

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

2022

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GLOSSARY OF ABBREVIATIONS

A&C	Administrative and Clerical
AFC	Agenda for Change
APV	Abnormal Predictive Value
ASD	Advanced Specialist Diploma
BAC	British Association for Cytopathology
BMS	Biomedical Scientist
BSCC	British Society for Cervical Cytopathology
BSCCP	British Society for Colposcopy and Cervical Pathology
CBMS	Consultant Biomedical Scientists
CCT	Certificate of Completion of Training
CHCCT	Certificate in Higher Cervical Cytopathology Training
CHI	Community Health Index
CIN	Cervical Intraepithelial Neoplasia
CoP	Code of Practice
COSHH	Control of Substances Hazardous to Health
CPCs	Clinical-Pathological Conferences
CPD	Continual Professional Development
CSADs	Cervical Screening Administration Departments
CSAS	Cervical Screening Administration Service
CSET	Cervical Screening Education and Training
CSP	Cervical Screening Programme
CSPL	Cervical Screening Provider Lead
CSW	Cervical Screening Wales
CSWACC	Cervical Screening Wales Audit of Cervical Cancer
CTC	Cytology Training Centre
EQA	External Quality Assessment
FRCPath	Fellow of the Royal College of Pathologists
GDPR	General Data Protection Regulation
GMC	General Medical Council
HCPC	Health and Care Professions Council
HCSW	Health Care Support Worker
HPV	Human Papilloma Virus
HPVPS	Human Papilloma Virus Primary Screening
HR	Human Resources
HSC PHA	Health & Social Care Public Health Agency
IBMS	Institute for Biomedical Science
ICE	Integrated Clinical Environment
IG	Information Governance
IQC	Internal Quality Control
ISO	International Standard for Organisation
IT	Information Technology
KPIs	Key Performance Indicators
LBC	Liquid-based Cytology
LIMS	Laboratory Information Management System

LLETZ	Large Loop Excision of the Transformation Zone
MDT	Multidisciplinary Team Meetings
MLA	Medical Laboratory Assistants
MSDS	Material Safety Data Sheets
NHSCSP	National Health Service Cervical Screening Programme
NHSEI	NHS England and NHS Improvement
NICA	National Invasive Cervical Cancer Audit
NICSP	Northern Ireland Cervical Screening Programme
PA	Programmed Activity
PHA	Public Health Agency
PINs	Personal Identification Numbers
PPV	Positive Predictive Value
QA	Quality Assurance
RCPATH	Royal College of Pathologists
RV	Referral Value
SCCRS	Scottish Cervical Call Recall System
SCSP	Scottish Cervical Screening Programme
SLA	Service Level Agreement
SOP	Standard Operating Procedures
SQAS	Screening Quality Assurance Service
STDB	Sample Taker Database
TATs	Turnaround Times
TPV	Total Predictive Value
UAT	User Acceptance Testing
UKAS	United Kingdom Accreditation Service
WTE	Whole Time Equivalent

FOREWORD

The UK NHS Cervical Screening Programmes (NHS CSPs) have been extremely successful in reducing both the incidence of and mortality from cervical cancer in women in the UK, by detecting pre-cancerous changes, which if left untreated may develop into cancer. Whilst the cervical screening laboratory is only one element of the programme it has a pivotal role, and previous versions of this code of practice (CoP)¹ for cytology laboratories, and its predecessor the British Society of Cervical Cytology (BSCC) CoP², have been instrumental in providing 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, wherever possible, captured and illustrated within this document.

The British Association for Cytopathology (BAC) code of practice was last updated five years ago, and while much of the guidance remains relevant, there have been such significant changes to both the technology and terminology used within the UK in recent years, that the BAC felt a significant update was required if the CoP was to remain relevant. It is intended that this version of the CoP will be more concise and easier to update, in order to reflect any future changes to the NHS CSPs. It is anticipated that regular reviews will be undertaken, with appropriate revisions, rather than completely rewriting the document on a periodic basis.

