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THE NATIONAL CERVICAL SCREENING PROGRAMME

QUALITY ASSURANCE IN CERVICAL SCREENING LABORATORIES

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Laboratory Quality Systems

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Objectives:

- Support provision of high quality health-care
- Ensure credibility of lab
- Generate confidence in lab results

By means of:

-quality control of the analytical results
-thorough documentation of the system
-efficient maintenance of records
-regular audits of all aspects of the system
-quality assurance measures

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Quality Control

Quality control measures apply to each analytical test in the laboratory:

-Verified standard manufacturer control samples- HPV positive and negative samples in each run

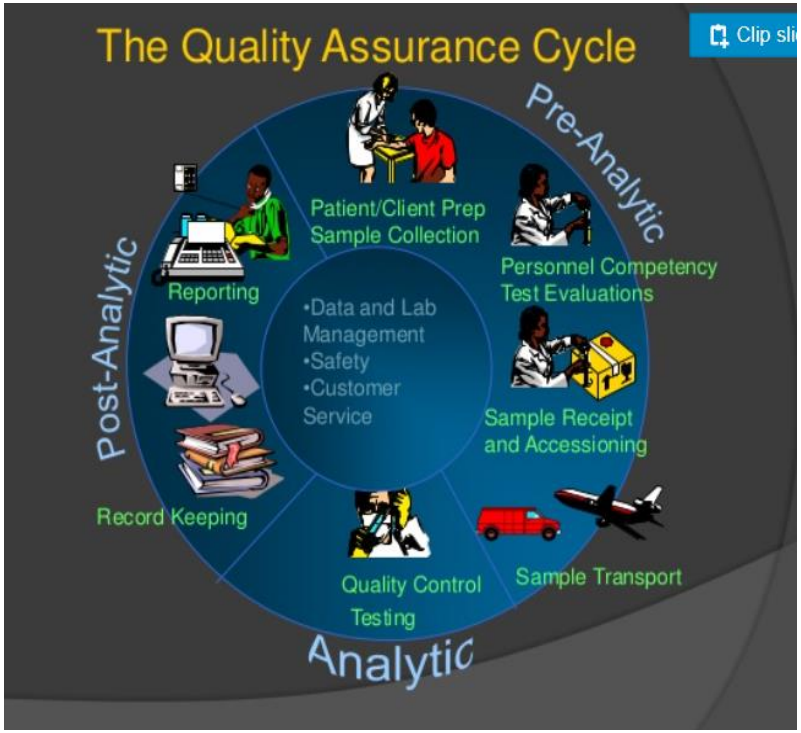
-Replicate analyses and control charts

Quality control ensures results generated are correct.
Continuous and concurrent assessement
Total process beginning with sample collection up to final reporting

Quality Assurance

Quality assurance =
Internal quality control + External quality assessment

Quality assurance ensures the right test is carried out on the right specimen, and that the right result and interpretation are delivered to the right person at the right time.
Assures the system
Retrospective and periodic



External Quality Assurance

- According to the ISO definition, EQA (also known as ‘proficiency testing’ (PT) or ‘EQ Control = EQC’) refers to:

  -a system of objectively checking laboratory results by means of an external agency

  -including comparison of a laboratory's result at intervals with those of other laboratories

  -the main objective being the establishment of trueness

Accreditation

Is a process of inspection of laboratories and their licensing by a third party to ensure conformity to pre-defined criteria

- Long task requiring documentation of all processes and evidence of compliance to set standards
- ISO 15189 or national equivalent e.g. College of American Pathologists Accreditation.
- Last step of the quality process

