.4.3.5 Biopsy Methods/Indications

A histological diagnosis can be obtained by taking one or more diagnostic punch biopsies (using a special tissue sampling forceps or small loop biopsy) or by complete removal of the atypical area using an excisional biopsy (usually by means of a large loop excisional of the Transformation Zone or LLETZ). The aim is to sample an area which is indicative of the most abnormal area to provide confirmation of the colposcopic impression¹⁴²⁻¹⁴⁴. The accuracy of these biopsies is dependent on the target site chosen by the colposcopist¹⁴⁵. Efforts should be made to provide a high quality sample and to deliver adequate clinical information with the specimen to the pathology department.

Outlined below are situations where diagnostic biopsy must be performed including:

If the cytology shows HSIL (moderate dyskaryosis or worse)	<ul style="list-style-type: none"> An excisional biopsy could be performed at the first visit if the colposcopy impression is of high grade disease
If there is any evidence of atypia on the Transformation Zone (TZ)	<ul style="list-style-type: none"> The sensitivity and specificity of colposcopy using a threshold of low and high grade ranged from 30-90% and 67-97% respectively (Olanyan, 2002)
If there is a completely visible normal TZ and a confirmed low grade cytological abnormality	<ul style="list-style-type: none"> The sensitivity and specificity of colposcopy using a threshold of normal and abnormal ranged from 87-99% and 26-87% respectively (Olanyan, 2002)
In the presence of an biopsy result which is inadequate for analysis	<ul style="list-style-type: none"> More than 95% of biopsies should be suitable for pathology assessment Multiple biopsies should be taken for large lesions

Figure 20: Situations Where a Colposcopically Directed Biopsy should be Performed¹⁴⁶

Colposcopically directed punch biopsy can be a misleading investigation¹⁴⁷ particularly if there is any degree of endocervical involvement¹⁴⁸, suspicion of microinvasion¹⁴⁹ or for women with adenocarcinoma in situ¹⁵⁰ (AIS). Therefore there are situations when diagnostic punch biopsy may not be adequate and excisional biopsy should be considered. These include the following circumstances:

Where there is a suspicion of invasive cancer	<ul style="list-style-type: none"> A diagnostic punch biopsy alone provides insufficient stroma to allow accurate assessment of invasion
In the presence of significant endocervical extension	<ul style="list-style-type: none"> The accuracy of diagnostic punch biopsies is reduced to 58% in women with endocervical extension of the atypical lesion
In the presence of abnormal glandular disease	<ul style="list-style-type: none"> Abnormal glandular disease is often located in the endocervical canal and associated with skip lesions. It therefore is likely to be missed with a diagnostic punch biopsy

Figure 21: Situations Requiring Excisional Biopsies

6.4.3.6 Clinico Pathological Conference (CPC)/Multidisciplinary Team (MDT) Meetings

It is essential that clinico pathological correlation be an integral part of any cervical screening programme as a form of integrated quality assurance for cytology colposcopy and histopathology services. This involves the setting-up of standardised procedures for allowing the evaluation of cytology sampling techniques as well as the evaluation of the positive predictive value of cytology tests. Interaction between cytology and pathology personnel with clinicians adds greatly to diagnosis and patient management decisions.

Cyto-clinical correlation. Contact with clinicians and access to cancer registry data is essential	<ul style="list-style-type: none"> Laboratories should establish a mechanism to ensure follow-up of patients with cytology suggesting high-grade intraepithelial lesions and invasive carcinoma
Cyto-histological correlation is a major tool in internal education for both cytology and histology	<ul style="list-style-type: none"> The laboratory should compare abnormal cytology reports with subsequent histopathology and determine the causes of any discrepancy
The correlation process should be documented in the laboratory quality assurance programme	<ul style="list-style-type: none"> Positive predictive value for high-grade cytology provides a measure of accuracy of cytology reporting

Figure 22: The Importance of Clinico Pathological Correlation

It is recommended that one of the team act as programme co-ordinator to collate the relevant woman's details. A copy of the MDT report should be forwarded to the CervicalCheck programme via the colposcopy co-ordinator as well as all relevant clinicians including the referring doctor.

6.4.3.6.1 Web-Based Interactive Meetings between Clinicians, Histopathologists and the Cytology Service

Interaction between clinicians, histopathology and cytopathology expertise for the purposes of clinical and pathological correlation can be achieved through web-based meetings. Two solutions are required (a) formal clinico pathological conference (CPC) meetings and (b) individual case based discussions or consultations. Any solution needs to be carefully planned and delivered in a seamless way to meet the needs of clinicians and the pathologists reading the biopsy specimens as well as providing feedback to the cytopathology laboratory for audit purposes.

6.4.3.6.2 Primary Requirements

Necessary components include materials, expertise, a minimum level of IT infrastructure as well as an organisational process for scheduling case based discussions.

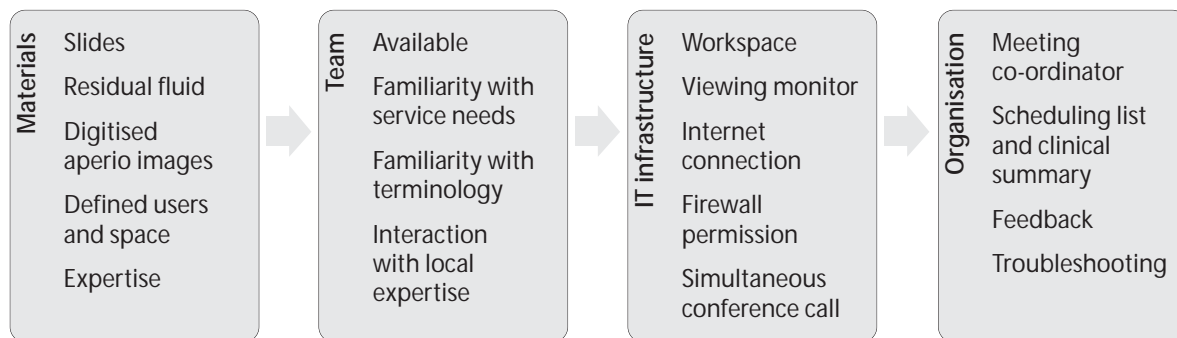


Figure 23: Tools for Clinico Pathological/Multidisciplinary Team (MDT) Meetings

6.4.3.6.3 Notification and Scheduling of Meetings

Colposcopy clinics should nominate a MDT co-ordinator who is responsible for scheduling meetings, defining the specific cases to be discussed and requesting as part of that package that the necessary cytology materials be made available for consultation. Ideally this should be done by using a standardised form detailing case number, name, DOB, hospital ID, PPS No., and reason for discussion with details filled in by the colposcopy clinic staff.

The MDT co-ordinator should link with both the histopathology and the cytopathology services to ensure the availability of materials for interactive discussion and dissemination of the list of cases should be sent 10 working days before the meeting. The cytopathology laboratory should scan the slides using a specialised scanner and to have those slides uploaded onto meeting specific folders on the internet. These should be uploaded in a sufficiently timely fashion to allow viewing by both pathologists with consultation if required before the meeting. Access to the colposcopic digitised images should also be organised. Where slides are required in addition to digitised images, these should be made available sufficiently early to facilitate consultation and review.

Currently different solutions exist for histopathology as part of clinico pathological meetings for colposcopy. It is vital that the histopathology be digitised to facilitate viewing by all. This can be done either before the meeting or during the meeting with the aid of a special microscope with the provision for instant digitisation. In addition this has the advantage of storage of the image for subsequent review.

Web-based meetings reduce the need for travel and represent a time efficient solution. Specialised online meeting services enable meetings to be accessed by up to 16 individual users. The advantage of these services is that they allow for change of presenter thus enabling presentation to alternate between the computers of different attendees. Simultaneous audio can be provided by either telephone or VOIP (voice over IP via special computer microphone/speakers) so that any programme accessed by the presenter can be viewed by all of the other attendees. Thus the colposcopist can access the colposcopy computerised management system, showing the colposcopy images, the histopathologist can access the stored images using presentation software or the instant digitiser and the cytopathologist can access the cytopathology images. This software also has the option of recording these meetings to enable playback at a later stage for invitees who could not attend in real time and for future audit.

Table 1: Suggested Approach to Issues of Correlation at Clinico Pathological Meetings

Cytology	Colposcopy	Histology	Review	Action
Normal	Abnormal	Abnormal	Smear test	Discuss
High grade	Normal	Abnormal	Colposcopy	Discuss
High grade	High grade	Normal	Histology	Repeat biopsy
High grade	Unsatisfactory	Normal	Smear test	Repeat biopsy
Abnormal Glandular cells	Normal	Normal	Smear test	Consider further investigations

6.4.4 Treatment at Colposcopy

The treatment of any identified precursors of cancer is vital to the success of any cervical screening programme. This treatment should be effective, safe and acceptable. It should aim to eradicate all CIN from the cervix and should be tailored to the circumstances of the individual woman



Figure 24: Aspects of Treatment at Colposcopy

6.4.4.1 What Treatment?

The treatment of CIN has evolved over the last 30 years away from invasive inpatient procedures such as hysterectomy and knife cone biopsy towards simpler outpatient treatments under local anaesthetic. Initially these treatments involved tissue ablation and included radical diathermy¹⁵¹, cryotherapy¹⁵², carbon dioxide laser^{153,154} and cold coagulation¹⁵⁵⁻¹⁵⁷. The availability of these treatments was of significant benefit to the patient in time and money saved, as well as to the saving of hospital bed space and theatre time. They were considered particularly useful for the young patient who had not yet completed her family as they did not significantly impact on subsequent fertility¹⁵⁸⁻¹⁶¹.

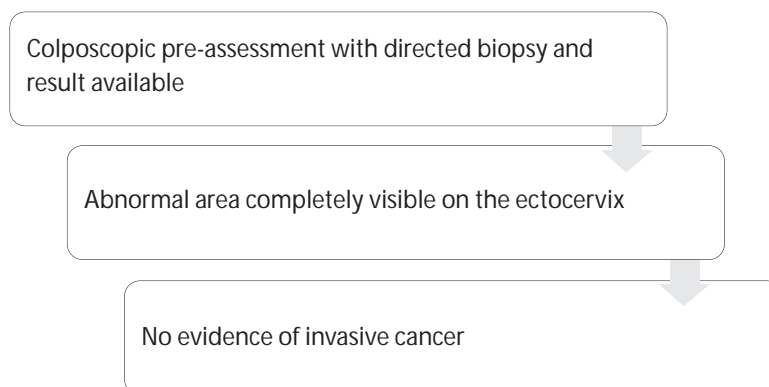


Figure 25: Criteria for Local Ablative Treatment at Colposcopy

Strict criteria need to be adhered to when using local ablative treatment. These include a thorough pre-treatment assessment including colposcopy and a colposcopic directed biopsy, an ectocervical lesion which is completely visible and an absence of colposcopic features of invasive cancer¹⁶². Concerns regarding the reliability of colposcopic directed biopsies^{163,164} and the lack of sensitivity of colposcopy to detect underlying early invasive cancer¹⁶⁵ fuelled considerable debate in the early 1990s as to the efficacy and safety of ablative techniques.

Large loop excision of the Transformation Zone (LLETZ) was introduced in 1988 as a simple outpatient excisional procedure which allowed histological examination of the entire Transformation Zone, thus facilitating confirmation of the diagnosis and margins of excision¹⁶⁶.

This procedure is associated with a low morbidity¹⁶⁷ and a single LLETZ does not have an adverse effect on subsequent fertility^{168,169}. Its ease of use and the opportunity to treat the patient at the first visit^{170,171} led to concerns regarding overtreatment in women with negative histology¹⁷². Despite these concerns LLETZ has been established as the most widely used method of treatment in the developed world^{173,174} during the last decade with recommendations that treatment at the first visit be selectively employed by experienced colposcopists who are able to distinguish high grade from low grade disease¹⁷⁵.

The comparative efficacy of the available treatments has been studied^{176,177}. The benchmarks of success of any treatment are the rates of invasive cervical cancer following the treatment as well as the subsequent incidence of recurrent CIN. Conservative outpatient therapy in women with CIN reduces the risk of invasive cancer of the cervix by 95 per cent during the first eight years after treatment¹⁷⁸ (Figure 26).

However, even with careful, long-term follow-up, the risk of invasive cervical cancer among these women is about five times greater than that among the general population of women throughout that period. The effectiveness of alternative surgical treatments for cervical intraepithelial neoplasia was examined in a Cochrane review of randomised trials which concluded that no individual type of treatment was superior¹⁷⁷. Reported non-randomised series of cryotherapy has suggested that single freeze techniques are associated with a higher risk of persistent disease than a double freeze technique (6.2% versus 16.3%)¹⁷⁹. Women should be counselled regarding the risk of persistent or recurrent disease and the need for careful and thorough follow-up.

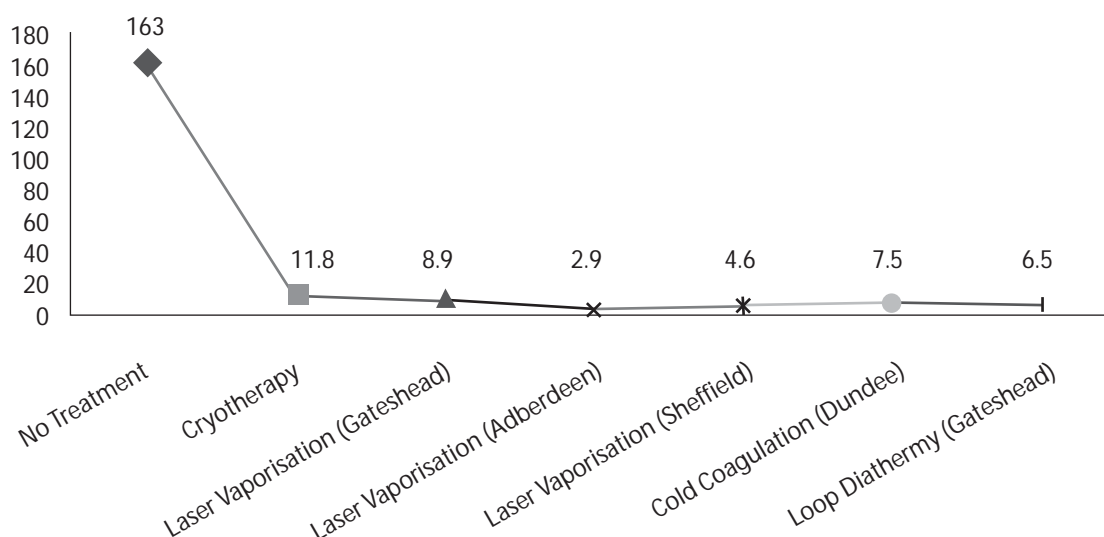


Figure 26: Invasive Cancer after Treatment; Cumulative Risk per 1000 Women¹⁸⁰

6.4.4.2 Who should be Treated?

Women with biopsy proven high grade CIN (2 or 3) or adenocarcinoma in situ (AIS, CGIN) should be treated. The natural history of CIN3 has demonstrated it as a true cancer precursor⁸⁸ and the recognised interobserver variation in histological reporting between grades of CIN¹⁸¹ has resulted in the widespread adoption of treating CIN2 as high grade disease.

Women with biopsy proven adenocarcinoma in situ (AIS) should be regarded as pre-cancerous¹⁸² and treated by conisation¹⁸³ or LLETZ¹⁸⁴ with the aim of obtaining negative excisional margins in a single specimen. Women who present with a smear test suggestive of high grade disease and who have a colposcopic suspicion of high grade disease can be treated at the first visit using a 'select and treat' policy¹⁸⁵.

The management of women with biopsy proven CIN1 is controversial in part due to the lack of reliable data on the natural history of this condition. One study which followed 566 women for a total of 881 years reported resolution of the abnormalities in 306 (54.1%) women, persistent disease in 138 (24.4%) and treatment in 122 (21.5%)¹⁸⁶. Surveillance is a viable option for these women if circumstances are favourable in terms of available facilities and patient compliance. Certain safeguards must be applied with treatment of those being observed if they continue to have an abnormality persisting for two years or if the lesion worsens in grade or size¹⁸⁷.

6.4.4.3 Treatment of Invasive Cancer of the Cervix

The diagnosis of invasive cancer is usually made on a LLETZ or cone biopsy specimen. The management is based on the stage. In 1995 microinvasive cancer was reclassified as Stage Ia and divided into Stage Ia1 and Ia2 (see figure below)^{235,236}. Women with stage Ia1 disease have less than 1 per cent risk of lymph node metastases and can be treated conservatively with local excision provided the margins show no abnormality. The excision should be repeated in the presence of positive margins²³⁷. All of these cases should be discussed at the multidisciplinary CPC. On the other hand, women with stage Ia2 disease need pelvic lymph node dissection as up to 6 per cent will have positive nodes²³⁸. Women with disease at stage Ia2 or more should be referred to a gynaecological oncology service for further treatment.

Stage I: Carcinoma confined to the cervix	<ul style="list-style-type: none"> • Ia1: Invasion < 3 mm deep, horizontal spread < 7 mm • Ia2: Invasion > 3 mm and not greater than 5 mm deep and < 7 mm wide • Ib1: Invasion > 7 mm wide or 5 mm deep but < 4 cm in size • Ib2: Tumour > 4 cm diameter
Stage II: Carcinoma extending beyond the cervix but not to the pelvic sidewall or the lower third of vagina	<ul style="list-style-type: none"> • IIa: No parametrial involvement • IIb: Parametrial involvement
Stage III: Tumour extends to the pelvic sidewall, or involves the lower third of vagina	<ul style="list-style-type: none"> • IIIa: No extension to pelvic sidewall • IIIb: Extension to sidewall or non functioning kidney
Stage IV: Extension beyond the true pelvis or to mucosa of the bladder or rectum	<ul style="list-style-type: none"> • IVa: Adjacent organ involvement* • IVb: Distant organ involvement

Figure 27: International Federation of Gynaecology and Obstetrics (FIGO) Staging of Cancer of the Cervix 2009

6.4.4.4 Other Treatment Issues; Glandular Abnormalities

Abnormal glandular abnormalities are relatively uncommon compared to their squamous counterparts but are of increasing importance because the incidence of adenocarcinoma of the cervix is rising especially in young women. This rise is seen even in countries with well organised screening programmes²³⁹. The difficulty is that glandular abnormalities are difficult to detect, difficult to treat and difficult to follow-up^{113,240,241}. Physical characteristics of glandular abnormalities which provide particular challenges when considering treatment include their endocervical location as well as the tendency for non-confluent or skip lesions²⁴²⁻²⁴⁴. Conisation should aim to be a cylindrical shape and 25 mm in depth and performed with a knife, straight wire or laser.

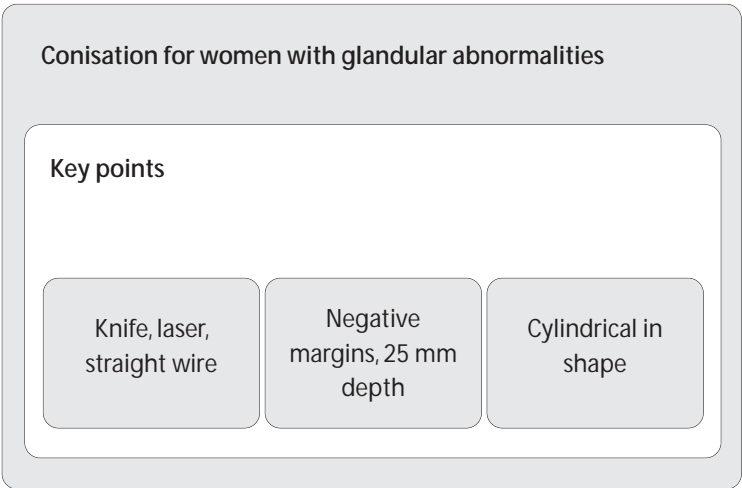


Figure 28: Treatment for Women with Glandular Abnormalities^{245,246}

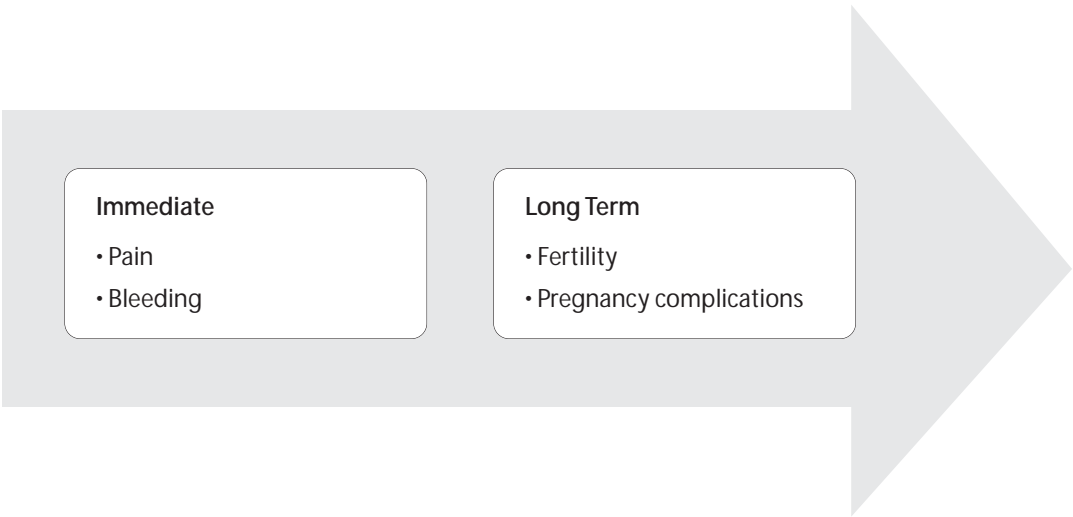


Figure 29: The Physical Effects of Treatment

6.4.5 The Follow-up of Treated Women

Women who have been treated for pre-cancerous conditions of the cervix continue to have an increased risk of both CIN^{188,189} and invasive cancer¹⁹⁰. These risks are more likely to be explained by the progression of inadequately treated persistent disease¹⁹¹ than the development of new or incident CIN.

All women should therefore be followed-up carefully after treatment using more intensive screening schedules to facilitate the early detection of any such persistent disease. The difficulty is that cytology testing may not be as effective at detecting residual CIN particularly where there is endocervical involvement or if there is post treatment cervical stenosis.

Strategies up to now have relied upon more frequent testing to compensate for any reduction in the sensitivity of cytology due to difficulties in sampling. The effectiveness of any schedule should be balanced against both the psychological impact of more intensive screening, the risk of default and the health resource implications of following-up large numbers of treated women. More recently, schedules have been tailored to the risk of recurrent disease allowing women who are at low risk to return to routine screening following less intensive surveillance¹⁹².

6.4.5.1 Risk Factors for Recurrence

Excisional treatment methods have the advantage that the margins of excision can be determined. Women with negative margins have a lower risk of residual disease and women with positive margins have a higher risk of residual disease¹⁹³⁻¹⁹⁸. This is particularly true when the endocervical margins are involved¹⁹⁹⁻²⁰¹.

Age is a risk factor with older women at increased risk²⁰²⁻²⁰⁴. Women aged 40 or more at the time of treatment who have high grade disease at the margins of excision are a small minority group at particular risk. In one series of 3,560 LLETZ treatments, 93 women were in this high risk group and all of the cancers diagnosed in the follow-up period came from this group²⁰⁵.

Fertility may not be such an issue for this group of women and consideration should be given to retreatment or possible hysterectomy rather than conservative follow-up.

Cigarette smoking^{206,207} was found to be an independent risk factor for recurrence of high grade CIN in two studies. This risk is potentially mediated through the disruptive effect of nicotine on the local immunological competence of the cervix²⁰⁸, effects which have been shown to be reversible through smoking cessation.

Persistent infection with high risk HPV virus types has been studied extensively in recent years as a risk factor for recurrence and has been proven to be associated with an increased risk of recurrent high grade CIN²⁰⁹⁻²¹⁵. This risk has been shown to be related to the viral load present at the time of treatment with increasing loads associated with increasing risk of persistent infection²¹⁶.

The absence of HPV infection on the other hand has been shown to be a valuable marker of low risk in many studies – most recently from a British multicentre study involving 917 treated women²¹⁷. As a result of these studies HPV testing is being introduced in many countries as an adjunct to cytology as a 'test of cure'²¹⁸⁻²²⁰.

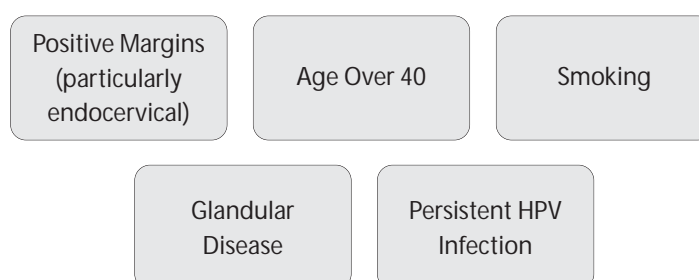


Figure 30: Risk Factors for Recurrence of CIN Following Treatment

6.4.5.2 Timing of Increased Surveillance Following Treatment

Most recurrences of CIN are detected in the first 24 months²²¹⁻²²³ which is compatible with the view that most recurrences result from persistent disease. It makes sense therefore to focus increased surveillance during this time period. Older long term follow-up studies following treatment of high grade CIN have demonstrated increased risk for at least 10 years following treatment²²⁴. This led to programmes extending the period of increased surveillance from five to 10 years for all women. These blanket policies did not discriminate between women at low risk and women at high risk of recurrence resulting in over management of some women. In addition, compliance with long term follow-up has been shown to be less effective than expected with a risk of default from surveillance²²⁵. BSCCP recommendations are tailored to the risk of recurrence with women under the age of 40 with completely excised low grade CIN identified as low risk with return to normal recall following three consecutive negative smear tests at six, 12 and 18 months following treatment⁵.

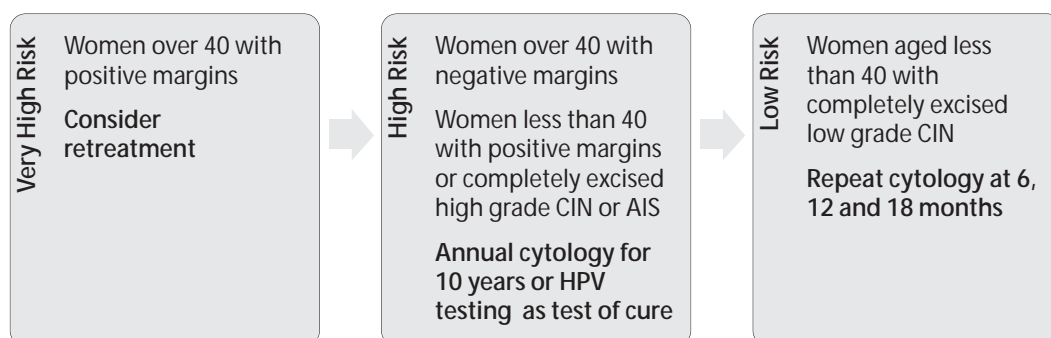


Figure 31: Risk Groups Following Treatment and Suggested Management

6.4.5.3 The Role of Additional Tests in the Follow-up of Treated Women

The relative merit of colposcopy in addition to cytology in the follow-up of treated women is unproven. Some authors have suggested that it facilitated earlier detection of residual disease^{226,227} while others have not demonstrated an advantage²²⁸. The difficulty is that cases which are potentially high risk of both residual disease and false negative cytology (older women, those with endocervical lesions or following treatment for glandular intraepithelial neoplasia²²⁹ are also the cases that colposcopy is least likely to detect abnormalities.

