



**British Association
for Cytopathology**

**Recommended code of practice
for cytology laboratories
participating in the UK cervical
screening programmes**

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Updated
2017

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FOREWORD

The NHS cervical screening programmes (CSPs) (appendix 1A) have been successful in reducing both the incidence of and mortality from cervical cancer in women in the UK. While the laboratory is only one element of the screening programme, it has a pivotal role, and the previous BSCC code of practice for cytology laboratories (CoP)¹ has been instrumental in providing certain common principles and standards for laboratories to work within, irrespective of their geographical location. Over time, the screening programmes in the constituent parts of the UK have developed different approaches to screening women and these differences are illustrated elsewhere in this document.

The previous BSCC CoP was last updated five years ago and, while much of the guidance remains relevant, there have been such significant changes both to the technology and the terminology used within the UK that the British Association for Cytopathology (BAC) felt that a further update was required if the code was to remain relevant. It is intended that the code will be more concise and easier to update in the light of expected changes to the various NHS cervical screening programmes (NHS CSPs) in the future. It is anticipated that an annual review, with appropriate revisions, will take place rather than completely rewriting the document on a periodic basis.

As before, the recommendations in the guidance will be evidence-based if possible. Where current hard scientific evidence is lacking, the recommendations remain based on professional consensus. Relevant publications from UK institutions such as the NHS Cervical Screening Programme in England (henceforth referred to as the NHSCSP), Cervical Screening Wales (CSW), Scottish Cervical Screening Programme (SCSP), The Royal College of Pathologists (RCPath), Institute of Biomedical Science (IBMS) and, of course, the BAC itself are referenced. Links to relevant documentation have been embedded within the code and differences between the four UK nations are acknowledged and highlighted. Whilst this guidance is aimed specifically at laboratories providing cervical screening services for the NHS CSPs, it may prove valuable to other cytology laboratories, particularly those in the UK.

The members of the current working party would like to acknowledge the debt they owe to colleagues for their hard work in preparing previous editions of the code of practice and to thank members of the BAC executive and representatives of the NHS screening programmes for their comments and contribution to this latest edition.

MEMBERS OF THE WORKING PARTY

Mrs Melanie Buchan

Dr Paul Cross

Mrs Alison Cropper

Dr Karin Denton

Dr Fraser Mutch

Dr Louise Smart (Chair)

Mr Allan Wilson

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1. KEY PRINCIPLES

Whatever the model of service delivery, size and workload repertoire of the laboratory, these elements of organisation and staffing should apply:

- Cytology laboratories must have a sufficient throughput of work to maintain expertise and quality assurance and to deliver the service to the specification required by the relevant CSP (appendix 1B)
- There is a medical consultant in charge of cervical cytology and a named deputy for the consultant in charge. The latter may be a medically qualified pathologist or a consultant biomedical scientist; in practical terms, this may be more than one individual to allow for cross cover. Medical leads and deputies must be actively involved in the reporting of abnormal cervical cytology. In Wales, there are alternative, specified governance arrangements, appropriate to the service delivery structure for CSW (appendix 1B)
- Local services must ensure that there is adequate and appropriate consultant cover. This may be from another site or through a network arrangement, outlined in Royal College of Pathologists, Clinical responsibility for cytology services, 2012_ <https://www.rcpath.org/asset/81DCAA1F-23DB-48AF-AE6F1F00B4727ADF/>. There is a lead biomedical scientist, with designated one or more deputies, responsible for the day to day management of the cervical cytology laboratory
- Laboratories should comply with quality standards and accreditation requirements of their respective national screening programmes
- All screening and reporting for the NHS CSPs must take place in a laboratory where the cervical cytology repertoire is accredited to ISO standard 15189 by the United Kingdom Accreditation Service (UKAS). Laboratories may be Clinical Pathology Accreditation (CPA) accredited until the transition to UKAS is complete. (appendix 1C)
- It is not appropriate for slides to be screened in a non-laboratory setting and screening and reporting from home must not be carried out. The RCPATH has some general guidance in

this area: Guidance for cellular pathologists on reporting at home (3rd edition) April 2014 http://www.rcpath.org/resourceLibrary/cellular-pathologists-reporting-at-home_apr_14.html . The laboratory should ensure appropriate ergonomic conditions for microscopy as outlined in NHSCSP* publication 17 (2003) - Ergonomic working standards for personnel engaged in the preparation, scanning and reporting of cervical screening slides <https://www.gov.uk/government/publications/cervical-screening-ergonomic-working-standards>

- Cervical cytology is reported using current terminology as detailed in NHSCSP professional guidance - Achievable standards, benchmarks for reporting, and criteria for evaluating cervical cytopathology (3rd Edition) (2013) <https://www.gov.uk/government/publications/cervical-screening-cytopathology-standards-and-evaluation-criteria>. In Scotland, there are modifications to terminology and reporting guidance and, in Wales, additional terminology and associated codes are in use. (appendix 1H)
- High risk human papillomavirus (HPV) test reporting must follow national protocols and laboratories undertaking HPV testing must have appropriate protocols, training and governance systems in place (appendix 1I)
- Laboratories should have links and processes in place with histopathology, colposcopy, gynaecology and other clinical departments to allow for participation in invasive cancer audits, multidisciplinary team meetings (MDTMs), and other relevant forums such as local working groups
- All staff must have an annual appraisal appropriate to their role
- Laboratories must have a suitable information technology (IT) system to process, log and report cytology and export it to other relevant systems (e.g. call/recall office, primary care,) as required by their national CSPs
- All staff must have access and be able to attend suitable and relevant training and educational needs as required by their national CSPs

*All NHSCSP guidance is applicable to laboratories in England and Northern Ireland. Cervical Screening Wales and the Scottish Cervical Screening programme may follow this guidance but with nation-specific modifications.

2. ORGANISATION AND STAFFING

2.1` Networks

There are various models of networked pathology departments. For informal hub and spoke networks, laboratories will work independently and submit separate KC61 or equivalent data. For a network to be considered as one department, they must submit a single KC61 or equivalent and all sites within the network that perform cervical cytology screening must adhere to the same policies and protocols and have a single clinical lead; with this latter arrangement, a single management structure, one employing Trust and consultant lead are necessary to give strategic direction.

Networks must adhere to the following core principles:

- There must be clear written service level agreements (SLAs) in place detailing relevant responsibilities between all laboratories and their host organisations, the cover required and provided and the sessional medical consultant/ consultant biomedical scientist input to meet service needs. The SLA must make clear which Trust or organisation has medico-legal responsibility
- Excellent communication, including IT systems, across the network is essential to facilitate a unified service
- Where there is movement of personnel or workload around the network there must be an effective tracking system so that specimens and staff can be easily traced and responsibility for screening, checking and reporting identified
- Transportation of specimens between networked laboratories must comply with the guidance laid down in this document and must adhere to NHS Code of Practice for

Information security management

- The BAC recommends that staff between all sites who report abnormal cytology should meet at least quarterly to establish a common understanding of competency and working practices.

2.2 Staffing roles and responsibilities

Staff of differing grades will have different roles and responsibilities within the laboratory.

There should be an accountability structure in place and all staff must have roles and responsibilities clearly defined in their job description. Agenda for change (AFC) pay banding of a post will depend on the particular job profile and is for the employer to determine but, as guidance, AFC bandings generally considered appropriate to the skills, knowledge and responsibilities of the roles below are included. Appendix 1D gives links to information on national job profiles and career framework stages and for biomedical scientist and cytology screener staff.

Requirements include:

- Appropriate qualifications and training in accordance with national requirements and local guidance
- Health and Care Professions Council (HCPC) registration for all biomedical scientist staff
<https://www.ibms.org/registration/hcpc-registration/>
- For all non-medical staff reporting cervical cytology in the NHSCSP: completion of the mandatory NHSCSP training in cervical cytology which includes a screening test and written question paper sat under examination conditions (or the City & Guilds Level 3 Diploma in Cervical Cytology [3166-01 & 3165-01], NHSCSP Certificate in Cervical Cytology or IBMS/BSCC Certificate of Competence)
- Knowledge of local standard operating procedures (sop), Health & Safety policies and procedures, COSHH, Information Governance, Data Protection and Caldicott Guardian principles. The use and security of personal information is subject to the provisions of the Data Protection Acts and unauthorised disclosure of personal information is a criminal

offence. Further general information on NHS information governance can be found at <http://systems.hscic.gov.uk/infogov>

- Participation in the relevant national external quality assessment (EQA) scheme
- The undertaking of continuing professional development (CPD) and update activities as required
- Mandatory retraining after a prolonged period of absence
- The lead consultant for the department has the roles outlined as below, and acts as the point of main contact for NHS management needs.

Lead Consultant

The lead consultant as clinical lead for the service has overall responsibility* for laboratory aspects of cervical screening programme management including establishment of procedures, maintenance of safe and effective working practices, performance monitoring in cytology and also high risk human papillomavirus (HPV) testing if it is part of the laboratory repertoire. The role will be identified in the job plan and will be subject to annual appraisal.

Whilst responsibility for delivering specific aspects of the screening programme will be held by other members of the team, the lead consultant will be responsible for ensuring the programme is delivered and the standards achieved. This will include oversight of performance statistics, providing evidence for commissioners/quality assurance, implementing actions required to maintain the standards of the service and ensuring there are suitable opportunities for staff training. The lead consultant is also responsible for determining the strategic direction of the department.

The lead consultant will be responsible for handling complaints, claims and internal audit reviews.

*In Wales, some of these responsibilities lie with the Director of Screening Division.

Consultant pathologist

Doctors appointed will be on the Specialist Register of the General Medical Council. Consultant pathologists trained in the UK will have completed approved specialist training, including attainment of either the Fellow of the Royal College of Pathologists (FRCPath) part 2 and the Certificate in Higher Cervical Cytopathology Training (CHCCT) or FRCPath part 2 including the cervical cytology option (curricula pre-2010), and gained a Certificate of Completion of Training (CCT). Doctors with postgraduate training outside the UK will have obtained specialist registration by demonstration of equivalent training, qualifications and experience through Article 14. Further information <https://www.rcpath.org/trainees/training/specialist-registration.html> . A consultant pathologist working in the cervical screening programmes must have experience and understanding of the multidisciplinary and multi-institutional nature of the programme, and have appropriate managerial skills. As such, training in management is desirable.