Factors influencing internal quality

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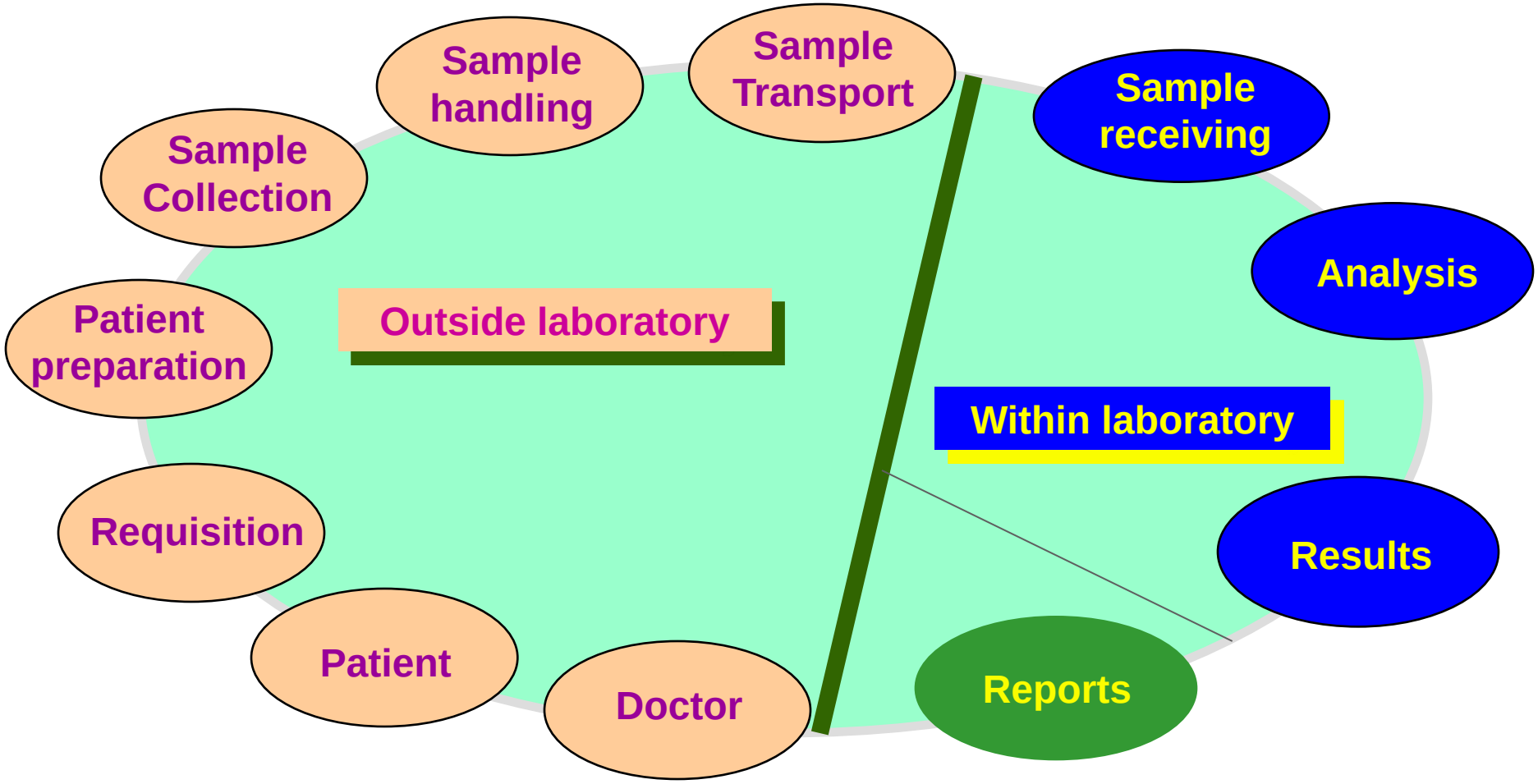