As in previous versions, the recommendations given in the CoP will be evidence-based wherever possible. Where hard scientific evidence is currently lacking, the recommendations will remain based on professional consensus opinion. Relevant publications from UK institutions such as the NHS Cervical Screening Programme in England (referred to in this CoP as the NHS CSP), Cervical Screening Wales (CSW), the Scottish Cervical Screening Programme (SCSP), the Royal College of Pathologists (RCPATH), the Institute of Biomedical Science (IBMS) and, of course, the BAC itself are referenced. Links to relevant documentation have been embedded within the CoP and any differences between the four UK nations are acknowledged and highlighted where appropriate.

Whilst this guidance is aimed specifically at laboratories providing cervical screening services for the NHS CSPs, it may prove valuable to other laboratories providing a diagnostic cytology service, 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 thank members of the BAC executive and representatives of the UK NHS CSPs for their comments and contribution to this latest edition.

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1. KEY PRINCIPLES

Primary screening for high-risk Human Papilloma Virus (HPV) was fully implemented in Wales in 2018, England in 2019, and Scotland in 2020; implementation in Northern Ireland is anticipated during 2022/23 (see appendix 1A).

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

- Cervical screening laboratories must deliver the service provided according to the specification required by the relevant Cervical Screening Programme (CSP), which includes ensuring a sufficient throughput of work to maintain expertise and meet quality assurance standards (see appendix 1B).
- There must be a named consultant (medical or biomedical scientist) in charge of cervical cytology to act as overall clinical lead for the service, and they must have a named deputy. Leads and deputies must be actively involved in the reporting of abnormal cervical cytology. In Wales and Scotland there are alternative, specified governance arrangements, appropriate to the national CSP service delivery structure (see appendix 1B).
- All services must ensure that there is adequate and appropriate medical consultant cover as outlined in the Royal College of Pathologists (RCPATH) best practice recommendation 'Clinical responsibility for cytology services, 2019'
<https://www.rcpath.org/uploads/assets/81dcaa1f-23db-48af-ae6f1f00b4727adf/BPR-Clinical-responsibility-for-cytology-services.pdf>
- There must be a named lead biomedical scientist (BMS) with one or more designated deputies, responsible for the day-to-day management of the cervical screening service.
- All laboratories must comply with the appropriate quality standards and accreditation requirements of their respective national CSP.
- All HPV testing, cytology screening and reporting for the NHS CSPs must take place in a laboratory where the whole repertoire is accredited to (International Standard for Organisation) ISO standard 15189 by the United Kingdom Accreditation Service (UKAS) (see appendix 1C).
- HPV testing and reporting must follow national protocols and all laboratories must have appropriate standard operating procedures (SOPs), training and governance systems in place (see appendix 1D).
- Only NHSCSP approved HPV testing platforms can be used:
<https://www.gov.uk/government/publications/cervical-screening-acceptable-hpv-tests>
- Cervical cytology slides cannot currently be screened in a non-laboratory setting and screening and reporting from home must not be performed. However, work is

currently being undertaken by the CSPs as to the feasibility of home reporting, which may be permissible in the future.

- The laboratory must 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' [Cervical screening: ergonomic working standards - GOV.UK \(www.gov.uk\)](http://www.gov.uk)
- Cervical cytology must be reported using current NHSCSP terminology as detailed in <https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services>

Note - in Scotland there are modifications to terminology and reporting guidance and in Wales there are additional codes and terminology in use (see appendix 1E).