If a consultant pathologist without training specifically in an NHS CSP is appointed to a post involving practice in an NHS CSP, appropriate training in the organisation and operation of the cervical screening programme must be arranged by the employing body/Trust.

Consultant biomedical scientist (AFC band 8a or above)

For the purpose of this document those who hold the Advanced Specialist Diploma in Cervical Cytopathology (ASD) are called consultant biomedical scientist although the BAC recognises that post holders may have a variety of different job titles. Consultant biomedical scientist staff must hold the Advanced Specialist Diploma in Cervical Cytology.

The following roles and responsibilities are common to both consultant pathologist and consultant biomedical scientist staff. They may:

- Screen cases referred as abnormal by primary screeners and checkers, report abnormal cervical cytology samples and recommend patient management
- Participate in regular MDTMs and clinical-pathological conferences (CPCs) as described by local policy
- Participate in clinical audit and research
- Act as an intermediary between the laboratory and other clinical staff including general practitioners providing diagnostic opinions and advice on appropriate cytological investigations, suggestions for further investigations and management of patients
- Educate trainee medical and non-medical staff spending time in cervical cytopathology as part of their training in cellular pathology
- Be the Hospital Based Programme Coordinator (HBPC), as described in detail in appendix 2, and may deputise for the clinical lead.

Lead biomedical scientist in cytology

The lead biomedical scientist will work collaboratively with the medical consultants and consultant biomedical scientist, laboratory managers and HBPC to maintain and monitor a high quality service. The role of the lead biomedical scientist will vary depending on departmental complexity and management structure; however, the lead biomedical scientist in either an independent cytology department or a cytology section within a larger cellular pathology department must be active in cervical cytology and will usually perform a checker role or be a consultant biomedical scientist. This role is distinct from an overall laboratory manager who may not be active in cervical cytology. The lead biomedical scientist is the principal link between the primary screeners and checkers and the consultant pathologists. They will manage the screening room and preparation laboratory and work closely with the training officer, quality manager and the senior biomedical scientists to ensure the service runs efficiently and effectively. Where the lead biomedical scientist is a consultant biomedical scientist, these operational management aspects of the role may be devolved to a named senior biomedical scientist or laboratory manager.

The duties of the lead biomedical scientist should include:

- Development and review of laboratory policies and procedures
- Laboratory performance monitoring and performance monitoring of screening staff and checkers
- Implementation of failsafe policy
- Assisting training officers in establishing and maintaining of a training and continuing education programme for laboratory staff.

The lead biomedical scientist may also have a role in HPV testing where this is carried out on site.

Supervisory biomedical scientist and checkers (AFC band 7 or above)

As well as primary screening of cervical samples and checking of referred cases from primary screeners, the supervisory biomedical scientist should participate in the discussion of abnormal and equivocal cases with staff, supervision and training of primary screeners and support staff, and other duties such as quality management and liaison with primary care and suppliers.

As recommended in the previous CoP¹, checkers should be AFC band 7 or above, and must have a minimum of five years' experience in cervical cytology post registration and certification.

There is no recognised qualification to enable checkers to demonstrate competence in this role.

Before a biomedical scientist takes on the full reporting role of a checker there should be a period of documented in-house training or shadow reporting, audit and review to ensure their competency in this role.

Biomedical scientist (AFC band 5 or 6)

Biomedical scientist staff can participate in the primary and rapid screening of cervical cytology slides, including double screening of samples examined by trainees. Duties may also include supervision of support staff, monitoring of quality of preparations, HPV testing where this is carried out on site and quality control.

Cytology screeners* (AFC band 4 or 5)

Cytology screeners can undertake primary screening and rapid screening of cervical cytology slides and report samples screened as negative or inadequate**, provided that they have successfully completed the NHSCSP training programme in cervical cytology or one of the preceding recognised UK screening qualifications. All potentially abnormal cases MUST be passed on to a checker, consultant biomedical scientist or consultant pathologist.

Cytology screeners may carry out general tasks suitable for healthcare support workers under supervision of a biomedical scientist but these tasks should not prevent the cytology screener from having sufficient time to carry out cervical screening.

There is no current route for professional regulation of cytology screeners post qualification, but they must participate in routine laboratory internal quality control and EQA schemes.

*Within this code "cytology screener" refers to non-biomedical scientist staff trained to undertake cytology screening, "primary screener" is the person (of any grade) undertaking the primary screen and "screener" describes a member of staff participating in cervical cytology screening (primary or rapid).

** In Scotland, "unsatisfactory" is the terminology used on reports.

Health Care Support Worker (HCSW)

HCSWs (often called medical laboratory assistants) perform a range of routine technical tasks in laboratories under the supervision of a biomedical scientist but do not participate in screening. There are no minimum entrance qualifications and training is entirely in-service (see section 9). The HCSW should be continually monitored.

Clerical and secretarial staff

The large numbers of specimens received by cytopathology laboratories require the support of efficient clerical and secretarial staff. Duties may include data entry such as entering results, label printing, printing, collating and dispatch of results and letters, archiving and telephone enquiries.

Locum (agency) staff

When locum /agency staff are employed to screen/report CSP cytology the following must be provided:

- A full and current CV
- A minimum of two references which include information on previous workload and performance data that satisfies NHSCSP standards
- Evidence of appropriate mandatory training in cervical cytology
- Certificates of liquid based cytology (LBC) conversion training as appropriate
- Evidence of current EQA scheme participation.

On commencing screening, all primary screening should be double screened by checker staff for a minimum of one week. If no substandard performance² is identified then the locum's primary screening can be subjected to the usual quality control of the department. Locum screening staff must adhere to all NHSCSP guidelines, including the maximum number of hours permitted for microscopy in any one day (see section 2.4).

Hospital based programme coordinator (HBPC) (see appendix 2)

In England, all Hospital Trusts providing any element of the NHSCSP must have a hospital based programme coordinator (HBPC) formally appointed to oversee the coordination, quality and effectiveness of the cervical screening programme linked to that Trust. They must have a thorough understanding of the NHSCSP and be sufficiently knowledgeable and experienced to be comfortable with discussions at Board level.

The HBPC may be employed in any discipline within the programme (cytology, histology, colposcopy, gynaecology) but the responsibilities of the role are common and are outlined in appendix 2. Their role in cancer audit is outlined in NHSCSP professional guidance - Audit of Invasive Cervical Cancers (2006) <https://www.gov.uk/government/publications/cervical-screening-auditing-procedures>

The HBPC role does not operate in Wales or Scotland. In Wales, HBPC functions are carried out by Regional Programme Coordinators who report to the Director of Screening Division, Public Health Wales. In Scotland, the functions are undertaken by lead pathologists and colposcopists with input from primary care and public health leads.

2.3 Limits of practice

- Biomedical scientists **not** holding the ASD and cytology screeners must **not** sign out abnormal cervical cytology reports
- Trainee screeners (biomedical scientist or cytology screener) must **not** report out any cervical screening reports or participate in routine rapid pre-screening or rescreening
- HCSWs must **not** screen cytology samples
- Senior biomedical scientists in a checker role may overrule the opinion of a primary screener
- Only consultant biomedical scientists and consultant pathologists can report abnormal samples
- Cases referred by the primary screener as high grade dyskaryosis and considered to be negative or inadequate by the checker must be passed to a second checker or more senior staff to review before the case can be reported as such
- The BAC recommends that cases referred by checkers as high grade dyskaryosis or above and considered negative by a consultant biomedical scientist or a consultant pathologist must be referred for an opinion to another consultant biomedical scientist or a consultant pathologist before being reported.

2.4 Staffing levels and workloads

NHS England requires a cervical cytology laboratory to report a minimum of 35,000 samples per annum (Service specification 25, appendix 1B). No minimum is specified for Scotland or Wales. Productivity/screening rates are difficult to evidence as staff members perform many different duties and the amount of time available for primary screening varies between departments. However, it is desirable to have systems in place to monitor productivity and screening rates.

Medical consultant and consultant biomedical scientist

Laboratories that provide a cervical screening service and employ consultant biomedical scientists require the following staffing arrangements:

In a stand-alone laboratory: A minimum of two medical consultants, who actively practise cervical cytology, in addition to the consultant biomedical scientists.

In laboratories that form part of a network: A minimum of one medical consultant who is actively practising cervical cytology reporting on site with consultant biomedical scientists. There must be a minimum of two consultants across the network. Under normal circumstances, consultants who work in more than one hospital must report cervical cytology at the cervical cytology screening laboratory where the slides are screened.

The BAC endorses the recommendation in the previous BSCC CoP¹ that to maintain a medical and biomedical scientist consultant's diagnostic skill in cervical cytopathology, their minimum yearly workload must be not less than one programmed activity in cervical cytology and a consultant should report or review a minimum of 750 cases/year. This can include slides reviewed for audit and correlation. The RCPATH have published recommendations on consultant workload: Guidelines on staffing and workload for histopathology and cytopathology departments (4th edition) September 2015 http://www.rcpath.org/resourceLibrary/g107_guidelinesstaffingworkload_sep15-pdf.html

Under normal circumstances medical consultants will be present in the laboratory every working day. When this is not possible, arrangements **must** be made to ensure that staff have access to medical support, particularly when these absences extend over several days. Consultant absence should not prevent consultant biomedical scientists from reporting abnormal cases in these limited circumstances.

Programmed activities or equivalent should be allocated for laboratory and screening programme management, audit, teaching, continuing medical education and research.

Supervisory biomedical scientists/checkers

As recommended in previous BSCC CoP¹ a suitable ratio of supervisory biomedical scientists to biomedical scientist, cytology screeners, healthcare support workers and trainees is necessary to provide satisfactory supervision for the checking of cervical samples, training, service development and quality control. A supervisory biomedical scientist may supervise up to four other members of staff.

Checking requires additional interpretive skills to routine primary screening and the BAC recommends a checker should see at least 750 referred cases per annum. If participating in primary screening, a checker should also screen a minimum of 1000 slides per annum.