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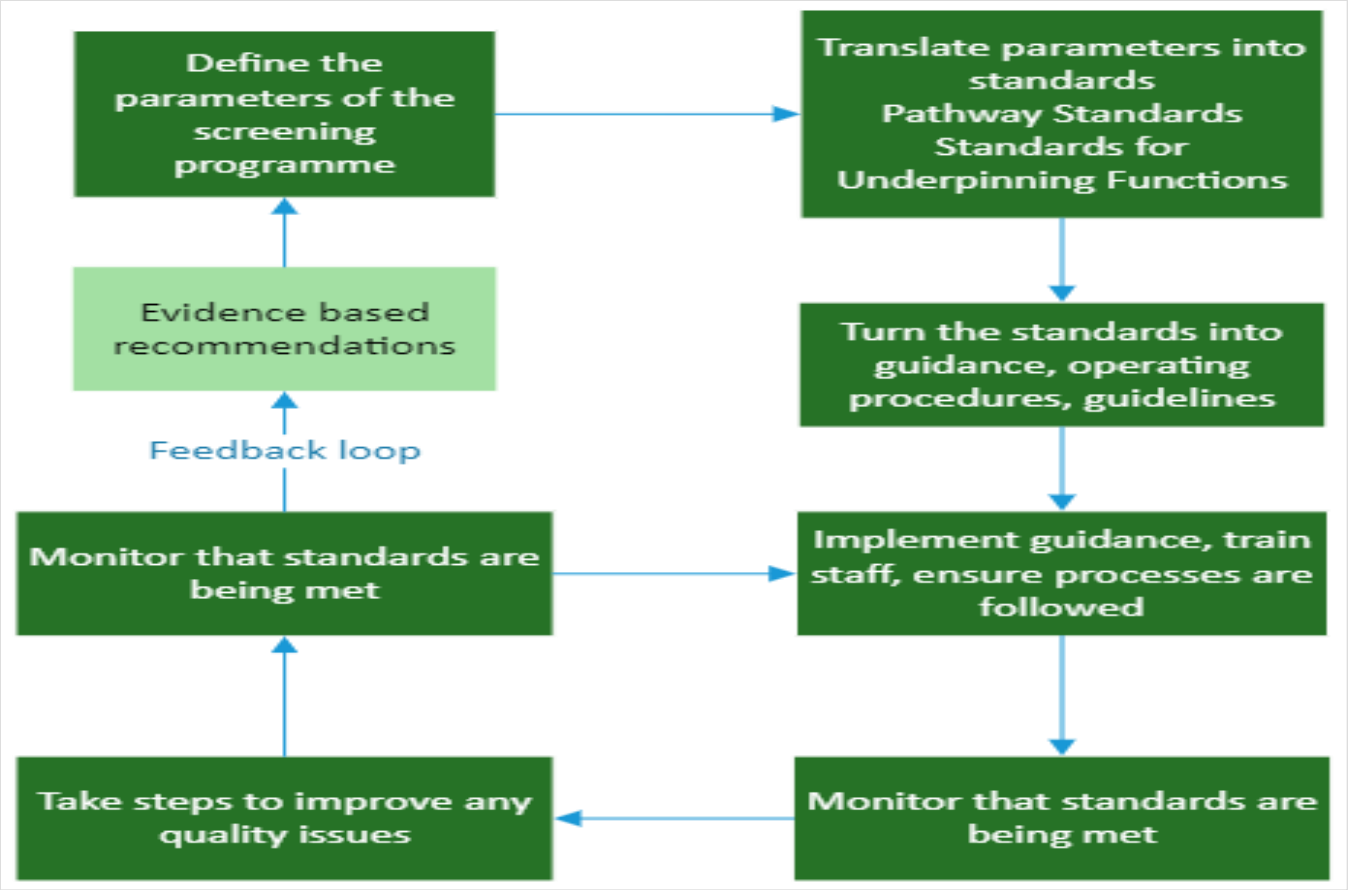
Screening Programmes, a short guide, WHO 2020



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National Screening Service

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

QA in Cervical Screening

- Laboratory Standards and Requirements for QA in Cervical Screening:
  - Cytopathology
  - Molecular HPV Testing
  - Cervical Histopathology
- Contracts and memoranda of understanding (MOU) – explicit requirement for compliance with latest QA guidelines