Women who test positive for HPV DNA following treatment for CIN are at an increased risk of recurrent or persistent disease^{230,231}. The absence of HPV DNA combined with negative cytology at six months following treatment has a negative predictive value of 99 per cent and has been suggested as useful in identifying low risk women²³²⁻²³⁴. These findings have the potential to be incorporated into screening programme policies allowing more women to be categorised as low risk and returned to routine recall earlier. Women with persistent HPV infection should have a colposcopy with a repeat treatment if they have persistent CIN. If the colposcopy is normal then these women should have annual cytology for at least 10 years as it is likely that they will remain at an increased risk of CIN.

6.4.6 The Management of Untreated Women

The management of women with low grade abnormalities has been the subject of considerable debate for the last number of years²⁴⁷⁻²⁵⁴. Many of these women have trivial changes which will regress spontaneously over time but a proportion have underlying high grade CIN and will require treatment. These are the most common abnormalities and represent 40 per cent of new referrals to colposcopy per year in Britain. While cytological surveillance in the community is still the normal management of women with a single smear test showing mild dyskaryosis (LSIL), the alternative strategy of immediate colposcopy is increasingly applied where capacity and resources allow.

Any colposcopic management plan has to balance early diagnosis and effective treatment with reduction of risk and appropriate use of resources. Previous policies of universal 'see and treat' reduced the demands on resources but were associated with considerable rates of overtreatment. Women who present with a low grade cytological abnormality and who have a normal colposcopy should have the smear test repeated and should be discharged from the clinic to routine recall following two negative smear test results²⁵⁵.

6.4.6.1 Women Who Present With Low Grade Abnormalities and Who Have Biopsy Proven CIN 1 or Less

Any woman with an atypical Transformation Zone should have a biopsy unless there is a good reason for not doing so (e.g. pregnancy). The natural history of biopsy proven low grade cervical abnormalities is one of spontaneous regression in up to 62 per cent²⁵⁶⁻²⁵⁸ of cases and conservative management is therefore recommended²⁵⁹. Whilst the majority of these lesions will regress, a significant excess incidence of invasive cancer was described in women with mild dysplasia²⁶⁰ with rates of between 0.6 per cent⁹⁷ and 1 per cent so careful cytological follow-up²⁶¹ is required.

While this surveillance should take place at colposcopy, the incremental benefits of routine colposcopy in addition to cytological surveillance at every visit have not been demonstrated conclusively. An alternative strategy of six monthly cytology at the colposcopy clinic with repeat colposcopy and consideration of treatment if there is cytological evidence of progression or if there is persistent disease at 18 months. Any management should be tailored to the needs of the woman however with age, patient choice and risk of default or non compliance as important factors which should be considered. A suggested strategy is included in the following figure.

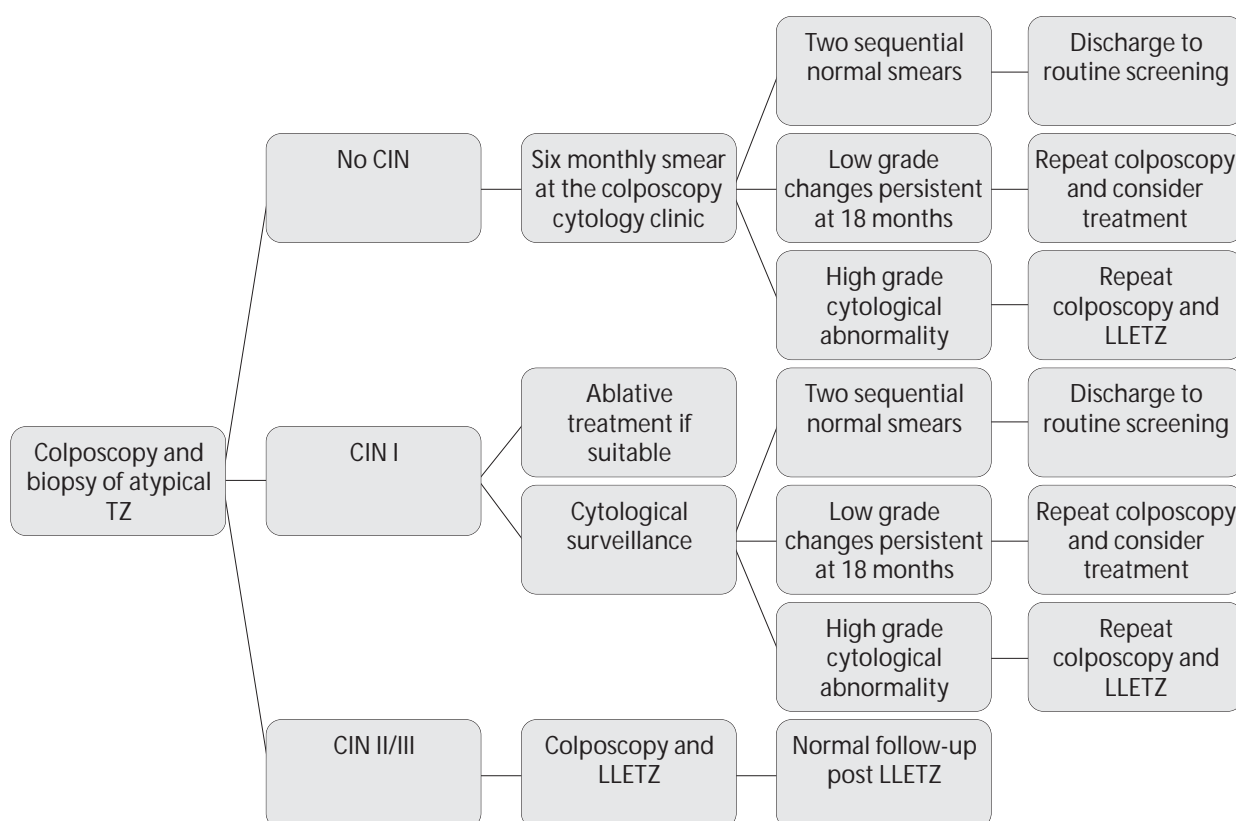


Figure 32: Suggested Colposcopic Management of Women with Low Grade Cytological Changes

6.4.6.2 The Management of Pregnant Women

Women who are pregnant and who require colposcopy should have this done as usual during the pregnancy²⁶². The focus of these visits is to rule out cancer and to provide reassurance for the woman²⁶³. Biopsies and treatment are avoided because of the risk of bleeding but must be done if there is any suspicion of invasive cancer^{264, 265}. Experienced colposcopists should perform these examinations as the increased blood flow to the uterus during pregnancy is associated with more marked vascular patterns. The woman is seen once or twice during the pregnancy and treatment is deferred until the woman is 10 weeks post partum.

6.4.7 Training in Colposcopy

Training in colposcopy has been identified as a key strategic objective for the promotion of quality assured colposcopy services across Europe by the European Federation of Colposcopy (EFC)²⁶⁶. In the UK, the BSCCP established a training programme for colposcopy in 1998. This programme includes theoretical as well as standardised practical experience²⁶⁷. It aims to provide core knowledge as well as the development of the necessary technical and communications skills to enable competency in colposcopy. In addition it promotes the development of professional attributes including a commitment to ongoing development including audit and evidence based practice.

The course consists of a diagnostic core with an optional treatment module. Trainees need to attend an entry level basic theoretical colposcopy course before the performance of at least 150 colposcopies under supervision. Histology and cytology sessions are also required; trainees should be familiar with the workings of the cytology and histopathology laboratories and spend at least one session in each. Nurse trainees must dedicate three sessions each to cytopathology and histopathology. In addition all trainees should attend clinico pathological (CPC) meetings.

The curriculum covers a wide range of topics which include understanding normal cervical cytology and histology, theories relating to cervical and lower genital tract neoplasia and related clinical areas that include bacteriology and virology with particular focus on the role of the Human Papillomavirus (HPV) in lower genital tract neoplasia. In addition there is a requirement to understand the aims and organisation of cervical screening programmes, as well the principles of audit and clinical governance.

Trainees learn by seeing and managing cases and through reflection and discussion with their trainers. Once competency in an aspect of practice is achieved, the relevant key competency can be ticked in the log book. In 2009 an electronic log book has been introduced to improve the experience for the trainee. This should be checked by the trainer on a regular basis to ensure that all topics are covered. It is recommended that training be completed within 12 months. Trainees should be encouraged to undertake at least one audit topic during their training, whether or not they had previous audit experience. Wherever possible they should be encouraged to participate in research studies.

Theoretical understanding	<ul style="list-style-type: none"> • 12 modules with a number of individual subjects • When this topic in reading has been addressed, the relevant box should be ticked
Practical experience	<ul style="list-style-type: none"> • 8 separate modules, each with targets with varying levels of competence • The trainer should sign-off attainment of the targets following assessment
The personal case record	<ul style="list-style-type: none"> • Includes 50 cases under direct supervision; 20 cases must be new including 10 high grade cases • A further 100 cases must be seen with indirect supervision; 30 must be new including 15 high grade

Figure 33: The BSCCP/EFC Training Log

6.4.7.1 Assessment of Progress during Training

The means of assessment of a trainee's progress during the training period has recently been changed by the BSCCP. During training the trainee will be assessed by a variety of educational tools.

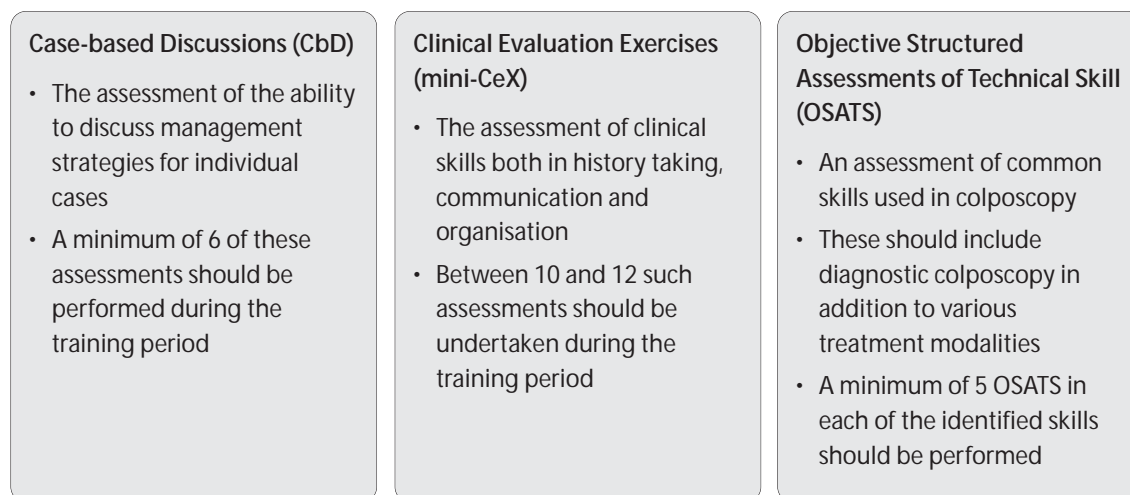


Figure 34: Colposcopy Training Assessment Tools

The objective of these assessments is to ensure that a trainee is progressing and improving and their level of skill is appropriate at each stage for their progress in training. It is recommended that a minimum of two independent assessors should undertake the above assessments. Successful completion of the above assessments is required prior to a candidate sitting the OSCE exam. In addition, a candidate would still submit to their case log of patients seen under indirect and direct supervision.

6.4.7.2 OSCE Examination

These examinations are organised by the BSCCP currently three times per year. Candidates must sit the examination within two years of being signed-off as having completed training. The examination consists of a combination of written, interactive and simulated patient stations. The candidate must pass a minimum of two thirds of the stations to be successful.

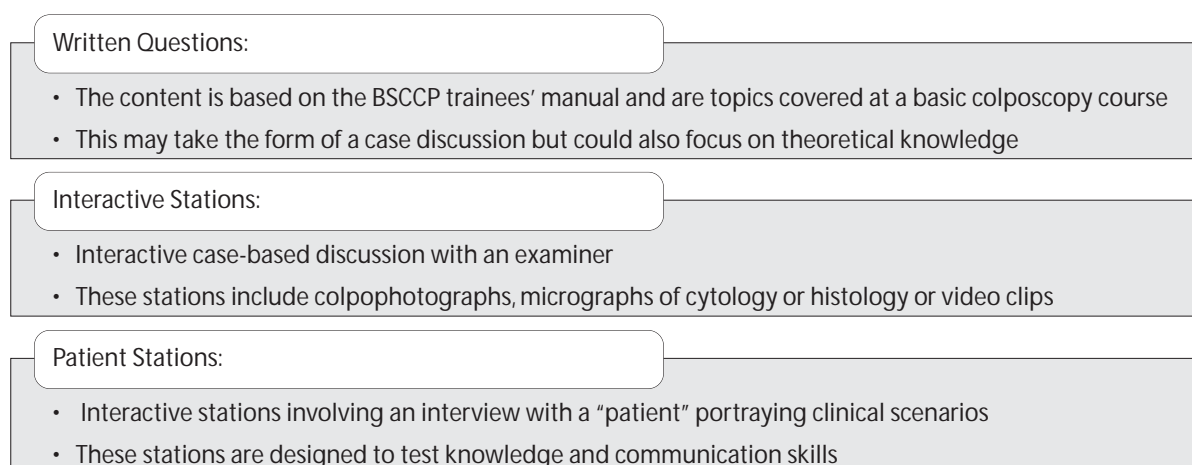


Figure 35: The OSCE Examination

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Appendix 1: Assessment Tools for Training in Colposcopy

Case Based Discussion

Please refer to curriculum and logbook for details of expected competencies for colposcopy

Case-based Discussion (CbD) – Colposcopy

Please complete the questions using a cross x				Please use black ink and CAPITAL LETTERS			
Doctor's		Surname Forename					
GMC Number		<u>GMC NUMBER MUST BE COMPLETED</u>					
Clinical Setting:		Colposcopy clinic		In-patient		Other	

Clinical problem	New Patient	Follow Up
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Focus of clinical encounter:	History	Diagnosis	Management	Explanation
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Complexity of case:	Low	Average	High	Assessors' status	Consultant	SpR (specify year)	Sister
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Please grade the following areas using the scale below	Below expectations for ATSM completion	Borderline for ATSM completion	Meets expectations for ATSM completion	Above expectations for ATSM completion	U/C*
1 Medical record keeping	1 2	3	4	5 6	
2 Clinical assessment					
3 Investigation and referrals					
4 Treatment					
5 Follow-up and future planning					
6 Professionalism					
7 Overall clinical judgement					

*U/C Please mark this if you have not observed the behaviour and therefore feel unable to comment

Anything especially good? Agreed action:	Suggestions for development
---------------------------------------------------------------	------------------------------------

Assessor's Signature:

Assessor's Surname:

Date: / /
Time taken for observation:
(in minutes)

Time taken for feedback:
(in minutes)

Objective Skills Assessment Tool (OSAT)

Diagnostic colposcopy				
Trainee Name:		StR year		Date:
Assessor Name:				
Clinical details of complexity/difficulty of case				
Preparation of patient	Performs independently	Needs help	Not applicable	
Ensures correct positioning of the patient				
Correct positioning of colposcope				
Demonstrates knowledge of equipment and can trouble shoot problems				
Operative procedure				
Correct use of speculum				
Correct use of magnification				
Correct use of green filter				
Inspects entire cervix				
Applies acetic acid				
Attempts to identify SCJ or upper extent of lesion, correct use of endocervical speculum if necessary				
Applies Lugol's iodine				
Correct identification of TZ type (i.e 1,2 or 3)				
Correct interpretation of findings				
Correct technique to obtain a cervical biopsy				
Correct technique to bring about haemostasis from biopsy sites				
Maintains a clean working area and does not contaminate equipment				
Comments				

Treatment

Treatment – Large Loop Excision of Transformation Zone				
Trainee Name:		StR		Date:
Assessor Name:				
Clinical details of complexity/ difficulty of case				
Preparation of patient	Done independently	Needs help	Not applicable	
Ensures correct positioning of the patient				
Correct positioning of colposcope				
Demonstrates knowledge of equipment, safety issues and can trouble shoot problems				
Operative procedure				
Correct use of speculum				
Correct use of magnification				
Correct use of green filter				
Inspects entire cervix				
Applies acetic acid				
Attempts to identify SCJ or upper extent of lesion, correct use of endocervical speculum if necessary				
Applies Lugol's iodine				
Correct identification of transformation and area to treat				
Correct technique in use of local anaesthetic				
Correct technique in use of loop diathermy to excise transformation zone				
Able to switch on diathermy machine and choose correct blend and power settings				
Correct technique in use of ball diathermy				
Completes treatment within 10 minutes from start of excision				
Maintains a clean working area and does not contaminate equipment				



7

Quality Assurance in Histopathology

7.1 Introduction

The following is based on the European guidelines for quality assurance in cervical cancer screening¹ and other relevant documentation (see Bibliography) and aims to list the standards required for histopathology services as part of CervicalCheck – The National Cervical Screening Programme.

Histopathology:

- Provides the final diagnosis of cervical neoplasia, thus forming the basis for which treatment is planned
- Serves as the 'gold standard' for quality control of cytology and colposcopy
- Is the source of diagnostic data stored at the cancer registry and used for evaluation of screening programmes. It is therefore important that histopathology standards are monitored and based on agreed diagnostic criteria
- 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 suggest either glandular abnormalities or be suggestive of high grade CIN, (adenocarcinoma in situ) AIS or invasive cancer

Histopathologists must be aware of, and familiar with the nature of cytological changes which may be relevant to their reports.

The accuracy of the histopathological diagnosis of tissue specimens depends on adequate samples, obtained by colposcopically directed punch biopsies (with endocervical curettage if necessary) or excision of the Transformation Zone (TZ) or conisation.

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

This chapter proposes guidelines for sampling and processing of cervical tissue specimens obtained by biopsy, excision and/or curettage.

Cervical cytology currently represents the primary screening method, but does not provide the final diagnosis. Abnormal cervical cytology should be followed by colposcopy and microscopic evaluation of cervical tissue².

Colposcopy on the other hand is necessary to locate the most abnormal areas of the cervix³.

The validity of the histopathological report will also depend on the quality of the biopsy. Since these specimens are often very small (in the range of millimeters), careful handling and work-up is required. If positive cytology does not correlate with the histological findings from the biopsies, the pathologist has to consider that a dysplastic lesion could be small and missed by the biopsy or alternatively not visible due to endocervical localisation. Histology and cytology should be closely correlated to give the gynaecologist a clear impression of the individual patient situation.

Excision biopsy represents a special type of tissue specimen. Its objective is the complete removal of dysplastic lesions found by a previous biopsy and/or cytology. The histopathological report of an excision biopsy should include a clear diagnosis of the primary lesion, a description of the resection margins and a comment in relation

to other identified lesions. Since possible microinvasion has a major impact on the management of patients, complete work-up of excised tissue examined at different step levels is recommended. Additional immunohistochemistry in selected cases may support a diagnosis of possible microinvasion or vessel involvement and might help in the distinction between squamous or glandular neoplasia^{4,5}.

As stated in a RCPATH publication, and reiterated by The Faculty of Pathology, Royal College of Physicians of Ireland (Faculty of Pathology – April 2009), it is important to recognise that the interpretative reports provided in histopathology and cytopathology are the opinion of the reporting pathologist^{6,7}.

There is therefore a subjective element in the content of any report. This is relevant when more than one pathologist reviews diagnostic material, as legitimate variations in opinion may be expected in some clinical contexts, especially due to the variability in inter-observer reproducibility. The degree of uncertainty may also reflect the adequacy of the material provided for assessment and the nature of the disease process.

The pathologist's training and experience, continued professional development (CPD), and participation in competency assessment schemes play an important role in managing this uncertainty.

Adequate resourcing by The Health Service Executive (HSE), and hospital management is essential to ensure successful implementation of this QA programme at a local level. Pathologists should work with hospital management to ensure that the agreed quality assurance processes are appropriately resourced.

A diagnostic pathology service requires appropriate laboratory staffing, space, equipment and consumable funding so that pathologists have sufficient time and scientific support to provide a good quality report for patient care⁴. Aspects of this are considered as part of laboratory accreditation. The resource implications (pathologists' time and other laboratory resources) will vary considerably according to how quality assurance procedures are implemented and should normally be commissioned by local agreements with hospitals/laboratory management.

Demonstration of compliance with standards will include site visit, inspection of all relevant documentation and audit of policies, procedures and records against the NCSS standards.

7.2 Definitions and Terms

7.2.1 Punch Biopsies: Punch biopsies are small pieces of tissue a few millimetres in diameter that are removed from the cervical mucosa with a biopsy forceps.

7.2.1.1 Diagnostic Goal: When colposcopy is satisfactory and obvious area/s of CIN can be visualised, histological examination of punch biopsies can be sufficient to obtain a correct diagnosis.

7.2.1.2 Macroscopic Description: The number, diameter, colour and consistency of the specimens should be documented.

7.2.1.3 Technique: In case of multiple cervical biopsies, each area of the cervix from which the biopsies have been taken should be identified separately. Specimens are fixed in 10 per cent buffered formalin at room temperature, followed by paraffin processing and embedding according to routine procedures. Four µm paraffin tissue sections at three levels are stained for Haematoxylin & Eosin (H&E) and/or processed for special stains and immunohistochemistry, if indicated.

7.2.1.4 Histological Diagnosis: The histological report should include:

- Tissue type
- Absence or presence and type of neoplastic lesions
- Grade of identified lesions:
 - Squamous lesions: cervical intraepithelial neoplasia 1-3 (CIN1-3)
 - Invasive cancer
 - Glandular lesions: high grade and low grade cervical glandular intraepithelial neoplasia (CGIN) invasive adenocarcinoma or adenosquamous carcinoma
 - Other neoplastic lesions (e.g. lymphoma, melanoma etc.)
 - Other non-neoplastic lesions
 - Presence of HPV-associated changes (koilocytes, dyskeratosis)
 - Size of the lesion (in mm)
 - Characterisation of non-neoplastic lesions
 - Stromal reaction: presence and extent of inflammation or desmoplastic reaction
 - In case of invasive cancer, depth of invasion, presence of lymphovascular involvement and the degree of differentiation should be documented^(*,**)

* CIN1 (flat condyloma; koilocytosis; mild dysplasia): Neoplastic, basaloid cells and mitotic figures occupy the lower third of the epithelium in CIN1 lesions. These lesions frequently show marked HPV cytopathic effects including perinuclear halos, multinucleation and nuclear membrane irregularities, and hyperchromasia (e.g. 'koilocytosis'). CIN2 (moderate dysplasia): In CIN2, neoplastic basaloid cells and mitotic figures occupy the lower two thirds of the epithelium. CIN3 (severe dysplasia lumped with carcinoma in situ): The characteristic histological feature of CIN3 is the presence of neoplastic basaloid cells and mitotic figures that occupy the full thickness of the epithelium. These cells have high nuclear:cytoplasmic ratios, with scant cytoplasm and dense, hyperchromatic nuclei having coarse clumped chromatin and irregular nuclear outlines (IARC, 2005).

** CGIN is recognised histologically by a combination of architectural and cytological abnormalities, though a consistent feature is the presence of nuclear abnormalities. Not all features are seen in every case.

Architectural features include glandular crowding, branching and budding; intraluminal papillary projections; cribriform pattern. Cytological features include abrupt junction between normal and abnormal epithelium; intestinal / goblet cell metaplasia; loss of mucin-secretion in cells of endocervical type; cellular stratification but only when combined with nuclear changes; loss of nuclear polarity; nuclear enlargement, pleomorphism, hyperchromasia; mitotic activity, some of which may be abnormal forms; prominent nucleoli; apoptosis. It can usually be distinguished from microinvasive adenocarcinoma by its limitation to the glandular field, admixture of normal and abnormal glands, lack of stromal response and lack of cytological changes seen in microinvasive adenocarcinoma (increased pleomorphism, paler, more copious and eosinophilic cytoplasm). Invasion should not be excluded on small punch biopsies.

These guidelines strongly recommend the CIN classification for histological diagnosis. Careful attention to criteria for diagnosis of the three grades of CIN (CIN1-3) should be observed⁸. Carcinoma in-situ (CIS) is usually combined with CIN3. Broadly speaking CIN1/koilocytosis (correlating to LSIL) is likely to be reversible and associated with productive HPV infection⁹. CIN2 and CIN3/carcinoma in situ (correlating to HSIL) are more likely to persist or progress if left untreated and also more likely to be associated with HPV integrated into the host genome⁹.

Two meta-analyses of follow-up studies indicate a greater likelihood of regression and a lesser likelihood of progression of CIN2 compared to CIN3^{10,11}. CIN3 is a more robust diagnosis than CIN2 and is therefore more useful as a gold standard for outcome.

In small biopsies, it may occasionally be necessary to report CIN as ungraded but where possible diagnoses such as CIN1-2 should be avoided.

The distinction between individual grades of CIN is poorly reproducible but improves with increasing grade. Diagnoses of CIN3 and invasive cancer are the most reproducible^{12,13}. Immature squamous metaplasia and atrophic squamous epithelium are documented sources of misinterpretation and may be mistaken for CIN1-2¹⁴. In such cases, p16 staining and repeat biopsy after oestrogen may be helpful¹⁵⁻¹⁸.

Precise grading of cGIN is poorly reproducible and there is little evidence that it forms a biological spectrum⁸. High grade cGIN equates to adenocarcinoma in situ and low grade cGIN is usually managed in the same way. Low grade cGIN should be reported infrequently and care must be taken to distinguish it from benign conditions that may mimic it¹⁹. The same strictures apply to diagnoses of glandular dysplasia and atypia^{8,20}.

7.2.2 Excision Biopsies: Excision biopsies represent nearly cone-shaped portions of cervical tissue including the lower part of the endocervical canal and a portion of the ecto-cervix. Excision biopsies include cold knife conisation, laser conisation, Large Loop Excision of the Transformation Zone (LLETZ*), Needle Excision of the Transformation Zone (NETZ) and Straight Needle Excision of the Transformation Zone (SWETZ). Cold knife (and laser) cone biopsies are indeed cone-shaped tissue specimens whereas LLETZ excisions in most cases represent a more disc shaped, ectocervical portion sometimes with an extra biopsy from the middle of the endocervical canal (top hats). The histopathologist should be able to recognise and deal with these different forms of excision biopsies.