There is currently no guidance on the amount of time that checkers can safely undertake microscopy per working day. Because the nature of checking differs from primary screening, checkers may exceed five hours of microscopy (see below) and, provided that regular breaks are taken and appropriate IQC is undertaken, it is acceptable for checkers to undertake microscopy beyond this time. The BAC recommends that microscopy duties do not extend beyond a maximum of eight working hours (including breaks) in a working day.

Biomedical scientist /cytology screeners

For performance monitoring purposes, the BAC continues to endorse the recommendation of previous codes of practice¹ that biomedical scientist primary screeners and cytology screeners must

screen a minimum of 3000 slides per annum. With respect to workload, the BAC endorses the rates of working recommended in NHSCSP publication 14³. Nevertheless, this is a minimum; with LBC and imager technology, greater numbers are achievable⁴⁻⁷. Provided that staff satisfy NHSCSP quality standards and are not exceeding the hours of screening below, the BAC can make no evidence based recommendation regarding a maximum number of slides per annum.

The BAC recommends that screeners can safely undertake primary and rapid screening for up to five hours in any working day. No one should exceed this amount of time routinely on primary or rapid screening. Some screeners may work in more than one laboratory; however, the BAC recommends that no screener works more than six days in any single week in this role.

If biomedical scientist staff participate in other duties such as pre-screening of non-cervical cases, andrology and audit, these tasks should not prevent a screener from being allowed sufficient time to carry out the cervical screening for which they are primarily trained. Screening time must not be compromised by the inappropriate use of skilled screening staff to perform clerical or specimen reception duties on a regular basis.

With regard to screeners in training:

- A trainee screener should not be employed on a less than 0.5 WTE contract.
- For workload calculations trainees must be considered supernumerary.

2.5 Backlog management

For a variety of reasons, (e.g. sickness leave, maternity leave, increased workloads) cervical cytology backlogs can develop. This is usually in reporting rather than in processing. To achieve the required turnaround times (TATs) (appendix 1E) staff may be required to undertake extra reporting to reduce/eradicate any backlog. Any extra hours must be agreed in advance with the laboratory management and staff, and must comply with usual laboratory practice. If undertaken, the extra screening/reporting must not cause health or quality issues for the service or staff involved. Overtime should not be used on a regular or permanent basis.

It may be that work is sent to a partner laboratory in a network or outsourced to a laboratory with screening capacity. An appropriate service level agreement and protocols must be in place (in Scotland guidance is available from the Cervical Cytology Laboratory Steering Group), in addition to transport and tracking arrangements outlined in section 3.

For both the originating and outsource laboratory to produce accurate laboratory and screener performance data, accurate records of samples screened including screener and reporter opinions and screener identification must be kept by the outsource laboratory. The originating laboratory must provide details of outcomes to the outsource laboratory to ensure that screener performance on all workload is monitored. The outsource laboratory will need to highlight to the originating laboratory if substandard performance is identified.

3. SAMPLE TRANSPORT AND PROCESSING

The Trust and laboratory must have standard operating procedures and guidance to cover sample transport both to and between laboratories, reception and processing in accordance with UKAS accreditation standards ISO 15189, formally CPA accreditation, <https://www.ukas.com/services/accreditation-services/clinical-pathology-accreditation/> to support contractual requirements for compliance with national turnaround targets (appendices 1B, 1D). The NHSCSP provides professional guidance for England on achieving a 14-day turnaround - Cytology improvement guide: achieving a 14 day turnaround time in cytology (2009) <https://www.gov.uk/government/publications/cervical-screening-cytology-improvement-guide> .

All staff, including supervisory staff, involved with sample receipt, booking-in and processing must be appropriately trained, assessed as competent and be familiar with all relevant guidance and protocols including manufacturers' information for the handling of sample reagents.

NHS laboratories are currently using one of two NHS approved liquid based cytology (LBC) technologies, the Hologic™ ThinPrep® system (ThinPrep) <http://www.hologic.com/products/clinical-diagnostics/assays-and-tests/thinprep-pap-test> or the Source Bioscience BD SurePath® and BD PrepStain™ system (SurePath)

<http://www.healthcare.sourcebioscience.com/cytology/> . Package inserts and datasheet information for ThinPrep are found at: <http://www.hologic.com/package-inserts/clinical-diagnostics/assays-and-tests/thinprep-pap-test> . For SurePath, these are available at [http://www.healthcare.sourcebioscience.com/cytology/documents- data-sheets/?rd=1](http://www.healthcare.sourcebioscience.com/cytology/documents-data-sheets/?rd=1) (see also appendix 1F).

3.1 Transport

Cervical sample vials, slides, and HPV samples may be transported to and between laboratories. The objective is speedy, safe and secure transit conforming to UKAS ISO 15189.

- Only LBC vials within the expiry date must be used for the collection of samples. Samples should be despatched from sample taker locations on the day of sample collection or, where this is not possible, the next working day
- Courier/NHS staff must be made aware of the importance of the confidential nature of the samples being transported
- Samples awaiting transport and in transit may be stored at ambient temperature; there is no need to refrigerate samples
- Appropriate packaging suitable for daily transportation of potentially hazardous material must be used. **These must be fit for purpose and sealable to avoid leakage, cross-contamination and breakage.** Samples should be transported in clearly addressed labelled containers
- LBC samples may be sent by post if packaged according to Royal Mail requirements_ http://www.royalmail.com/sites/default/files/6966_Dangerous_Goods_A5_Business_customer_booklet_TAG.pdf). SurePath vials are 95kPa certified and may be sent through the post provided they are packaged according to UN3373 packaging requirements
- Procedures and equipment to deal with spillage and leakage must be available
- To comply with the Data Protection Act 1998, patient identifiable data must not be written on the outside of the transport packaging. There must, however, be appropriate labelling
In Scotland, where there is online submission of request forms via the Scottish Cervical

Call and Recall System (SCCRS), the smear taker location details should be enclosed in the courier bag

- Slides being sent out from a laboratory should be logged out and receipt confirmed in compliance with NHS information and governance regulations and ISO 15189 standards.

3.2 Sample receipt and booking in

The objectives are to ensure prompt reception and booking in and to ensure accuracy of sample identity. Request forms received must be date-stamped promptly and an electronic record created within 24 hours or one working day of sample receipt. Sample vials and their corresponding forms must be checked for correlation and for acceptance into the laboratory. There should be a cervical screening programme specific or local sample acceptance policy conforming to UKAS ISO 15189 standards which outlines minimum patient identifiers; it should provide guidance on dealing with rejected samples. Error logging and audit trails should be in place. The BAC makes the following recommendations with regard to cervical cytology sample acceptance:

- There must be a minimum of three unique patient identifiers on both sample and form conforming to IBMS requirements_
<https://www.ibms.org/go/media/publications/professional-guidance> including:
 - o Full name – surname, forename
 - o Date of Birth
 - o Unique patient number (e.g. NHS number, CHI number in Scotland)
- Where there is a major discrepancy/mismatch or multiple minor discrepancies, or the vial is out of date, the vial should be destroyed. It should NOT be returned. A record and audit trail of discarded vials must be kept. In some regions, there is variation to this but only by written agreement by the laboratory and the relevant QA structure
- Minor discrepancies may be dealt with by telephone or by referring to Open Exeter/SCCRS to obtain required clarification/confirmation – this should be clearly documented on the form

- It is acceptable to reject and return samples received that do not satisfy NHSCSP screening intervals/age-related invitations in accordance with local commissioning agreements
- Rejected/destroyed samples or returned forms should be documented, providing a complete audit trail
- If there is any doubt as to whether a sample should be accepted, advice should be sought from supervisory staff
- In Scotland, where requesting is electronic via SCCRS, for a sample arriving without a legible barcoded label, effort should be made to contact the sender to inform them that there is one unlabelled sample which cannot be processed. The sample should then be destroyed
- Where possible, data entry staff should use the unique patient' NHS number or CHI number as the preferred method of searching/creating an electronic entry, thereby avoiding multiple patient entries on computer databases.

3.3 Sample preparation and staining

Whether it is the ThinPrep or SurePath system that is used:

- Preparation must conform to the manufacturers published protocols
- All equipment and machinery should be regularly cleaned and maintained by appropriately trained staff
- Prepared slides must be stained using a Papanicolaou based method and there must be regular quality control checks of staining quality
- Staining quality should be checked and recorded daily and with each new batch of stain by appropriately trained screening staff, to ensure consistency and reliability for either human or machine screening. Issues arising should be investigated promptly and once resolved, the staining quality should be rechecked
- Laboratories must participate in a cervical cytology technical EQA scheme (appendix 1L)

4. SCREENING AND REPORTING OF CERVICAL CYTOLOGY

Screening must be undertaken by suitably qualified staff and only within a laboratory environment. There should be at least one break after no more than two hours of continuous screening at the microscope. Other, non-microscopic duties, can act as breaks from microscopy as outlined in NHSCSP publication 14 - Laboratory organisation: a guide for laboratories participating in the NHS cervical screening programme (2003) <https://www.gov.uk/government/publications/cervical-screening-laboratory-organisation>

4.1 Manual Primary screening

All the material on the slide must be examined. Screening should be carried out using a 10x objective lens. Areas of interest must be examined at higher magnification. Whatever system or screening technique is used, individual screeners must overlap fields by at least 30%⁸. Potentially abnormal cells identified should be marked for checking according to agreed laboratory protocol.

4.2 Criteria for adequacy

Since the introduction of LBC, there has been to date, no definitive guidance in England for assessing adequacy, both in terms of minimum cell number and the method of cell counting. Current NHSCSP guidance² recommends that an adequate LBC sample is defined as one containing the "minimum level of squamous epithelial cellularity necessary to ensure a squamous abnormality detection rate equivalent to that offered by conventional smears". A number of studies have addressed LBC adequacy⁹⁻¹¹ and a study commissioned by the National Institute for Health Research Health Technology Assessment (HTA) programme involving 56 NHS laboratories has recently been completed and published¹² <http://www.journalslibrary.nihr.ac.uk/hta/volume-19/issue-22>. This study concludes that for SurePath slides a minimum average cell count (MACC) of 15,000 would achieve a sensible balance between sensitivity to detect cytological abnormalities and the maintenance of low rates for inadequate samples. A MACC of 5000 for ThinPrep slides would achieve a similar balance between sensitivity and inadequate rates.