QA Standards and Guidelines

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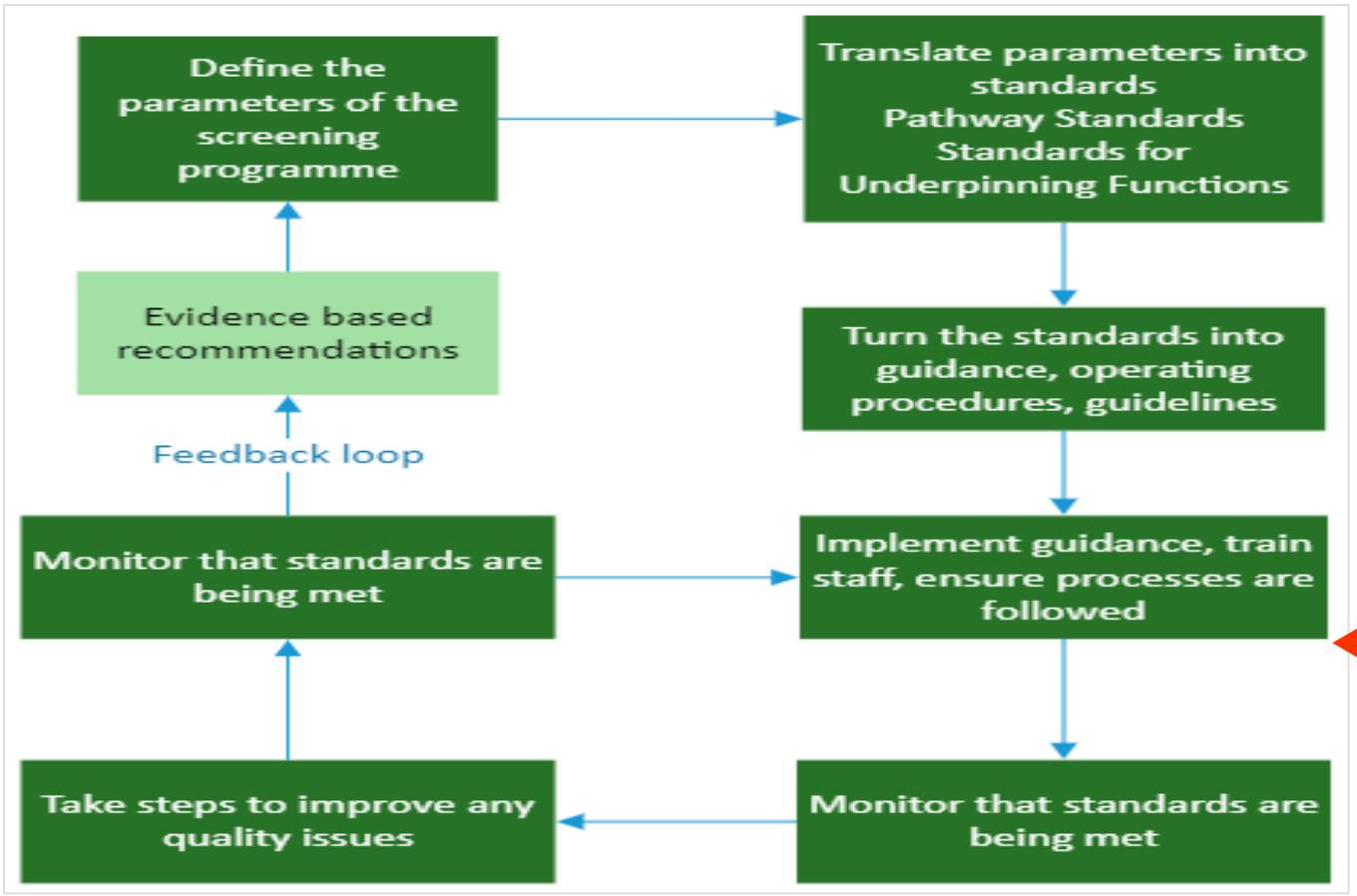
Guidance for laboratories providing HPV testing and cytology services in the CervicalCheck Cervical Screening Programme

- Introduction
- Section A Screening Laboratories (Primary hrHPV testing and Cytology triage)
- 1. Laboratory organisation
- 2. Clinical governance
- 3. Laboratory Personnel (Roles and Responsibilities and Staff Qualifications)
- 4. Sample Acceptance, Reception and Data Entry
- 5. Sample Processing and analysis
- 6. Reporting and classification of cervical screening samples
- 7. Management of Women
- 8. Storage and Archiving
- 9. Quality Metrics and performance monitoring
- 10. Quality Assurance visits
- 11. Audit of invasive cervical cancers
- 12. Risk and incident management
- 13. Business planning and Service continuity

Screening Programmes, a short guide, WHO 2020



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Laboratory Monitoring

- Turnaround Times for Results
- Screening result profiles
- Screening result profile for follow up results post HPV detected, cytology NAD
- PPV for high grade cytology referral
- Referral value
- Compliance with min and max screening numbers
- Compliance with working time requirements
- MDT attendance.
- Screening sensitivity rates

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Laboratory turnaround time (TAT)

- TAT: time from sample received date in lab to result received date (from CSR)
- Monitored as a percentage reported within target.
- Measured on a weekly basis.