- Laboratories should have robust links in place with histopathology, colposcopy, gynaecology, and other relevant clinical departments to allow for participation in invasive cancer audits, multidisciplinary team meetings (MDTs), and other relevant forums such as screening management groups. Service Level Agreements (SLA) may be required for some of these functions if provided by a different organisation.
- All staff must have an annual appraisal appropriate to their role.
- Laboratories must have a suitable Laboratory Information Management System (LIMS) to log, process, and report cervical screening samples and to export results to other relevant systems (e.g., call/recall office, primary care) as required by their national CSP, and to extract data for performance monitoring purposes.
- All staff must have access to and be able to attend suitable and relevant training to meet their educational needs as mandated by their national CSPs and for Continual Professional Development (CPD) as required by their professional bodies.
- There should be a clear procedure for staff to escalate concerns on any elements of the laboratory service including the option of confidentially contacting the appropriate external Quality Assurance (QA) group. Further guidance can be found at:

<https://inwo.spsso.org.uk/national-whistleblowing-standards>

<http://www.wales.nhs.uk/document/240483/info/>

<https://www.england.nhs.uk/ourwork/whistleblowing/freedom-to-speak-up-whistleblowing-policy-for-the-nhs/>

<https://www.health-ni.gov.uk/sites/default/files/publications/health/hsc-whistleblowing.PDF>

2. ORGANISATION AND STAFFING

2.1 Organisation

The move to HPV primary screening (HPVPS) and consolidation of cervical screening laboratories has resulted in a small number of large independent departments across the UK. As part of their business continuity/disaster planning, these laboratories should consider the potential need to partner with another cervical screening programme (CSP) laboratory for the continued delivery of its CSP service should it become necessary.

2.2 Staffing

Staff of differing grades will have different roles and responsibilities within the laboratory. There must be a clear accountability structure in place and all staff must have specific roles and responsibilities clearly defined in their job descriptions.

2.2.1 Professional requirements

There is clear guidance for required qualifications in accordance with relevant professional requirements:

- Medical doctors must be on the Specialist Register of the General Medical Council (GMC). 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 can be found at:
<https://www.rcpath.org/trainees/training/specialist-registration.html>
- Biomedical scientists must be registered with the Health and Care Professions Council (HCPC) <https://www.ibms.org/registration/hcpc-registration/> and <https://www.hcpc-uk.org/>
- All non-medical staff reporting cervical cytology in the NHSCSPs must have successfully completed the mandatory NHSCSP introductory training programme in cervical cytology (which includes attendance at an introductory course, follow up course, a preparatory course for a screening test and written question paper sat under examination conditions), or hold one of its predecessors - the City & Guilds Level 3 Diploma in Cervical Cytology, the NHSCSP Certificate in Cervical Cytology or the former IBMS or British Society for Cervical Cytopathology (BSCC) Certificate of Competence.

2.3 Roles and responsibilities

All staff working in NHSCSP laboratories must have knowledge of relevant local SOPs, Health & Safety policies and procedures, Control of Substances Hazardous to Health (COSHH) regulations, Information Governance (IG), 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 <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance>

All screening and reporting staff must:

- Participate in the national external quality assessment (EQA) scheme <https://www.gov.uk/government/publications/cervical-screening-gynaecological-cytopathology-external-quality-assessment/gynaecological-cytopathology-eqa-background-aims-and-governance>
- Undertake mandatory update training in line with NHSCSP requirements (see section 4).
- Undergo mandatory retraining after a prolonged period of absence (see section 4).
- Participate in continuing professional development (CPD) and educational activities as required for their role.

The BAC acknowledge that each laboratory will have different staffing/management structures within their service, depending on complexity and wider management structures, but each CSP laboratory should, where required, have the roles identified below.

The Agenda for Change (AFC) pay banding of a post will depend on the particular job profile and is for the employer to determine, but AFC bandings generally considered appropriate to the skills, knowledge and responsibilities of the roles below are included for guidance.

The IBMS position statement gives recommended bandings for scientists undertaking reporting within Cellular Pathology departments

<https://www.ibms.org/resources/documents/position-statement-role-requirements-and-banding-reporting/>

Appendix 1F gives links to information on national job profiles and career framework stages for biomedical scientists and cytology screeners.