Thus, with respect to LBC cell adequacy:

- The BAC recommends that CSP evidence based guidelines that define specimen adequacy for reporting of ThinPrep or SurePath slides, when available, should be incorporated into laboratory practice. In Scotland, where all labs use ThinPrep, the Scottish CSP recommendation for adequacy is 10,000 cells (Laboratory Quality Assurance group 2013, 2015) and there is a national agreed protocol for estimating cellularity_ <http://www.sccrs.scot.nhs.uk/Documents/2017-04-18%20nap%201-14%20April%202017.pdf> (nhs site)
- Laboratories should ensure that cytology reporting staff are able to assess cell numbers so that they do not report as negative, slides that do not meet their current adequacy criteria. The HTA study above found that all the SurePath laboratories participating used a MACC of 15,000 cells; ThinPrep laboratories used adequacy limits ranging from 5000 to 15,000 cells. In the absence of CSP guidance, the BAC would recommend that laboratories do not have limits lower than these, given the evidence¹² that sensitivity for detection of abnormal cells is reduced in low cellularity samples
- Most LBC samples contain sufficient cells for assessment and, therefore, a formal cell count is required only for slides where there is doubt as to adequacy
- Laboratories should monitor inadequate/unsatisfactory rates and ensure that these remain within expected upper and lower ranges, investigating reasons for unexpectedly high or low inadequate rates

Other points relating to adequacy are:

- A sample must be reported as inadequate if the sample taker has not completely visualised the cervix, or if the sample has been taken with a sampling device not approved by the NHSCSP²
- A sample may be deemed inadequate for morphological reasons such as epithelial cells obscured by mucus or blood, marked cytolysis or the absence of endocervical cells in follow-up of cervical glandular intraepithelial neoplasia²

- Samples must not be reported as inadequate if they contain any evidence of borderline change or dyskaryosis
- Protocols for HPV triage testing of scanty samples reported as borderline and low grade dyskaryosis are described in NHSCSP professional guidance - Achievable standards, benchmarks for reporting, and criteria for evaluating cervical cytopathology (3rd Edition) (2013) <https://www.gov.uk/government/publications/cervical-screening-cytopathology-standards-and-evaluation-criteria> and illustrated in NHSCSP publication 20: guidelines for commissioners, providers and programme managers, for providing the NHS cervical screening service <https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management>

4.3 Computer assisted primary screening

Rules for implementation of computer assisted screening vary between the different countries of the UK (appendix 1G) and national policies must be followed. Where computer assisted screening technology is used, primary screeners must adhere to the screening protocol as described by the manufacturers.

Currently laboratories in Scotland are using the Hologic™ ThinPrep® Imaging System. The primary screener examines 22 fields of view, assessing the whole of each field. Slides where a potential abnormality is identified on review of the image identified fields (approximately 20% of slides) must be subjected to a full manual screening as outlined above, as must slides that have proved unsuitable for the automated imager to scan. Further information about the ThinPrep Imaging System can be found at <http://www.hologic.com/products/clinical-diagnostics/instrument-systems/thinprep-imaging-system> The BD FocalPoint™ Slide Profiler has been approved for use in England and Wales to identify slides that do not require full manual screening and can, after rapid review or preview, be reported as negative¹³. Guidance on the use of BD Focal Point is available in the NHSCSP Good Practice Guide No 4: Implementation of 'No Further Review' (NFR) using the BD FocalPoint™ Slide Profiler (2013) <https://www.gov.uk/government/publications/cervical-screening-bd-focalpoint-slide-profiler>

4.4 Checking

The checker should examine the whole slide, paying particular but not exclusive attention to any marked areas. Ideally, the checker should form an opinion before noting the primary screener opinion; this minimises interpretation bias. Where the primary screener has indicated that the sample shows high grade dyskaryosis and the checker considers the test to be negative or inadequate, the slide should be passed to a second checker (or consultant biomedical scientist or pathologist) to review the slide before allowing it to be reported as such. If both agree that the slide is negative or inadequate, then the first checker should authorise the case. The lead medical consultant takes responsibility for cases authorised by a checker as negative, and as such they should be satisfied that checkers have sufficient experience and training at this level.

The BAC acknowledges that consultant biomedical scientist staff may from time to time perform a “checker” role. Where this occurs, cases considered abnormal can be directly reported by the consultant biomedical scientist without a third opinion, although screening programme policy, as in Wales, may require this. However, the BAC recommends that where the consultant biomedical scientist (or consultant pathologist) wishes to report a case that has been referred as high grade dyskaryosis by a primary screener as negative or inadequate, it is shown to a second checker, consultant biomedical scientist or medical consultant.

The BAC does not support the use of medical or biomedical scientist consultant staff as checkers on a permanent basis as this is an inappropriate use of resources. It recommends that laboratories maintain the checker role which serves a valuable function in maintaining interpretive skills among more senior scientific staff and facilitates career development in relation to the Advanced Specialist Diploma in Cervical Cytology.

The nature of checking necessitates feedback to primary screeners on cases where there are differences of opinion. For this reason, the checker should have access to a teaching microscope, preferably away from the screening room, where review of slides and discussion can take place.

4.5 Reporting abnormal cytology

All slides passed to a consultant biomedical scientist or a medical consultant must be carefully

examined, paying particular, but not exclusive, attention to any marked areas on a slide.

Where the consultant biomedical scientist or medical consultant wishes to report a sample considered to be high grade dyskaryosis or glandular neoplasia by a checker as negative or inadequate, the BAC recommends that it is best practice to show the slide to a second medical consultant or second consultant biomedical scientist before reporting. The medical consultant or consultant biomedical scientist should have experience in screening negative slides, especially for the rescreening of negative slides as part of clinical audit.

Feedback from the consultant pathologist or consultant biomedical scientist on discrepant slides should be given to screeners and checkers on a regular basis.

The BAC suggests that it is good practice that samples reported as ?glandular neoplasia or ?invasive are referred to another consultant before being reported. This has two benefits (i) it can help to improve specificity of the report given that this group of patients is more likely to have “see and treat” (ii) such a report is a rare occurrence and ensures that the consultants in the department will see these presentations more frequently.

Everyone who expresses an opinion on a slide must have their opinion recorded in an individually identifiable and retrievable manner for quality assurance/audit purposes.

4.6 Rapid rescreening/prescreening

Rapid screening¹⁴ is the mandatory method for routine quality control of primary screening and all slides considered negative or inadequate must be subject to a rapid screen

Key points are:

- Both prescreen (preview) and rescreen (review) methods of rapid screening are acceptable
- Rapid screening must only be carried out by qualified members of staff
- The rapid screener must be a different individual from the primary screener
- Individuals should undergo training in rapid screening before they are permitted to carry it out and in-house evaluation should be undertaken
- A prescreen/rescreen should take approximately 60 to 90 seconds

- If rapid prescreening is used then the laboratory must ensure that any abnormal samples identified on rapid prescreening are not removed or marked in any way and that all the original slides (normal and abnormal) are included in the primary screening workload
- The prescreen opinion must be blinded to the primary screener
- If a discrepancy is identified during rapid screening then this must be recorded and passed to a more senior staff member to resolve
- Rapid screening data must be recorded to allow for individual screening numbers/sensitivities to be calculated
- The number of rapid screens that individuals undertake is expected, on average, to approximate to the number of primary screens, and no individual undertaking full slide LBC screening should rapid screen more than 50 slides in a working day, as outlined in NHSCSP publication 14 - Laboratory organisation: a guide for laboratories participating in the NHS Cervical Screening Programme (2003).

<https://www.gov.uk/government/publications/cervical-screening-laboratory-organisation>.

In laboratories using imager technology, however, with screeners reporting around 40-60 slides per day, similar numbers of rapid screens may be undertaken in the course of the working day, provided total hours at the microscope remain within accepted limits (section 2.4).

4.7 Reporting categories and management recommendations

With respect to the reporting of cytological samples, NHSCSP professional guidance - Achievable standards, benchmarks for reporting, and criteria for evaluating cervical cytopathology (3rd Edition) 2013 <https://www.gov.uk/government/publications/cervical-screening-cytopathology-standards-and-evaluation-criteria> outlines current terminology to be used in the UK. Management recommendations for these reporting categories are also detailed in NHSCSP publication 1 and are applicable in England, Wales and Northern Ireland. In Scotland, an addendum to NHSCSP publication 1 highlights areas of difference:

<http://www.nsd.scot.nhs.uk/Documents/ABCCervicalPublication.pdf>. Detailed nationally agreed protocols for the reporting of cervical cytology samples must be followed; these are available on

the SCCRS laboratory section of the National Services Division website:

<http://www.sccrs.scot.nhs.uk/lab.html> (NHS site).

4.8 HPV testing

Triage and Test of Cure (appendix 1I)

The screening programme in England has introduced HPV testing for triage of women with borderline and low grade cytology and for test of cure. Detailed NHS guidance on pathways for management is available in NHSCSP publication 20: guidelines for commissioners, providers and programme managers, for providing the NHS cervical screening service

<https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management> which includes provision for clinically indicated tests after discussion at an MDT meeting. Ideally such cases should be discussed in this setting prior to HPV testing and afterwards if required for correct patient management. HPV tests should not be undertaken outside of these pathways.

In Scotland, HPV testing is undertaken for test of cure and for clinically indicated tests after discussion at an MDT meeting. Detailed standard operating procedures and user manuals are available on the SCCRS laboratory section of the National Services Division (NHS) website <http://www.sccrs.scot.nhs.uk/lab.html>. Cervical Screening Wales is performing HPV test of cure and national policies should be followed (appendix1I). Only HPV testing platforms/assays that have been approved by the NHS CSPs should be used.

HPV primary screening

This is currently being piloted in six NHS laboratories in England. Staff at all sites should ensure they are familiar with the protocol as women may move from a pilot area (appendix 1I).

Location and Governance of HPV testing

HPV testing may be carried out in a number of settings, for example cytology laboratories, virology or molecular pathology settings. All laboratories undertaking HPV tests must include this in their quality management systems and repertoire for UKAS inspection, and participate in appropriate EQA. All staff performing HPV testing must have appropriate training in use of the technology and competency should be assessed regularly.