7.2.2.1 Diagnostic Goals: An excision biopsy should aim to remove all pathological tissue (identified by colposcopy) including a part of the endocervical canal and the Transformation Zone. The procedure should be diagnostic (provide a precise histological diagnosis) and therapeutic (resection of the lesion).

The specimen may be received in three formats:

- Complete excision of the lesion including the cervical os (Figure 36)
- Opened excision (at the time of removal) with the open position designated and the specimen either pinned to a cork board/cardboard or loose in the specimen container (Figure 37)
- As multiple fragments (Figure 38)

* In American terminology most often the term LEEP (Lus Electrosurgical Procedure) is used, whereas in the English literature, usually the term LLETZ (Large Loop Excision of the Transformation Zone) is used. In this document, only LLETZ is used.

7.2.2.2 Macroscopic Description: Description should include the size of the specimen (length and diameter), number of pieces, localisation of the cervical canal (central, paracentral or marginal), any visible lesion, and the position of any markings and sutures for orientation of the specimen²¹.

7.2.2.3 Technique: Usually an excision biopsy removes the whole Transformation Zone, including a portion of the lower endocervical canal. The biopsy should be clearly marked (e.g. colour or threads at 12 o'clock) to enable adequate orientation throughout the future work-up^{22,23}. The integrity of the cervical canal should be preserved and not altered by prior dilatation.

Several techniques for sectioning excision biopsies have been described²⁴. The methods used include opening, pinning and serially sectioning the specimen – or fixing and serially sectioning the unopened specimen at right angles to the os. A simple and easily reproducible method is the division of the tissue into two equal halves along the axis of the cervical canal. Each half is embedded in separate deep (1 cm) cups followed by complete step (0.1 mm) serial sectioning.

This method is described in the guidelines of the Austrian Society of Pathology²⁵ and results in histological slides that are easy to orient and interpret, including in most cases an accurate evaluation of the resection margins (see Figure 36).



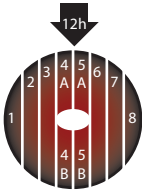
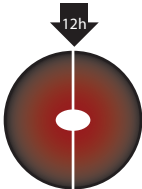
	<p>Radial cutting includes opening longitudinally and pinning. Sequential identification of each section allows accurate mapping of the lesion</p> 
	<p>Parallel antero-posterior cutting from left to right (or vice versa) should include ink application of one margin in minimum, application of multiple colour inks simplifies proper identification of various margins. If divided into an anterior and posterior fraction numbering of the posterior part should follow the same order as the anterior part</p>
	<p>Division into two equal halves along the axis of the cervical canal. Each half should be marked by colour inking of one margin as a minimum, and is then embedded in separate deep (1cm) cups followed by complete step (0.1mm) serial sectioning</p>

Figure 36: Examples of Techniques for Sectioning Excision Biopsies

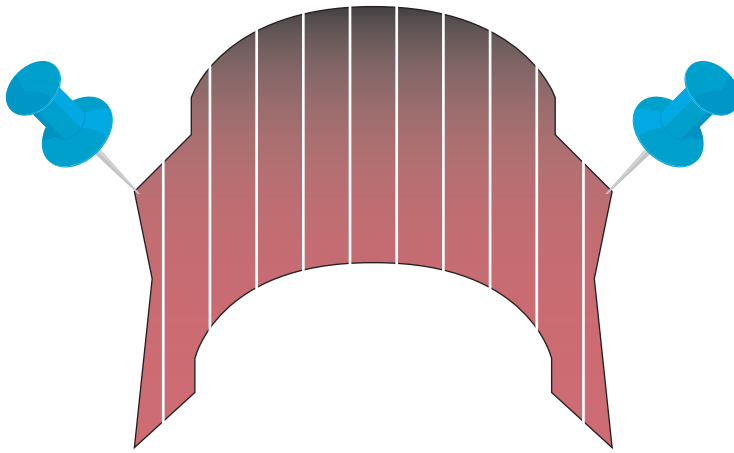


Figure 37: Example of an Opened LLETZ/SWETZ/NETZ Pinned to a Corkboard/Card

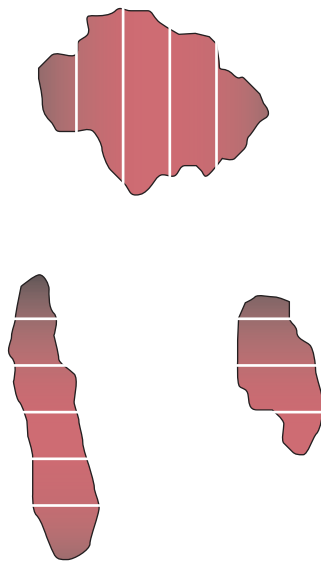


Figure 38: Example of Multiple Fragment Cone, LLETZ, NETZ, SWETZ Biopsy

7.2.2.4 Histological Diagnosis: Histological reports on an excision biopsy should provide a well formatted pathological diagnosis as summarised below. The diagnosis should also be in concordance with the WHO histological classification of tumours of the uterine cervix (Tables 1 and 2).

In addition to a precise description of the histological type of the lesion, the report should include information concerning the:

- Grade of neoplastic lesion
- Localisation of the lesion within the excision biopsy
- Uni/multifocality of the lesion
- Extent of the lesion (in cases of microinvasive and invasive cancer, measurement of vertical and horizontal diameters is crucial for adequate staging)
- Stromal reaction
- Involvement of microvessels
- Relation of tumour tissue to all resection margins (distance)
- Description and characterisation of additional non-neoplastic lesions (tuboendometroid metaplasia, microglandular hyperplasia, endometriosis, regenerative and repair changes)

Table 2: Histological Classification of Preinvasive Intraepithelial Lesions of the Uterine Cervix

Dysplasia classification	Cervical intraepithelial neoplasia (CIN and CGIN) classification	Bethesda classification (used for cytology)
Mild dysplasia	CIN 1	LGSIL
Moderate dysplasia	CIN 2	HGSIL
Severe dysplasia	CIN 3	HGSIL
Carcinoma in situ	CIN 3	HGSIL
Endocervical dysplasia	CGIN (low-grade, high-grade)	AGC
Adenocarcinoma in situ	CGIN (high-grade)	AIS

The term 'microinvasive carcinoma' may be applied to squamous cell carcinomas and adenocarcinomas, but only when accompanied by measurements of depth and lateral extent of a completely excised lesion. The diagnosis can then be defined according to the FIGO (International Federation of Gynecology and Obstetrics) definitions of stage 1A1 and 1A2 (Table 3), for which there is an evidence base for outcome after treatment^{8,26}.

Depth of invasion should be measured from the base of the epithelium from which the invasive lesion arises and the lateral extent from the section in which the width is widest. Stage 1A1 lesions (less than 3 mm depth and less than 7 mm width) should be specified as either one or more foci of early stromal invasion or a confluent lesion. Stage 1A2 lesions are defined as 3-5 mm depth and less than 7 mm width.

Adenocarcinomas should be measured and recorded in the same way but there are no reliable criteria for distinguishing 1A1 and 1A2 tumours. If an invasive lesion cannot be measured as indicated above, it should be described as a small invasive carcinoma and classified as 1B1. The presence of lymphovascular invasion should be recorded but does not affect the FIGO stage.

7.2.3 Endocervical Curettage (ECC): Endocervical curettage (ECC) is a sampling procedure to obtain endocervical tissue. This practice is rarely used in the Republic of Ireland.

7.2.3.1 Diagnostic Goal: The objective of ECC is:

- To evaluate any ectocervical squamous cell lesion extending to the endocervical canal
- To detect endocervical adenocarcinoma and its precursor lesions
- To determine cervical involvement of any non-cervical malignancies

Endocervical curettage combined with colposcopically directed ectocervical punch biopsies allows histological assessment of both the ecto- and endo-cervix, without excising a substantial amount of cervical tissue²⁷. However, ECC has a limited sensitivity to detect endocervical CIN or cGIN. ECC also alters the architecture of the endocervical canal, compromising the assessment of a later conisation.

Collection of endocervical cells, using an endocervical brush, has in several studies shown a higher sensitivity (but a lower specificity) than ECC²⁸⁻³⁰. Other authors support the use of ECC, since it allows the detection of colposcopically hidden lesions³¹.

7.2.3.2 Macroscopic Description: The number, diameter, color and consistency of the specimen fragments should be documented.

7.2.3.3 Technique: ECC provides tissue from the endocervical canal by using an endocervical curette. Tissue from all four sides of the cervical canal should be obtained. Very small specimens should be wrapped in paper prior to paraffin processing and embedding. Serial sections of the biopsy specimens are recommended.

7.2.3.4 Histological Diagnosis: The description of tissues found in the curetted material should specify:

- The presence of endocervical glands, endometrial tissue, squamous epithelium
- Glandular or squamous intraepithelial neoplastic and non-neoplastic changes
- Evidence of invasion
- Neoplastic or non-neoplastic stromal alterations
- Presence and kind of inflammatory processes

7.2.4 Trachelectomy

In gynaecologic oncology, trachelectomy, also cervicectomy, is a surgical removal of the uterine cervix. As the uterine body is preserved, this type of surgery is a fertility preserving surgical alternative to a radical hysterectomy and applicable in selected younger women with early cervical cancer.

Trachelectomies, broadly, can be divided into the simple and radical variants.

The formal name of this operation is radical vaginal trachelectomy (RVT) and also known as the Dargent operation and radical trachelectomy.

The word radical is used as, in addition to the cervix (like in radical hysterectomies), the parametria (tissue adjacent to the cervix) and vaginal cuff (the end of the vagina close to the cervix) are also excised as a part of the operation. It is usually done with a lymphadenectomy, to assess for tumour spread to the lymph nodes.

A simple trachelectomy refers to the removal of the cervix; this can be considered to be a very large conisation procedure.

Radical trachelectomy is considered to be the optimal treatment for women of age ≤ 40 years with a desire to preserve fertility and stage IA2 or mild stage IB1 disease; more specifically, it is deemed appropriate when the disease consists of a tumour less than or equal to 2 cm in largest dimension and has not spread to lymph nodes. However, it is not yet considered the standard of care; hysterectomy is the standard of care. Conisation is considered the standard treatment for less advanced cancers (stage 1A1).

7.2.4.1 Diagnostic Goals: A trachelectomy should aim to remove all pathological tissue (identified by colposcopy) including a part of the endocervical canal and the Transformation Zone (simple trachelectomy) and parametria and vaginal cuff +/- lymphadenectomy (radical trachelectomy). The procedure should be diagnostic (provide a precise histological diagnosis) and therapeutic (resection of the lesion).

The specimen may be received in three formats:

- Complete excision of the lesion including the cervical os
- Opened excision (at the time of removal) with the open position designated and the specimen either pinned to a cork board/cardboard or loose in the specimen container
- As multiple fragments

7.2.4.2 Macroscopic Description: Description should include the size of the specimen (length and diameter), number of pieces, localisation of the cervical canal (central, paracentral or marginal), any visible lesion, and the position of any markings and sutures for orientation of the specimen. In the case of radical trachelectomy, specific comment must be made in relation to the parametrial tissues, vaginal cuff and any resected lymph nodes.

7.2.4.3 Technique: Usually a trachelectomy (simple trachelectomy) removes the whole Transformation Zone, including the endocervical canal. The specimen should be clearly marked (e.g. colour or threads at 12 o'clock) to enable adequate orientation throughout the future work-up. The integrity of the cervical canal should be preserved and not altered by prior dilatation. Several techniques for sectioning trachelectomies can be used. The methods used include opening, pinning and serially sectioning the specimen – or fixing and serially sectioning the unopened specimen at right angles to the os. In the case of radical trachelectomy, the parametrial and vaginal cuff tissues need to be inked using differential inking and blocked separately. If concomitant lymphadenectomy is performed, then lymph nodes should be counted, described and one lymph node embedded in a separate histology block.

7.2.4.4 Histological Diagnosis: Histological reports on trachelectomy should provide a well formatted pathological diagnosis as summarised below. The diagnosis should also be in concordance with the WHO histological classification of tumours of the uterine cervix (Tables 1 and 2).

In addition to a precise description of the histological type of the lesion, the report should include information concerning the:

- Grade of neoplastic lesion
- Localisation of the lesion within the excision biopsy
- Uni/multifocality of the lesion
- Extent of the lesion (in cases of microinvasive and invasive cancer, measurement of vertical and horizontal diameters is crucial for adequate staging)

- Stromal reaction
- Involvement of microvessels
- Relation of tumor tissue to all resection margins (distance)
- Description and characterisation of additional non-neoplastic lesions (tuboendometroid metaplasia, microglandular hyperplasia, endometriosis, regenerative and repair changes)
- Comment on the vaginal and parametrial margins (radical trachelectomy)
- Comment on resected lymph nodes (if performed in radical trachelectomy)

7.2.5 Hysterectomy

Hysterectomy can be performed in different ways. Traditionally, it has been performed via either abdominal incision (total abdominal hysterectomy [TAH] via laparotomy) or vaginal canal (vaginal hysterectomy). The following are the types of hysterectomy performed.

Radical hysterectomy: Complete removal of the uterus, upper vagina, and parametrium. Wertheim's hysterectomy (for cervical cancer) involves removal of the uterus, parametrium, tissues surrounding the upper vagina, and pelvic lymph nodes.

Subtotal hysterectomy: Removal of the fundus of the uterus, leaving the cervix in situ

Total hysterectomy: Complete removal of the uterus including the corpus and cervix

In relation to CervicalCheck and the NCSS any of the above hysterectomy types could be encountered, with total and radical types more likely.

7.2.5.1 Diagnostic Goal: The objective of hysterectomy is:

- To identify previous biopsy sites (if any)
- To evaluate the extent of any cervical pre-neoplastic/neoplastic lesion (squamous or glandular)
- To comment on excision of such lesions
- To comment on vaginal margin excision (if applicable)
- To comment on the radial excision margin/s of the cervix
- To comment on the presence of extension of disease into the lower uterine segment
- To comment on the presence of extension of disease into endometrium, myometrium or parametrium
- To confirm the presence or absence of lymph node metastasis (Wertheim's hysterectomy)

7.2.5.2 Macroscopic Description: The hysterectomy must be measured in (mm):

- Fundus to cervix
- Cornu to cornu
- Anterior surface of the body to the posterior surface
- Attached vaginal wall in three dimensions

Any lesions must be measured and anatomically described with particular reference to excision margins. The use of inked margins is strongly recommended to include:

- Vaginal resection margin
- Radial cervical resection margin/paracervical margin
- Parametrial resection margin (if included)

The lesion size should be given as width, depth and height and the vertical distance of the lesion in the cervical canal must be indicated. The anatomical position of the lesion must also be given and a distance from the nearest resection margin (i.e. vaginal, radial cervical margin etc.) must be given.

7.2.5.3 Technique: In the context of CervicalCheck, hysterectomy specimens may be encountered in the following situations:

- In cases of unsuspected CIN, cGIN or invasive cervical squamous or adenocarcinoma (most likely scenario: total hysterectomy for some other cause)
- In cases following previous biopsy (punch, cone, LLETZ, SWETZ, NETZ) of a pre-neoplastic lesion (CIN/cGIN) (total hysterectomy and/or radical hysterectomy)
- In cases following previous biopsy (punch, cone, LLETZ, SWETZ, NETZ) of an invasive squamous or glandular lesion (radical hysterectomy) to include complete excision and full pathological and clinical staging of the lesion

7.2.5.4 Histological Diagnosis: Histological reports on a hysterectomy, should provide a well formatted pathological diagnosis as summarised below. The diagnosis should also be in concordance with the WHO histological classification of tumours of the uterine cervix (Tables 1 and 2).

In addition to a precise description of the histological type of the lesion, the report should include information concerning the:

- Grade of neoplastic lesion
- Localisation of the lesion
- Uni/multifocality of the lesion
- Extent of the lesion (in cases of microinvasive and invasive cancer, measurement of vertical and horizontal diameters is crucial for adequate staging)
- Stromal reaction
- Involvement of microvessels
- Relation of tumor tissue to all resection margins (distance)
- Description and characterisation of additional non-neoplastic lesions (tuboendometroid metaplasia, microglandular hyperplasia, endometriosis, regenerative and repair changes)

The term microinvasive carcinoma may be applied to squamous cell carcinomas and adenocarcinomas, but only when accompanied by measurements of depth and lateral extent of a completely excised lesion. The diagnosis can then be defined according to the FIGO definitions of stage 1A1 and 1A2 (Table 3), for which there is an evidence base for outcome after treatment^{8, 26}.

Depth of invasion should be measured from the base of the epithelium from which the invasive lesion arises and the lateral extent from the section in which the width is widest. Stage 1A1 lesions (less than 3 mm depth and less than 7 mm width) should be specified as either one or more foci of early stromal invasion or a confluent lesion. Stage 1A2 lesions are defined as 3-5 mm depth and less than 7 mm width.

Adenocarcinomas should be measured and recorded in the same way but there are no reliable criteria for distinguishing 1A1 and 1A2 tumours. If an invasive lesion cannot be measured as indicated above, it should be described as a small invasive carcinoma and classified as 1B1. The presence of lymphovascular invasion should be recorded but does not affect the FIGO stage.

7.2.6 Frozen Section: The frozen section procedure is a pathology laboratory procedure carried out to perform rapid microscopic analysis of a specimen. It is used most often in oncological surgery.

7.2.6.1 Diagnostic Goal:

- Assessment of resection margins (cervical cancer). Assessment of metastasis
- Sentinel node procedure, a sentinel node containing tumour tissue prompts a further lymph node dissection, while a benign node will avoid such a procedure
- If surgery is explorative, rapid examination of a lesion might help identify the possible cause of a patient's symptoms
- For detection of rare antigen and use of immunocytochemistry only applicable to frozen section material

The quality of the slides produced by frozen section is of lower quality than formalin fixed, paraffin embedded tissue processing. While diagnosis can be rendered in many cases, fixed tissue processing is preferred in many conditions for more accurate diagnosis.

7.2.6.2 Macroscopic Description: The size, colour and consistency of the tissue specimen must be described.

7.2.6.3 Technique: Specimen dissection is carried out in a class I or class II laminar flow cabinet, taking full infection hazard precautions. The frozen section is carried out on a dedicated cryostat and is performed by a medical scientist.

7.2.6.4 Histological Diagnosis: The description of the histopathological report should include answers to the specific question that is being asked on the Cervical Histology Form (request form). Comment (where applicable) should be made in relation to:

- Histological type of cancer
- Margin involvement
- Presence or absence of lymph node metastasis

7.2.7 Immunohistochemistry: Immunohistochemistry might be helpful in some cases, if H&E stained sections do not provide enough information for inclusion or exclusion of intraepithelial or invasive neoplasia. Immunohistochemical staining of dysplastic lesions of the cervix with a variety of antibodies to cell cycle-associated proteins can provide additional information in those difficult cases.

Proliferation markers are widely used by pathologists and can be easily applied on formalin-fixed and routinely-processed cervical tissues.

The Ki-67 antigen is a non-histone protein expressed in the nucleus in all phases of the cell cycle except G0. The most commonly used monoclonal antibody for immunohistochemical detection of the Ki-67 antigen in paraffin sections is clone MIB1. The extent of Ki-67 immunostaining generally parallels increasing grades of dysplasia³². Moreover, expression of Ki-67 allows distinction of atrophic cervical epithelium (negative for Ki-67) from neoplastic or dysplastic cervical epithelium (positive for Ki-67)³³.

The proliferating cell nuclear antigen (PCNA), identified as a polymerase-associated protein and is synthesised in early G1 and S phases of the cell cycle and may also be helpful³⁴.

The minichromosome maintenance proteins mcm 2, 3, 5, 7 and Topoisomerase II alpha have also been proposed as additional biomarkers of CIN and cGIN³⁵.

In cervical neoplasia, the epithelium expresses high levels of the cyclin-dependent kinase inhibitor p16 (ink4A), suggesting that staining for this marker can provide diagnostic support to distinguish true CIN/dysplasia from immature metaplasia or other non-neoplastic changes of the cervix. Immuno-detection of p16 in dysplastic epithelium using monoclonal antibodies in routinely processed histological cervical tissue was recently described^{17,18,36}. Other immunohistochemical markers like antibodies directed to extracellular matrix components (e.g. laminin, collagen type IV) of the basement membrane can be used for the assessment of possible microinvasion in selected cases.

Several studies have shown that routine H&E slides are not always adequate for detection of vascular invasion, especially in cases with strong inflammatory stromal reaction. Antibodies against endothelial marker proteins, e.g. Factor VIII-related antigen, CD31, CD34 stain both lymphatic and blood vessel endothelium and therefore represent a useful tool for the detection of lymphovascular invasion in cervical cancer.

For detection of lymph vessel involvement, immunostaining with newly recognised lymphendothelial proteins (like podoplanin) can be performed^{4,5}.

Table 3: WHO Histopathological Classification of Malignant Tumours of the Cervix*

Epithelial Tumours

A. Squamous tumours and precursors

1. Squamous cell carcinoma, (not otherwise specified)
 - Keratinising
 - Non-keratinising
 - Basaloid
 - Verrucous
 - Warty
 - Papillary
 - Lymphoepithelioma-like
 - Squamotransitional
2. Early invasive (microinvasive) squamous cell carcinoma
3. Squamous intraepithelial neoplasia
 - Cervical intraepithelial neoplasia (CIN)3/squamous cell carcinoma in situ
4. Benign squamous cell lesions
 - Condyloma acuminatum
 - Squamous papilloma
 - Fibroepithelial polyp

B. Glandular tumours and precursors

1. Adenocarcinoma
 - Mucinous adenocarcinoma
 - Endocervical
 - Intestinal
 - Signet ring cell
 - Minimal deviation
 - Villoglandular
 - Endometroid adenocarcinoma
 - Clear cell adenocarcinoma
 - Serous adenocarcinoma
 - Mesonephric adenocarcinoma
2. Early invasive adenocarcinoma
3. Adenocarcinoma in situ
4. Glandular dysplasia
5. Benign glandular lesions
 - Müllerian papilloma
 - Endocervical polyp

C. Other epithelial tumours

- 1 Adenosquamous carcinoma
 - Glassy cell carcinoma variant
- 2 Adenoid cystic carcinoma
- 3 Adenoid basal carcinoma
- 4 Neuroendocrine tumours
 - Carcinoid
 - Atypical carcinoid
 - Small cell carcinoma

Mesenchymal Tumours and Tumour-like Conditions

- A. Leiomyosarcoma
- B. Endometrioid stromal sarcoma, low grade
- C. Undifferentiated endocervical sarcoma
- D. Sarcoma botryoides
- E. Alveolar soft part sarcoma
- F. Angiosarcoma
- G. Malignant peripheral nerve sheath tumour
- H. Leiomyoma
- I. Genital rhabdomyoma
- J. Post-operative spindle cell nodule

Mixed Epithelial and Mesenchymal Tumours

- A. Carcinosarcoma (malignant Müllerian mixed tumour, metaplastic carcinoma)
- B. Adenosarcoma
- C. Wilms tumour
- D. Adenofibroma
- E. Adenomyoma

Melanocytic Tumours

- A. Malignant melanoma
- B. Nevus cell nevus

Miscellaneous Tumours

- A. Tumours of germ cell type
 - Yolk sac tumour
 - Dermoid cyst
 - Mature cystic teratoma

Lymphoid and Haematopoietic Tumours

- A. Malignant lymphoma
- B. Leukemia

Secondary Tumours

* Table reprinted from Pathology and Genetics of Tumours of the Breast and Female Genital Organs (2003). World Health Organization Classification of Tumours, IARC Press, Lyon with permission from IARC.

Table 4: TNM Categories and FIGO Staging

TNM Categories	FIGO Stages	Explanation Applicable to Both Systems
TX		Primary tumour cannot be assessed
T0		No evidence of primary tumour
Tis	0	Carcinoma in situ (pre-invasive carcinoma)
T1	I	Cervical carcinoma confined to uterus (extension to corpus should be disregarded)
T1a	IA	Invasive carcinoma diagnosed only by microscopy. Stromal invasion no more than 5 mm in depth and 7 mm horizontal spread. All macroscopically visible lesions — even with superficial invasion — are T1b/Stage IB
T1a1	IA1	Stromal invasion no greater than 3.0 mm in depth and 7.0 mm or less in horizontal spread
T1a2	IA2	Stromal invasion more than 3.0mm and not more than 5.0 mm with a horizontal spread 7.0 mm or less
Note: The depth of invasion should not be more than 5 mm taken from the base of the epithelium, either surface or glandular, from which it originates. The depth of invasion is defined as the measurement of the tumour from the epithelial-stromal junction of the adjacent most superficial epithelial papilla to the deepest point of invasion. Vascular space involvement, venous or lymphatic, does not affect classification.		
T1b	IB	Clinically visible lesion confined to the cervix or microscopic lesion greater than T1a2/IA2
T1b1	IB1	Clinically visible lesion 4.0 cm or less in greatest dimension
T1b2	IB2	Clinically visible lesion more than 4 cm in greatest dimension
T2	II	Tumour invades beyond uterus but not to pelvic wall or to lower third of the vagina
T2a	IIA	Without parametrial invasion
T2b	IIB	With parametrial invasion
T3	III	Tumour extends to pelvic wall, involves lower third of vagina, or causes hydronephrosis or non-functioning kidney
T3a	IIIA	Tumour involves lower third of vagina, no extension to pelvic wall
T3b	IIIB	Tumour extends to pelvic wall or causes hydronephrosis or non-functioning kidney
T4	IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum.
T4	IVA	Tumour invades mucosa of bladder or rectum or extends beyond true pelvis
Note: The presence of bullous oedema is not sufficient to classify a tumour as T4.		
M1	IVB	Distant metastasis

For details see L.H. Sobin, Ch. Wittekind (eds.): TNM Classification of Malignant Tumours. Sixth edition 2002, Wiley-Liss, Inc. and WHO 2003 and Pecorelli S. Revised FIGO staging for carcinoma of the vulva, cervix, and endometrium. Int J Gynaecol Obstet. 105(2):103-104. FIGO, 2009^{26, 37}.

7.3 Quality Assurance Standards in Histopathology (overview analysis)

The following standards have been issued by The Faculty of Pathology, Royal College of Physicians of Ireland (RCPI): issue date April 20097.

7.3.1 Departmental Workload: The following data should be measured and reported annually for each department.

Case Type Number

- 1(a). Total number of cases
- 1(b). Total number of blocks
- 1(c). Total number of slides
 - Number of Biopsies
 - Number of Non-Biopsies
 - Number of cancer resections
 - Number of other
 - Number of Immunohistochemical stains (excluding controls)
 - Number of cases
 - Number of stains
 - Number of Special Stains (excluding controls)
 - Number of cases
 - Number of stains
 - Number of frozen sections
 - Total number of cases/patients
 - Total number of specimens

7.3.2 Inter-institutional Consultation: Inter-institutional case review provides an additional mechanism for evaluating diagnostic accuracy at the original institution. It occurs when a patient's treatment is transferred to another institution triggering a review of original diagnosis. It can also occur when a clinician requests a review of original diagnosis by an external institution. It is a very useful form of peer review and should be distinguished from inter-institutional opinions, which are requested because of diagnostic uncertainty or lack of peer group consensus. The following indicators should be measured and reviewed quarterly for inter-institutional consultation.

