Quality Assurance & Audit in Cervical Screening Histopathology

Session learning objectives: By the end of this session you should know:

- What quality assurance is and its three main arms
- What the quality standards are for cervical screening histopathology
- How quality is assured in the laboratory by internal and external mechanisms and by education/training
- How audit applies to cervical screening, and to service and individual improvement

During this course you will be directed, via links, to relevant reading materials which will further facilitate your understanding of quality assurance and audit.

What is Quality Assurance?

Definition: Quality assurance is a framework for ensuring that a quality service is provided within a timely manner. For histopathology, that means providing an accurate diagnosis for the patient in a report that contains all the necessary data for the requestor to act on. That report should be available to the requestor within a specified timeframe. Quality should be to defined standards.

Quality standards for cervical screening histopathology:

1. A lead pathologist must be in place with appropriate time commitment and job description signed off by the line manager.
2. All personnel reporting cervical screening cases must report a minimum of 150 cervical samples per year.
3. Regular individual and overall laboratory data must be provided to those reporting cervical screening samples at least quarterly to include case load, turnaround times and reporting profiles.
4. Turnaround times for cervical histology samples must be within specified targets. 80% of samples should be reported within 7 days and 90% within 10 days. This should be calculated monthly. These targets have previously been specified by the RCPath. The NHSCSP will continue to monitor services against this standard, even though the RCPath suggest agreeing local standards, in order to promote consistency across the programme.

https://www.rcpath.org/discover-pathology/news/kai-pathology-services-published.html

5. All personnel reporting cervical screening histopathology samples should participate in histopathology EQA schemes and update their knowledge every two years by undertaking a specific cervical screening histopathology e-learning module.
6. All personnel must participate in the RCPath CPD scheme or other recognised CPD scheme. CPD relevant to cervical screening is provided in the new e-learning module.
7. Reports of cervical loop excisions must contain all the relevant dataset items as specified in histopathology guidance for the NHS cervical screening programme

https://www.gov.uk/government/publications/cervical-screening-histopathology-reporting-handbook/cervical-screening-programme-histopathology-reporting-guidance

8. Reports of cervical cancers in loop excision specimens must comply with RCPath cancer datasets and tissue pathways which can be found at https://www.rcpath.org/profession/guidelines/cancer-datasets-and-tissue-pathways.html

Once cervical cancer is diagnosed, a woman is no longer considered to be within the cervical screening programme. However, it is best practice to report any major resection specimens using RCPath minimum datasets.

Reports of cervical cancers in hysterectomy specimens should comply with RCPath cancer datasets and tissue pathways.

https://www.rcpath.org/profession/guidelines/cancer-datasets-and-tissue-pathways.html

There are three main arms to quality assurance:

1. Internal Quality Control (IQC)
2. External Quality Assessment (EQA)
3. Education and training

1 Internal Quality Control

Laboratories should have mechanisms in place to ensure that samples are handled in an appropriate way on their path through the laboratory to make sure that a safe diagnosis can be made by the histopathologist. These mechanisms should include standard operating procedures for each stage of the sample pathway ie sample receipt/rejection, booking in, trimming, processing, embedding, cutting, staining and coverslipping and technical checks before release to pathologists. There should be recording of who does what to the sample so that there is a clear audit trail if something has gone wrong and someone needs to investigate. Any errors should be logged and error logs monitored to ensure that there are no systematic failures.

Quality of histopathology slides will also be assessed by the histopathologist and any problems fed back to the laboratory. The assessment will include any mismatch in samples, substandard staining which interferes with diagnosis, problems with orientation of samples and incomplete epithelial surfaces. Again, error logging is essential to monitor and improve the quality of service.

2 External Quality Assessment

External quality assessment is a mechanism for checking the quality of a service or individual by an external body.

EQA Schemes

Histopathologists have previously been required by the National Health Service Cervical Screening Programme to undertake a relevant EQA. This currently includes the National Gynaecological Histopathology EQA Scheme and regional general histopathology schemes.

The former now always contains two cervical samples, as scanned slides, in each round. Inclusion of cervical cases in general schemes is variable. It is not appropriate for a histopathologist who does not report gynaecological malignancies to participate in the National Gynaecological Histopathology scheme and most general schemes do not reliably assess a pathologist's competence in reporting cervical samples hence the introduction of the new e-learning module which contains an element of self-assessment and reassessment.

The laboratory also is involved in EQA at a technical level. Laboratories' staining will be assessed by the United Kingdom National External Quality Assessment Service (UKNEQAS) https://ukneqas.org.uk/ for a range of staining techniques including Haematoxylin and Eosin staining and immunohistochemical staining.