HPV testing is often centralised so that samples are sent off site for testing. Sending and recipient laboratories must have governance mechanisms in place to ensure that the whole pathway including transport, laboratory information systems and transfer of results is robust. There must be formal contractual arrangements between Trusts to provide this service.

Whatever model is used it must be able to deliver the relevant national turnaround requirement.

Where HPV testing is carried out other than in a virology laboratory, there must be an agreement that the very rare difficult cases which do occur can be discussed with a virologist.

4.9 Referral for colposcopy

The BAC endorses the requirement in the NHSCSP professional guidance - Colposcopy and programme management guidelines for the NHS cervical screening programme (2nd edition) (2010) <https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management> that colposcopy referrals resulting from a cervical screening test should be made as a direct referral from the cytology laboratory to colposcopy.

In England, the HBPC is responsible for ensuring that procedures are in place in both cytology and all associated colposcopy units to support the direct referral process, particularly a robust failsafe mechanism. While it is currently NHS policy in England to telephone the General Practice when the cytology result is severe dyskaryosis ?invasive or ?glandular neoplasia¹⁵ the cost effectiveness of this is yet to be determined.

In Wales, the responsibility for direct referral and follow-up of abnormal cytology is the responsibility of the regional programme coordinator and managed via the Cervical Screening

Administration Departments. In Scotland, direct referral is coordinated through SCCRS by sending appropriate electronic referral messages to the responsible NHS Board.

4.10 Histopathology reporting

Histopathology reporting of cervical biopsy samples is integral to the cervical screening programmes and there may be laboratories that do not undertake cervical cytology but, nevertheless, contribute through histopathology provision to the NHS CSPs. Guidelines for reporting of cervical histopathology samples are outlined in NHSCSP professional guidance - Histopathology reporting in cervical screening: an integrated approach (2nd edition) (2012)

<https://www.gov.uk/government/publications/cervical-screening-histopathology-reporting-handbook>, the RCPATH Dataset for histological reporting of cervical neoplasia (3rd edition) April 2011 <https://www.rcpath.org/resourceLibrary/g071cervicaldatasetapril11-pdf.html> and the RCPATH tissue pathways for gynaecological pathology, January 2015

<https://www.rcpath.org/resourceLibrary/tissue-pathways-for-gynaecological-pathology--january-2015-.html>

The lead consultant pathologist should ensure that there is a review by an appropriately experienced histopathologist of histological biopsies that are included in MDTMs and invasive cancer audit.

4.11 Multidisciplinary team meetings (MDTMs) within the CSPs

The role of any MDTM is to ensure that, when required, an individual case is discussed in the presence of a multidisciplinary team (MDT) of relevant specialists and a consensus management plan determined. It is considered best practice to hold MDTMs monthly and as a minimum every two months.¹⁶

The above helps shape individual patient management, but there is also a need for a meeting to discuss apparent discrepancies between cytology/histology/colposcopy and where patient

management will often also be decided. Correlation can only be undertaken by a person who can interpret and report both CSP cytology and histology or through close collaboration between reporting cytologist and histopathologist.

In general, a correlation type MDTM should discuss cases:

- Where there is a major discrepancy between cytology/HPV and histology/colposcopic findings (in practical terms, two or more grade of difference)
- Of glandular abnormality not confirmed on histology/colposcopy
- Where clinical management/follow up requires clarification
- Requiring a clinically indicated HPV test
- That are cervical cancer cases (if they have not been discussed at another MDT/Oncology meeting that includes cervical cytology and HBPC representation)
- That are of educational value.

The MDT may wish to include other categories of cases but there is no need to discuss routinely cases with:

- Only one grade of difference between cytology and histology or
- High grade cervical intraepithelial neoplasia (CIN) where the cytology was low grade but the HPV result was positive, in keeping with histological outcome.
- Previous biopsy confirmed CIN and a subsequent negative excisional sample
- CIN reaching to a margin (incomplete excision).

Key requirements of the MDTM are:

- Meetings must have an identified lead

- The core composition of the MDT should include colposcopists, histologists and cytologists as well as relevant nursing/laboratory staff or trainees who contribute or may benefit educationally by attending
- An attendance register should be maintained
- A history should be produced for each case detailing indications for discussion, the relevant medical and screening history, and any relevant colposcopy or histology, outcomes from the review of relevant previously reported cytology and histology samples and reason for discussion
- Sufficient time should be identified in the job plan/working time of whoever prepares and reviews the pathology element of the meeting. Cases should be identified sufficiently in advance to allow collection and review of cytological/histological material, particularly as this may involve material from several hospitals and such a review may involve undertaking extra work (e.g. levels on histological samples). Specific administrative time and support will also be required for the smooth running of the meeting
- All outcomes should be recorded, and a copy placed within the patient medical records. Where a report is revised, this should be recorded and supplementary report issued if required. Any amendment should be fed back to the original reporting pathologist/cytologist
- Split or multisite working may require the use of videoconferencing but at least some of the MDTMs should involve direct face to face contact to help maintain and develop professional working relationships among all members of the MDT.

5. CYTOLOGY LABORATORY INFORMATION TECHNOLOGY (IT)

5.1 Principles of IT systems used in cervical cytology laboratories

No laboratory should be providing a CSP service without suitable information technology (IT) that conforms to data requirements of NHS CSPs, information governance and data protection

requirements, and UKAS ISO 15189 standards. Whilst in some countries (e.g. Scotland) there is a fully bespoke integrated system across the whole of the CSP pathway, in other parts of the country several systems may be operating in an integrated, or semi-integrated, way. Laboratory information management systems (LIMS) are often not focused on cervical cytology and it is vital that senior cytology professionals have input into the choice of system. The system requirements for cervical cytology are very different from blood sciences. In the absence of any IT guidance in the CSPs in general, the following are points that must be considered in the implementation or upgrade to any existing IT system within the CSP:

- Systems must have flexibility built in by design to accommodate projected changes in the screening programme such as the facility to record HPV test results and vaccination status
- Systems must be capable of interfacing with other IT systems such as HPV vaccination database and national screening programme systems
- Systems should be capable of interfacing with other testing platforms such as imaging systems and HPV testing platforms
- Where possible, single systems incorporating all elements of the screening programme should be used. Interfaces with related systems can be difficult to design and may be a source of error or system failure
- Transfer of legacy data to a new LIMS is vitally important for call recall and management of women. Transfer of data between systems must be carefully tested and a minimum of 10% of transferred data must be checked before going live
- Only IT providers with a broad support and development base should be used to ensure continuing support and development
- Hardware and networking infrastructure must be robust and back-up facilities to remote servers must be used. All back up processes must be regularly tested and validated
- Data must be able to be retained for long as legislation/guidance requires (section 6)
- Paper free electronic requesting and reporting should be considered for all new systems.
- A clear audit trail of all data entry for every record must be easily accessible
- The security of data is paramount. Access to data must be controlled and hardware must be stable, regularly monitored and secure

- Patient identifiable data must only be stored on protected systems that meet all NHS requirements and data protection policies must be strictly adhered to
- Users must have access appropriate to their role
- Entry screens must contain fields for all data items on the request form in a logical sequence
- Where possible barcodes should be used instead of manual entry of data
- Rule based systems must be used to prevent entry of illogical or inappropriate decisions.
- Careful consideration must be given to section of data fields which may impact on performance monitoring reports.

5.2 Specific requirements of a cervical cytology IT system

Data entry and sample receipt

Entry of sample requests may be carried out by the sample taker in systems where paper free electronic requesting is established or by laboratory staff when the paper request is received in the laboratory. Both approaches require a minimum dataset to ensure unique identification of the patient. Where electronic requesting exists it is the responsibility of the sample taker to enter the patient demographics and clinical information directly into the IT system. These minimum data items must be mandatory fields in the system to ensure inadequately identified requests cannot be accepted. Minimum patient identifiers are surname, forename, date of birth and NHS or CHI number.

Where the information is transcribed from a request form, the system must record the identity of the staff entering the data in a manner that can be audited.

The request must include sufficient information to ensure the report is sent to the correct recipient. If this information is not present on the request form, data can be sourced from other systems such as the patient administration system or call recall.

Laboratory request numbers can be allocated and entered manually or generated by the IT system. The latter method is recommended to reduce risk of error.

The system must have the facility to print labels for all elements of the processing pathway including slide and vial labels if required

Reporting cervical cytology requests

Each microscopy workstation should have a personal computer linked to the IT system. The workstation must be ergonomically designed to minimise the risk of injury from repetitive strain.

All demographics and clinical information provided by the sample taker must be available to all staff entering an opinion on the sample

The system must permit easy access to the complete screening history, including cytology and histology results and previous management decisions. Ideally, HPV results and HPV vaccination status should also be available. A facility for patient notes to describe the background in complex cases or to provide additional information to explain management decisions should be available.

All individuals who gave an opinion on the sample must be recorded in the system. All reports must have a primary screener opinion and at least one other opinion entered. The system must use diagnostic codes as agreed by the national screening programme. The codes used must be easily updated to reflect changes in terminology.

The system should permit entry of HPV results either manually or through an interface with the HPV testing platform. Reporting of cytology and HPV test results on the same report should be supported.

Validation and authorisation of reports must be controlled by setting appropriate access levels which reflect the hierarchy of reporting described in section 4.

Internal quality control (IQC) of primary screening (rapid screening)

The rapid prescreen or rescreen result must be entered in a field that can be compared to the primary screener report. This comparison will be used to calculate sensitivity and specificity of primary screening.

~~The system must not permit the same individual to enter an IQC opinion and a final report.~~

Laboratories using rapid pre-screen for IQC must ensure that the system design “blinds” the primary screener to the pre-screen opinion.

Issuing reports

Reports must be computer generated and contain the following:

- Name of reporting laboratory
- Clear text report and management advice
- Name of individual who authorised final report
- Date of report
- Date of sample receipt or sample taken

Amended results

A clear audit trail must be retained of:

- The original report
- The amended result
- Explanation of why it was amended
- The name of the individual who reported and who authorised the amended report

Transfer of results to call/recall databases

In England and Wales the system must allow mapping of laboratory codes to standard national result codes for the NHSCSP. This must be an automatic function. Where transfer to call/recall databases is required this must be an electronic transfer.