Phase	Monitor	Indicators	Review Schedule
Analytic	Inter-institutional consultation	Cases referred externally for review <ul style="list-style-type: none"> • No. of cases referred • % agreement Cases received internally for review <ul style="list-style-type: none"> • No. of cases received • % agreement Cases referred externally for opinion <ul style="list-style-type: none"> • No. of cases referred 	Quarterly

7.3.3 Intra-departmental Consultation: Intra-departmental consultation is where a consultant pathologist seeks a second opinion from another consultant pathologist within his/her department on a particular case. It is difficult to specify for all situations the types or proportions of cases that should be subject to review. Generally a pathologist should seek a second opinion if there is any doubt about the correct diagnosis. Pathologists should record the involvement of colleagues, with their agreement, in the QA system and if deemed necessary in the final report. The following indicator should be measured and reviewed on a six monthly basis for intradepartmental consultation.

Phase	Monitor	Indicators	Review Schedule
Analytic	Inter-institutional consultation	Case type <ul style="list-style-type: none"> • % of total cases for each case type with intradepartmental consultation 	6 monthly

7.3.4 Correlation of Frozen Section Diagnosis with Final Diagnosis: Monitoring the correlation of frozen section diagnosis and permanent section diagnosis is an integral component of a quality assurance/quality improvement programme. It provides a very important measure of performance with respect to frozen section diagnostic accuracy. It is recommended that permanent section slides should be analysed with the accompanying frozen section slides to establish if any discrepancy exists. It is recognised that certain frozen section activities (e.g. Sentinel lymph node, surgical margin analysis) have a high discordance rate. Each frozen section disagreement (major) should be treated as an event that requires investigation and action, and discrepancies should be reconciled in the final pathology report. Local protocols should outline the process for treatment of a sentinel event. The following indicators should be measured and reviewed monthly for frozen section correlation with final diagnoses.

Phase	Monitor	Indicators	Review Schedule
Analytic	Correlation of frozen section diagnoses versus final diagnoses	<ul style="list-style-type: none"> • Period of review • Summary of case types • No. of cases • No. of blocks • Correlation results <ul style="list-style-type: none"> ◦ % concordance ◦ % deferral rate ◦ % major discordance • Turnaround time <ul style="list-style-type: none"> ◦ Mean ◦ Range 	Monthly

7.3.5 Cytological/Histological Correlation and Follow-up: Cytological/histological correlation and follow-up is the comparison of a cytology diagnosis with final histopathology diagnosis. Real time quarterly review of correlation of all cases with follow-up histology is recommended. Cytopathology and histopathology should be reviewed by the same pathologist where a discrepancy arises (a review should be undertaken of the original glass slides and not digitised images). The focus should be on discrepancies that change management decisions. For clinical demonstration, education or training purposes digitised images are an acceptable alternative. The following indicators should be measured and reviewed quarterly for gynaecological cases with cytological/histological correlation and follow-up.

Phase	Monitor	Indicators	Review Schedule
Analytic	Cytological/histopathological correlation and follow-up	Period of review Case type <ul style="list-style-type: none"> • No. of cytology cases with histopathology follow-up • Total no. of all cytology cases (with and without follow-up) Correlation results <ul style="list-style-type: none"> • No. of cases with discordance • No. of false positive cases <ul style="list-style-type: none"> ◦ Discrepancy* classification • No. of false negative cases <ul style="list-style-type: none"> ◦ Discrepancy* classification 	Quarterly

* Discrepancy: equates to one grade difference between cytology and histology result

7.3.6 Retrospective Review

7.3.6.1 Focused Real Time Review: It is recommended that focused review of previous negative cases is conducted. A suggested list of case types for focused review must be included. Local protocols should determine which case type to review, frequency, and number of cases to be considered. It is recommended that a minimum of one review is performed yearly and in a real time manner such that if a significant discrepancy that would affect patient care is found, the physician is notified as soon as possible. The following indicators should be measured and reviewed for retrospective review.

Phase	Monitor	Indicators	Review Schedule
Analytic	Focused real time review	Case type No. of reviews • Period of review • No. of cases per review • % agreement	Minimum of 1 review per year

7.3.6.2 Report Completeness: Measuring the completeness of pathology reporting is an important component of a department quality assurance (QA) and quality inspection (QI) plan and serves as one indicator of quality of care. College of American Pathologists (CAP) report that many studies have shown that standardised reporting forms, including synoptic reports or checklists, are highly effective in improving report adequacy, particularly for cancer reporting³⁸. Association of Directors of Anatomical and Surgical Pathology (ADASP)³⁹, Royal College of Pathologists (RCPATH) and College of American Pathologists (CAP) Standards and Datasets for Histopathology on Cancers and Tissue Pathways have been written to help pathologists work towards a consistent approach for the reporting of the more common cancers and to define the range of acceptable practice in handling pathology specimens. It is recommended to conduct a minimum of one review yearly with particular emphasis on completeness of cancer reporting in accordance with these datasets.

The following indicators should be recorded as a minimum for report completeness. It should be noted that discrepancies noted during this review process should be recorded and reviewed in local QA committee meeting.

Phase	Monitor	Indicators	Review Schedule
Analytic	Report completeness	Case type No. of reviews • Period of review • No. of cases per review	Minimum of 1 review per year

7.3.7 Multidisciplinary Team (MDT) Meetings: Organisation of Clinico Pathological Conference (CPC) meetings and determining cases for review is the responsibility of the CPC co-ordinator within the hospital. It is the responsibility of the pathologist to prepare the cases assigned for review at MDT, to reconcile any discrepancies noted prior to MDT and issue an addendum report if required, to attend MDT meetings, maintain records of which cases were discussed at MDT, record if disagreement arises between the final diagnosis in the pathology report and consensus reached at conference and issue an addendum report when required. The pathologist is not responsible for determining what cases are presented at MDT or clinical follow-up. The following indicators should be measured and reviewed quarterly for multidisciplinary team meetings.

Phase	Monitor	Indicators	Review Schedule
Analytic	Multidisciplinary team	<ul style="list-style-type: none"> • Conference type • No. of each conference held • No. of cases reviewed per conference • % agreement 	Quarterly

7.3.8 Laboratory Based Incidents (non conformances): Reporting of laboratory based incidents is a requirement for laboratory accreditation (ISO 15189)⁴⁰. Each histopathology laboratory should have existing policies, processes and procedures in place for reporting incidents and determining corrective and preventative action. The following indicators should be measured and reviewed quarterly for laboratory based incidents.

Phase	Monitor	Indicators	Review Schedule
Pre-analytic Analytic Post-analytic	Incident reporting	<p>Pre-analytic</p> <ul style="list-style-type: none"> • Total no. of incidents (expressed as a % of total cases) • Impact <p>Analytic</p> <ul style="list-style-type: none"> • Total no. of incidents (expressed as a % of total cases) • Impact <p>Post analytic</p> <ul style="list-style-type: none"> • Total no. of incidents (expressed as a % of total cases) • Impact 	Quarterly

7.3.9 Laboratory Based External Quality Assessment

External quality assessment (EOA) schemes in histopathology form a key part of laboratory quality management. It is mandatory that all histopathology laboratories participate in external quality assessment schemes (e.g. National External Quality Assessment Service [NEQAS]) where available that assess and score the quality of slide preparation and staining. Some areas where EQA is not available, participation in inter-laboratory comparison schemes is mandatory. The following indicators should be measured and reviewed yearly for external quality assessment schemes.

Phase	Monitor	Indicators	Review Schedule
Analytic	Benchmarking- (external quality assessment)	List of external quality assessment schemes participated in by laboratory (and their results)	Yearly

7.3.10 Turnaround Time (TAT): TAT is a key indicator of the overall function of the laboratory service and is considered a critical element of quality because of the impact on clinical management of patients. Turnaround time is measured from the time the lab receives the specimen to the time the final report is issued. To ensure a meaningful representation of hospital case turnaround time it is recommended to classify into Biopsy TAT and Non Biopsy TAT. Non Biopsy cases should be further classified into Cancer Resections (by organ type) and into All Other Cases. The Health Information Quality Authority (HIQA) has released national standards for symptomatic breast disease⁴¹. Lung, prostate and colon standards are in development, and it is recommended to report cancer resections TAT by organ type. The following indicators should be measured and reviewed yearly for turn around time.

Phase	Monitor	Indicators	Benchmark Level (ADASP)	Review Schedule
Analytic	Turnaround time (TAT)	Case type <ul style="list-style-type: none"> No. of biopsies % completed by day 1,2,3,4,5,6,7 Non biopsies No. of cancer resections % completed by day 3,4....10 	* See note below	Yearly

*Association of Directors of Anatomic and Surgical Pathology (ADASP) recommended benchmarks for TAT as follows:

Urgent biopsies: 2 days TAT; 80% threshold

Biopsies: 3 days TAT; 80% threshold

Surgical specimens: 3 to 5 days TAT, 80% threshold

Additional time for special procedures:

Re-cuts: 1 day

Immunohistochemistry: 1-2 days

Intra-departmental consultation: 1 day

7.3.11 Addendum Reports: An addendum report refers to any pathology report issued subsequent to the final report and should be classified as corrected, supplementary or amended. The following indicators should be measured and reviewed on a quarterly basis.

Phase	Monitor	Indicators	Review Schedule
Analytic Post-analytic	Addendum reports	Review period Report type <ul style="list-style-type: none"> • % corrected reports • % supplementary reports • % amended reports 	Quarterly

7.3.12 Reports Communicated Directly to Clinician by the Pathologist: Laboratory policies and professional judgement of the pathologist will determine when to communicate directly with the clinician. The following indicator should be measured and reviewed yearly.

Phase	Monitor	Indicators	Review Schedule
Post-analytic	Reports communicated directly to clinician by pathologist	Number of cases reported to clinician (expressed as a % of total cases)	Yearly

7.4 Organisational Standards

7.4.1 Facilities

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.1.1	Laboratory Areas and Buildings (general standards)	Histopathology services should be provided in a dedicated laboratory area/facility	Yes	Physical inspection
		The histopathology laboratory must comply with national, regional and Federal guidelines and legal requirements	Yes	Physical inspection
		The laboratory is located, constructed and equipped in such a way that all functions can be properly performed within agreed safety standards All areas should be well lit, well ventilated, quiet and spacious	Yes	Physical inspection
		The reporting room, the sample-preparation room (cut-up) and the secretarial room should be separate rooms	Yes	Physical inspection
		The specimen preparation area (cut-up), must be equipped with effective exhaust systems and approved biological safety cabinets, together with adequate bench space and sinks	Yes	Physical inspection
		There must be storage cabinets for flammable and toxic chemicals and storage must be carried out in accordance with national, regional and Federal legislation and requirements	Yes	Physical inspection
		Medical laboratory scientists and histopathologists should have an ergonomically designed chair with back support and desk space to permit microscopic examination of slides and record keeping	Yes	Physical inspection
		Measures should be taken to prevent repetitive strain injuries and other injuries due to ergonomic problems	Yes	Physical inspection

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.1.2	Equipment Required for Performance of Cut-up	<p>Dedicated facilities for the performance of cut-up must be provided</p> <p>The cut-up room must be well ventilated and operate according to regional, national, Federal Health & Safety Legislation</p> <p>The cut-up room should have a formaldehyde monitor installed or have quarterly environmental monitoring</p> <p>Details of formaldehyde monitor reports must be made available</p> <p>A dictation system (for specimen description) should be provided in the cut-up room</p> <p>A laboratory information terminal/PC must be provided in the cut-up room</p> <p>Access to the cut-up room must be restricted</p> <p>Adequate specimen storage facilities must be provided in ventilated cabinets/areas</p> <p>Logs of specimens retained and for throw-out must be maintained and may be examined by the NCSS</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p>	Yes	Physical inspection and records
7.4.1.3	Equipment Required for Processing of Specimens	<p>Dedicated facilities must be provided for sample processing</p> <p>The sample processor must be sited in an adequately ventilated area</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p>	Yes	Physical inspection and records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.1.4	Equipment Required for Embedding of Specimens	<p>Dedicated facilities must be provided for sample embedding including cooling and heating plates and storage area</p> <p>Embedding equipment should be used in an ergonomically designed area</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p>	Yes	Physical inspection and records
7.4.1.5	Equipment for Staining of Histopathology Slides	<p>Dedicated facilities must be provided for sample staining and immunohistochemistry</p> <p>The equipment required depends on whether staining is automated or manual</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p> <p>For histopathology, the H&E stain is mandatory</p> <p>Special stains for histopathology in the context of NCSS service provision include:</p> <p>PAS</p> <p>PAS-D</p> <p>Trichrome stains and other stains required for diagnosis</p> <p>Immunohistochemistry for histopathology in the context of NCSS service provision includes:</p> <ul style="list-style-type: none"> • All immunohistochemistry stains required for diagnosis • All immunohistochemistry to confirm a diagnosis of squamous or glandular intraepithelial lesions: <ul style="list-style-type: none"> ◦ p16 ◦ Ki67 ◦ Minichromosome maintenance proteins (MCMs) ◦ Other markers as they are discovered 	Yes	Physical inspection and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> • All immunohistochemistry to confirm vascular invasion (CD31, CD34) • All immunohistochemistry to confirm micro-invasion (laminin, collagen type IV) • All other immunohistochemistry investigations required for establishment of diagnosis 		
		After staining, histopathological material should present well-stained chromatin, differential cytoplasmic counterstaining and cytoplasmic transparency	Yes	Physical inspection and records
7.4.1.6	Equipment for Coverslipping Histopathology Slides	<p>Dedicated facilities must be provided for coverslipping of histopathological slides</p> <p>The equipment required depends on whether coverslipping is automated or manual</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p>	Yes	Physical inspection and records
7.4.1.7	Microscopes	<p>A high quality binocular microscope should be available for slide checking for all staff and must be serviced (in accordance with the manufacturer's specifications), including a check of its technical set up that includes adequacy of the stage and objectives</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p> <p>For conventional histopathology, 4x, 10x and 40x objectives are essential. 4/5x objectives should be present to allow convenient marking of areas of interest on the slide</p>	Yes	Physical inspection and records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.1.8	Dictation Systems for Report Generation	<p>Dedicated facilities must be provided for dictation of histopathological reports by pathologists. Each pathologist should be provided with either a manual or digital dictation system</p> <p>Dictated reports are then given to relevant secretaries and reports formulated using a standard report format in MS Word or some other reporting system, compatible with the laboratory information management system</p> <p>Provision should be made for incorporation of images into the report either by direct image insertion or digital palette formats</p> <p>Details of equipment maintenance must be available for examination by the NCSS</p>	Yes	Physical inspection and records
7.4.1.9	Record Systems (see also Information Technology Standards 7.4.5)	All histopathological results must be entered onto a computerised system laboratory information management system (LIMS) to allow quality assessment	Yes	Records
		The LIMS should be operational to recognised national and Federal standards	Yes	Records
		The LIMS should be in a secure facility with hierarchical control of access level by staff	Yes	Physical inspection and records
		Data storage and data exchange should be in accordance with regional, national and Federal data protection	Yes	Physical inspection and records
		In relation to provision of services to the NCSS, all data protection issues (storage, access and data transfer) must be compliant with Irish and European legislative instruments: the Data Protection Act 2003; EU Data Protection Directive 95/46/EC ^{42,43} .		

7.4.2 Systems Management (handling and management of cervical histopathological samples including submission, dissection, embedding, sectioning, staining, further investigations and report generation and content).

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.2.1	Laboratory Preparation (specimen log-in and cut-up)	<p>All laboratory procedures should be documented and controlled, and duties allocated to an appropriately qualified and trained member of the staff</p> <p>All personnel should be familiar with safety guidelines and procedures in case of emergency</p>	Yes	Standard operating procedure, training records and job descriptions
		<p>All histopathological specimens must be received either</p> <ul style="list-style-type: none"> - a) In 10% buffered formalin (either supplied by the laboratory or the hospital/clinic) <p>or</p> <ul style="list-style-type: none"> - b) Fresh <p>All specimens should be received in an appropriate specimen container</p> <p>Small biopsies: small specimen container with the patient identifier label attached</p> <p>Larger biopsies (including LLETZ, NETZ, SWETZ, cone biopsies etc.): large specimen container with the patient identifier label attached to the body of the container and with a cork board/pin-out board for attachment of specimen. Preferably, the cork board/pin-out board should have marking lines which allow distinction of margins (i.e. ectocervical/endocervical margins)</p> <p>Resection specimens –hysterectomies etc: large specimen container, with the patient identifier label attached</p>	Yes	Standard operating procedure and records
		When delivered, all specimens should be accompanied by a Cervical Histology Form giving as a minimum, the patient's identification data, data of the physician in charge and clinical information including the appearance of the cervix (constituting minimum acceptance criteria) (Appendix 1)	Yes	Records

	Category	Description of Standard	Standard	Demonstration of Compliance
		Any irregularities concerning the Cervical Histology Form and/or the histopathological specimen should be recorded and resolved if possible in communication with the person/s sending the test	Yes	Records
		After verification of correct correlation of the sample and the corresponding Cervical Histology Form, both should be labelled with a unique identification laboratory accession number The sample should be labelled on the top and side of the specimen container	Yes	Laboratory standard operating procedure
		Specimen log-in should be performed by a dedicated member/s of staff specifically trained for this purpose Evidence of training must be provided to the NCSS	Yes	Laboratory records and training records
		The unique laboratory identifier number is generated by the LIMS and should be sequentially derived Systems for provision of unique laboratory accession numbers by LIMS must be made available to the NCSS	Yes	Records
		The labelled specimen is then placed in a cut-up line and entered into a cut-up worklist/log for that day Cut-up wordlists/logs must be made available to the NCSS upon request	Yes	Laboratory standard operating procedure and records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.2.2	Assessment of the Sample (general comments)	<p>The cut-up of the histopathological specimens is performed by either a laboratory scientist or pathologist and should follow RCPATH guidelines in relation to Gynaecological specimens⁴⁴</p> <p>Complex specimens including large resections and LLETZ, NETZ, SWETZ and cone biopsies should be described and cut by a pathologist and/or a designated medical scientist</p> <p>The specimen is described, measured and or weighed where appropriate. Any abnormality must be clearly described. Any orientation marks of the specimen should be clearly described</p> <p>For LLETZ, NETZ SWETZ and cone biopsies (excisional biopsy samples) resection margins must be inked. This may involve one colour inking or separate two colour (for ectocervical margins and endocervical margins)</p> <p>For large resections, margins must be inked according to the laboratory protocol (e.g. vaginal, radical cervical margins, paracervical, parametrial margins etc.)</p> <p>Details of protocols for description and margin assignment of large resection specimen (including cases of pre-cancer and cancer) must be made available to the NCSS</p> <p>Description of specimens and block taking should follow the protocols described below</p> <p>The description is entered into the LIMS via the electronic or manual dictation system which should allow electronic date stamp verification</p> <p>Details of specimen description protocols and electronic dictation systems must be made available to the NCSS</p> <p>Appropriate blocks of tissue are then taken as per the protocols described below</p>	Yes	Laboratory standard operating procedure, training records and laboratory records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.2.3	Types of Sample and Sample Handling	<p>Character of the biopsies and specimen submission</p> <p>The specimen may be received fresh or in formalin (see above)</p> <p>The biopsies are usually colposcopically directed biopsies that may be several millimeters long and 2-4 mm in thickness</p> <p>In some institutions, such biopsies are mounted onto cards/cork boards</p> <p>In other institutions no mounting of specimens occurs</p> <p>Fixation of small biopsies in eosin-tainted formalin may facilitate identification</p> <p>Careful handling of specimens is recommended to prevent surface trauma and disruption or loss of surface epithelium</p> <p>Specimen dissection:</p> <p>The specimen container and the undersurface of the specimen container lid should be searched so that all stray fragments of tissue are recovered</p> <p>If fragments are very small, they should be wrapped or placed between layers of foam sponge or in mesh bags or wire cages to avert tissue loss during processing</p> <p>The number of fragments or aggregated size must be noted</p> <p>The number of pieces received is recorded, as is their size (maximum dimension if small, or in three dimensions), shape, colour and texture (muroid, granular, friable)</p> <p>If biopsies are >5 mm in dimension, they may be bisected/trisected transversely, perpendicular to the mucosal surface, to produce 2-3 pieces (with an ink dot to aid in orientation)</p>	Yes	Laboratory standard operating procedure, national proforma reports and records
7.4.2.3.1	A. Cervical Biopsy (not otherwise specified) and Cervical Punch Biopsy			