2.3.1 Lead Consultant / Clinical Lead

The BAC endorses the RCPATH view that the lead consultant must be a suitably qualified person, either a pathologist or a consultant BMS:

<https://www.rcpath.org/uploads/assets/81dcaa1f-23db-48af-ae6f1f00b4727adf/BPR-Clinical-responsibility-for-cytology-services.pdf>

but acknowledge that current CSP guidance stipulates a Pathologist.

The clinical lead for the service has overall responsibility for all laboratory aspects of the cervical screening service, which includes establishment of procedures, maintenance of safe and effective working practices, performance monitoring in HPV testing and cytology reporting. Responsibility for delivering specific aspects of the service may be delegated to other members of the team but there must be clear accountability and reporting mechanisms in place. The role must be identified in the post-holder's job description/plan and is subject to annual appraisal *.

The lead consultant/clinical lead has overall responsibility for determining the strategic direction of the department, working closely with the senior management team, and is also responsible for handling complaints, claims and internal audit reviews. If the clinical lead is not a medically qualified pathologist, then a medical lead – who is a qualified consultant pathologist reporting within the CSP – should also be identified to offer clinical advice and support to the clinical lead.

There must be a named deputy for the lead consultant/clinical lead.

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

2.3.2 Consultant pathologist

A consultant pathologist working in the cervical screening must have experience and understanding of the multidisciplinary and multi-institutional nature of the programme. If a consultant pathologist is appointed to a post involving practice in one of the NHS CSPs but has not previously worked in that CSP or has had a gap in practice, appropriate training in the organisation and operation of the CSP must be arranged by the employing body/trust.

2.3.3 Consultant Biomedical Scientist (AFC band 8c or above)

Consultant biomedical scientist staff must hold the Advanced Specialist Diploma (ASD) in Cervical Cytology <https://www.ibms.org/education/advanced-qualifications/cervical-cytology/>

Although the BAC recognises that post holders may have a variety of different job titles, we endorse that those who hold the ASD and are actively reporting cervical cytology, should be called consultant biomedical scientists (CBMS).

The following roles and responsibilities are common to both consultant pathologist and CBMS staff. They will:

- Screen and report slides referred to them as potentially abnormal by cytology screeners and checkers, and recommend appropriate patient management
- Participate in MDTs and clinical-pathological conferences (CPCs) as described by national and local policy
- Participate in clinical audit and research

- Act as an intermediary between the laboratory and other clinical staff, providing diagnostic opinions and advice on appropriate cytological investigations, suggestions for further investigations and management of patients
- Educate and train medical and non-medical staff in cervical cytopathology

2.3.4 Lead Biomedical Scientist (AFC band 8a or above)

A single named lead biomedical scientist is responsible for the delivery of the CSP laboratory service. This should ideally be a senior manager within the department and not necessarily be held by a CBMS.

There should be a named deputy for the lead biomedical scientist.

The lead biomedical scientist will work collaboratively with the consultants, the wider laboratory management team and the organization's Cervical Screening Provider Lead (CSPL) to maintain and monitor a high-quality service.

2.3.5 Lead HPV Scientist (AFC band 8a or above)

A named lead scientist is responsible for the delivery of the HPV testing element of the service. This role may be held by a biomedical scientist in cytology or a virology scientist, depending on the model of service delivery, but there must be clear lines of accountability if not within cytology.

2.3.6 Clinical Lead Virologist for HPV testing

Whether employed directly by the CSP laboratories' host organisation or via a service level agreement (SLA) with another organisation, there must be an integral consultant virologist to provide clinical advice for the HPV testing element of the service.

