



Guidelines for
**Quality Assurance in
Cervical Screening**

Second Edition

Chapter 4

Quality assurance in cytopathology

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4.1 References

4.1 Introduction

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

The cervical screening pathway involves three key stages:

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

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

- The first edition of 'Guidelines for Quality Assurance in Cervical Screening'
- European guidelines for quality assurance in cervical cancer screening¹.
- The evolution of standards and guidelines in response to technological developments and research outcomes in other cervical screening programmes. Particular reference is given to revisions in the NHS CSP Publication No. 1 (revised 2012)² and the BSCC 'Code of Practice for Laboratories Participating in the UK Cervical Screening Programmes' (2010)³
- The activity and performance metrics for cytopathology collated since the commencement of CervicalCheck.

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

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

4.2 Quality requirements and standards in cytopathology

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

Quality requirements are stated as a description. There are no targets associated with a requirement as service providers must fulfil the requirement.

Quality standards are stated as a description of an activity with a measurable level of performance, with an associated target for achievement. The standards are designed to be measurable i.e. quantitative with criteria that are valid, reliable and feasible.

4.2.1 Organisational requirements

Standard 4-1

Accreditation

The laboratory will have and maintain accreditation to ISO15189 standard⁴ or equivalent, certified and documented by an approved accreditation body. The scope of the laboratory accreditation must include cytopathology.

External accreditation at least once every 2 years.

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

Standard 4-2

Capacity

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

Min: 25,000 samples per annum.
Achievable: 35,000 samples per annum.

Quality requirement

Data protection

In relation to the provision of services to the National Cancer Screening Service (NCSS), all data protection requirements (storage, access, security, confidentiality and data transfer) should be compliant with the Data Protection Act 1988⁵, the Data Protection (Amendment) Act 2003⁶ and any future revisions or amendments of the Act as well as the EU Directive 95/46/EC - The Data Protection Directive⁷.

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

Quality requirement

Health and safety compliance

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

Quality requirement

Quality management system

The laboratory should have a quality management system (QMS) in place as required by their accreditation standard.

The laboratory should have a designated person responsible for quality management who will liaise with the NCSS to resolve any quality issues that may arise.

Any complaints in relation to the provision of the cytology services on behalf of NCSS will be notified to the NCSS.

Quality requirement

Laboratory information management system (LIMS)

A computerised laboratory information management system (LIMS) should be installed and be in operation in the laboratory. The LIMS should be in a secure facility with adequate back-up arrangements, on- and off-site. Access to the LIMS should be by privilege-level access control. The LIMS should be capable of generating periodic quality metrics and audit returns to the NCSS.

In addition the LIMS should:

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

Quality requirement

Data capture

The LIMS should be capable of recording the data required by the NCSS (Cervical Screening Register (CSR) information system data entry standards demographic details⁸) from the CervicalCheck Cervical Cytology Form⁹.

Quality requirement

Reporting

The LIMS should be capable of recording screening results including management recommendations. The LIMS should be capable of recording the identity of the reporting screeners and pathologists.

Quality requirement

Format and timing of electronic data exchange with programme

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

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

Quality requirement

Capability and format for electronic orders and results

It is desirable that laboratories should be capable of receiving orders electronically and issuing results electronically to and from ordering doctors or clinics, according to a specified messaging standard. Electronic laboratory order format is HL-7 based and conforms to the laboratory order message specifications of the Health Information and Quality Authority's (HIQA) current GP Messaging Standard¹⁰. HL-7 based orders and results use the Healthlink Message Broker System. The physical form for electronic orders includes a barcode, which laboratories should be able to scan and extract the included details for automatic import into their data entry system.

Quality requirement

Segregation, identification and traceability of programme samples

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

Quality requirement

Telephone support

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

Quality requirement

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

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

Quality requirement

Other laboratories

Laboratories should make relevant clinical information and follow-up data available to other laboratories providing services to CervicalCheck.