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>All biopsies (including mucoid fragments) are processed and small biopsies (placed in mesh bags or wire/mesh baskets)</p> <p>Embedding of specimens: If bisected/trisected, the flat, cut end is embedded downwards to ensure that this surface is cut by the microtome</p> <p>Intact biopsies are orientated carefully and embedded on edge, with the epithelial surface perpendicular to the face of the block to be cut by the microtome</p> <p>Sectioning of specimens: In general, it is recommended that levels of such biopsies are cut</p> <p>Although the precise number of levels is not always specified, three levels are recommended</p> <p>Step-serial sectioning is not necessary as a routine</p> <p>Staining: H&E</p> <p>Further investigations: Additional levels may be necessary</p> <p>Mucin histochemistry (AB/PAS+/-D and/or other mucin staining techniques) can be helpful to identify intestinal type differentiation in endocervical glandular elements</p> <p>Immunohistochemical marker studies may be necessary to differentiate between metaplastic and neoplastic changes in endocervical glands, or to assist in the differentiation between atrophy and CIN</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Surgical pathology report content:</p> <p>The report should incorporate the macroscopic description of the specimen, and identify the area/s of the cervix from which the biopsy has originated, i.e. ectocervix, endocervix, Transformation Zone</p> <p>Where artefact or epithelial loss impairs interpretation of the biopsy, this must be stated in the report</p> <p>The pathologist reports all grades of squamous and/or glandular intraepithelial neoplasia, and invasive lesions are reported and graded according to national protocols and guidelines</p> <p>It is recommended that koilocytosis and koilocytosis-associated changes are reported, but CIN is mentioned first unless the CIN represents only a minor component of a predominantly koilocytic lesion</p> <p>The pathologist must be mindful of the cytological report when writing the histology report, and include all pathological lesions (neoplastic and non-neoplastic) that may be associated with, or account for the reported cytological abnormalities</p> <p>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</p> <p>The limitations of punch biopsies in the detection of CIN and particularly high grade CIN are recognised. If cGIN is identified in a punch biopsy, the report should include a caveat to indicate that the possibility of an invasive component cannot be excluded</p> <p>The use of proforma reporting forms is advised (see Appendices 2 & 3)</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.2.3.2	B. Cervical Cone Biopsy and Cervical Loop Biopsy/Large Loop Excision of the Transformation Zone (LLETZ, NETZ, SWETZ and Cone)	<p>Character of the biopsies and specimen submission: Fresh or fixed material</p> <p>Cone/LLETZ/NETZ/SWETZ/loop biopsies are carried out for women with abnormal smear tests as part of a 'select and treat' or following a positive punch biopsy, i.e. the biopsy can be either a diagnostic or therapeutic procedure</p> <p>Cone biopsies are performed using a scalpel (cold knife) but more commonly, large loop diathermy methods are used to the same effect, with the advantage of reduced bleeding, better healing and preservation of cervical anatomy</p> <p>Loop diathermy methods also have the advantage of being performed without a general anaesthetic, as an outpatient procedure</p> <p>A disadvantage of loop diathermy is the artefact at the resection margins that results from electrothermal damage. This may impair histological diagnosis, and also the assessment of resection margins, especially in cases of glandular neoplasia. For this reason, cone biopsy is a preferred procedure for the assessment of glandular lesions of the cervix</p> <p>Specimen dissection and block selection: Intact cone or loop biopsies are roughly conical in shape</p> <p>In some centres, a specific position (usually 12 o'clock) is marked with a suture, or the specimen orientated and pinned to a cork board (Figure 36)</p> <p>The specimen may be opened at one end (giving a U-shape), opened at one end and drawn out into a flattened, curved specimen or in some instances submitted as multiple specimens/loops (Figures 37 and 38)</p>	Yes	Laboratory standard operating procedure, national proforma reports and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>The specimen/s are measured</p> <p>An intact central loop/cone biopsy is measured in three dimensions (antero-posterior, lateral and thickness)</p> <p>A flat/opened loop biopsy is also measured in three dimensions and care taken to provide a clear statement of exactly what is being measured – the circumference of an opened, flattened loop/cone biopsy is markedly different from that of an intact conical specimen</p> <p>If multiple loop biopsies are submitted, the number of pieces is noted and the smallest and largest measured, maximum dimension if small, or in three dimensions</p> <p>The colour, consistency and presence of any surface lesions are recorded</p> <p>If specific margins have not been indicated, the entire excision margin must be painted with ink to assist with their identification in the histological sections</p> <p>Differential inking (ectocervical margin and endocervical margin is strongly recommended if possible, when the specimen has been orientated by the clinician)</p> <p>Pathologists should be aware that opening an intact loop/cone biopsy may result in damage to the surface epithelium. This is not advised. Similarly the os must not be probed</p> <p>Intact central loop/cone biopsies can be sectioned in one of several ways, although there are two preferred, widely used methods. Because the external os in most parous women is transverse and slit-like, loop/cone biopsies can be sliced serially at 2-3 mm intervals, from one edge to the other in a sagittal and parasagittal plane (beginning at the 3 or 9 o'clock edge),</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>perpendicular to the transverse axis of the external os. This avoids the problems of interpretation that may arise when dysplastic epithelium arises on the narrow end of a wedge shaped block (if a loop/cone specimen is sectioned radially, and facilitates assessment of tumour volume in small lesions or neoplasms. However, this method does not easily allow direct correlation of CIN with the specific position on a clock face that the radial method of sampling permits (Figure 36)</p> <p>The radial method involves the sampling of an intact loop radially, in wedge-shaped slices, according to the hours on a clock face. This is a useful method of sampling if accurate mapping of a lesion is desired, although this is not usually necessary (Figure 36)</p> <p>In either case, the slices are submitted in separate, sequentially numbered blocks (corresponding to the hours on a clock face if radial sampling has been carried out, e.g. block 1 = 1 o'clock etc.)</p> <p>An opened loop biopsy is processed in serial transverse blocks, as are the individual loops if multiple specimens are submitted, in specifically designated cassettes (Figures 37 and 38)</p> <p>Care is taken to ensure that the correct cut face is placed face down in the cassette. If desired, the opposite cut face can be marked with ink, to ensure that the correct (non-inked) side is embedded downwards to be cut by the microtome</p> <p>Placing multiple slices in one cassette must be avoided. This practice makes it impossible to measure the horizontal size of any small invasive lesion and compromises accurate staging of such lesions</p> <p>In all cases, all of the tissue is submitted</p> <p>The deep radial margin is not trimmed off</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Embedding of specimen: The sections are embedded cut face down to ensure that the correct orientation (a full-face squamous mucosa) is cut by the microtome</p> <p>Sectioning of specimens: A single level from each block may be likely to suffice initially, but further levels may be required</p> <p>Some laboratories provide a 'deeper' as standard along with the index section. Deeper levels will be required if there are difficulties in identifying a lesion that might account for the abnormal cells in an antecedent smear test</p> <p>If invasive disease is suspected on the basis of the cytological, colposcopic or histological features, further levels are examined</p> <p>Staining: H&E</p> <p>Additional investigations: Additional levels may be necessary (see above)</p> <p>Histochemistry and immunohistochemistry may also be required (see above)</p> <p>Surgical pathology report content: The report should incorporate the macroscopic description of the specimen, and identify the tissue components that are present, i.e. ectocervix, endocervix, Transformation Zone, isthmus.</p> <p>Features that impair interpretation are recorded, e.g. opened loop, fragmentation, surgical/operative trauma, thermal artefact, and pathologists must have access to the cytological report when writing the histology report</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>All grades of squamous and/or glandular intraepithelial neoplasia are reported and the presence of endocervical crypt involvement recorded in cases of CIN</p> <p>The distribution of a lesion is noted if an orientated specimen has been submitted. Any invasive lesions are classified and graded according to national protocols and guidelines (CIN grading and WHO classification system)</p> <p>If there is significant inflammation, or inflammation associated with specific pathological features, e.g. follicular cervicitis, herpesvirus infection, this is reported. Koilocytosis is also recorded, as are pathological lesions (neoplastic and non-neoplastic) that may be associated with, or account for, the reported cytological abnormalities</p> <p>The report must indicate whether or not the abnormal squamous or glandular epithelium has been completely excised. Fragmentation usually precludes an adequate assessment of the margins</p> <p>Pathologists should exercise caution in the assessment of excision of a lesion when opened, fragmented or multiple loop biopsies have been submitted</p> <p>The use of proforma reporting forms is advised (see Appendices 2 and 3)</p>		
7.4.2.3.3	C. Cervical Wedge Biopsy	<p>Character of the biopsies and specimen submission:</p> <p>Fresh or fixed material</p> <p>Wedge biopsies are larger than punch biopsies, but generally smaller than cone/LLETZ biopsies</p>	Yes	Laboratory standard operating procedure, national proforma reports and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>They are carried out at the time of colposcopy for women with abnormal smear tests as part of a 'select and treat' therapeutic procedure, and also as a diagnostic procedure as an alternative to a punch biopsy, or to confirm neoplasia before definitive treatment</p> <p>Specimen dissection and block selection: Wedge biopsies may be over 10 mm in maximum dimension, and occasionally more than one biopsy is submitted</p> <p>The maximum size in three dimensions is provided for each biopsy or just maximum dimension if small</p> <p>The colour, consistency and presence of any surface lesions are recorded</p> <p>The specimen/s is/are cut perpendicular to the Transformation Zone (this is usually visible macroscopically) or perpendicular to the long axis to ensure that both ectocervical and endocervical edges of the specimen appear in their normal anatomical context in the sections. The resection margins are inked (with one or two inks, depending on whether specimen orientation allows)</p> <p>Such specimens are processed in their entirety</p> <p>Embedding of specimen: The blocks are embedded cut face down to ensure that the correct orientation (a full squamous mucosa) is cut by the microtome</p> <p>Sectioning of specimens: A single level from each block is likely to suffice initially, but further levels may be required</p> <p>Some laboratories provide a 'deeper' as standard along with the index section</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Deeper levels will be required if there are difficulties in identifying a lesion that might account for the abnormal cells in an antecedent smear test</p> <p>If invasive disease is suspected on the basis of the cytological, colposcopic or histological features further levels are examined</p> <p>Staining: H&E</p> <p>Additional investigations: Additional levels may be necessary (see above)</p> <p>Histochemistry and immunohistochemistry may also be required (see above)</p> <p>Surgical pathology report content: The report should incorporate the macroscopic description of the specimen, and identify the tissue components that are present, i.e. ectocervix, endocervix, Transformation Zone</p> <p>Features that impair interpretation are recorded, e.g. fragmentation, surgical/operative trauma, thermal artefact, and pathologists must have access to the cytological report when writing the histology report</p> <p>All grades of squamous and/or glandular intraepithelial neoplasia are reported and the presence of endocervical crypt involvement recorded in cases of CIN</p> <p>The distribution of a lesion is noted if an orientated specimen has been submitted</p> <p>Any invasive lesions are classified and graded according to NCSS recommendations (this document)</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>If there is significant inflammation, or inflammation associated with specific pathological features, e.g. follicular cervicitis, herpesvirus infection, this is reported</p> <p>Koilocytosis is also recorded, as are all pathological lesions (neoplastic and non-neoplastic) that may be associated with, or account for, the reported cytological abnormalities</p> <p>The report must indicate whether or not the abnormal squamous or glandular epithelium has been completely excised</p> <p>Pathologists should exercise caution in the assessment of excision of a lesion when fragmented or multiple biopsies have been submitted</p> <p>The use of proforma reporting forms is advised (Appendices 2 and 3)</p>		
7.4.2.3.4	D. Endocervical Curettage (ECC)	<p>Character of the biopsies and specimen submission:</p> <p>Such specimens are submitted to identify the presence of squamous or glandular intraepithelial neoplasia in the endocervical canal or to assess whether endometrial carcinoma has spread to involve the cervix. They are typically scanty and comprise mucus and blood admixed with light grey or brown tissue fragments, usually of small size. Because of this, they are handled with caution</p> <p>Specimen dissection and block selection:</p> <p>The aggregated size (in three dimensions) of the sample is measured after it has been filtered into a mesh bag, and the colour and texture (mucoid, spongy, firm) described.</p> <p>The whole sample is processed in a mesh bag or wire/mesh basket to avert the loss of tiny fragments</p>	Yes	Laboratory standard operating procedure, national proforma reports and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Filter paper and sponges are avoided because of the possibility of losing tissue fragments becoming entrapped or adherent</p> <p>Embedding options: No specific issues</p> <p>Sectioning: A single H&E stained section, representing a full face of the block, is adequate for the initial microscopic examination</p> <p>Depending on the appearances, levels may be requested at the discretion of the reporting pathologist</p> <p>Staining: H&E</p> <p>Surgical pathology report content: The report should incorporate the macroscopic description of the specimen</p> <p>The presence of neoplasia (either intraepithelial neoplasia of glandular or squamous type, or invasive carcinoma) is reported, but classification and grading according to NCSS guidelines may be hindered by the small volume of material available for examination in such specimens</p> <p>The use of proforma reporting forms is advised (see Appendices 2 and 3)</p>		
7.4.2.3.5	E. Trachelectomy	<p>Character of the biopsies and specimen submission: Fresh or fixed material</p> <p>Trachelectomy (simple or radical) is carried out for women with abnormal smear tests as part of a 'select and treat' or following a positive punch biopsy</p>	100%	Laboratory standard operating procedure, national proforma reports and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Simple trachelectomy involves removal of the cervix, the endocervical canal and the lower uterine segment (including endometrium)</p> <p>Radical trachelectomy involves removal of the cervix, endocervical canal, lower uterine segment, parametrium, vaginal cuff ± lymphadenectomy</p> <p>Specimen dissection and block selection: Trachelectomies are roughly conical in shape</p> <p>In some centres, a specific position (usually 12 o'clock) is marked with a suture, or the specimen orientated and pinned to a cork board</p> <p>The specimen may be opened at one end (giving a U-shape), opened at one end and drawn out into a flattened, curved specimen or in some instances submitted as multiple specimens/loops</p> <p>The specimen/s are measured</p> <p>An intact trachelectomy is measured in three dimensions (antero-posterior, lateral and thickness)</p> <p>A flat/opened trachelectomy is also measured in three dimensions and care taken to provide a clear statement of exactly what is being measured</p> <p>If multiple fragments are submitted, the number of pieces is noted and the smallest and largest measured, maximum dimension if small, or in three dimensions</p> <p>The colour, consistency and presence of any surface lesions are recorded</p> <p>If specific margins have not been indicated, the entire excision margin must be painted with ink to assist with their identification in the histological sections</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Differential inking (ectocervical margin and endocervical margin is strongly recommended if possible, when the specimen has been orientated by the clinician) (simple trachelectomy)</p> <p>In radical trachelectomy, the vaginal and parametrial margin must be differentially inked using different coloured inks</p> <p>In the case of radical trachelectomy with lymphadenectomy, lymph nodes are measured, described and counted. One lymph node is embedded per block. Large lymph nodes are dissected and embedded in one block</p> <p>Pathologists should be aware that opening an intact trachelectomy may result in damage to the surface epithelium. This is not advised. Similarly the os must not be probed</p> <p>Intact trachelectomy specimens can be sectioned in one of several ways, although there are two preferred, widely used methods. Because the external os in most parous women is transverse and slit-like, loop/cone biopsies can be sliced serially at 2-3 mm intervals, from one edge to the other in a sagittal and parasagittal plane (beginning at the 3 or 9 o'clock edge), perpendicular to the transverse axis of the external os. This avoids the problems of interpretation that may arise when dysplastic epithelium arises on the narrow end of a wedge shaped block (if a loop/cone specimen is sectioned radially, and facilitates assessment of tumour volume in small lesions or neoplasms. However, this method does not easily allow direct correlation of CIN with the specific position on a clock face that the radial method of sampling permits</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>The radial method involves the sampling of an intact trachelectomy radially, in wedge-shaped slices, according to the hours on a clock face</p> <p>This is a useful method of sampling if accurate mapping of a lesion is desired, although this is not usually necessary</p> <p>In either case, the slices are submitted in separate, sequentially numbered blocks (corresponding to the hours on a clock face if radial sampling has been carried out, e.g. block 1 = 1 o'clock etc.)</p> <p>An opened trachelectomy is processed in serial transverse blocks, as are the individual loops if multiple specimens are submitted, in specifically designated cassettes</p> <p>Care is taken to ensure that the correct cut face is placed face down in the cassette. If desired, the opposite cut face can be marked with ink, to ensure that the correct (non-inked) side is embedded downwards to be cut by the microtome</p> <p>Placing multiple slices in one cassette must be avoided. This practice makes it impossible to measure the horizontal size of any small invasive lesion and compromises accurate staging of such lesions</p> <p>In all cases, all of the tissue is submitted</p> <p>The deep radial margin is not trimmed off</p> <p>In the case of radical trachelectomy, the parametrial margins, vaginal margins are submitted in separate blocks</p> <p>Lymph nodes resected as part of a radical trachelectomy are submitted in separate blocks</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Embedding of specimen: The sections are embedded cut face down to ensure that the correct orientation (a full-face squamous mucosa) is cut by the microtome</p> <p>Sectioning of specimens: A single level from each block may be likely to suffice initially, but further levels may be required</p> <p>Some laboratories provide a 'deeper' as standard along with the index section</p> <p>Deeper levels will be required if there are difficulties in identifying a lesion that might account for the abnormal cells in an antecedent smear test</p> <p>If invasive disease is suspected on the basis of the cytological, colposcopic or histological features, further levels are examined</p> <p>Staining: H&E</p> <p>Additional investigations: Additional levels may be necessary (see above)</p> <p>Histochemistry and immunohistochemistry may also be required (see above)</p> <p>Surgical pathology report content: The report should incorporate the macroscopic description of the specimen, and identify the tissue components that are present, i.e. ectocervix, endocervix, Transformation Zone, isthmus</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Features that impair interpretation are recorded, e.g. opened/not opened, fragmentation, surgical/ operative trauma, thermal artefact, and pathologists must have access to the cytological report when writing the histology report</p> <p>All grades of squamous and/or glandular intraepithelial neoplasia are reported and the presence of endocervical crypt involvement recorded in cases of CIN</p> <p>The distribution of a lesion is noted if an orientated specimen has been submitted. Any invasive lesions are classified and graded according to national protocols and guidelines (CIN grading and WHO classification system)⁸</p> <p>If there is significant inflammation, or inflammation associated with specific pathological features, e.g. follicular cervicitis, herpesvirus infection, this is reported. Koilocytosis is also recorded, as are pathological lesions (neoplastic and non-neoplastic) that may be associated with, or account for, the reported cytological abnormalities</p> <p>The report must indicate whether or not the abnormal squamous or glandular epithelium has been completely excised. Fragmentation usually precludes an adequate assessment of the margins</p> <p>In the case of radical trachelectomy, specific comment must be made upon the vaginal and parametrial margins</p> <p>Pathologists should exercise caution in the assessment of excision of a lesion when opened, fragmented or multiple loop biopsies have been submitted</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.2.3.6	F. Uterus (hysterectomy)	<p>Character of the biopsies and specimen submission: Fresh or fixed material</p> <p>A hysterectomy may be performed for:</p> <ul style="list-style-type: none"> • Prolapse (± repair) • Fibroids • Adenomyosis • Endometriosis • Dysfunctional uterine bleeding • Tumour • Persistently abnormal smear tests (± previous cervical biopsy/LLETZ) • Obstetric causes <p>The clinical history is relevant as there are a variety of preoperative treatments such as hormonal manipulation or embolisation which significantly alter the appearance of fibroids</p> <p>These treatments can give rise to changes which simulate the gross appearances of malignant tumours</p> <p>Hysteroscopic/transcervical endometrial resection also changes the appearances of the endometrium and myometrium, even with potential for mural perforation</p> <p>Specimen dissection and block selection: The specimen must be orientated and the resection margins inked appropriately (e.g. vaginal, radial resection margin of cervix, parametrium etc.)</p> <p>Identify the anterior and posterior surfaces, cervix, fundus and body, fallopian tubes and other adnexal structures</p> <p>Typically the peritoneal reflection is lower in the pouch of Douglas in comparison with the anterior peritoneal reflection</p>	Yes	Laboratory standard operating procedure, national proforma reports and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Any lesions must be measured and anatomically described with particular reference to excision margins. The use of inked margins is strongly recommended to include:</p> <ul style="list-style-type: none"> • Vaginal resection margin • Radial cervical resection margin/paracervical margin • Parametrial resection margin (if included) <p>Where possible all lesions should be photographed and archived on an appropriate image archiving system</p> <p>Normal ovaries are posterior to the fallopian tubes</p> <p>Identify surgical or traumatic wounds, or serosal abnormalities (adhesions, endometriosis and endosalpingiosis)</p> <p>Measure the size of the uterus in three dimensions and give a description of the shape and symmetry. Note any developmental abnormalities (arcuate, bicornuate, didelphys, unicornuate)</p> <p>Measure (mm):</p> <ul style="list-style-type: none"> • Fundus to cervix • Cornu to cornu • Anterior surface of the body to the posterior surface • Attached vaginal wall in three dimensions <p>The weight of the uterus adds little clinically valuable information and can be omitted if desired</p> <p>Laparoscopic specimens may be received in multiple pieces (morcellated). This procedure should not be performed if there is a history of atypical endometrial hyperplasia or gynaecological neoplasia. There should be a previous pipelle or curettage to exclude endometrial abnormality</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Measurements can be approximated, if appropriate</p> <p>The parts should be identified, orientated if possible and routine blocks taken of the cervical surface, endometrium and any abnormality</p> <p>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)</p> <p>Specimen dissection:</p> <p>If a cervical lesion is present or suspected, amputate the cervix and dissect the cervix as per a cone biopsy</p> <p>Do not probe the uterine cavity as this may damage the Transformation Zone and endocervix</p> <p>Probing the uterus may be necessary to identify the orientation of the cavity</p> <p>However, this may remove diagnostic tissue from the endocervical canal or uterine cavity and is not needed if the uterus is bisected as detailed below</p> <p>The uterus may be formally bivalved to expose the uterine cavity</p> <p>Alternatively, a midline sagittal bisection of the uterus will expose the endometrium and indicate the shape of the uterine cavity</p> <p>The myometrium can then be examined by multiple parasagittal or horizontal incisions</p> <p>If the uterus is markedly distorted, for example, by multiple fibroids the plane of bisection can be adjusted to optimally expose the uterine cavity</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Note the nature of the myometrium</p> <p>Flecks of calcification are often seen in association with blood vessels in the myometrium of older women</p> <p>Describe:</p> <ul style="list-style-type: none"> • Endometrial thickness (atrophic, thickened, cystic) • Endometrial polyps (number, size, ulceration, haemorrhage) • Intrauterine devices (IUD) – type • Adenomyosis (fibroid-like mass with coarse trabecular bands of tissue, small slit-like spaces and brown fluid) • Caesarian section scars (usually anterior wall below the peritoneal reflection) • Adenomatoid tumours (subserosal, cornual, adnexal) • Uterine perforation • Serosal adhesions (pelvic inflammatory disease, previous surgery) • Endosalpingiosis (one explanation for a gritty serosal surface) • Fibroids: <ul style="list-style-type: none"> ◦ Intramural ◦ Subserosal ◦ Submucosal ◦ Number (or an estimate if numerous) and range of sizes ◦ Nature of boundary (may reflect an infiltrative growth pattern) <p>Degenerative changes such as:</p> <ul style="list-style-type: none"> - Cystic spaces filled with thin serous or mucoid fluid - Fatty change - Myxoid areas - Foci of calcification - Necrosis - Red degeneration (common in pregnancy) - Haemorrhage 		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> • Epithelial tumours (see RCPATH cancer dataset: Appendix 2) • Sarcoma • Obstetric <ul style="list-style-type: none"> ◦ Removed at delivery or during pregnancy ◦ Intractable haemorrhage ◦ Uterine rupture ◦ Abnormal placental implantation (e.g. placenta praevia, placenta accreta, increta, percreta) ◦ Previous Caesarean section <p>In the case of radical hysterectomy, the number of lymph nodes, lymph node description and anatomical location from whence derived must be noted</p> <p>Block selection: Sample as follows:</p> <ul style="list-style-type: none"> • A representative block of tissue, including the Transformation Zone, from the anterior and the posterior lip of the cervix • The entire Transformation Zone if there is a recent past history of intraepithelial neoplasia or invasive cancer and if the most recent smear test was abnormal • The number of blocks taken is related to the cervical anatomy as it is better to have fewer blocks with good representation of the zone rather than more blocks with poor representation • Lower uterine segment – one to two blocks dependent on pathology present • Endometrium – anterior and posterior wall ensuring that the full thickness is represented • Ideally this should include the underlying myometrium with serosa at one end of the block and endometrium at the other end 		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> • Multiple blocks are taken if there is a preoperative diagnosis of simple or complex hyperplasia. Atypical hyperplasia requires the same dissection as for endometrial adenocarcinoma • Polyp/s: thoroughly sampled including the base where it abuts the surrounding normal tissue • Myometrium, including the serosa, if not included with the endometrial blocks • Representative fibroids, especially if large (>5 cm) or abnormal – necrosis, myxoid change, poor circumscription. Include the junction of the lesion with the surrounding myometrium. Take one block per 1-2 cm of the maximum diameter, up to 4 for an otherwise unremarkable fibroid • Obstetric – numerous blocks of the Caesarean section scar should be taken <p>Retained adherent placental tissue is seen as ragged, haemorrhagic tissue lining the surface of the uterine cavity</p> <p>In placenta previa and placenta accreta, increta, percreta, the junction of the placenta and myometrium is required</p> <p>The edge of a traumatic rupture in pregnancy must be sampled</p> <p>In the case of radical hysterectomy, large lymph nodes should be bisected. One lymph node should be embedded per tissue block. Large lymph nodes may require more than one block and this should be indicated on the gross description report</p> <p>Embedding options:</p> <p>The cervical blocks are embedded cut face down to ensure that the correct orientation (a full squamous mucosa) is cut by the microtome</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Ensure a vertical section of the endometrium, myometrium and serosa are obtained from the uterus</p> <p>Lymph nodes are embedded face down to ensure full face sections of the node</p> <p>Sectioning: A single H&E stained section, representing a full face of the block, is adequate for the initial microscopic examination</p> <p>Depending on the appearances, levels may be requested at the discretion of the reporting pathologist</p> <p>Staining: H&E</p> <p>Additional investigations: Special stains and/or immunohistochemistry as required</p> <p>Surgical pathology report content: The report should incorporate the macroscopic description of the specimen, and identify the tissue components that are present, i.e. ectocervix, endocervix, Transformation Zone</p> <p>Features that impair interpretation are recorded, e.g. fragmentation, surgical/operative trauma, thermal artefact, and pathologists must have access to the cytological report when writing the histology report</p> <p>All grades of squamous and/or glandular intraepithelial neoplasia are reported and the presence of endocervical crypt involvement recorded in cases of CIN</p> <p>The distribution of a lesion is noted if an orientated specimen has been submitted</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Any invasive lesions are classified and graded according to NCSS recommendations (this document)</p> <p>If there is significant inflammation, or inflammation associated with specific pathological features, e.g. follicular cervicitis, herpesvirus infection, this is reported</p> <p>Koilocytosis is also recorded, as are all pathological lesions (neoplastic and non-neoplastic) that may be associated with, or account for, the reported cytological abnormalities</p> <p>The report must indicate whether or not the abnormal squamous or glandular epithelium has been completely excised</p> <p>Pathologists should exercise caution in the assessment of excision of a lesion when fragmented or multiple biopsies have been submitted</p> <p>The use of proforma reporting forms is advised (see Appendices 2 and 3)</p> <p>Endometrium (phase, cyclical abnormality, hyperplasia, neoplasia – (see RCPATH endometrial cancer dataset), endometrial polyps⁴⁴</p> <p>Myometrium (leiomyoma including comment on atypical features, STUMP, adenomyosis, adenomatoid tumour, stromal tumours)</p> <p>Leiomyoma, smooth muscle tumour of uncertain malignant potential (STUMP)</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Comment on:</p> <p>Mitotic activity (normal or abnormal forms) – expressed as count/mm²</p> <ul style="list-style-type: none"> • Necrosis • Infarction • Nuclear atypia/symplastic change • Diffuse/localised • Myxoid change • Margin • Vascular space involvement • Perinodular/hydronic growth pattern • Dissecting growth pattern • Variant types: <ul style="list-style-type: none"> ◦ Usual ◦ Cellular ◦ Epithelioid ◦ Symplastic ◦ Myxoid ◦ With tubules ◦ Lipoleiomyoma ◦ With lymphoid infiltration ◦ Diffuse uterine leiomyomatosis ◦ Dissecting ◦ With vascular invasion ◦ Intravenous leiomyomatosis ◦ Plexiform tumorlet <p>Adenomyosis – comment on:</p> <ul style="list-style-type: none"> • Extent • Glandular atypia/hyperplasia • Stromal atypia <p>Stromal tumours: stromal nodule, stromal sarcoma, uterine sarcoma. Comment on:</p> <ul style="list-style-type: none"> • Mitotic activity (normal or abnormal forms) – expressed as count/mm² • Nature of margin (invasive/circumscribed) • Necrosis • Vascular pattern • If malignant – progesterone receptor status • Serosa 		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Endometriosis. Comment on:</p> <ul style="list-style-type: none"> • Extent • Glandular atypia/hyperplasia • Stromal atypia <p>Endosalpingiosis. Comment on:</p> <ul style="list-style-type: none"> • Epithelial types • Atypia <p>Obstetric samples:</p> <ul style="list-style-type: none"> • Caesarean section scar • Abnormal rupture • Placental implantation <ul style="list-style-type: none"> ◦ Accreta ◦ Increta ◦ Previa <p>Ectopic implantation:</p> <ul style="list-style-type: none"> • Interstitial • Cornual • Serosal • Cervical <p>In the case of radical hysterectomy, the report must contain specific comment on resected lymph nodes, including site designation, number (in total), number involved by tumour (if applicable)</p> <p>In the case of pelvic lymph node groups, specific comment should be made in relation to % fat replacement and presence or absence of hyalinisation</p>		

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.2.4	Reporting (general comments)	The results should be reported according to the NCSS national standard classification system (CIN and the WHO classification system for gynaecological tumours) ⁸	Yes	Laboratory standard operating procedure, national proforma reports and records
		Conclusion and recommendations should be given in concordance with guidelines of the NCSS	Yes	National proforma reports
7.4.2.5	Archiving of Cervical Histology Forms, Samples, Slides and Reports	Laboratory staff are responsible for proper administration and archiving of Cervical Histology Forms, samples, blocks, slides and written and/or computerised reports Procedures must comply with national legislation, including that relating to patients' data security	Yes	Laboratory records
		Cervical Histology Forms or their electronic equivalent should be stored for a minimum of 30 years ⁴⁵	Yes	Laboratory records
		Histopathology slides and blocks: All slides must be stored for a minimum of 10 years and a maximum of 30 years (if storage permits) and blocks must be stored for at least 30 years (if storage permits) in conditions adequate for preservation. This is important for patient management as well as quality control Specimens should be maintained for at least 1 month or until the surgical pathology report is completed	Yes	Laboratory records
		Reports: The storage of written or computerised reports is primarily dependent on national regulations and in compliance with Irish Data Protection legislation and instruments	Yes	Laboratory records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>It is recommended that reports should be stored for a minimum of 30 years</p> <p>It is an advantage to keep coded records of histopathology results for future reference, even if the results and slides are no longer available</p>		

7.4.3 Recording of Results and Results Management

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.3.1	Recording of Results	<p>There must be a record-keeping system, preferably computerised</p> <p>It must be accurate and easily accessible to all laboratory personnel</p>	Yes	Physical inspection and laboratory records
		<p>The record system should include at least:</p> <ul style="list-style-type: none"> • 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 • Indication for examination: screening, follow-up or clinical indication • Type of examination requested: histological and/or virological • The results of the laboratory examination in accordance with the current standard classification system and data format, including a judgment of the quality/adequacy of the histopathological slide (if necessary), date of authorisation of the final report, and name of pathologist who has evaluated the sample 		

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Further requirements are that the information system should:</p> <ul style="list-style-type: none"> • 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, biopsies, reasons for biopsies not being taken • Provide the data necessary for evaluation of the population screening programme • All or a selection of the recorded data mentioned above must be forwarded to the NCSS and the National Cancer Registry according to current directives by the NCSS 		
7.4.3.2	Authorisation of Results	Every report must be checked for inconsistencies before authorisation and may then be manually or electronically authorised	Yes	Laboratory standard operating procedure and records
		All histopathology reports must be signed by the authorising pathologist (electronic and/or manual)	Yes	Laboratory standard operating procedure and records
7.4.3.3	Laboratory Response Time (turnaround time)	<p>All efforts should be directed to report results of the specimen within 3 working days counted from specimen arrival within the laboratory for small specimens and 3-5 working days for larger specimens</p> <p>If the above-mentioned time limit cannot be met, the referring doctor and the NCSS should be informed</p>	<p>Minimum ≥80%</p> <p>Achievable ≥95%</p>	Laboratory standard operating procedure and records