2.3.7 Pathway Manager

Laboratory providers are expected to identify a pathway manager to ensure that inter-organisational systems are in place to maintain the quality of the whole screening pathway across the whole geographical footprint of the provider laboratory. This is detailed in the NHS public health functions Service Specification for cervical screening: https://www.england.nhs.uk/wp-content/uploads/2017/04/Service-Specification-No.25-Cervical_Screening.pdf

This document states that English CSP providers must have the following roles identified:

- CSPL (see appendix 2)
- Lead cytopathologist
- Lead histopathologist
- Lead laboratory biomedical scientist
- Lead colposcopist

- Lead colposcopy nurse
- Pathway manager – may be combined with the CSPL role or another senior role in the laboratory

Note - there is no requirement for the following roles in Scotland:

- CSPL
- Lead colposcopy nurse
- Pathway manager

And in Wales, the roles of CSPL, pathway manager, lead histopathologist, lead colposcopist and lead colposcopy nurse sit within CSW and are not the responsibility of the laboratory.

2.3.8 Supervisory biomedical scientists (AFC band 7 or above)

Supervisory biomedical scientists are responsible for the day-to-day management of the service, supervision and training of primary screeners and support staff, and other duties such as Human Resource (HR) and quality management, liaison with primary care and other services users and suppliers.

Supervisory biomedical scientists may also be cytology checkers. The BAC recommends that 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 role of a checker there should be a period of documented in-house training or shadow reporting, audit and review to ensure competency.

2.3.9 Biomedical scientists (AFC band 5 and 6)

Biomedical scientist staff can participate in the primary and rapid re-screening of cervical cytology slides, including double screening of samples examined by trainees. Additional duties may also include supervision of support staff, monitoring of quality of preparations, HPV testing, non-gynaecological cytology and quality control.

2.3.10 Cytology screeners (AFC band 4)

Cytology screeners are non-biomedical scientist staff who are trained to undertake initial screening and rapid review of cervical cytology slides; they can report samples screened as negative or inadequate/unsatisfactory, but all potentially abnormal cases must be passed on to a checker or consultant.

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

There is no current route for professional regulation of cytology screeners post qualification.

2.3.11 Health Care Support Worker (HCSW) (AFC Bands 2-3)

HCSWs, often called medical laboratory assistants (MLAs) 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 4). HCSWs should undertake update training and competency assessments appropriate to their roles.

2.3.12 Administrative and clerical (A&C) staff (AFC Bands 2-4)

The large numbers of specimens received by cervical screening laboratories requires the support of efficient A&C staff, but numbers will vary depending on the use of electronic requesting and whether paperless reporting is in place. Duties may include data entry, entering of results, label printing, report printing, collating and dispatch of results and letters, archiving and telephone enquiries.

Other duties appropriate for A&C staff within cervical screening laboratories are:

- Management of direct referrals sent from the laboratory to colposcopy units
- Sending of electronic result files to call & recall
- Preparation of paperwork and slides for review at colposcopy MDTs
- Administration of the regional sample taker database (STDB) where this is held by the laboratory and may include allocation of sample taker codes/Personal Identification Numbers (PINs)
- Sending of electronic result files to the call & recall agency and dealing with consequent queries or issues regarding the transfer of results

2.3.13 Locum (agency) staff

When locum /agency staff are employed to screen/report cytology slides in the NHSCSPs 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 appropriate to role (see 2.2.1)
- Certificates of liquid-based cytology (LBC) conversion training as appropriate
- Evidence of current gynaecological cytology External Quality Assurance scheme participation
- Evidence of relevant professional body registration where required

On commencing screening/reporting, all slides should be double screened by senior staff for a minimum of one week. If no substandard performance³ 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 3).

2.4 Limitations of practice

- Cytology screeners and biomedical scientists not holding the ASD must not sign out abnormal cervical cytology reports
- Only consultants can report abnormal cytology samples
- Trainee screeners (biomedical scientist or cytology screener) must not report out any cervical screening reports or participate in routine rapid pre-screening or rescreening until qualified
- HCSWs must not screen cytology samples
- Checkers may overrule the opinion of a primary screener, although any cases referred to them as high grade dyskaryosis or borderline changes in endocervical cells but considered to be negative / inadequate by the checker must be passed to either a second checker or consultant for reporting.
- Cases referred to a consultant as high grade dyskaryosis or borderline changes in endocervical cells by a checker, but considered to be negative by the consultant, must be referred for further opinion by another consultant(s) before consensus reporting³.