Reports for monitoring programme performance

The system must be capable of generating routine reports for performance monitoring of all aspects of the programme. A pre-programmed list of routine reports should be readily available as

well as the ability to perform ad-hoc queries. If reports on call-recall, sample taker and colposcopy are required, consultation with these groups will ensure data requirements are captured.

Laboratory reports that must be available include the following:

- Laboratory workload by source
- Laboratory reporting profile
- Individual reporting profiles
- National statistical returns such as KC61
- Individual screener and overall laboratory sensitivity and specificity
- PPV, TPV and APV reports
- Turnaround time reports
- Sample taker inadequate rates

Failsafe

The system must have a function to identify women who have been referred for colposcopy and are subject to laboratory failsafe. Automated detection of women who have not had subsequent colposcopy and biopsy should be available. The system may be used to generate standard result letters (see section 7).

6. STORAGE AND RETENTION OF DATA AND SAMPLES

There should be a single point of reference to describe the records and materials to be retained, their storage location, how long they should be retained for and the source of the retention advice. This document should form part of the quality management system conforming to ISO 15189. There is national guidance on retention of some records such as request forms; local guidance should be sought regarding retention of staff, equipment and procurement records. In Scotland, a code of practice for document management can be found at <http://www.gov.scot/Publications/2012/01/10143104/0> .

The main UK general reference guidance for slide, request form and sample retention is in the joint RCPATH & IBMS publication - The retention and storage of pathological records and specimens (5th edition) (2015): <https://www.rcpath.org/resourceLibrary/the-retention-and-storage-of-pathological-records-and-specimens--5th-edition-.html> or <https://www.ibms.org/go/media/publications/professional-guidance>.

Current specific requirements pertinent to cervical cytology are presented in tabular form in appendix 3:

The BAC recommends that for data arising from the cervical cytology screening programme (request forms, reports, work logs, reporter opinions and correspondence) as much as possible should be stored electronically (see section 5) either by being entered directly into the laboratory/hospital IT system or by scanning and uploading of paper records. Records and information held within a computer system must be retrievable throughout their full period of retention (with consequent legacy requirements if IT systems change during that period), secure and auditable.

Retention of records and specimens for historical purposes beyond 30 years, other than in the case of authorised historical or teaching or research archives requires regulatory approval. Details can be found in the RCPATH/IBMS guidance <https://www.rcpath.org/resourceLibrary/the-retention-and-storage-of-pathological-records-and-specimens--5th-edition-.html>

6.1 Legacy data and materials

When laboratory services change, access to legacy data must be maintained. If the organisation providing cervical cytology changes, legacy data and material remain the responsibility of the original reporting organisation. Therefore, SLAs between organisations should be in place encompassing arrangements for review of previously reported material and for the provision of data to support failsafe, audit and data collection. Cervical cytology data must be retained in a form that facilitates future data collection and performance monitoring.

7. FAILSAFE

Comprehensive details on failsafe systems in the cervical screening programme and the responsibilities of all organisations involved in the programme, including laboratories, are given in NHSCSP professional guidance - Guidelines on failsafe actions for the follow-up of cervical cytology reports (2004) <https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe>. Cervical cytology laboratories are responsible for operating a failsafe system for women referred to colposcopy and the HBPC is responsible for ensuring that an effective failsafe system is in operation. In Scotland, the laboratory component of failsafe is incorporated in SCCRS and, in Wales, failsafe actions for the follow up of cytology reports are carried out by the Cervical Screening Administration Departments (CSADs).

8. QUALITY ASSURANCE

The following key principles should underpin quality assurance within cervical cytology laboratories:

- The lead medical consultant is responsible for the quality of the work including the establishment of monitoring procedures and maintenance of efficient working practices although some duties can be delegated to other consultants and biomedical scientist staff
- Departments should have a named quality manager in line with UKAS ISO 15189 requirements
- There must be systems in place to ensure appropriate quality checks are in place, undertaken and documented at all stages in the receipt, processing and reporting of cervical samples. Quality checks should be appropriately designed to be able to identify possible quality problems should they exist

- All potential quality issues that arise should be documented, fully investigated and action taken as required to address any shortfalls identified
- Individuals reporting cervical cytology must participate in an appropriate national gynaecological cytopathology external quality assessment (EQA) scheme and laboratories must participate in a relevant technical EQA scheme.

8.1 Performance monitoring

The lead consultant is generally responsible for performance monitoring of the laboratory as a whole and of individual staff although screening programmes (e.g. Wales) may specify alternative arrangements.

Programme Performance

A detailed description of performance monitoring criteria for evaluating cervical cytology is given in NHSCSP professional guidance - Achievable standards, benchmarks for reporting, and criteria for evaluating cervical cytopathology (3rd Edition) (2013)

<https://www.gov.uk/government/publications/cervical-screening-cytopathology-standards-and-evaluation-criteria>. Mandatory NHS CSP performance measures are inadequate/unsatisfactory rates, positive predictive value (PPV) and referral value, with the satisfactory performance range being the 5th-95th percentile. Other parameters that may be useful in determining laboratory performance are total predictive value, abnormal predictive value (APV) and PPV/APV plot diagram, mean CIN score and HPV positive rate for borderline/low-grade samples. It should be remembered that these measures are influenced by histology and colposcopy as well as cytology performance.

Laboratory sample turnaround times must be monitored as these are a component of national programme and performance targets (appendices 1B, 1D).

Individual performance monitoring

Screening sensitivities and specificities as determined from rapid screening and rates of abnormal results should be regularly monitored and ideally calculated on a 12 month rolling basis to ensure statistical validity.

All staff should receive performance profiles at least quarterly with the opportunity to discuss issues arising with a senior member of staff. There must be a mechanism in place for identifying and managing poor performance and instigating action.

In England, all laboratory results and an analysis of results are published in the NHS Cervical Screening Programme Statistical Bulletin (appendix 1J) and, similarly, annual statistical reports are produced by Cervical Screening Wales. In Scotland, laboratory profiles are produced quarterly by SCCRS and are formally reviewed at national laboratory quality assurance meetings. Screening programme statistics are published by NHS Scotland Information and Statistics Division (ISD).

8.2 Audit

Invasive Cancer Audits of the performance of the NHS CSP

The audit of invasive cancers of the cervix is an integral component of the understanding of cervical cancer development. All laboratories in England must participate in the audit of invasive cancers as described in NHSCSP professional guidance - Audit of invasive cervical cancers (2006) and Audit of invasive cervical cancers: protocol changes for 2012 to 2013 (2012)

<https://www.gov.uk/government/publications/cervical-screening-auditing-procedures>

The HBPC (or equivalent in Scotland, Wales & Northern Ireland) should be responsible for the audits and liaise with their regional QA service with regard to collation and statistical support.

Where cervical cytology and subsequent histology from the same patient are reported in different laboratories there should be a robust system to ensure transfer of information including a process for slide review.

In Wales, there is the Cervical Screening Wales Audit of Cervical Cancer (CSWACC) (appendix 1K). All cervical cancers diagnosed in Wales will be audited using the CSWACC protocol. Responsibility for the audit lies with the CSWACC coordinator. Arrangements for cross border requests for audit of slides or biopsies in Wales should be via the CSWACC coordinator.

In Scotland, each Health Board area undertakes comprehensive audit of invasive cervical cancers. A national audit protocol was implemented in 2015.

Review of cases requiring discussion the MDTM provides an opportunity for audit and education.

Other audits

Although not mandatory, the BAC recommends that laboratories undertake cytology review and additional audit of their practices for educational purposes and as part of external quality assurance.

8.3 External quality assessment (EQA) schemes

Participation in an appropriate EQA scheme is integral to assuring a quality cervical screening service. The BAC endorses the national requirements:

- Any individual reporting cervical cytology samples in the UK cervical screening programmes must participate in the appropriate national EQA scheme (appendix 1L). The national EQA schemes in England, professional and technical, are operated by the Screening Quality Assurance Service (Midlands & East). Northern Ireland laboratories participate in an English EQA scheme. Wales operated its own scheme in 2015; however, as numbers of participants have dropped, the intention is to explore inclusion of Welsh laboratories in the English Scheme. A similar EQA scheme operates in Scotland. (appendix 1L).

- All laboratories must participate in a relevant technical EQA scheme. Protocols and operating procedures for this are included in NHSCSP professional guidance - External quality assessment scheme for the evaluation of Papanicolaou staining in cervical cytology (2004) <https://www.gov.uk/government/publications/cervical-screening-pap-staining-quality-assessment> . In Wales the technical EQA scheme follows protocols laid down in the above document, but it is administered by Cervical Screening Wales. Details of protocol and procedures can be found in the Quality Manual on the CSW website_ <http://howis.wales.nhs.uk/screeningprofessionals/quality-manual> (NHS site). In Scotland, laboratories use the Hologic imager stain and are required to participate in the manufacturer's own EQA scheme.
- Laboratories providing HPV testing must formally participate, and show adequate performance, in an accredited external quality assurance scheme such as the UK NEQAS scheme for molecular detection of human papillomaviruses._ <http://www.ukneqas.org.uk/content/PageServer.asp?S=356723642&C=1252&Type=N&AID=16&SID=174>. Any performance issues should fully assessed and documented with any associated corrective actions recorded.

8.4 Quality assurance of cervical screening programmes

Quality assurance (QA) of screening programmes in England became the responsibility of Public Health England (PHE) from April 2013. Following external review of PHE QA in 2014, a single screening QA service (SQAS) was developed to provide a consistent and standardised approach to delivering QA across screening programmes in England¹⁷. It is delivered through four regional QA services (RQAS), quality assuring local screening services. Regional QA centres are based in each of the four NHS regions (North, Midlands and East, London, and South)

<https://www.gov.uk/government/publications/nhs-population-screening-regional-quality-assurance-teams-in-england> and are supported by a national QA team, responsible for coordinating operations and development of SQAS.

The RQAS will monitor how services meet standards and support improvement. This includes monitoring the quality of the programme using information gathered through data collection and validation, a process of questionnaires, regular multidisciplinary visits by quality assurance representatives and a variety of other means. They will identify practice outside the norm and coordinate investigation to assess if this represents an underlying problem; they also seek to identify and disseminate good practice.