7.4.4 Quality Management

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.4.1	Internal Quality Management	The laboratory must have in place and have documentary evidence that a quality management system exists which will help to ensure optimal patient care and minimise the risk of liability claims	Yes	Quality Manual, laboratory standard operating procedure and records
7.4.4.1.1	Laboratory Quality Management	<p>The laboratory must designate a person who, in addition to daily work in histopathology is trained in collecting and managing documents, process descriptions and manuals, and is either a quality manager or has access to a quality manager</p> <p>A Quality Manual should be in place and subject to examination by the NCSS</p>	100%	Quality Manual, laboratory standard operating procedures and job descriptions
		<p>General management documents should include:</p> <ul style="list-style-type: none"> • Overview of the histopathology laboratory • Description of personnel in the organisation (including levels of competence and responsibilities and roles of each person, lines of communication and infrastructure) • Structure of management documents (Quality Manual) 	Yes	Laboratory standard operating procedures and records
		<p>The process network should include:</p> <ul style="list-style-type: none"> • Customer definition • Management processes • Core processes • Processes of improvement and resources 	Yes	Quality Manual and laboratory standard operating procedures
		<p>The detailed process description should include:</p> <ul style="list-style-type: none"> • Step-wise protocols • Description of personnel responsible for specific processes • Methods of detecting and minimising errors (e.g. checklists) 	Yes	Laboratory standard operating procedures and records

	Category	Description of Standard	Standard	Demonstration of Compliance
		All staff must be informed, and protocols should be checked yearly and adjusted according to continuing medical/professional education of all personnel	Yes	Laboratory standard operating procedures and training records
7.4.4.1.2	Analytical Quality Management (histopathology)	<p>Accuracy of histopathology must be monitored with previously agreed-upon protocols for defining and dealing with performance management</p> <p>Measurements of histopathology reporting accuracy should also account for variations in accuracy of the final report, which must also be monitored</p> <p>Methods used for quality assessment should incorporate a process of continuous dialogue within the lab and improve individual histopathology reporting accuracy</p>	Yes	Laboratory standard operating procedure and records
		<p>There are 5 main methodologies for internal quality control of histopathology:</p> <ul style="list-style-type: none"> • Periodic audit of histopathology outcomes • Methods based on MDT review of slides • Methods based on monitoring histopathology detection and reporting rates • Methods based on correlation of cytology with clinical/histological outcome • Methods based on double reporting of all malignant cases 		
7.4.4.1.3	Monitoring Pathologists' Reporting Rates	Pathologists' reporting rates for low grade, high grade and inadequate results must be made available to the NCSS	Yes	Laboratory records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.4.1.4	Internal Quality Control Based on Correlation with Cytological /Histopathological Outcome	Correlation of cytology with clinical outcome is mandatory and such correlation data must be provided to the NCSS	Yes	Laboratory standard operating procedure and records
		<p>Cyto/clinical correlation: Contact with clinicians and access to cancer registry data is essential</p> <p>Cyto/histopathological correlation is a major tool in internal education for both cytology and histology</p> <p>The laboratory must have a clearly defined policy regarding the methods used for cyto/histopathological correlation</p> <p>The laboratory must compare all histopathology reports with abnormal cytology reports if available, and determine the causes of any discrepancy</p> <p>The correlation process should be documented in the laboratory quality assurance programme</p> <p>Positive predictive values for high grade cytology provides a measure of accuracy of cytology and histopathology reporting and must be provided to the NCSS</p>	Yes	Quality Manual and laboratory records
		Cyto-virological correlation: If HPV testing can be used as a triaging test for patients with diagnosis of atypical squamous cells of undetermined significance (ASC-US), BNA/CIN1 correlation analysis must be provided to the NCSS	Yes	Laboratory standard operating procedure and records
		Audit of interval cancers: Re-screening of smear tests and re-evaluation of biopsies from patients with negative or low grade test results less than 3-5 years before the diagnosis of invasive cancer is mandatory	Yes	Laboratory standard operating procedure and records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.4.1.5	Internal Continuing Education	<p>Discussion of difficult cases between pathologists is strongly advised</p> <p>There should be a good supply of up-to-date histopathology textbooks available for consultation in the histopathology laboratory</p> <p>The laboratory should have a subscription or online access to one or more of the histopathology journals</p> <p>Cytotechnologists/cytopathologists, medical scientists and histopathologists should participate in regular meetings on review cases</p> <p>Performance evaluations should be used to identify those with training requirements</p>	Yes	Training records/records
7.4.4.2	External Quality Management			
7.4.4.2.1	External Continuing Education	<p>Ongoing education is a requirement for proficiency in histopathology</p> <p>This requirement can be fulfilled by:</p> <ul style="list-style-type: none"> • Attending workshops and symposia • Regional inter-laboratory slide review sessions • Participation in proficiency testing • Teaching histopathology students, pathology residents and fellows • Independent study contributions to laboratory handbooks or work in committees of the relevant medical/scientific societies • Evidence of CME/CPD 	Yes	Inspection of relevant documentation in relation to continuing professional development (CPD)

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.4.2.2	External Quality Control of Histopathology Skills	<p>Results of proficiency testing and continuing professional education (CPD) must be made available to the NCSS</p> <p>Results of external quality assurance via test cases and technical EQA must be made available to the NCSS</p>	Yes	Laboratory records
7.4.4.2.3	Accreditation	<p>The laboratory must be ISO 15189 compliant</p> <p>Evidence of compliance with ISO 15189 from the relevant competent accrediting authority must be provided to the NCSS</p> <p>Any change in accreditation status must be immediately notified to the NCSS</p>	Yes	Certification
7.4.4.3	Responsibilities for Quality Control			
		The laboratory manager is responsible for the quality system within the laboratory and is responsible for the approval of working guidelines and procedures in the laboratory providing services to the NCSS	Yes	Quality Manual and job descriptions

7.4.5 Information Technology

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.5.1	Infrastructure	A computerised laboratory information management system (LIMS) must be installed in the laboratory	Yes	Documentary evidence of system validation
		The system must be networked in an accessible form	Yes	Documentary evidence of system validation
		The LIMS should be interfaced with the NCSS CervicalCheck information management system	Yes	Documentary evidence of system validation
7.4.5.2	Training	Training in the use of the LIMS should be available to all staff working on NCSS sourced material A training log for LIMS users working on NCSS histopathology material must be made available to the NCSS	Yes	Documentary evidence of training and laboratory records
		Adequate numbers of concurrent user licenses should be available to enable efficient data entry and retrieval	Yes	Documentary evidence of user licences
7.4.5.3	Utilisation	The LIMS should generate data pertinent to the NCSS based on requests and clinical material received from the NCSS	Yes	Relevant reports
		The LIMS should be used for specimen management of NCSS histopathology specimens and reports	Yes	Laboratory standard operating procedures
		The LIMS should be used for data storage and back-up of all relevant data pertinent to NCSS histopathology specimens	100%	Documentary evidence of system validation and relevant records

	Category	Description of Standard	Standard	Demonstration of Compliance
		The LIMS should be used to enter test results	100%	Laboratory standard operating procedures
		The LIMS should be used to enter follow-up and management plans	100%	Laboratory standard operating procedures
		The LIMS should be able to generate periodic mandatory audit returns to the NCSS	100%	Laboratory standard operating procedures and reports

7.4.6 Staffing and Organisation

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.6.1	Chief Medical Scientist/Senior Medical Scientist	<p>In cervical cancer detection, the main task of the chief medical scientist is the organisation of an efficient and properly run histopathology service</p> <p>To reach the goal of correctly identifying precursor lesions and invasive lesions, administrative tasks, technical laboratory tasks, monitoring of follow-up results and activities related to quality assurance, and archiving slides and results are included in the working process of the chief medical scientist</p>	Yes	Job descriptions, training records and CPD records
		<p>Administrative tasks include contact with smectakers, general practitioners (GPs), gynaecologists, other laboratories and hospitals and the NCSS</p> <p>Daily management of the histopathology laboratory, including personnel affairs and annual staff review</p>	Yes	Job descriptions, training records and CPD records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> • Management of periodical circulation and discussion of special cases among medical scientists, and between medical scientists and histopathologists • Timely forwarding of histopathology reports to the NCSS and the National Cancer Registry according to current directives issued by the NCSS <p>Chief medical scientists must respect patient confidentiality and must be trained in country-specific legal requirements</p> <p>The chief medical scientist must be able to undertake technical laboratory tasks including handling specimens, carrying out relevant laboratory techniques and performing prescribed health and safety procedures</p> <p>The chief medical scientist must participate in continuing education, feedback sessions. Quality control programmes are mandatory for all histopathology medical scientists</p> <p>Ensure training and education of all relevant laboratory personnel</p>		
7.4.6.2	Medical Laboratory Scientist (histopathology)	The medical laboratory scientist will be responsible for internal quality control of all steps within the histopathology process, including administration, processing, embedding and staining and should be familiar with external quality protocols	Yes	Job descriptions, training records and CPD records
		<p>Specific tasks of the medical laboratory scientist will be:</p> <ul style="list-style-type: none"> • Direction and completion of laboratory processes and sample preparation • Assistance and supervision of other technical laboratory staff in the performance of analytical procedures and tests 	100%	Job description, standard operating procedures, examination of training records/ CPD and visit

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> • Communication with the histopathologist to whom they are responsible • Assistance in the maintenance of supplies, equipment, and instruments, and in the day-to-day function of the laboratory • Participation in QC and EQA • Co-operation with other laboratory staff to ensure smooth running of the histopathology service • Perform training and education of all relevant laboratory personnel 		
7.4.6.3	Other Technical Laboratory Staff including Medical Laboratory Assistants (MLAs)	<p>Other technical laboratory personnel must be educated and experienced in accordance with their role</p> <p>Other technical laboratory personnel must be able to:</p> <ul style="list-style-type: none"> • Handle relevant laboratory techniques according to guidelines and procedure descriptions • Perform prescribed health and safety procedures • Take part in specific quality control programmes 	Yes	Job descriptions and training records and CPD records
7.4.6.4	Histopathologist	<p>The histopathologist is responsible for the assessment of the histopathological sample</p> <p>Specific tasks of the histopathologist with respect to cervical screening derived material are:</p> <ul style="list-style-type: none"> • Assessment and authorisation of all cases including relevant Snomed coding e.g. Snomed CT • Resolving discrepancies between cytopathological and histopathological diagnoses, if those diagnoses would lead to differing recommendations to the requesting physician 	Yes	Job descriptions and training records

	Category	Description of Standard	Standard	Demonstration of Compliance
		<ul style="list-style-type: none"> • Participates in cancer audit protocols (in accordance with the Irish Medical Council requirements) • Review and intra-laboratory discussion of cases showing serious discrepancy between the cytological and/or histological follow-up • Communication with gynaecologists with respect to specific cases • Communication includes a periodical report to gynaecologists with respect to the quality aspects of the samples • Communication and education of histopathology medical scientists with respect to difficult cases and cases with discrepant cyto-histological results • Guidance and support for adequate (continuing) education of cytotechnologists, medical laboratory scientists (histopathology) and junior medical staff • Participation in quality assurance programmes including preparation of an annual report concerning the outcomes of the cytological and histological follow-up examinations • Participation in multidisciplinary team meetings (MDTs) • Participation in CervicalCheck performance review initiatives required by the NCSS 		
7.4.6.5	Administrative Personnel	<p>Secretarial and administrative employees:</p> <ul style="list-style-type: none"> • Must be trained to carry out relevant duties • Must be educated in relevant medical terminology • Must be able to work with current Word processors and with automated database systems • Must respect patient confidentiality 	Yes	Job descriptions and training records

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.6.6	Final and Overall Responsibility	<p>Final responsibility is contingent on national legal regulations and responsibility to the NCSS</p> <p>The pathologist (certified for histopathology) is responsible for their reports</p>	Yes	Yes

7.4.7 Governance

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.7.1	Governance	The histopathology service should have regular meetings with the NCSS, and participation in MDT/CPC meetings	100%	Attendance records and minutes of meetings and Quality Manual
		Management reports including personnel attending and operational decisions need to be communicated to the NCSS	100%	Minutes of meetings and reporting systems
		The service should have regular clinico pathological meetings on a monthly basis at a minimum	100%	Attendance records and minutes of meetings

7.4.8 Administrative Standards

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.8.1	Departmental Workload	Details of departmental workload must be provided to the NCSS	Yes	Histopathology returns (quarterly)
7.4.8.2	Inter-institutional Consultations	Details of departmental inter-institutional consultations must be provided to the NCSS	Yes	Histopathology returns (quarterly) and visit
7.4.8.3	Intra-departmental Consultations	Details of intra-departmental consultations must be provided to the NCSS	Yes	6 monthly histopathology returns and visit
7.4.8.4	Correlation of Frozen Section Diagnosis with Final Diagnosis (if service requested)	Details of correlation between frozen section on gynae-oncology cases must be provided to the NCSS	Yes	Monthly histopathology returns
7.4.8.5	Cytological/ Histological Correlation and Follow-up	Details of cytology/histology correlation must be provided to the NCSS	Yes	Quarterly histopathology reports
7.4.8.6	Retrospective Review	Two types of review should take place: A: Focused real time review B: Report completeness review Details of departmental retrospective review must be provided to the NCSS	Yes	Minimum of 1 review per year
7.4.8.7	Multidisciplinary Team Meetings (MDTs)	Details of departmental MDT meetings must be provided to the NCSS	Yes	Laboratory quarterly report
7.4.8.8	Laboratory Based Incidents/Non-Conformances	Details of departmental laboratory incidents must be provided (in relation to reporting incidents, determining corrective and preventative actions) to the NCSS	Yes	Laboratory quarterly report

	Category	Description of Standard	Standard	Demonstration of Compliance
7.4.8.9	Laboratory Based External Quality Assessment (EQA)	Details of laboratory EQA must be provided to the NCSS	Yes	Laboratory quarterly report
7.4.8.10	Turnaround Times (TATs)	Details of laboratory TATs must be provided to the NCSS	Yes	Laboratory quarterly report
7.4.8.11	Addendum Reports	Details of laboratory addendum reports must be provided to the NCSS	Yes	Laboratory quarterly report
7.4.8.12	Reports Communicated Directly to the Clinician by the Pathologist	Details of reports communicated to the clinician directly by the pathologist must be provided to the NCSS	Yes	Laboratory quarterly report

7.5 Key Performance Indicators for Histopathology

The Key Performance Indicators (KPIs) pertinent to the histopathology service for the NCSS are detailed in 7.3 (Quality Assurance Standards in Histopathology [overview analysis]). The KPIs delivered to the NCSS should refer to specimens pertaining to patients within CervicalCheck.

The purpose of key performance indicators (KPIs) is to:

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

	Category	Description of Standard	Standard	Demonstration of Compliance
7.5.1	Departmental Workload	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> • Total number of cases • Total number of blocks • Total number of slides • Number of biopsies • Number of non-biopsies <ul style="list-style-type: none"> ◦ No. of cancer resections ◦ No. of other cases • Number of immunohistochemical stains (excluding controls) <ul style="list-style-type: none"> ◦ No. of cases ◦ No. of stains • Number of special stains (excluding controls) <ul style="list-style-type: none"> ◦ No. of cases ◦ No. of stains • Number of frozen sections <ul style="list-style-type: none"> ◦ Total No. of cases/patients ◦ Total No. of specimens 	Yes	Histopathology returns (quarterly)

	Category	Description of Standard	Standard	Demonstration of Compliance
7.5.2	Inter-institutional Consultations	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> Cases referred externally for review <ul style="list-style-type: none"> No. of cases % agreement Cases received internally for review <ul style="list-style-type: none"> No. of cases % agreement Cases referred externally for opinion <ul style="list-style-type: none"> No. of cases referred 	Yes	Histopathology returns (quarterly)
7.5.3	Intra-departmental Consultations	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> Case type <ul style="list-style-type: none"> % of total cases for each case type with intra-departmental consultation 	Yes	6 monthly histopathology returns
7.5.4	Correlation of Frozen Section Diagnosis with Final Diagnosis (if service requested)	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> Period of review Summary of case types No. of cases No. of blocks Correlation results <ul style="list-style-type: none"> % concordance % deferral rate % major discordance Turnaround time Mean and range 	Yes	Annual histopathology returns
7.5.5	Cytological/ Histological Correlation and Follow-up	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> Period of review Case type Correlation results <ul style="list-style-type: none"> No. of cases with discordance No. of false positive cases <p>(Discrepancy classification)</p> <ul style="list-style-type: none"> No. of false negative cases <p>(Discrepancy classification)</p>	Yes	Quarterly histopathology reports

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Discrepancy equates to one grade or greater difference between cytopathology and histopathology results</p> <p>Note: The NCSS will provide details of cytology smear tests to participating histopathology departments</p>		
7.5.6	Retrospective Review	<p>The following information must be supplied to the NCSS:</p> <p>A: Focused real time review: Case type No. of reviews:</p> <ul style="list-style-type: none"> • Period of review • No. of cases per review • % agreement <p>B: Report completeness: Case type No. of reviews:</p> <ul style="list-style-type: none"> • Period of review • No. of cases per review 	Yes	Minimum of 1 review per year
7.5.7	Multidisciplinary Team Meetings (MDTs)	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> • Conference type • No. of conferences held • No. of cases reviewed • % agreement 	Yes	Quarterly histopathology reports
7.5.8	Laboratory Based Incidents/Non-Conformances	<p>The following information must be supplied to the NCSS:</p> <p>Pre-analytic</p> <ul style="list-style-type: none"> • Total no. of incidents (expressed as a % of total cases) • Impact 	Yes	Quarterly histopathology reports

	Category	Description of Standard	Standard	Demonstration of Compliance
		<p>Analytic</p> <ul style="list-style-type: none"> • Total no. of incidents (expressed as a % of total cases) • Impact <p>Post-analytic</p> <ul style="list-style-type: none"> • Total no. of incidents (expressed as a % of total cases) • Impact 		
7.5.9	Laboratory Based External Quality Assessment (EQA)	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> • List of external quality assessment schemes (technical and diagnostic, including slide clubs etc.) participated in by the laboratory 	Yes	Yearly histopathology report
7.5.10	Turnaround Times (TATs)	<p>The following information must be supplied to the NCSS:</p> <p>Case type</p> <p>No. of biopsies</p> <ul style="list-style-type: none"> • % completed by day 1,2,3,4,5,6,7 <p>Non biopsies</p> <ul style="list-style-type: none"> • No. of cancer resections • % completed by day 3,4,...10 	Yes	Quarterly histopathology reports
7.5.11	Addendum Reports	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> • Review period • Report type <ul style="list-style-type: none"> • % corrected reports • % supplementary reports • % amended reports 	Yes	Quarterly histopathology reports
7.5.12	Reports Communicated Directly to the Clinician by the Pathologist	<p>The following information must be supplied to the NCSS:</p> <ul style="list-style-type: none"> • Number of cases reported to the clinician directly by the pathologist (expressed as a % of the total cases examined) 	Yes	Yearly histopathology report

7.6 Communication

	Category	Description of Standard	Standard	Demonstration of Compliance
7.6.1	Other Laboratories	<p>The laboratory/ies should make relevant clinical information and follow-up data available to other laboratories taking part in CervicalCheck</p> <p>All communications are confidential</p>	Yes	Laboratory records
7.6.2	Gynaecologists and Other Smear takers	<p>Smear takers (gynaecologists and nurse colposcopists) must be informed annually about their percentage of unsatisfactory samples versus the mean percentage of the country/region/laboratory</p> <p>Smear takers must provide the essential information using the standard Cervical Histology Form (Appendix 1)</p> <p>Gynaecologists should make relevant clinical information and follow-up data available to the laboratories taking part in CervicalCheck</p>	Yes	Laboratory records
7.6.3	Health Agencies and Authorities	<p>Cytological and histological records must be sent at regular intervals to the NCSS and/or cancer registry that is responsible for the monitoring of screening programmes</p> <p>This condition is mandatory and should include all records irrespective of indication for the examination, status of the woman, the smear taker or the laboratory</p> <p>The laboratories should receive reports with the results of process and impact evaluation of screening</p>	Yes	Laboratory records and reports

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Appendix 1: Cervical Histology Form (sample)

Cervical Histology Form		 THE NATIONAL CERVICAL SCREENING PROGRAMME	
INCOMPLETE FORMS MAY BE RETURNED			
WOMAN'S DETAILS		Colposcopy Clinic / Gynaecology Service	
Personal Public Service Number <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;">Numbers</div> <div style="width: 15px;">Letters</div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	Hospital / Clinic Name <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	Consultation Date <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;">Day</div> <div style="width: 15px;">Month</div> <div style="width: 15px;">Year</div> </div>	
CSP ID <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	Referral Reason <div style="border: 1px solid black; height: 20px;"></div>		
Hospital Chart No. <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	Index / Referral Smear Cytology LB ID <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		
Date of Birth <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;">Day</div> <div style="width: 15px;">Month</div> <div style="width: 15px;">Year</div> </div>	Cytology Lab accession number <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		
Surname: <i>Block capital letters to be used in filling out form</i> <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		Date of Smear <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;">Day</div> <div style="width: 15px;">Month</div> <div style="width: 15px;">Year</div> </div>	
First Name <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		Smear Result <div style="border: 1px solid black; height: 20px;"></div>	
Middle Name <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		<div style="border: 1px solid black; padding: 10px;"> <div style="display: flex; justify-content: space-between;"> <div>Colposcopy</div> <div style="width: 100px; height: 100px; border-radius: 50%;"></div> </div> <div style="margin-top: 10px;">Impression</div> </div>	
Surname at Birth <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>			
Mother's Maiden Name <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>			
Postal Address for Correspondence <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>			
Contact Telephone No. <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		Specimen site Priority: <input type="checkbox"/> <input type="checkbox"/> Please tick	
Mobile No. <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		1. _____ 2. _____ 3. _____	
<div style="background-color: black; color: white; padding: 2px;"> I have read and understood the information given to me I consent to take part in CervicalCheck </div>		Examiner ID <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	
Previous Consent <input type="checkbox"/> Yes <input type="checkbox"/> No or Woman's Signature:		Consultant ID <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	
HISTOLOGY LABORATORY USE ONLY			
Label ID <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>		Barcode <div style="display: flex; justify-content: space-between;"> <div style="width: 15px;"></div> <div style="width: 15px;"></div> </div>	
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The National Cancer Screening Service encompasses BreastCheck - The National Breast Screening Programme and CervicalCheck - The National Cervical Screening Programme			

Appendix 2: Dataset for Histological Reporting of Cervical Neoplasia

(2nd edition): Royal College of Pathologists, London.



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Editor: Professor Glenn McCluggage

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1. Introduction

This document provides the datasets for the histological reporting of cervical cancers in small resection and hysterectomy specimens and replaces the previous datasets of 2001. Meticulous reporting of cervical cancers is important because gross pathological and histological parameters will determine patient treatment. Accurate recording of pathological parameters in the datasets has both direct and indirect implications for the prognosis of individual patients. The use of datasets (and the background information that forms part of the datasets) in the context of the multidisciplinary team (MDT) meeting is advocated to optimise decisions related to patient treatment, to facilitate regular audit and review of all aspects of the service, to enable the collection of accurate data for cancer registries and to provide feedback for those caring for patients with cancer. It is important to have robust local mechanisms in place to ensure that the MDT Clinical Leads and Cancer Registries are apprised of supplementary or revised histology reports which may affect patient treatment and data collection.

The new datasets are largely based on the original version. The presentation of data items in the small resection specimen protocol has been re-ordered so that invasive tumours are covered before preinvasive lesions. Some data items have been removed because of recent developments in the NHSCSP (National Health Service Cervical Screening Programme) e.g. the implementation of the audit of cervical cancers, in which changes associated with HPV infection and epithelial changes of uncertain significance are included.

Details regarding tumour margins have been expanded and clarified in the dataset covering the reporting of cervical cancer in hysterectomy specimens. Perhaps the most important and controversial changes are those related to use of the term 'microinvasive carcinoma'. Because of the lack of clarity of this term and the wide variation in the criteria that are applied in its use, the British Association of Gynaecological Pathologists (BAGP) Working Group has advocated the avoidance of this term in histological reporting and recommends using the FIGO stage as a specific descriptor of small invasive carcinomas. Measurement of multifocal carcinomas is also discussed in some detail because of the risk of over-staging FIGO stage IA1 or IA2 cancers as IB cancers, and thereby influencing treatment decisions.

Most gynaecological oncologists use the FIGO staging system for gynaecological cancers. However, TNM staging is included in this dataset to allow standardisation of staging across all cancer sites. Depending on local protocols, clinicians may elect to include TNM staging in gynaecological cancer datasets.

Evidence for the revised dataset was obtained from a review of relevant literature up to 2007.

The following organisations have been consulted during the preparation of the dataset:

- Working Group of the British Association of Gynaecological Pathologists (BAGP) comprising BAGP Council and co-opted members
- National Health Service Cervical Screening Programme (NHSCSP)
- British Society for Clinical Cytology (BSCC)
- British Society for Colposcopy and Cervical Pathology (BSCCP)
- British Gynaecological Cancer Society (BGCS).

2. Clinical Information Required on the Specimen Request Form

This should include full patient details, cervical screening history (if available), clinical appearance of the cervix, the results of previous biopsies and radiological investigations that have been carried out for tumour staging, colposcopic appearance and comprehensive details of the surgical procedure. The details of surgical specimens from multiple sites should be provided and specimen pots should be labelled to correspond to the specimen details on the request form.

3. Preparation of Specimen before Dissection

The usual surgical procedure for cervical carcinoma is a radical hysterectomy and lymph node dissection. In cases of advanced cervical tumours, adjacent organs may be involved and specimen preparation will depend on whether adjacent organs have been resected, whether or not the tumour is visible macroscopically, and the extent of tumour spread.

If adherent or adjacent organs are attached these will need to be opened (to allow fixation) in a way that will not compromise resection margins, and margins may need to be painted with ink or appropriate dye prior to specimen opening. However, nowadays advanced cervical cancers (>FIGO IIA) are unlikely to be surgically resected and are usually treated with chemoradiation.

Preparation of radical hysterectomy specimens will depend on the size of the cervical tumour and the extent of spread. Parametrial, paracervical and vaginal margins may require painting with ink/dye before opening the uterus (this may be done before sampling to allow adequate fixation of the corpus). Opening the uterus should allow optimal visualisation of the cervical tumour and facilitate block taking to ensure that all of the core data items can be assessed. There is no one proscriptive method of opening the uterus and the BAGP Working Group was of the opinion that this can be done according to the preference of the individual pathologist. In the case of large tumours, opening the specimen in the sagittal plane may be appropriate but for very small tumours or tumours that are not obvious macroscopically it may be advantageous to open the uterus in the coronal plane. Some pathologists advocate amputation of the cervix before opening the uterus so that the cervix can be dissected and processed in a similar way to a cone or loop biopsy, but this will depend on tumour size – large, bulky tumours may not be amenable to sampling in this way.

A photographic record of the specimen may be useful.

4. Specimen Handling and Block Selection

Cone and loop biopsies are performed mainly for preinvasive lesions but occasionally an early invasive carcinoma is identified. Wedge biopsies are usually performed for the confirmation and typing of tumours.