3. STAFFING LEVELS AND WORKLOAD

NHS England and NHS Improvement (NHSEI) requires a cervical screening laboratory to report a minimum of 35,000 cytology slides per annum (Service specification 25, appendix 1B), although this is currently under review. No minimum workload is specified for Scotland or Wales.

3.1 Consultants

Laboratories that employ consultant BMS staff also require a minimum of two medical consultants who actively practise cervical cytology in addition to the consultant biomedical scientists <https://www.rcpath.org/uploads/assets/81dcaa1f-23db-48af-ae6f1f00b4727adf/BPR-Clinical-responsibility-for-cytology-services.pdf>

The BAC endorses the recommendation in previous versions of the CoP¹ that to maintain a consultant's diagnostic skill in cervical cytopathology, their minimum yearly workload must be not less than one programmed activity (PA) in cervical cytology and a consultant should report or review a minimum of 750 cases per year. This can include slides reviewed for audit and correlation. The RCPATH has previously published recommendations on medical consultant workload and this guidance is currently being updated and should be available later in 2022.

These guidelines are currently being updated and are expected to be available during 2022.

Under normal circumstances, a medical consultant should be present in the laboratory every working day. When this is not possible, arrangements must be made to ensure that all staff have access to medical support, particularly when these absences extend over several days.

All consultants should have PAs, or the equivalent time, allocated for laboratory and screening programme management, audit, teaching, research, and CPD.

3.2 Supervisory biomedical scientists

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. The BAC endorses a previous recommendation that a supervisory biomedical scientist may supervise up to four other members of staff¹.

3.3 Checkers

Checkers are biomedical scientists with significant experience that have undergone training and competency assessment for this role. The use of checkers is specified in the HPVPS contract and experience from many laboratories is that they have an important role in maintaining specificity of results. They can report slides as negative which have been queried as possibly abnormal by the primary screeners. Slides referred to a checker as high

grade dyskaryosis or borderline changes in endocervical cells which the first checker considers to be negative must be passed to a second checker for an opinion or consultant for reporting.

Checking requires additional interpretive skills to routine primary screening and the BAC recommends that a checker should see at least 750 referred cases per annum. If participating in initial slide screening in addition to checking, then it is recommended that the checker should also primary screen a minimum of 1000 slides per annum. (These figures may change when more data about laboratory practice with HPVPS is available and is currently under review).

There is 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 the five hours of microscopy recommended for primary screening (see below) and, provided that regular breaks are taken and appropriate IQC (such as double screening of slides considered high grade by a primary screener but negative by the first checker) is undertaken, it is acceptable for checkers to undertake microscopy beyond this time.

The BAC recommends that checkers' total microscopy duties do not extend beyond a maximum of eight working hours (including breaks) in a working day and that laboratories should continually monitor the workload and effectiveness of checking staff. Reporting profiles for all checkers must be provided on a regular basis to audit the negative reporting rates and abnormal referral rates of individual checkers. Any outliers should be investigated and appropriate action taken as required (see section 10.3.3).

3.4 Biomedical scientist /cytology screeners

Current performance monitoring measures state that biomedical scientist primary screeners and cytology screeners must screen a minimum of 3000 slides per annum, although this is also under review. With respect to workload, the BAC endorses the rates of working recommended in NHSCSP publication 14⁴ and subsequent updated national guidance [Cervical screening: laboratory HPV testing and cytology services - GOV.UK \(www.gov.uk\)](http://www.gov.uk) Provided that staff satisfy NHSCSP quality standards and are not exceeding the hours of screening stated, then the BAC can make no evidence-based recommendation regarding a maximum number of slides per annum.

Productivity/screening rates are difficult to evidence as members of staff may 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 individual productivity/screening rates.