Updated detailed cervical screening programme-specific guidance on how QA is undertaken will be provided with effect from April 2016. QA structures are in place in Scotland, Wales and Northern Ireland; appendix 1M provides links to current QA arrangements.

9. TRAINING AND EDUCATION

9.1 Provision and supervision of training

In a laboratory providing training in cervical cytology:

- The lead biomedical scientist is responsible for ensuring that trainee non-medical staff have access to a training officer and appropriate educational training opportunities.
- There should be a named consultant with responsibility for educating trainee medical staff and there must be a designated consultant mentor for those training to become a consultant biomedical scientist
- Consultant pathologists and consultant biomedical scientists may have a role in teaching and training of medical and non-medical staff
- A departmental training officer should oversee the training of individual trainees and liaise with the appropriate training centre. The BAC recommends that those appointed to training officer position should have a minimum of five years post qualification experience in cervical cytology. With respect to roles and responsibilities:
 - o They are responsible for the training of all nonmedical trainees including both trainee biomedical scientist and cytology screeners

- o A major role of the training officer is to act as an assessor for the NHSCSP training programme in cervical cytology. All training officers with a trainee must be registered with their local cytology training centre and the national centre. Information on this is available through local cytology training centres.
- o Training officers would usually be responsible for co-ordinating in-house and formal education of all non-medical staff members.
- o The commitment required to support trainee staff in training and assessment should not be underestimated and training officers should be allocated sufficient resources and time to enable them to undertake this task. A minimum of four hours per week should be allocated to those undertaking this role. This would need to be increased where assessors have more than one trainee.

Biomedical scientist and cytology screener training in cervical cytology

For all non-medical staff intending to participate in cervical screening, training is aimed at successful completion of the mandatory NHSCSP training in cervical cytology for all new staff reporting samples within the screening programmes within the UK. Recognising the different knowledge levels at entry, trainee biomedical scientist staff can complete the training in 18 months, whereas the training period for cytology screeners is 24 months.

Individuals appointed to trainee biomedical scientist posts can come from a range of graduate backgrounds:

- IBMS approved degrees for registration with the HCPC
- Degrees which require to be "topped-up" before they can be approved by the IBMS for HCPC registration
- Holders of co-terminus or integrated degrees
- IBMS approved Masters degrees

Candidates who apply for trainee biomedical scientist posts are encouraged to have their qualifications assessed by the IBMS. Completion of the mandatory NHSCSP training in cervical

cytology should be a priority for trainee biomedical scientist staff in cytology and this will need to be balanced with completion of the portfolio that leads to HCPC registration. The IBMS Specialist Diploma Portfolio is designed to accommodate candidates who are undertaking the mandatory NHSCSP training in cervical cytology <https://www.ibms.org/education/specialist-qualifications/specialist-diploma/>. Completion of this training is a mandatory component of the IBMS Specialist Diploma. Additional assignments to complete the IBMS Specialist Diploma are described within the portfolio.

Trainees should be considered supernumerary. Although, whilst in training, a trainee screener can perform other duties, it is important that the employing laboratory allows trainees sufficient time to undertake both the practical and theoretical elements of the NHSCSP training programme.

Post registration training

After registration and completion of the mandatory NHSCSP training in cervical cytology and the IBMS Specialist Diploma, biomedical scientists can follow a career pathway of post-registration training and advanced qualifications. The IBMS has developed a framework of qualifications <https://www.ibms.org/education/>. Professional qualification allows biomedical scientists to demonstrate their expertise and skills and aids career progression. Resources should be available to support staff to study towards qualifications within this framework and further education courses, for example, MSc in Biomedical Science.

Healthcare support worker training in cervical cytology

Training is in-house. It is recommended that the HCSW is provided with an individual log/training plan and competencies recorded. HCSWs should not undertake duties for which they have not been trained and competency assessed. The IBMS offers Certificate of Achievement qualifications for support staff, <https://www.ibms.org/education/certificate-of-achievement/>

Trainee histopathologists

Trainees in histopathology are required to undertake training and acquire knowledge of cervical screening and to gain practical experience in cervical cytology to the end of stage B (2-2.5 years of training and FRCPath part1 exam pass). Requirements are specified in the RCPATH curriculum for specialty training in histopathology and cytopathology as a subspecialty, June 2015 <https://www.rcpath.org/resourceLibrary/histopathology-curriculum--2015-.html>. Trainees who wish to obtain a qualification in cervical cytology allowing them to practice in the screening programmes must complete the Certificate in Higher Cervical Cytopathology Training in addition to the FRCPath part 2 qualification.

Sample taker training

Laboratories have a vital role to play in sample taker training. Laboratories are reminded that they may be the only site over a large area that sample takers have access to and therefore may be requested to be involved in direct provision of training for sample takers from many centres.

9.2 Continuing education/professional development (CPD)

All individuals practising in the NHS CSPs must participate in relevant continuing education schemes and activities (appendix 1N).

All medical consultants, including those employed on a part time or locum basis or in private practice, must maintain their licence to practice through revalidation by the General Medical Council (GMC). To do this, evidence of successful participation in appraisal and CPD relevant to their clinical practice will be required. More information on CPD is available from

<https://www.rcpath.org/profession/professional-standards/cpd.html> For Health and Care Professions Council (HCPC) registration all biomedical scientists are required to undertake CPD to maintain their registration and work as biomedical scientists. Evidence of appropriate CPD relevant to current or future practice must be available to the HCPC on request. Further information is available from <http://www.hcpc-uk.org.uk/registrants/cpd/>.

All non-medical staff involved in the reporting of cervical cytology must:

- Undertake three days of NHSCSP approved external update training in cytology every three years
- Undertake in-house training.

For screeners, the BAC supports the guidance in the previous BSCC CoP¹ that individuals should undertake four days of in-house training per annum. The BAC is not prescriptive about how these days are provided: training may comprise CPD type lectures, grand round talks, slide review meetings and other activities such as journal based learning. The laboratory training officer should ensure that all staff record these activities in individual portfolios. Where possible, slide review meetings must take place at least once per month and all staff should be encouraged to attend.

9.3 Training needs assessment

Assessment of cytology staff training needs should be a component of appraisal and be used to inform laboratories and cytology training centres of the training provision required to meet these needs.

9.4 Returning to work

All staff involved in the reporting of cervical cytology must undertake relevant formal documented in-house training if returning to cervical cytology after a period of absence of more than three months. If the absence exceeds six months then external training may be required. Guidance for staff on return to work training is available from cytology training centres.

9.5 Changing cytology preparation and reporting systems

All staff who wish to practise using a collection and preparation system (currently ThinPrep or SurePath) other than that in which they were trained must undertake appropriate conversion

training. This can only be delivered by an NHS approved cytology training centre. The national cervical cytology education and training committee (NCCETC) is reviewing its guidance on LBC conversion training and will offer recommendations to the CSPs as to conversion training requirements.

Image assisted screening

Primary screeners using imager assisted screening must have successfully completed formal training, validation and competency assessment in the use of the equipment provided by Hologic on site, and have demonstrated the required competencies in interpreting imager stained and directed slides.

APPENDIX 1

Four Nation and UK professional body links

A	Cervical screening programme websites
	<p>England:</p> <p>https://www.gov.uk/topic/population-screening-programmes/cervical</p> <p>Cervical cancer screening intranet (user registration required)</p> <p>https://www.csp.nhs.uk/logon.aspx</p> <p>Wales:</p> <p>http://www.cervicalscreeningwales.wales.nhs.uk/home</p> <p>http://howis.wales.nhs.uk/screeningprofessionals/home</p> <p>(NHS site)</p> <p>Scotland:</p> <p>http://www.nsd.scot.nhs.uk/services/screening/cervicalscreening/index.html</p> <p>http://www.sccrs.scot.nhs.uk/</p> <p>Northern Ireland:</p> <p>www.cancerscreening.hscni.net/1827.htm</p>
B	Service specifications
	<p>England:</p> <p>Service Specification 25</p> <p>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192976/25_Cervical_Screening_programme_service_specification_VARIATION_130415_new_template_-_NA.pdf</p> <p>Wales:</p> <p>Welsh Statutory Instruments: 2009 No. 2058 (W.177). NHS Wales The Public Health Wales National Health Service Trust (Establishment) Order 2009</p> <p>http://www.legislation.gov.uk/wsi/2009/2058/made</p> <p>National Service Framework for the Cervical Screening Programme in Wales, 1999. Welsh Office (no link)</p>
C	UK Standards and Professional Guidance
	<p>UKAS ISO 15189:</p> <p>https://www.ukas.com/services/accreditation-services/clinical-pathology-accreditation/</p> <p>IBMS professional guidance:</p>

	<p>https://www.ibms.org/go/media/publications/professional-guidance</p> <p>Royal College of Pathologists:</p> <p>Key performance indicators – proposals for implementation July 2013</p> <p>https://www.rcpath.org/profession/clinical-effectiveness/key-performance-indicators-kpi.html</p>
D	Career Framework
	<p>UK</p> <p>National job profiles for biomedical scientist and clinical support workers:</p> <p>http://www.nhs Careers.nhs.uk/explore-by-career/healthcare-science/pay-for-healthcare-science-staff</p> <p>http://www.nhsemployers.org/your-workforce/pay-and-reward/agenda-for-change</p> <p>Key elements of the career framework:</p> <p>http://www.skillsforhealth.org.uk/index.php?option=com_mtree&task=att_download&link_id=163&cf_id=24</p>
E	Turnaround times
	<p>England:</p> <p>14 day turnaround for 98% of women</p> <p>NHSCSP professional guidance - Cytology improvement guide: achieving a 14 day turnaround time in cytology (2009)</p> <p>https://www.gov.uk/government/publications/cervical-screening-cytology-improvement-guide</p> <p>Wales:</p> <p>Overall - 4 weeks from date sample taken to result received by the patient.</p> <p>Laboratory - 3 weeks from receipt of sample to issue of result.</p> <p>Scotland:</p> <p>A minimum of 80% of smears are reported to smear-takers within three weeks (15 working days) 100% of smears are reported to smear-takers within five weeks (25 working days)</p> <p>The turnaround time for 95% of samples is monitored</p>
F	Further information on ThinPrep and SurePath systems
	<p>SurePath:</p> <p>http://www.healthcare.sourcebioscience.com/cytology/</p>