Trachelectomy specimens tend to be performed at specialist centres and, although their detailed assessment is outwith the remit of this document, it is recommended that local protocols should incorporate examination of all of the cervical, vaginal and parametrial tissue resected in a way that ensures accurate assessment of tumour dimensions, parametrial involvement and margin status, including distances from all margins.

4.1 Gross examination and dissection of excisional cervical biopsy specimens (wedge/cone/loop biopsy)

The number of pieces of tissue must be indicated on the proforma. It has become increasingly common to receive a second, separate loop biopsy that has been taken from the apex of the more superficial loop biopsy (so called "top hat") and both specimens should be processed in the same way. In some cases, more than two pieces of tissue may be received. All specimens should be measured in three dimensions, and must be examined in their entirety. The block designation of each separate specimen must be provided (e.g. first piece: blocks A–C; second piece: blocks D–F; etc.).

There are several methods of dissection of cone and loop biopsies (whether received opened or closed), although there are two preferred, widely used methods. The first is serial slicing at 2–3mm intervals,^{1,2} from one edge to the other in a sagittal and parasagittal plane (beginning at the 3 or 9 o'clock edge, if the 12 o'clock position has been marked by the surgeon), perpendicular to the transverse axis of the external os. This avoids the problems of interpretation that may arise when dysplastic epithelium arises on the narrow end of a wedge shaped block (if a loop/cone specimen is sectioned radially, see below), and facilitates assessment of tumour volume in small lesions or neoplasms³. However, this method does not allow direct correlation of CIN, CGIN or tumour with the specific position on a clock face⁴ that the second, radial method of sampling permits. Using this technique, wedge shaped slices are taken according to the hours on a clock face. Although this method of sampling may be useful if accurate mapping of a lesion is desired,² in practice, determination of the position of a cervical lesion is very rarely of relevance to subsequent treatment or management.

In either case, the slices should be submitted in sequential, individually designated cassettes, and local protocols must be in place to ensure that the sequential (not the apposing) faces of consecutive slices are blocked and cut for histology to enable measurement of the third dimension of cervical tumours when necessary. In some centres, for the purpose of expediency, the excision margins of loop biopsies are assessed by embedding the outer (curved) surface of the first and last slices of the loop face down for sectioning, instead of the cut surface. This avoids having to request additional levels to assess these margins.

Although it has been suggested for reasons of convenience and economy^{4,5} that if slices are small, two or three may be placed in one cassette, Members of the Working Party of The Royal College of Pathologists⁶ advocate that each slice of tissue should be placed in a single cassette, so that the sequence of the slices is unambiguous thus enabling assessment of unifocal versus multifocal disease, and reliable interpretation of the order of sequential slices to establish when the third dimension of a lesion may exceed 7mm (FIGO IB1). The BAGP Working Group is of the view that if more than one slice is placed in an individual cassette, local protocols should be in place so that it is known unequivocally which slices are adjacent and consecutive.

4.2 Gross examination and dissection of hysterectomy specimens

The specimen components (usually vaginal cuff, uterus, parametria, fallopian tubes, and ovaries), their dimensions and gross appearances should be recorded. Lymph nodes are usually sent in separate pots and labelled as to their sites of origin.

After appropriate measurements have been taken, it may be necessary to trim or remove the vaginal cuff to enable assessment of the cervical tumour. If this is done, the circumferential vaginal resection margin can be blocked in strips for histological assessment of this resection margin. If there is only a short length of vaginal cuff attached to the specimen, trimming will not be necessary and the vaginal cuff (and resection margin) is submitted in continuity with the cervix. Particular attention should be paid to the fornices. If there is macroscopic evidence of vaginal involvement the position and extent of involvement should be recorded.

If present and visible, the dimensions of a preceding loop or cone biopsy site should be recorded. Although it may be difficult to measure the cervical tumour in three dimensions, this should be attempted if possible. Tumour size remains one of the most important determinants of outcome and accurate measurement is important in ascertaining the FIGO stage.⁷ In most studies tumour size is based on two-dimensional measurements but, in a few studies, measurements in terms of volume have been shown to predict prognosis more reliably than measurements in only one or two dimensions^{8,9} although, in practice, management usually does not depend on tumour volume.

The position of the tumour in the cervix should be recorded. If tumour involves more than one quadrant of the cervix, the appropriate boxes should be marked on the proforma (e.g. anterior and right should be marked if both the anterior and right quadrants are involved). In one study, the risk of lymph node involvement was shown to increase progressively with involvement of one, two, three or four cervical quadrants (from 2% if one quadrant is involved to 13% if three or four quadrants are involved).¹⁰ Furthermore, systematic recording of the position of the tumour within the cervix enables audit of, and correlation with, radiological findings.

Macroscopic tumour involvement of the parametrial and paracervical tissues should be noted and recorded and may determine the method of dissection and block taking. It may be preferable to sample the tumour in continuity with the involved parametrial or paracervical tissues, rather than remove these to begin with, but either method can be used. There are few published data about the processing and sampling of parametrial and paracervical tissues whose volume and extent are dictated by the surgical procedure, but these were included as separate data items in the previous datasets for the reporting of cervical neoplasia of The Royal College of Pathologists (RCPATH).¹¹ It is recommended that this practice should continue to enable studies to be carried out to assess whether paracervical margin involvement simply reflects a correlate of radial margin involvement, or has the same prognostic implications as parametrial involvement. In one study, assessment of paracervical tissues was included with parametrial tissues¹² in order to determine the pattern of parametrial spread. This study, which involved the processing of hysterectomy specimens of 69 patients with early cervical carcinoma (FIGO stage IB1, IB2 and IIA) with a 'giant section technique' and separating paracervical and parametrial tissues to obtain a thorough three-dimensional assessment of these, revealed clinically undetected involvement in a significant percentage of cases, and metastasis to the pelvic lymph nodes was always associated with parametrial disease. Parametrial involvement is a poor prognostic indicator for early stage cervical carcinoma, regardless of lymph node status,¹³ and is an adverse prognostic indicator for advanced stage cervical carcinomas.¹⁴

Extension of the tumour into the uterine corpus should be recorded although this does not alter the stage of the cervical carcinoma.

4.3 Block selection for excisional cervical biopsy specimens (wedge/cone/loop biopsy)

These specimens should be blocked in their entirety. Cassettes should be separately identified, with a block designation to indicate their origin.

4.4 Block selection for hysterectomy specimens

Blocks of the cervix must be taken to demonstrate the maximum depth of invasion and the relationship of the tumour to the surgical resection margins, notably the vaginal, anterior cervix/bladder reflection, posterior cervix/rectovaginal septum and parametrial/paracervical margins.

For small tumours, or in cases where no macroscopic tumour is identified, the whole of the cervix should be blocked as in the case of cone/loop biopsies. For large, bulky tumours at least one section per centimetre of greatest tumour dimension should be blocked¹⁵ to include, if possible, the point of deepest invasion, i.e. full thickness of the cervical wall. Additional blocks should include the interface with adjacent cervix in order to demonstrate any CIN or CGIN from which the carcinoma may have arisen.⁵ Full thickness sections from the lower uterine segment, immediately proximal and adjacent to the tumour should be taken to identify upward extension.

Blocks of the vaginal resection margin may be taken in continuity with the tumour if the vaginal cuff is short (see above) or separate blocks of the trimmed circumferential vaginal resection margin should be blocked in specifically designated cassettes according to their origin (e.g. from the anatomical quadrants from which they have originated).

The parametria and paracervical tissues should be blocked in their entirety. The laterality of the blocks must be recorded and inking may be helpful to define the true surgical margins.⁵ The uterine corpus and adnexa should be sampled according to standard protocols^{1,2,4,5} if uninvolved, but additional blocks may be required if there is evidence of involvement by tumour.

The number of lymph nodes retrieved from each site should be recorded. The presence of macroscopic involvement of lymph nodes should be noted together with the dimensions of involved nodes. All resected lymph node tissue should be sampled and all lymph nodes from each location must be blocked. Each individual lymph node should be examined histologically in its entirety unless obviously grossly involved by tumour. Only one block is necessary from any grossly involved node. Nodes smaller than 5mm can be bisected or processed whole and large lymph nodes may require sampling in more than one block.

In departments where the facility for processing of oversize blocks is available a good overview of the tumour and resection margins can be obtained, but standard blocks of tumour should also be processed, to enable immunohistochemistry or other special stains to be performed more readily should these be required.

The origin/designation of all tissue blocks should be recorded. This is particularly important should the need for internal or specialist external review arise. The reviewer needs to be clear about the origin, relevant resection margin/s and laterality of each block in order to provide an informed specialist opinion.

5. Core Histological Data Item

In the case of loop/cone/wedge biopsies and hysterectomy specimens the presence or absence of cervical intraepithelial neoplasia (CIN) must be reported, and the grade provided (CIN 1, 2, 3). Cervical glandular intraepithelial neoplasia (CGIN) must be recorded and graded (low or high grade), as should stratified mucin-producing intraepithelial lesion (SMILE).¹⁶ It should be remembered that in loop/cone biopsies a final FIGO stage cannot be provided for incompletely excised lesions, including cases with CIN or CGIN at a margin; only a provisional FIGO stage can be applied.

Tumour type

Tumour type should be designated according to the WHO classification (see Section 7). There is controversy in the literature as to whether different tumour types are associated with different prognoses and, while some studies have reported a poorer prognosis for adenocarcinoma and adenosquamous carcinoma as opposed to squamous carcinoma,^{13,17,18} other studies have shown that the apparent poor prognosis of these tumour types may be due to the presence of bulkier disease and greater resistance to radiotherapy.^{19–21} Neuroendocrine carcinomas (both small and large cell types) must be separately identified because of their poor prognosis and the need for neo-adjuvant or adjuvant chemotherapy.^{22,23}

Tumour grade

Tumour grade is a controversial prognostic factor in cervical carcinoma. This is likely to reflect the variety of grading systems in use and lack of agreement on how to apply them. The systems that have shown close correlation with prognosis are those in which multiple criteria are assessed and individually scored, such as the Stendahl system²⁴ or invasive front grading.²⁵ These have been shown to work well when used by individuals, but have not been tested widely for reproducibility and are too cumbersome for routine use. It is currently recommended that squamous carcinomas should be graded according to a modified version of Broders as well differentiated (keratinising), moderately or poorly differentiated.²⁶ There is no agreed grading system for cervical adenocarcinoma. It has, however, been recommended that these tumours be graded according to the FIGO system for endometrial adenocarcinoma,⁶ but in cervical adenocarcinoma the nuclear grade may be more significant.²⁷ Grading of adenosquamous carcinomas as well, moderately or poorly differentiated according to the degree of differentiation of the squamous and glandular components is suggested by the Working Group.⁶ Neuroendocrine carcinomas are not graded and are, by definition, high grade carcinomas.

Tumour dimensions

The term 'microinvasive carcinoma' does not appear in the FIGO staging system for cervical cancer. Furthermore, use of the term 'microinvasive carcinoma' has different connotations in the United Kingdom and North America. In the United Kingdom, microinvasive carcinoma is considered to be synonymous with FIGO stage IA1 and IA2 disease in most, but not all, institutions (some use the term microinvasive carcinoma to indicate FIGO stage IA1). In the United States, the term is synonymous with stage IA1 disease.²⁸ The American Society of Gynecologic Oncology (SGO) has its own definition of FIGO stage IA tumours that is limited not only by the depth of tumour invasion, but also by the presence of lymphovascular invasion. According to the SGO, cancers that invade more than 3mm or those invading less than 3mm with lymphovascular involvement are classified as FIGO stage IB.²⁹ In order to avoid confusion, the BAGP Working Group has indicated a preference for avoiding the term 'microinvasive carcinoma' and for using the specific FIGO stage as a descriptor.

Depth of invasion must be measured in all cases. This measurement is taken from the base of the epithelium (surface or glandular) from which the carcinoma arises, as specified in the FIGO classification. If there is no obvious epithelial origin, the depth should be measured from the tumour base (deepest focus of tumour invasion) to the base of the nearest surface epithelium.

According to the FIGO classification two tumour dimensions are required but there is no guidance from FIGO with regard to measurement of the second dimension of horizontal spread. Several studies have suggested that tumour volume is the most reliable prognostic factor for early stage tumours.^{8,30–32} For practical purposes, measurement of tumours in two dimensions (depth and maximal horizontal extent) is adequate, although a third dimension to calculate volume may be required in individual cases.

In unifocal tumours the maximum horizontal dimension/width of tumour is measured in the section in which the width is greatest (from the edge at which invasion is first seen, to the most distant edge at which invasion is identified). There is controversy about this measurement because according to NHSCSP Publication Number 10 the measurement of width is not limited to the confluent component of the tumour.⁶ This becomes problematical because up to 12% of carcinomas with early invasion may be multifocal in origin.³³ It is unclear how the horizontal dimension of lesions with multiple invasive foci should be measured. In such circumstances it is important to distinguish multifocal FIGO stage IA1 or IA2 disease from clinically occult stage IB disease³⁴ although there is both anecdotal evidence and accumulating evidence in the literature that the prognosis of small FIGO stage IB tumours does not differ significantly from stage IA2 tumours.^{29,31} There is a paucity of published data about the measurement and subsequent staging of multifocal tumours,³⁴ and until further data emerge, the BAGP Working Group recommends that such cases are discussed individually and staged at the MDT meeting. If the small invasive foci are clearly separate, then some of these neoplasms may be regarded as multiple foci of stage IA1 disease while in other cases, where the foci are not clearly separate, then the measurement of horizontal spread may be taken from one edge of the whole lesion to the other. If invasive carcinoma is present in three or more adjacent sections of tissue the diameter of the lesion may exceed 7mm, i.e. the carcinoma may be more than FIGO stage IA2. An estimate of the thickness of the blocks can be calculated from the macroscopic description of the specimen, and the number of blocks taken, although pathologists should be mindful that thickness of large/outsize blocks can vary from block to block, as compared with standard-sized blocks.

All grossly visible lesions, even those with only superficial invasion, are clinical stage IB. Large tumours must also be measured in at least two dimensions.

Early invasive adenocarcinoma is a controversial entity and is not specifically mentioned in the 1995 FIGO staging, but nonetheless it is recommended that the FIGO classification be applied.²³ Identification of early invasion in a glandular lesion may be more difficult than in a squamous lesion. Early invasive adenocarcinoma is diagnosed on the basis of obvious invasion to 5mm or less, extension beyond the normal endocervical gland field and often a stromal response characteristic of invasive carcinoma.³⁵ The width of the tumour must be measured in a similar way to that described for squamous neoplasms, but in most cases the depth is measured from the epithelial surface, rather than the point of origin which can be difficult to establish in many cases^{23,36} i.e. the thickness, rather than the true depth of invasion is measured, and this should be indicated when completing the dataset proforma. There is now emerging evidence that the behaviour of early invasive adenocarcinoma is similar to its squamous counterpart.

Lymphovascular invasion

The presence or absence of lymphovascular space invasion must be recorded for tumours of all types and stages, be they tumours that show only early invasion or more than FIGO stage IA2. The significance of lymphovascular invasion is covered in detail in a review by Singh et al³⁷ but briefly, this finding is in itself a strong adverse prognostic indicator and correlates highly with other adverse prognostic indicators such as tumour type and stage.^{18,22} In patients with early invasive tumours the quantity of lymphovascular space invasion has been shown to be an independent prognostic factor for time to recurrence.³⁸

Resection margins

The status of all resection margins must be documented in the proforma. Depending upon its position, the closest radial margin may consist only of the minimum thickness of uninvolved cervical stroma. In hysterectomy specimens, if the closest radial margin is lateral, the thickness of any previously trimmed paracervical tissue must be added to the measurements that are taken from the relevant histological section. The position of closest margins must be indicated. In cone/loop biopsies, the status of ectocervical, endocervical and deep resection margins should be recorded as should their involvement by CIN, CGIN, SMILE or invasive carcinoma.

Lymph nodes

The number of nodes that are retrieved and involved at each site must be recorded, and the presence of extranodal spread must be sought and reported if present.

Staging

Tumours should be staged according to the FIGO and TNM staging systems.³⁹ It is recommended that final staging of cervical tumours should take place at the MDT meeting to ensure correlation with previous cone/loop specimens and other relevant radiological and clinical findings.

Summary of core data items

For excisional biopsies and hysterectomy specimens:

- tumour type
- tumour grade
- tumour size (in at least two dimensions)
- status of resection margins
- presence or absence of lymphovascular invasion.

Additional core data items for hysterectomy specimens:

- minimum tumour-free cervical stroma (tumour-free rim) and position
- closest radial resection margin
- presence or absence of lymph node metastases and extranodal spread
- involvement of other organs or tissues.

6. Non-Core Data Items

These may be recorded as a separate comment or within a complementary text report. Such items may include the presence of a cone/loop biopsy site within the cervix, extension of the carcinoma into the endometrial cavity, the results of histochemical stains for mucin on poorly differentiated tumours and the results of any immunohistochemical studies.

An additional parameter that has been reported to be of prognostic significance in cervical carcinomas and may be included within a complementary text report is the depth of infiltration in thirds of the cervical wall.^{40,41} In one study the disease-free interval was found to be 94.1% for tumours that infiltrated the superficial one third of the cervix, 84.5% for those that infiltrated the middle third, and 73.6% for those infiltrating the deep third.

In a study of FIGO stage I adenocarcinomas, univariate analysis showed that the thickness of the remaining cervical wall⁴⁰ was found correlate with overall survival. Where thickness of the remaining wall was >3mm, five-year survival was 82%, but in cases where the remaining wall thickness was 1–3mm, five-year survival fell to 62%.

7. Who Classification of Cervical Epithelial Tumours and Snomed Morphology Coding²³

Squamous tumours and precursors

Squamous carcinoma, not otherwise specified	80703
Keratinizing	80713
Non-keratinizing	80723
Basaloid	80833
Verrucous	80513
Warty	80513
Papillary	80523
Lymphoepithelioma-like	80823
Squamotransitional	81203
Early invasive (microinvasive) squamous cell carcinoma	80763
Squamous intraepithelial neoplasia	
Cervical intraepithelial neoplasia (CIN) 3	80772**
Squamous cell carcinoma in situ	80702

Glandular tumours and precursors

Adenocarcinoma	81403
Mucinous adenocarcinoma	84803
Endocervical type	84823
Intestinal	81443
Signet-ring cell	84903
Minimal deviation	84803
Villoglandular	82623
Endometrioid adenocarcinoma	83803
Clear cell adenocarcinoma	83103
Serous adenocarcinoma	84413
Mesonephric adenocarcinoma	91103
Early invasive adenocarcinoma	81403
Adenocarcinoma in situ	81402

Other epithelial tumours

Adenosquamous carcinoma	85603
Glassy cell carcinoma variant	80153
Adenoid cystic carcinoma	82003
Adenoid basal carcinoma	80983
Neuroendocrine tumours	
Carcinoid tumour	82403
Atypical carcinoid	82493
Small cell carcinoma	80413
Large cell neuroendocrine carcinoma	80133
Undifferentiated carcinoma	80203

** In the United Kingdom, the preferred SNOMED code for CIN 3 is 74008.

8. Small Biopsy Specimens

Small colposcopically directed punch biopsies may be up to several millimetres long, and 2–4mm thick. The number of pieces received should be recorded, as should their size (in 3 dimensions). Specimens that are mounted on filter paper before fixation are more likely to be optimally oriented, have a preserved squamocolumnar junction, and intact surface epithelium.⁴² Fixation in eosin-tinted formalin may facilitate their identification and orientation.^{6,42} It is important to search the container and the under surface of its lid to ensure that stray fragments of tissue are recovered, and care should be taken to avert tissue loss of very small fragments – these should be wrapped, placed between layers of foam sponge, placed in mesh bags or wire baskets according to local practice.

If biopsies are >5mm in dimension, they may be bisected transversely, perpendicular to the mucosal surface, to produce two pieces. All of the biopsy fragments should be processed.

The report should incorporate the macroscopic description of the specimen, and identify the area/s of the cervix from which the biopsy has originated, i.e. ectocervix, endocervix, transformation zone.

Where artefact or epithelial loss impairs interpretation of the biopsy, this must be stated in the report. The pathologist must report all grades of CIN and/or CGIN; invasive lesions should be reported, typed and graded according to national protocols and guidelines.⁶

It is recommended that koilocytosis and koilocytosis-associated changes also be reported. The pathologist must be mindful of the cytology/smear history, the result of the most recent smear when writing the histology report, and include all pathological lesions (neoplastic and nonneoplastic) that may be associated with, or account for, the reported cytological abnormalities. When a biopsy fails to reveal the source of the abnormal cells in a smear, 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. The limitations of small punch biopsies in the detection of high-grade CIN should be recognised⁴³. If invasive disease is suspected on the basis of the cytological, colposcopic, or histological features further levels should be examined.⁴⁴

9. Reporting of Frozen Sections

In most institutions, frozen sections are not used routinely for the assessment of resection margins. However, in some specialist centres frozen sections may be used where trachelectomies are carried out and the upper limit of the specimen may be examined intraoperatively. Intra-operative frozen sections may be performed on clinically suspicious lymph nodes to look for metastasis before proceeding with or abandoning radical surgery. Clinicians should be aware of the limitations of frozen sections in general, and of sampling and interpretational errors as they apply to lymph node frozen sections in particular.

10. Specific Aspects of Individual Tumours not covered elsewhere

In small biopsy samples, it may be necessary to differentiate between primary endocervical adenocarcinoma and endocervical extension from a primary endometrial adenocarcinoma. A panel of immunohistochemical markers is recommended.^{45–47} Occasionally metaplastic processes in the endocervix, such as tuboendometrioid metaplasia, may mimic CGIN. The use of p16, MIB1 and bcl2 immunostaining may prove helpful in this regard.⁴⁸

Both small and large cell neuroendocrine carcinomas may require a range of immunohistochemical markers to confirm the diagnosis. Small cell neuroendocrine carcinomas may not stain with most of the commonly used neuroendocrine markers and this does not preclude the diagnosis. p63 is a useful marker of squamous cervical neoplasms and may be of use in differentiating small cell neuroendocrine carcinoma (p63 negative) from small cell squamous carcinoma (p63 positive).⁴⁹ It is beyond the scope of this publication to describe in detail immunohistochemical markers of use in cervical neoplasia but the reader is referred to a recent review on this subject.⁴⁹

11. Acknowledgements

Members of the British Association of Gynaecological Pathologists (BAGP) Working Group. Professor M Wells, author of the 2001 dataset for the reporting of cervical cancers.

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Appendix A TNM and FIGO Pathological Staging of Cervical Carcinoma

TNM category	FIGO stage	Definition
TX		Primary tumour cannot be assessed
T0		No evidence of primary tumour
Tis	0	Carcinoma <i>in situ</i>
T1	I	Cervical carcinoma confined to the uterus (extension to the corpus should be disregarded)
T1a	IA	Invasive carcinoma, diagnosed by microscopy only (all macroscopically visible lesions even those with superficial invasion are pT1b/Stage IB)
T1a	1 IA1	Stromal invasion 3.0 mm or less in depth* and 7.0 mm or less in horizontal spread
T1a2	IA2	Stromal invasion more than 3.0 mm in depth and not more than 5.0 mm with a horizontal spread 7.0 mm or less
T1b	IB	Clinically visible lesion confined to the cervix or microscopic lesion greater than T1a2/IA2
T1b1	IB1	Clinically visible lesion 4.0 cm or less in greatest dimension
T1b2	IB2	Clinically visible lesion more than 4.0 cm in greatest dimension
T2	II	Tumour invades beyond the uterus but not to pelvic wall or to lower third of vagina
T2a	IIA	Tumour without parametrial invasion
T2b	IIB	Tumour with parametrial invasion
T3	III	Tumour extends to the pelvic wall and/or involves the lower third of the vagina, and/or causes hydronephrosis or non-functioning kidney
T3a	IIIA	Tumour involves lower third of vagina, no extension to pelvic wall
T3b	IIIB	Tumour extends to pelvic wall and/or causes hydronephrosis or non-functioning kidney
T4	IVA	Tumour invades the mucosa** of bladder or rectum and/or extends beyond true pelvis
M1	IVB	Distant metastasis

* The depth of invasion is measured from the base of the epithelium, either surface or glandular, from which it originates. The depth of invasion is defined as the measurement of the tumour from the epithelial-stromal junction of the adjacent most superficial epithelial papilla to the deepest point of invasion. Vascular space involvement, either venous or lymphatic, does not alter the staging.

** Presence of bullous oedema is not sufficient evidence to classify a tumour as T4. The lesion should be confirmed by biopsy.

Regional lymph nodes (N)^{***} (TNM staging system)

- NX Regional lymph nodes cannot be assessed
- N0 No regional lymph node metastasis
- N1 Regional lymph node metastasis

^{**} Regional lymph nodes include paracervical, parametrial, hypogastric (obturator); common, internal and external iliac; presacral and lateral sacral nodes. Metastasis to lymph nodes outside of the regional nodal group is classified as distant metastasis.

Distant metastasis (M) (TNM staging system)

- MX Distant metastasis cannot be assessed
- M0 No distant metastasis
- M1 Distant metastasis (excludes peritoneal metastasis)

Appendix B1 Reporting Proforma for Cervical Cancer in Excisional Cervical Biopsies

Surname _____	Forenames _____	Date of birth _____
Hospital _____	Hospital no _____	NHS no _____
Date of receipt _____	Date of reporting _____	Report no _____
Pathologist _____	Surgeon _____	

Description of specimen and core macroscopic items

Wedge ☐ Cone ☐ Loop ☐ biopsy of cervix: _____ mm x _____ mm and _____ mm thick/deep

Number of fragments received, measurement of each and block designation: _____

Core microscopic items

Invasive malignancy:

Type: squamous carcinoma ☐ adenosquamous carcinoma ☐ adenocarcinoma ☐
 neuroendocrine carcinoma ☐ other ☐ specify _____

Differentiation of invasive carcinoma: well/grade 1 ☐ moderate/grade 2 ☐ poor/grade 3 ☐ not applicable ☐

Distribution of invasive component: unifocal ☐ multifocal ☐

Tumour size: maximum horizontal dimension _____ mm
 maximum thickness/depth of invasion(delete as appropriate) _____ mm

Are invasive foci present in three or more sequential slices of tissue*: yes ☐ no ☐

Other features:

CIN (cervical intra-epithelial neoplasia):	present <input type="checkbox"/>	absent <input type="checkbox"/>			
	grade:	CIN 1 <input type="checkbox"/>	CIN 2 <input type="checkbox"/>	CIN 3 <input type="checkbox"/>	
CGIN (cervical glandular intraepithelial neoplasia):	present <input type="checkbox"/>	absent <input type="checkbox"/>			
	grade:	low <input type="checkbox"/>	high <input type="checkbox"/>		
SMILE (stratified mucin-producing intra-epithelial lesion):	present <input type="checkbox"/>	absent <input type="checkbox"/>			

Excision margins: (specify whether involved by CIN, CGIN or SMILE)

Ectocervical resection margin:	clear <input type="checkbox"/>	involved <input type="checkbox"/>	by (specify) _____
Endocervical resection margin:	clear <input type="checkbox"/>	involved <input type="checkbox"/>	by _____
Deep lateral/radial resection margin:	clear <input type="checkbox"/>	involved <input type="checkbox"/>	by _____
Lymphovascular space invasion:	present <input type="checkbox"/>	absent <input type="checkbox"/>	

*Note: If invasive foci are seen in three or more sequential sections of tissue, the third dimension of the lesion (which is not routinely measured) may exceed 7 mm (i.e. more than Stage IA2).