Laboratories undertaking NHSCSP work are required to be registered with an accreditation body to ISO 15189. The United Kingdom Accreditation Service (UKAS) Ltd https://www.ukas.com/ provides this service and aims to make sure that all laboratories operate to the required standard and thus aiming for uniformity in quality and safety of service.

Quality Assurance Visits

The screening QA service (SQAS) is part of NHSEI and works alongside NHS screening programme teams. Its function is to oversee the quality and performance of the cervical screening programme. This is measured against agreed national standards for the programme.

SQAS operates to a specific model
https://www.gov.uk/government/publications/cervical-screening-programme-specific-operating-model

SQAS is required to visit cervical screening services at least once in every five years. This may be sooner if a serious incident occurs or if there are particular concerns from routine data monitoring. Laboratories are required to submit regular data to SQAS in quarterly and annual returns. These data will be related to the national standards for the NHSCSP and will allow SQAS to assess performance against these standards and to make recommendations where the standards are not met. Recommendations are followed up by SQAS to ensure compliance.

3 Education and training

Consultant histopathologists will hold the Fellowship of the Royal College of Pathologists qualification or evidence of equivalent qualification, which demonstrates their competency in reporting histopathology samples. Biomedical Scientists obtaining the Institute of Biomedical Science's Advanced Specialist Diploma in Histopathology Reporting (cervical module) qualification will have demonstrated their competency in reporting cervical histopathology samples.

Specialist trainees (registrars) will undergo training in reporting of cervical histopathology as part of their general training. They will normally have their work checked by a consultant histopathologist. They are allowed to report samples independently according to RCPath guidance once competency has been assessed and signed off by their clinical supervisors. Level 4 competency must have been achieved for independent reporting of cervical histology.

https://www.rcpath.org/resourceLibrary/competency-based-framework-for-graded-responsibility-arranged-by-level-of-competence.html

Similar competency assessments should be undertaken for Advanced Biomedical Scientist Practitioners who are still in training. Once they obtain the IBMS Advanced Specialist Diploma in Histopathology Reporting https://www.ibms.org/education/advanced-qualifications/histopathology-reporting/ they can report independently.

All personnel should demonstrate Continuous Professional Development (CPD) and should belong to a recognised CPD scheme. CPD can be achieved by attending relevant training courses, lectures or self-learning exercises. Competency can be assessed and maintained by participation in EQA.

Further information is provided in https://www.gov.uk/government/publications/cervical-screening-histopathology-reporting-handbook/cervical-screening-programme-histopathology-reporting-guidance#lab

Audit in Cervical Screening

Audit is a process for measuring performance against an agreed standard which may be national or local. Where the audit identifies performance below the agreed standard, reasons for this should be identified and recommendations should be made and implemented to improve the outcome. A re-audit should be undertaken at a specified interval to see whether the implemented changes have led to the standards being achieved. This is commonly referred to as "closing the audit loop".

The NHSCSP cervical cancer audit
https://www.gov.uk/government/publications/cervical-screening-auditing-procedures/national-invasive-cervical-cancer-audit
requires review of a woman's screening history when cervical cancer is diagnosed. The index histology is not required to be reviewed as this will have been subject to review at the gynaecological oncology MDT meeting and the diagnosis agreed.
All previous histology must be reviewed but not by the original reporter. Requests for reviews will usually come from the Cervical Screening Provider Lead (CSPL), previously Hospital Based Hospital Coordinator, who should receive notifications of new cancers. The CSPL will then register the case with SQAS and receive a case reference number. Results of the review must be entered into the cancer review proforma.
Audit should be an integral part of all individual's work. All Trusts should have a clinical audit department. Histopathology departments should have an annual audit programme. This programme and audits will be subject to scrutiny by UKAS Ltd. Monitoring and improving the quality of your work is a requirement of The General Medical Council's Good Medical Practice
http://www.gmcuk.org/guidance/good_medical_practice/maintain_performance.asp
Supporting information is required for GMC revalidation for doctors and for appraisals. Part of this will include review of your practice and quality improvement activity https://www.gmc-uk.org/registration-and-licensing/managing-your-registration/revalidation/guidance-on-supporting-information-for-appraisal-and-revalidation
Review of your practice and quality improvement can be demonstrated by audit of some aspect of your work. Pathologists can easily do this by performing audits of their reports

against RCPath cancer datasets and tissue pathways. Audits must comply with guidance given by the RCPath https://www.rcpath.org/profession/clinical-effectiveness/quality-improvement/apply-for-certification-of-high-quality-audit/criteria-and-standards-for-clinical-audit.html if they are to be submitted to the RCPath when 5 credits can be allocated for this if the audit passes the evaluation process https://www.rcpath.org/profession/clinical-effectiveness/quality-improvement/audit-evaluation-process.html