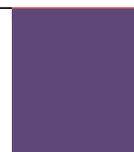


	<p>http://www.healthcare.sourcebioscience.com/cytology/documents-data-sheets/?rd=1 http://www.bd.com/en-us/offerings/capabilities/cervical-cancer-screening</p> <p>ThinPrep: http://www.hologic.com/products/clinical-diagnostics/assays-and-tests/thinprep-pap-test http://www.cytologystuff.com</p>
G	Approval of computer assisted screening
	<p>England, Wales: BD Focalpoint™ approved for no further review (NFR) https://www.gov.uk/government/publications/cervical-screening-bd-focalpoint-slide-profiler</p> <p>Scotland: ThinPrep® imager (Hologic™, Inc) system approved for primary screening http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/earlier_evidence_notes/evidence_note_34.aspx</p>
H	Terminology and reporting guidelines
	<p>UK: NHSCSP professional guidance - Achievable standards, benchmarks for reporting, and criteria for evaluating cervical cytopathology (3rd Edition) 2013 https://www.gov.uk/government/publications/cervical-screening-cytopathology-standards-and-evaluation-criteria</p> <p>Health Technology Assessment 2015, volume 19, issue 22: A study of cellular counting to determine minimum thresholds for adequacy for liquid-based cervical cytology using a survey and counting protocol http://www.journalslibrary.nihr.ac.uk/hta/volume-19/issue-22#abstract</p> <p>Scotland: Changes to Test Result Reporting Categories http://www.nsd.scot.nhs.uk/Documents/2013-02-26%20Test%20Result%20Reporting%20Categories.pdf</p> <p>Achievable standards, benchmarks for reporting and criteria for Evaluating cervical cytopathology (3rd edition) for SCSP http://www.nsd.scot.nhs.uk/Documents/ABCCervicalPublication.pdf</p> <p>SCCRS Nationally Agreed Procedures, 10 Assessment of adequacy of Cellularity of ThinPrep® Preparations. Lab QA Feb 2013</p>



	http://www.sccrs.scot.nhs.uk/Documents/2017-04-18%20nap%2014%20April%202017.pdf (nhs site)
I	Protocols and practice guidance for HPV testing
	<p>England:</p> <p>NHSCSP professional guidance - NHS Cervical Screening Programme Screening Protocol Algorithm for HPV Triage and TOC https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management NHSCSP good practice guide 3: HPV Triage and Test of Cure Implementation Guide https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215510/dh_128765.pdf NHSCSP professional guidance – HPV primary screening protocol algorithm (2015) https://www.gov.uk/government/publications/human-papillomavirus-hpv-primary-screening-protocol</p> <p>Wales:</p> <p>Cervical screening Wales quality manual http://howis.wales.nhs.uk/screeningprofessionals/hpv and http://howis.wales.nhs.uk/sitesplus/documents/1123/7H%20HPV.pdf (NHS site)</p> <p>Scotland:</p> <p>NSD/SCCRS Test of Cure standard operating procedure: http://www.sccrs.scot.nhs.uk/lab.html (NHS site)</p> <p>Northern Ireland:</p> <p>http://www.cancerscreening.hscni.net/2161.htm</p>
J	National statistics
	<p>England:</p> <p>https://www.gov.uk/government/statistics/cervical-screening-programme-2015-to-2016</p> <p>Wales:</p> <p>http://www.cervicalscreeningwales.wales.nhs.uk/statistical-reports</p> <p>Scotland:</p> <p>http://www.isdscotland.org/Health-Topics/Cancer/Cervical-Screening/</p> <p>Northern Ireland:</p> <p>http://www.cancerscreening.hscni.net/2162.htm#reports</p>
K	Invasive cancer audit
	<p>England:</p> <p>https://www.gov.uk/government/publications/cervical-screening-auditing-procedures-</p> <p>Wales:</p>

	http://howis.wales.nhs.uk/screeningprofessionals/quality-manual section 6AU audit(nhs site)
L	EQA schemes
	<p>England, Northern Ireland, Wales:</p> <p>NHSCSP professional guidance - External quality assessment scheme for gynaecological cytopathology (2013) https://www.gov.uk/government/publications/cervical-screening-gynaecological-cytopathology-quality-assessment For scheme participation queries email: PHE.csp-geqa-admin@nhs.net</p> <p>NHSCSP professional guidance - External quality assessment scheme for the evaluation of Papanicolaou staining in cervical cytology (2004) https://www.gov.uk/government/publications/cervical-screening-pap-staining-quality-assessment</p> <p>Scotland:</p> <p>http://www.nsd.scot.nhs.uk/services/screening/cervicalscreening/index.html</p>
M	Quality Assurance
	<p>England:</p> <p>Guidelines for quality assurance visits in the cervical screening programme (2008) https://www.gov.uk/government/publications/cervical-screening-quality-assurance-guidelines</p> <p>Wales:</p> <p>Cervical screening Wales , Quality manual http://howis.wales.nhs.uk/screeningprofessionals/quality-manual</p> <p>Scotland:</p> <p>http://www.nsd.scot.nhs.uk/services/screening/index.html</p>
N	CPD schemes
	<p>RCPATH:</p> <p>https://www.rcpath.org/professionals/professional-standards/cpd.html IBMS:</p> <p>https://www.ibms.org/cpd/cpd/ BAC CEC scheme:</p> <p>http://www.britishcytology.org.uk/</p>



APPENDIX 2

Hospital Based Programme Coordinator (HBPC)

The HBPC role was introduced into the NHSCSP in 1997 but has since expanded to encompass changes and additional responsibilities introduced in subsequent NHSCSP publications.

Accountability for the HBPC role must ultimately be to the Chief Executive of the Trust, or a nominated deputy at Trust Board level, independent of the post-holder's directorate. A formal annual appraisal which incorporates the HBPC role must be undertaken by someone in a position to be able to discuss all aspects of the role covered. The HBPC must have identified time in their job plan in order to fulfil the role, a minimum of 1 programmed activity or 1 half day per week. A minimum of 0.2 WTE administrative / secretarial support should be provided.

Core responsibilities of the HBPC role are:

- To oversee the coordination, quality and effectiveness of the cervical screening programme linked to the Trust
- To act as a link for screening commissioners, programme leads and the regional quality assurance service
- To attend regional QA HBPC meetings and report back to Trust colleagues
- To support the QA visit process to whichever aspects of the programme are provided by the Trust
- To ensure that all new cases of invasive cervical cancer diagnosed within their Trust are registered and audited in accordance with NHSCSP publication 28 (2006) - Audit of Invasive cervical cancers <https://www.gov.uk/government/publications/cervical-screening-auditing-procedures>
- To ensure that the cytology/histology laboratory and/or colposcopy department performs in accordance with NHSCSP guidelines
- To monitor standards of all aspects of the programme provided locally, including histology, cytology and colposcopy



- To produce an annual performance report for the Trust on the laboratory and colposcopy based aspects of the service
- To ensure there is timely collection and submission of QA and national data in cytology, histology and colposcopy
- To ensure that cervical screening turnaround times are monitored in relation to NHSCSP guidelines
- To monitor, in conjunction with the lead colposcopist, the colposcopy waiting times and DNA (did not attend) rates in relation to NHSCSP guidelines
- To ensure there is an effective failsafe system in place in accordance with NHSCSP good practice guidance -Failsafe actions for the follow-up of cervical cytology reports_ <https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe>
- To ensure that links are maintained between primary care, laboratory and colposcopy
- To report to Trust clinical governance committees on performance and significant issues related to the cervical screening programme within the Trust
- To be a member of any incident panel if a 'serious incident' relating to the cervical screening programme is identified.

This list not exhaustive and may be added to according to local programme arrangements and requirements.

APPENDIX 3

Storage and retention of cervical cytology data and samples

Item	Storage time
Request forms (HMR 101)	One month after the final report has been dispatched. If there is information on the form that is not recorded elsewhere in the patient's record, it should be retained for 30 years. Ideally, the full content of request forms should be scanned electronically, including handwritten opinions
Daily work logs	4 years from specimen receipt
Protocols of Standard Operating Procedures	At least 30 years for both current and outdated protocols
Correspondence on patients - paper and electronic	Preferably entered electronically and linked to the patient record. Paper correspondence should be electronically scanned and retained for 30 years
Telephoned information	Details of results phoned and communication relating to a sample should be logged within the patient's record (with date and identifying details of the informant).
IQC records/ error logs	8 years* minimum. Data relating to a sample error should ideally be recorded electronically in the patient's record
Slides	10 years minimum, longer if possible
EQA records	8 years*
LBC vials	Minimum 48 hours after final report has been issued, maximum in line with manufacturers' recommendations**
Equipment records	Lifetime of instrument plus 4 years
Invasive cancer audit records	Forwarded to QA service and retained nationally
Screeener and laboratory performance records	8 years*
Staff training records	Retained according to employing organisation's human resources policy

*Retention for 8 years ensures availability for review through two accreditation cycles

** Cytological samples in PreservCyt® Solution for ThinPrep Pap testing should be stored at between 15°C (59°F) and 30°C (86°F) for up to 6 weeks. Rules for storage of flammable liquids apply. Information is available from the ThinPrep Material Safety Data Sheets (MSDS): http://www.thinprep.com/hcp/professional_resources/downloadable_materials.html. SurePath vials which contain 24% ethanol can be stored at room temperature and do not require any special storage location such as a flammable cupboard. Samples can be stored at room temperature for up to 4 weeks or up to 6 months if stored in the fridge. Additional local storage requirements may apply.

As stated in NHSCSP professional guidance - Advice for cytopathology laboratories on the implementation of liquid based cytology for cervical screening, LBC implementation guide, No 2 (2004) <https://www.gov.uk/government/publications/cervical-screening-cytopathology-laboratory-guidelines> disposal of vials should be carried out according to locally agreed clinical waste disposal protocols or by an appointed agent who holds the necessary waste disposal licences.

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