The BAC recommends that screeners can safely undertake primary and rapid screening for up to five hours in any working day⁴. No individual should spend more than this on routine

primary or rapid screening and no cytology screener should work more than six days in any single week in this role.

If BMS staff participate in other duties such as pre-screening of non-cervical cytology 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 cytology screeners in training:

- A trainee screener should not be employed on a less than 0.5 Whole Time Equivalent (WTE) contract
- For workload calculations all trainees must be considered supernumerary

3.5 Workflow management

For a variety of reasons (e.g. sickness leave, maternity leave, increased / fluctuating workloads), backlogs can develop at any stage in the screening process. To achieve the required programme turnaround times (TATs) (appendix 1G) staff may be required to undertake additional sessions to reduce / eradicate any backlog. Extra hours must be agreed in advance with the laboratory management, must comply with usual laboratory practice and must not cause health or quality issues for the service or staff involved. Overtime should not be used on a regular or permanent basis, and no more than 6 consecutive days should be worked in any single week by any individual.

3.6 Cytology screening backlogs

If cytology slides need to be outsourced to another laboratory with screening capacity, then an appropriate SLA and SOP must be in place, in addition to the transport, tracking and audit arrangements as outlined in section 5.

The outsource laboratory must keep accurate records of samples screened, including screener and reporter opinions and screener identification, in order to produce accurate laboratory and screener performance data. The originating laboratory should provide details of outcomes to the outsource laboratory to ensure that screener performance can be monitored. The outsource laboratory will need to highlight to the originating laboratory if any substandard performance is subsequently identified.

3.7 Remote working

The CSPs do not currently permit off-site screening or reporting of cervical cytology in any capacity or at any staff grade, although this is currently under review by NHSEI.

Some aspects of cervical screening duties such as audit, policy/SOP development and data management can be undertaken off-site as part of an overall cervical screening role as long as the person and systems used comply with the relevant data, information governance (IG), information technology (IT) and security requirements.

In Wales clinical reporting staff work as part of a formal pathology network, with the majority working off site from the screening laboratory, but within a laboratory setting.

4. TRAINING AND EDUCATION

Provision and supervision of training – key principles:

- The lead BMS is responsible for ensuring that all trainee non-medical staff have access to a training officer and assessor and are given appropriate educational training opportunities
- A training officer / enrolled assessor should oversee the training of individual trainees and liaise with an appropriate NHSCSP approved cytology training centre (CTC).
- There should be a named consultant within the cervical screening laboratory with responsibility for the education of trainee medical staff
- There must be a designated consultant mentor for those training to become a consultant BMS
- All consultants should participate in the teaching and training of both medical and non-medical staff

4.1 Laboratory Training Officer

The BAC recommends that any biomedical scientist appointed to a training officer position should have a minimum of five years post qualification experience in cervical cytology. With respect to roles and responsibilities, training officers:

- Are responsible for the training of all non-medical trainees including both trainee biomedical scientist and cytology screeners
- May act as an assessor for the NHSCSP training programme in cervical cytology or may delegate this responsibility to other appropriate staff.
- All training officers with a trainee must be enrolled with an approved regional CTC and the Cervical Screening Education and Training (CSET) administration centre.
- Are responsible for co-ordinating all in-house and formal education of all non-medical staff members
- Must be allocated sufficient resources and time to enable them to undertake this role. A minimum of four hours per week should be allocated to those undertaking this role and this will need to be increased where assessors have more than one trainee. Additional assessors may be trained if required.
- Information about this role is available from any regional CTC

4.2 Biomedical scientist and cytology screener training in cervical cytology

All non-medical staff must be enrolled and successfully complete the NHSCSP training programme in cervical cytology. Biomedical scientist staff can complete the training in 18 months, whereas the training period for cytology screeners is 24 months, reflecting the different knowledge levels at entry.

Biomedical scientists undertaking cervical cytology training 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
- Overseas qualifications - existing guidance on training requirements for non-medical staff working in the NHSCSP (NHSCSP 12, 2000)⁵ is currently being updated and will include the eligibility requirements for graduates from overseas.