Quality requirement

Health agencies and authorities

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

4.2.2 Laboratory facilities

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

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

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

4.2.3 Staff qualifications

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

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

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

4.2.4 Specimen reception

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

Quality requirement

Acceptance of samples

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

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

Only those samples accompanied by a CervicalCheck Cervical Cytology Form⁹ or Cervical Cytology and HPV Form¹¹ should be accepted.

Quality requirement

Indication of consent

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

Quality requirement

Matching of vials and forms

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

Quality requirement

Discrepancy handling and resolution

A discrepancy handling and resolution process should be in place to manage all discrepancies with received CervicalCheck samples. A CervicalCheck guidance document is available¹².

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

Quality requirement

Vial and form tracking

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

4.2.5 Data entry and notification to CervicalCheck

Quality requirement

Data capture

Data entry of the details recorded on CervicalCheck forms accompanying submitted sample vials should conform to CervicalCheck data capture requirements⁸.

All relevant data recorded on the Cervical Cytology Form by the smearer should be entered onto the LIMS (Cervical Cytology/Cervical Cytology+ HPV/Cervical HPV Requests and Results¹³).

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

Quality requirement

Laboratory accession number

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

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

Quality requirement

Assignment to ordering doctor or clinic

Samples should be assigned to the correct clinically responsible doctor or clinic (CervicalCheck Registered Smearers Types and Identification¹⁴) as per the received form.

Standard 4-3

Access to received Cervical Cytology Forms

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

Standard 4-4

Notification of sample receipt to programme

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

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

Note 2: A weekly reconciliation of files sent or received should be in place between CervicalCheck and the cytology laboratory.

Quality requirement

Programme ineligible samples

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

4.2.6 Sample processing

Quality requirement

Cytology technology

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

Quality requirement

Staining

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

Quality requirement

Identification of case/slide

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

4.2.7 Proficiency and competency of staff

Quality requirement

Pathologists

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

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

Standard 4-5

Pathologist - proficiency

To maintain a medical consultant's diagnostic skill in cervical cytopathology, a minimum number of cases will be reviewed. Min: 750 cases per annum.

Standard 4-6

CPC/MDT meetings

Pathologists reporting Irish workload will participate in regular CPC/ MDT meetings. Min: 50% of meetings. Achievable: 90% of meetings.

Quality requirement

Lead medical scientist, cytology manager and supervisory scientific staff

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

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

Standard 4-7

Lead medical scientist, cytology manager, supervisory scientific staff

If the role involves cervical screening then a minimum number of cases will be reviewed. 750-3,000 cases per annum depending on role.

Quality requirement

Cytology screening staff

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

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

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

Standard 4-8

Screener proficiency

In order to maintain proficiency, a minimum number of smear tests per year must be screened per screener.

Min: 3,000 cases per annum.

Standard 4-9

Primary screening

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

Max: 5 hours per day.

Standard 4-10

All screening – maximum hours

Screening should be limited within a 24-hour period.

Max: 6 hours per day.

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

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

Standard 4-11

All screening – maximum numbers per annum

Maximum primary screening numbers per screener per annum must not be exceeded.

Max: 12,000 per annum.

Quality requirement

Continuing education

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

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

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

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

4.2.8 Microscopy

Quality requirement

Access to a woman's previous screening history

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

Quality requirement

Primary screen

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

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

Screeners should record their results independently on the LIMS.

**Quality
requirement**

Rapid review/re-screen

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

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

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

Screening performance will be monitored.

**Quality
requirement**

Internal quality control

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

Internal quality control of cytology screening must be monitored by:

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

4.2.9 Results management

Quality requirement

Cytology screening results – reporting

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

Quality requirement

Cytology terminology and assignment of management recommendations

All cytology results must have a management recommendation accompanying the cytology pattern as a P and R code combination (Cervical Cytology Management Recommendations Explanatory Guide¹⁵ and Cytology Terminology Table¹⁶).