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Laboratory and individual result profiles

- Laboratory and screener result profiles monitored by operational reports and Combined HPV and Cytology Return.
- Compared to national profiles, NHS published rates and CAP percentile reporting rates. HSIL rates are based on UK published ranges
- Outliers flagged for further investigation and feedback.
- Individual screeners identified by unique number which remains the same over reporting periods.

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Screener sensitivity

- Individual screener sensitivity rates are calculated by the laboratories and provided via statistical reports
- Individuals with sensitivity of <95% for HSIL and <90% for all grades of abnormality are requested to be placed on a remedial action plan
- May include additional rescreen of their work / multi-header sessions / discussion of missed cases / refresher training/ removal from screening if necessary.

Cyto-histological correlation
PPV / APV / TPV

- Histology results received to the Cervical Screening Register are used as the ‘gold standard’ to perform Cyto-histological correlation.
- A purpose-designed report is run on an annual basis to calculate the predictive values.
- Also calculated using data that is extracted from the colposcopy IT systems.
- Published in the annual reports.

Cyto-histological correlation
PPV / APV / TPV

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2016-17 Programme PPV

Table 21: Correlation measures between cytology and histology

Cytology-histology correlation	
Positive Predictive value (PPV)	81.3%
Referral Value (RV)	2.22

NHS 5th- 95th percentile reporting range: *76.7 - 92.3%*

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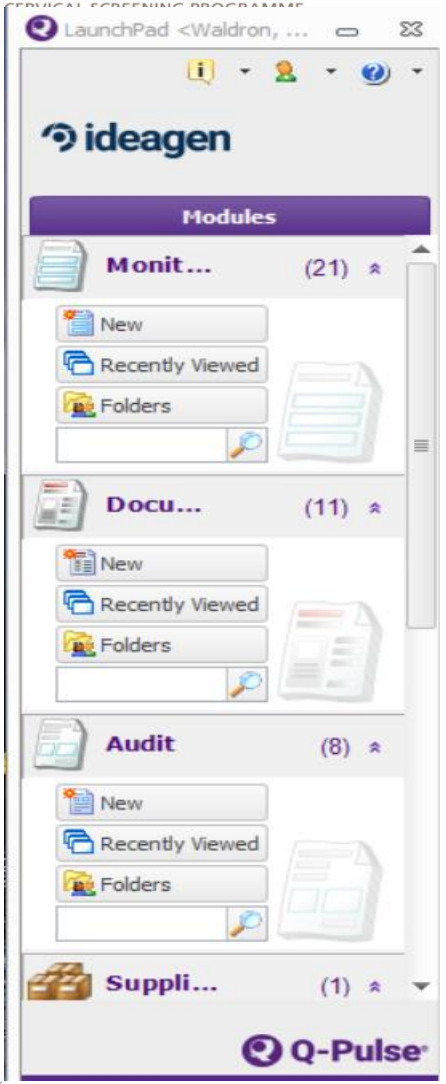
On-site audit

- Conducted in 2011 and in 2014.
- 2017 scheduled audit delayed due to HPV planning
- Conducted in 2019
- New standards- QA visit every 2 years
- Laboratory facilities, records and procedures audited against QA standards and guidelines
- Interim inspections can be carried out where deemed necessary (e.g. as a result of an identified non-conformance).

Quality Management System

CervicalCheck is also subject to quality control and assurance.
Operate a document control, monitoring and audit system – tool used is Q pulse.
Raise non conformances, preventive actions, continuous improvement initiatives, audits, occurrences and incidents
Performance reported in annual report.



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Quality improvement projects Laboratory

3 year strategic plan

- Deliver electronic resulting via Healthlinks
- Deliver standardised timely histology data to the screening register
- Investigate electronic ordering and tracking of samples
- Workforce planning for screening laboratories
- Electronic referral to colposcopy (possible direct referral).

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Thank You!

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