Provisional pathological FIGO stage _____	pTNM stage: pT _____	pN _____	M _____
SNOMED codes: T _____	M _____		
T _____	M _____		

Signature of pathologist: _____ Date _____

Appendix B2 Reporting Proforma for Cervical Cancer in Hysterectomy Specimens

Surname _____	Forenames _____	Date of birth _____
Hospital _____	Hospital no _____	NHS no _____
Date of receipt _____	Date of reporting _____	Report no _____
Pathologist _____	Surgeon _____	

Description of specimen and core macroscopic items

Wedge

Vaginal cuff: present ☐ absent ☐ length _____ mm diameter _____ mm

Dimensions of uterus: length _____ mm transverse _____ mm
anteroposterior _____ mm

Adnexa: present ☐ absent ☐
normal ☐ abnormal (specify) _____

No tumour seen Maximum dimensions of tumour: _____ mm x _____ mm

Position of cervical tumour: anterior ☐ posterior ☐ right ☐ left ☐ circumferential ☐
ectocervix ☐ endocervix ☐

Macroscopic involvement of vagina: yes ☐ no ☐

Macroscopic involvement of parametria: yes ☐ no ☐

Macroscopic involvement of paracervical tissues yes ☐ no ☐

Core microscopic items

Type: squamous carcinoma ☐ adenosquamous carcinoma ☐ adenocarcinoma ☐
neuroendocrine carcinoma ☐ other ☐ specify _____

Differentiation: well/grade 1 ☐ moderate/grade 2 ☐ poor/grade 3 ☐ not applicable ☐

Tumour size: maximum horizontal dimension _____ mm
thickness/depth of invasion (delete as appropriate) _____ mm

Minimum thickness of uninvolved cervical stroma (minimum tumour-free rim): _____ mm

Position of this: _____

Closest radial resection margin (include paracervical tissue thickness): _____ mm

Position of this: _____

Vaginal involvement: yes ☐ no ☐ Distance from distal vaginal epithelial margin: _____ mm

Position of this: _____

Paracervical involvement: yes ☐ no ☐ If involved: left ☐ right ☐

Parametrial involvement: yes ☐ no ☐ If involved: left ☐ right ☐

Lymphovascular invasion: yes ☐ no ☐

CIN: present ☐ absent ☐ Grade 1/2/3 CGIN: present ☐ absent ☐ Grade: low/high

SMILE: present ☐ absent ☐

Appendix B2 Reporting Proforma for Cervical Cancer in Hysterectomy Specimens (Continued)

Nodes: (pelvic group includes obturator, internal and external iliac)

Nodes (site and number)	Right	left	Common iliac	right	left
Total number					
Number involved					
Extranodal spread:	yes <input type="checkbox"/>	no <input type="checkbox"/>			
Para-aortic nodes:	positive <input type="checkbox"/>	negative <input type="checkbox"/>		not sampled <input type="checkbox"/>	
	total number of nodes <input type="checkbox"/>		number of positive nodes <input type="checkbox"/>		
Extranodal spread:	yes <input type="checkbox"/>	no <input type="checkbox"/>			
Other tissues and organs:	Normal	Abnormal (describe)			
Endometrium	<input type="checkbox"/>				
Myometrium	<input type="checkbox"/>				
Right adnexum	<input type="checkbox"/>				
Left adnexum	<input type="checkbox"/>				

Provisional pathological FIGO stage: _____ pTNM stage: pT _____ pN _____ M _____
 SNOMED codes: T _____ M _____
 T _____ M _____

Signature of pathologist: _____ Date _____

Appendix 3: National Reporting Proformas

3.1: National reporting proforma for CIN and cGIN in biopsy and excisional specimens

3.2: National reporting proforma for cervical cancer in excisional cervical biopsies

3.3: National reporting proforma for cervical cancer in hysterectomy specimens

Appendix 3.1: For CIN and cGIN in Biopsy and Excisional Specimens

NATIONAL REPORTING PROFORMA FOR CIN AND cGIN IN BIOPSY AND EXCISIONAL SAMPLES	
Surname _____	Forenames _____
Date of birth _____	
Hospital _____	Hospital no _____
CSP ID no _____	
Date of sampling _____	
Date of receipt _____	
Date of reporting _____	
Report no _____	
Pathologist _____	Gynaecologist _____
Description of specimen and core macroscopic items Wedge <input type="checkbox"/> Cone <input type="checkbox"/> Loop <input type="checkbox"/> Punch <input type="checkbox"/> biopsy of cervix: _____ _____ mm x _____ mm and _____ mm thick/deep	
Number of fragments received, measurement of each and block designation: _____	
CIN (cervical intraepithelial neoplasia): present <input type="checkbox"/> absent <input type="checkbox"/> grade: CIN 1 <input type="checkbox"/> CIN 2 <input type="checkbox"/> CIN 3 <input type="checkbox"/>	
cGIN (cervical glandular intraepithelial neoplasia): present <input type="checkbox"/> absent <input type="checkbox"/> grade: low <input type="checkbox"/> high <input type="checkbox"/>	
SMILE (stratified mucin-producing intraepithelial lesion): present <input type="checkbox"/> absent <input type="checkbox"/>	
Surface involvement present <input type="checkbox"/> absent <input type="checkbox"/>	
Crypt involvement present <input type="checkbox"/> absent <input type="checkbox"/>	
Number of blocks- % involved Stromal invasion: present <input type="checkbox"/> absent <input type="checkbox"/>	
Ectocervical resection margin: clear <input type="checkbox"/> involved <input type="checkbox"/> by (specify) _____ Endocervical resection margin: clear <input type="checkbox"/> involved <input type="checkbox"/> by _____	
Deep margin: clear <input type="checkbox"/> involved <input type="checkbox"/> by _____	
Lymphovascular space invasion: present <input type="checkbox"/> absent <input type="checkbox"/>	
Diathermy artefact: present <input type="checkbox"/> absent <input type="checkbox"/>	
Additional comments: SNOMED codes: T _____ M _____	
Signature of pathologist: _____ Date _____	

Appendix 3.2: For Cervical Cancer in Excisional Cervical Biopsies

NATIONAL REPORTING PROFORMA FOR CERVICAL CANCER IN EXCISIONAL CERVICAL BIOPSIES	
Surname _____	Forenames _____
Date of birth _____	
Hospital _____	Hospital no _____
CSP ID no _____	
Date of sampling _____	
Date of receipt _____	
Date of reporting _____	
Report no _____	
Pathologist _____	Gynaecologist _____
Description of specimen and core macroscopic items Wedge <input type="checkbox"/> Cone <input type="checkbox"/> Loop/LLETZ/NETZ/SWETZ <input type="checkbox"/> biopsy of cervix: _____ _____ mm x _____ mm and _____ mm thick/deep Number of fragments received, measurement of each and block designation: _____	
Core microscopic items Invasive malignancy: Type: squamous carcinoma <input type="checkbox"/> adenosquamous carcinoma <input type="checkbox"/> adenocarcinoma <input type="checkbox"/> neuroendocrine carcinoma <input type="checkbox"/> other <input type="checkbox"/> specify _____	
Differentiation of invasive carcinoma: well/grade 1 <input type="checkbox"/> moderate/grade 2 <input type="checkbox"/> poor/grade 3 <input type="checkbox"/> not applicable <input type="checkbox"/>	
Distribution of invasive component: unifocal <input type="checkbox"/> multifocal <input type="checkbox"/>	
Tumour size: maximum horizontal dimension _____ mm maximum thickness/depth of invasion(delete as appropriate) _____ mm	
Are invasive foci present in three or more sequential slices of tissue*: yes <input type="checkbox"/> no <input type="checkbox"/>	
Other features: CIN (cervical intraepithelial neoplasia): present <input type="checkbox"/> absent <input type="checkbox"/> grade: CIN 1 <input type="checkbox"/> CIN 2 <input type="checkbox"/> CIN 3 <input type="checkbox"/>	
cGIN (cervical glandular intraepithelial neoplasia): present <input type="checkbox"/> absent <input type="checkbox"/> grade: low <input type="checkbox"/> high <input type="checkbox"/>	
SMILE (stratified mucin-producing intraepithelial lesion): present <input type="checkbox"/> absent <input type="checkbox"/>	

Excision margins: (specify whether involved by CIN, CGIN or SMILE)Ectocervical resection margin: clear ☐ involved ☐ by (specify) _____Endocervical resection margin: clear ☐ involved ☐ by _____Deep lateral/radial resection margin: clear ☐ involved ☐ by _____Lymphovascular space invasion: present ☐ absent ☐

*Note: If invasive foci are seen in three or more sequential sections of tissue, the third dimension of the lesion (which is not routinely measured) may exceed 7 mm (i.e. more than Stage IA2).

Provisional pathological FIGO stage _____

pTNM stage: pT _____ pN _____ M _____

SNOMED codes: T _____ M _____

Signature of pathologist: _____ Date _____

Appendix 3.3: For Cervical Cancer in Hysterectomy Specimens

NATIONAL REPORTING PROFORMA FOR CERVICAL CANCER IN HYSTERECTOMY SPECIMENS	
Surname _____	Forenames _____
Date of birth _____	
Hospital _____	Hospital no _____
CSP ID no _____	
Date of sampling _____	
Date of receipt _____	
Date of reporting _____	
Report no _____	
Pathologist _____	Gynaecologist _____
Description of specimen and core macroscopic items Vaginal cuff: present <input type="checkbox"/> absent <input type="checkbox"/> length _____ mm diameter _____ mm Dimensions of uterus: length _____ mm transverse _____ mm anteroposterior _____ mm Adnexa: present <input type="checkbox"/> absent <input type="checkbox"/> normal <input type="checkbox"/> abnormal (specify) _____ No tumour seen Maximum dimensions of tumour: _____ mm x _____ mm Position of cervical tumour: anterior <input type="checkbox"/> posterior <input type="checkbox"/> right <input type="checkbox"/> left <input type="checkbox"/> circumferential <input type="checkbox"/> ectocervix <input type="checkbox"/> endocervix <input type="checkbox"/> Macroscopic involvement of vagina: yes <input type="checkbox"/> no <input type="checkbox"/> Macroscopic involvement of parametria: yes <input type="checkbox"/> no <input type="checkbox"/> Macroscopic involvement of paracervical tissues yes <input type="checkbox"/> no <input type="checkbox"/>	
Core microscopic items Type: squamous carcinoma <input type="checkbox"/> adenosquamous carcinoma <input type="checkbox"/> adenocarcinoma <input type="checkbox"/> neuroendocrine carcinoma <input type="checkbox"/> other <input type="checkbox"/> specify _____ Differentiation: well/grade 1 <input type="checkbox"/> moderate/grade 2 <input type="checkbox"/> poor/grade 3 <input type="checkbox"/> not applicable <input type="checkbox"/> Tumour size: Maximum horizontal dimension _____ mm Thickness/depth of invasion (delete as appropriate) _____ mm Minimum thickness of uninvolved cervical stroma (minimum tumour-free rim): _____ mm Position of this: _____ Closest radial resection margin (include paracervical tissue thickness): _____ mm Position of this: _____	

Vaginal involvement: yes ☐ no ☐
 Distance from distal vaginal epithelial margin: _____ mm
 Position of this:

Paracervical involvement: yes ☐ no ☐ If involved: left ☐ right ☐

Parametrial involvement: yes ☐ no ☐ If involved: left ☐ right ☐

Lymphovascular invasion: yes ☐ no ☐

CIN: present ☐ absent ☐

Grade 1/2/3

cGIN: present ☐ absent ☐

Grade: low/high

SMILE: present ☐ absent ☐

Nodes: (pelvic group includes obturator, internal and external iliac)

Nodes [site and number]	Right	Left	Common iliac	Right	Left
Total number					
Number involved					

Extranodal spread: yes ☐ no ☐

Para-aortic nodes:

positive ☐ negative ☐ not sampled ☐
 total number of nodes ☐ number of positive nodes ☐

Extranodal spread: yes ☐ no ☐

Other tissues and organs:

Tissue	Normal	Abnormal [describe]
Endometrium		
Myometrium		
Right adnexum		
Left adnexum		

Provisional pathological FIGO stage*

pTNM stage: pT _____ pN _____ M _____

(*Correlate with previous cone/loop specimen/s – final staging may follow MDT review)

SNOMED codes: T _____ M _____

T _____ M _____

Signature of pathologist: _____ Date _____

Glossary

Ablative Treatment	Treatment which involves the destruction of the cervical abnormalities using a variety of techniques. It does not allow for histological examination of the whole abnormal area and strict criteria must be followed therefore to minimise the risk of inadvertent treatment of hidden microinvasive cancer
'Abnormal' or 'Not Normal' Smear Test Result	A smear test which shows cells which are not typically normal or where pre-cancerous or cancerous cells are identified
Abnormal Vessels	Malignant changes in the cervical epithelium results in a marked increase in the number of blood vessels. This vascular growth is disorganised and results in chaotic patterns with odd shapes quite unlike the tree-like vascular patterns associated with non malignant tissue
Acetic Acid	Acetic acid is applied to the cervix and highlights atypical areas white epithelium, punctation, mosaic and atypical vessels by inducing changes in the protein of cells. This effect is transient which means that the solution may need to be reapplied during the examination process
Acetowhite Epithelium	White (or acetowhite) epithelium refers to the whitened appearance of an area under the colposcope after the application of acetic acid. In contrast to leukoplakia, white epithelium is visible only after the application of acetic acid because it represents epithelium with increased nuclear density. White epithelium is sometimes associated with cervical intraepithelial neoplasia (CIN) and therefore, should be biopsied
Adequate Smear Test Result	A smear test which is deemed satisfactory for evaluation by the laboratory
Adenocarcinoma	A cancer affecting the cervix, but involving the columnar (endocervical) cells rather than the squamous cells. The columnar cells are involved in glandular activity.
Atypical Transformation Zone	The term used when changes are detected by colposcopy in the Transformation Zone. These changes can include a variety of patterns including: leukoplakia, acetowhite epithelium and abnormal vascular patterns
Audit	Clinical audit is a process which involves setting standards, collecting information and reviewing practice to try and better meet the standards
Best Practice Guide	A recommendation that is supported by expert opinion and consensus and where no external evidence is available

Bethesda System of Classification	A cytological system that grades intraepithelial lesions into low grade and high grade (LSIL and HSIL)
Biopsy	Removal of a sample of tissue from the body for examination under a microscope
Biopsy Forceps	A variety of instruments which are specifically designed for directed biopsy of abnormal areas seen through the colposcope
Smear Test	This may be either a conventional Pap smear test or liquid-based cytology (LBC)
Cervical Cancer	Cancer of the cervix. Cancer cells have spread beyond the natural basement membrane boundary of the cervical skin. Cervical cancer can be squamous in origin (approximately 85%) or adeno/glandular (approximately 15%)
Cervical Cytology	A microscopic examination of a single layer of cells scraped from the surface of the cervix
Cervical Ectropian/Eversion	Occurs when the inside of the cervical cells (columnar) evert on to the surface of the cervix; a red roughened area may appear on the cervix. This is a normal hormonally influenced change
Cervical Intraepithelial Neoplasia (CIN)	CIN is not cancer but is the histological term referring to the abnormal growth of pre-cancerous cells in the surface layers of the cervix. It describes varying degrees of abnormality of the cells within and confined to the epithelium. There are three grades of CIN: CIN 1, CIN 2 or CIN 3
Cervical Os	The entrance to the endocervical canal
Cervical Screening	A process which involves the application of a screening test at regular intervals to a defined population of women to detect pre-cancerous changes
Cold Coagulation	A treatment which involves the destruction of cervical tissue by heating it to high temperatures
Colposcopy	An examination of the cervix using a specialised optic instrument (colposcope) that provides magnification to allow direct observation and study of vaginal and cervical epithelium. It identifies lesions on the cervix which can be biopsied and treated
Colp1	Standard CervicalCheck colposcopy statistical returns form
Columnar Epithelium	This type of glandular epithelium whose function is to secrete mucous. It has a good blood supply and is redder in colour and is mainly located in the endocervix. Changes in the cervix due to hormonal influences result in part of this epithelium being transposed to the ectocervix resulting in its transformation to squamous epithelium – a process known as squamous metaplasia

Cone Biopsy	A surgical removal of a cone-shaped section of the cervix to remove abnormal cells. It can be achieved with a knife (knife cone), laser (laser cone) or straight electric wire (SWETZ). The procedure is diagnostic but also curative in the majority of cases
Consent	Informed consent is the giving of all the necessary information by the smearer to the woman in order that she can fully understand the procedure and possible results so that she can make an educated decision to participate in the screening programme
Coverage	The proportion of women aged 25-60 years who have had a screening result recorded on the screening register
Cytopathology	A microscopic examination of a single layer of cells scraped from the surface of the cervix
Cyto1	Standard CervicalCheck cytology returns form
Data Protection Act 1988	http://www.irishstatutebook.ie/1988/en/act/pub/0025/index.html
Data Protection (Amendment) Act 2003	http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html
Deferral	Decision by the doctor with clinical responsibility not to proceed with the screening test until a future specified date
Diagnosis	A process aimed at the clarification of cervical abnormalities to inform decision making regarding treatment
Doctor with Clinical Responsibility	The doctor who holds a service contract with the screening programme. All doctors with clinical responsibility are also registered smear takers
Dyskaryosis	Term used in cytology to describe nuclear abnormalities in cervical cells
Ectocervix	The portion of the cervix exposed to the top of the vagina
Effectiveness	The extent to which an established screening programme meets its defined objectives
Efficacy	The extent to which an intervention/programme produces a beneficial result under ideal conditions. The determination of efficacy is based on the results of a randomised controlled trial
Efficiency	The production of the result achieved in terms of minimum waste of resources and time expended on a procedure of known efficacy and effectiveness

Eligible for Screening	Women aged 25-60 years for whom CervicalCheck recommends and funds screening according to national policy
Endocervical Speculum	An instrument designed to be inserted into the cervical os with the intention of exposing the endocervix
Endocervix	The portion of the cervix located within the canal between the vagina and the uterine cavity
Excisional Treatment	Treatment which involves the removal of the abnormality in its entirety thereby allowing histological examination of the entire Transformation Zone
Failsafe	The action taken by the clinically responsible doctor and Programme office to ensure a smear test result is appropriately followed-up. Laboratories and CervicalCheck also support the primary care failsafe process
False Negative	The result when the test does not detect the disease in an individual who actually has the disease
False Positive	The result when the test indicates the presence of the disease in an individual where it is not actually present
Gland Openings	Gland openings are the persistent appearance of the opening of the endocervical gland ducts on the squamous epithelial surface of the Transformation Zone
Green Filter	A filter applied to the colposcope to highlight blood vessels and vascular patterns
Gynaecological Oncology	A medical service which delivers treatment to women with gynaecological cancer
Histology	The microscopic study of the structure and composition of body tissue
Human Papilloma Virus (HPV)	A group of wart viruses of which a high proportion are sexually transmitted. Over 100 different types of HPV have been identified and each is known by number. Types 6 and 11 are associated with genital warts and types 16 and 18 are associated with high grade lesions
Hysterectomy	The surgical removal of the uterus (womb) – called total if it includes the cervix or subtotal/partial if the cervix is not entirely removed
‘Inadequate’ Smear Test	An ‘inadequate’ or ‘unsatisfactory’ smear test that cannot be assessed by the cytology laboratory
Incidence (rate)	The number of new cases of a disease or happening that occurs in a given period in a specified population

Informed Consent	The giving of all the necessary information by the smearer to the woman in order that she fully understands the smear test procedure and possible results so that she can make an educated decision to participate in the Programme. For the CervicalCheck informed consent process, the necessary information covers participation in the Programme, the transfer of data to third parties, limitations of screening, results, associated tests and treatment
Interval Smear Test	A smear test that is undertaken before a smear test is due according to a woman's screening requirements and national policy
Large Loop Excision of the Transformation Zone or LLETZ	Large Loop Excision of the Transformation Zone (LLETZ) is a diagnostic and/or treatment method to remove the cervical areas of abnormality. The procedure involves removal of the entire Transformation Zone using a thin wire electrode charged with a low-voltage, high frequency, alternating current and produces a tissue specimen suitable for histologic analysis in most circumstances
Lead Colposcopist	The role of the lead colposcopist is to ensure good practice and compliance with protocols, in addition to ensuring accurate collection of data to enable audit and the production of colposcopy audit returns
Lead Smearer	Designated smearer who co-ordinates smearing activity in a primary care setting
Leukoplakia	This term refers to a white area visible without magnification and before the application of acetic acid. It represents a thickening of the layers of epithelium
Liquid Based Cytology (LBC)	The placement of harvested cells into a special transport solution for sending to the laboratory, where the slide is made ready for examination
Lugol's Iodine	Lugol's solution is composed of iodine and potassium iodide in water. It stains the glycogen in mature squamous epithelium a dark brown colour. Areas devoid of glycogen such as immature squamous epithelium, columnar epithelium will not stain and will be orange in colour. This is known as Schiller's test and is used to delineate the Transformation Zone prior to treatment
Management Recommendation	A management recommendation is based on the individual woman's cytology report and her clinical history
Microinvasive Cancer	This represents early stage cervical cancer where the abnormal cells breach the basement membrane and invade to not greater than 5 mm in depth and not more than 7 mm in width
Morbidity	The number of cases of a specific disease during a defined period of time in a given period of time
Mortality	The number of deaths from a specific disease during a defined period of time in a given population

Mosaic	A vascular change of interconnecting vessels resulting in a cobblestone surface appearance through the colposcope. This pattern is often associated with CIN and should be biopsied
Multidisciplinary Team (MDT) Meetings	Meetings attended by staff from a range of disciplines with the aim of reviewing the clinical, colposcopic, cytological and histological information to inform high quality diagnosis and treatment
Nabothian Cysts	Nabothian cysts represent trapped glands which continue to produce mucous under the developing squamous epithelial surface
Nabothian Glands	These are glands present on the cervix whose function is to produce cervical mucous
NAD Smear Test Result	No abnormality detected
NCSS	The National Cancer Screening Service
Negative Predictive Value	The proportion of test-negative women who do not have pre-cancerous cervical predictive value abnormality. It is a measure of the likelihood that someone with a negative test is actually disease free
Opportunistic Smear Test	A smear test undertaken when the opportunity presents. This contrasts with a call/re-call system where smear tests are undertaken as a result of an invitation by the screening programme
PAP Test	Another name for a 'smear test' named after George Papanicolau, who invented the process of staining cells on a slide in preparation for examination under a microscope
Positive Predictive Value	The proportion of test-positive women who are truly positive. It can be considered a measure of the likelihood that a woman with a positive test truly has a pre-cancerous cervical abnormality
PPS Number	Personal Public Service Number
Practice Audit	A practice evaluation of adherence to the standards
Practice Protocol	A clinical practice guideline with the aim of standardising medical care
Prevalence (rate)	The total number of women who have a cervical pre-cancerous lesion or cancer at a particular time (or during a particular period) divided by the population at risk of having a cervical pre-cancerous lesion or cancer at the same point in time
Primary Care Setting	First contact care that is not hospital or specialist care e.g. general practice, Well Woman Clinics or Family Planning clinics

Punctuation	A zone of red dots which represent blood vessel loops reaching to the surface epithelium. When this pattern is identified through the colposcope, biopsy is indicated since this pattern is often associated with high grade CIN
Quality Issue	An important matter that is not measurable but when addressed will improve outcome
Registered Smertaker	A doctor or nurse who meets all the screening programme requirements as a smertaker and is registered with the Programme
Recorded Effort	A systematic documentation in a patient's medical health record of a communication by way of telephone, letter or consult
Retraining	Recognised training course successfully completed
Screening Programme	An organised approach to screening a defined population to determine the likelihood of a specific disease within the population with the aim of reducing the risk of the disease and improving the quality of life through early diagnosis
See and Treat	A process whereby women are treated at the first visit to colposcopy
Select and Treat	A process whereby women with suspected high grade disease are selectively treated at the first visit to colposcopy
Sensitivity	The ability of a test to detect a disease in all individuals in whom it is present
Smertaker Provider	A doctor or nurse who meets all the CervicalCheck registration requirements
Smear Test	A screening test where cells from the surface of the cervix are sampled, preserved immediately and sent to the laboratory for cytological analysis
Systematised Nomenclature of Medicine - SNOMED Codes	A coding system for recording histological diagnosis
Specificity	The ability of a test to accurately exclude those individuals in whom disease is not present
Specimen	A sample of tissue removed from the body for microscopic examination
Speculum	An instrument designed to be inserted into the vagina with the purpose of exposing the cervix
Squamo-columnar Junction (SCJ)	The transition between the multilayer squamous epithelium which covers the ectocervix and the single layered columnar epithelium.

Squamous	A type of multi-layers cells, which line the vagina and outer layer of the cervix
Squamous Cell Carcinoma/Cancer	The most common form of cervical cancer
Squamous Epithelium	A type of epithelium characterised by flat cells whose function is defence. It is paler in colour than columnar epithelium
Squamous Metaplasia	The normal physiologic process by which columnar epithelium evolves into squamous epithelium. This occurs under the effect of several factors including, hormonal stimulation, low pH and trauma. The area of change between the new and the old squamocolumnar junction (SCJ) is called the Transformation Zone (TZ)
Staging	A system for analysing a tumour to determine the extent or risk of spread or recurrence
Standards	A requirement against which performance can be measured
Transformation Zone (TZ)	The region of the cervix where the columnar cells of the inner cervix have, or are changing to outer squamous cells. The process of change is called metaplasia. It is the area most at risk of abnormal change
Transformation Zone Classification	A system for classification of type of Transformation Zone according to the location and visibility of the squamocolumnar junction defined by the International Society for Colposcopy and Cervical Pathology
Treatment	A process aimed at the eradication of cervical abnormalities thus restoring normal cytology and reducing the chance of subsequent cancer by 90%
TZ Cells	Evidence of cellular components from the Transformation Zone. The presence of TZ cells is considered a measure of smearer competency although it is not a necessary requirement to determine a smear test is adequate
Unsatisfactory Colposcopy	A term used to describe the inability to demonstrate the whole of the Transformation Zone colposcopically
Vault Smear Test	A smear test taken from the top of the vagina in women who have had their cervix removed during a hysterectomy



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The National Cancer Screening Service
encompasses BreastCheck – The National Breast
Screening Programme and CervicalCheck –
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