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

Quality requirement

Management recommendations with respect to screening history

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

The screening history of the woman provided by the smearer via the Cervical Cytology Form⁹ and by CervicalCheck from the CSR (where such history is available) must be referred to and taken into account during the results process, in order to assign the correct management recommendation.

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

Quality requirement

Check of result and recommendation

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

Quality requirement

Authorisation of results

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

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

Abnormal cytology results will only be reported by a pathologist.

Reports should identify the cytotechnologist or medical scientist and/or cytopathologist responsible for the conclusion and recommendation.

Quality requirement

Result codes notification to programme

Results, once authorised and released, will be issued in summary format (P & R codes as soon as possible by electronic means to CervicalCheck).

Standard 4-12

Laboratory response time (turnaround time [TAT])

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

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

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

Quality requirement

Adequacy of results reports

The contents of the results report to doctors and clinics must be in accordance with Cervical Cytology/Cervical Cytology+ HPV/Cervical HPV Requests and Results¹³.

Standard 4-13

Results reports to ordering doctors and clinics

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

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

Quality requirement

Delivery of results reports to ordering doctors or clinics

Results reports will be issued to the correct ordering doctor or clinic.

Documented processes are required to:

- Ensure that results are sent to the correct doctor
- Handle discrepancies between the number of samples/notifications received, the number of reports transmitted and the number of reports printed.

Quality requirement

Results reports by electronic means

It is desirable that all results reports in addition to paper format be issued to ordering doctors/clinics and CervicalCheck in full electronic format via a nominated telecommunications pathway. The electronic format for results is HL-7 based and conforms to the laboratory result message specifications of HIQA's GP Messaging Standard¹⁰.

Quality requirement

Re-screening requests and amended reports

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

4.2.10 Storage and archiving

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

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

Standard 4-14

Storage and archiving

Secure archiving of Cervical Cytology Forms, samples, slides and written and/or computerised reports is required for specific retention periods. 99% to be received within 5 working days.

| | |
|-------------------------|--------------|
| Cervical Cytology Forms | 30 years |
| Slides | Min 10 years |
| Sample vials | 6 weeks |
| Reports | 30 years |

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

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

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

Quality requirement

Access to materials

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

4.2.11 Clinico-pathological conferences (CPC)/multi-disciplinary team (MDT) meetings

Quality requirement

Support for CPC/MDT meetings

Cytology laboratories will provide facilities, participation and support for CPC/MDT meetings held in programme colposcopy services¹⁷.

Such support will include the following:

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

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

Quality requirement

Participation in CPC/MDT meetings

The cytopathologist(s) (with or without other scientific staff members) will participate in CPC/MDT meetings.

CPC/MDT meetings are convened by CervicalCheck colposcopy services. The locations, timing and frequency of CPC/MDT meetings may vary from time to time but reasonable notice should be provided by colposcopy services to the cytology laboratory. Cytology laboratories are encouraged to submit cases for discussion where of benefit.

Quality requirement

Protocol for CPC/MDT meetings

Participation, including a signed record of personnel attending and operational decisions, must be recorded¹⁷. Participants must be subject to national legislation relating to confidentiality and data security of personal health information^{5,6}.

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

Quality requirement

Provision of slides

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

4.2.12 Cancer review process

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

Quality requirement

Re-screening of smear tests

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

Quality requirement

Independent third-party review

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

4.2.13 Quality assurance and continuous improvement

Quality requirement

External quality assurance (EQA)

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

Standard 4-15

Quality metrics

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

Complete data at least quarterly, to be received by CervicalCheck within one month of quarter-end.

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

The quality metrics required are detailed in the current version of the CervicalCheck Cyto1¹⁸. The metrics should be readily available from the laboratories internal quality control processes. They include metrics for both the laboratory and for individual screeners and cytopathologists.

Quality requirement

Identification of individuals

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

Quality requirement

CervicalCheck workload

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

Quality requirement

Quality metrics improvement

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

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

Quality requirement

Quality assurance visits

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

4.3 References

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National Cancer Screening Service

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



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