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 and must not report live cases until they have been successful in the NHSCSP training examination. Whilst in training, a trainee screener can perform other duties, but it is important that the employing laboratory allows trainees sufficient time to undertake both the practical and theoretical elements of the NHSCSP training programme.

4.3 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 qualifications allow biomedical scientists to demonstrate their expertise and skills and aid career progression. Resources should be available to support staff to study towards qualifications within this framework and other further education courses such as a MSc in Biomedical Science.

4.4 Healthcare support worker (HCSW) training in cervical cytology

Training is in-house with a recommendation 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/>.

4.5 Trainee histopathologists

During the integrated cellular pathology phase of training (i.e. the first 2½ years of training and FRCPath part 1 exam pass), trainees in histopathology will undertake training to acquire knowledge of cervical screening and to gain practical experience in cervical cytology.

Generic capabilities in practice are outlined in the RCPATH histopathology curriculum 2021 <https://www.rcpath.org/uploads/assets/cec0e11a-45bc-4cf6-99479c1108ea63bf/676ec803-c849-450a-9a8db0db387ec2aa/Histopathology-2021-curriculum.pdf> and specific aspects of learning in cervical cytology are detailed in appendix A: Syllabus for ICPT and Histopathology Higher Specialty Training <https://www.rcpath.org/uploads/assets/2ffa6a0f-3bdf-4fdc-8d373223c4ef01c2/Histopathology-2021-Syllabus.pdf>.

Trainees who wish to obtain a qualification in cervical cytology allowing them to practice in the cervical screening programmes must complete the CHCCT in addition to the FRCPath part 2 qualification <https://www.rcpath.org/trainees/examinations/examinations-by-specialty/histopathology.html>.

4.6 Sample taker training

Laboratories have a vital role to play in sample taker training may be the only site within a large geographical 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. As a minimum, laboratories should provide a physical or virtual laboratory tour and a laboratory presentation to support accredited sample taker training programmes, as described in the NHSCSP programme guidance on the training of new cervical sample takers <https://www.gov.uk/government/publications/cervical-screening-cervical-sample-taker-training>

4.7 Colposcopy Trainees

Trainee medical colposcopists undergoing the British Society for Colposcopy and Cervical Pathology (BSCCP) training programme, leading to certification as an accredited colposcopist, are required to spend at least one session each in a cytology and histology laboratory to become familiar with the workings of these departments. Nurse trainees must dedicate 3 sessions each to cytopathology and histopathology, as detailed in the BSCCP guidance notes:

https://www.bsccp.org.uk/assets/file/uploads/resources/Colposcopy_Logbook.pdf.

4.8 Continuing professional development (CPD)

All individuals screening and reporting in the NHS CSPs must participate in relevant CPD schemes and activities (appendix 1I).

All medical consultants undertaking cervical cytology should provide evidence of relevant CPD participation at their appraisal. More information on CPD is available from <https://www.rcpath.org/profession/professional-standards/cpd.html>.

For HCPC registration all biomedical scientists are required to undertake CPD to maintain their registration and work as a biomedical scientist. Evidence of CPD relevant to their cervical cytology practice must be made available to the HCPC on request. Further information is available from <https://www.hcpc-uk.org/cpd/>.

4.9 NHSCSP update training

All non-medical staff involved in the screening and reporting of cervical cytology must undertake three days of NHSCSP approved external update training in cervical cytology every three years.

For cytology screeners, the BAC recommends that individuals should also undertake a minimum of four days of in-house training per annum. The BAC is not prescriptive about how these days are provided and 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 their individual portfolios. Slide review meetings should take place at least once per month and all staff should be encouraged to participate.

4.10 Training needs assessment

Assessment of cytology staff training needs should be an essential component of appraisal and be used to inform both laboratories and CTCs of the training provision required to meet these needs.

4.11 Returning to work

All staff who screen or report 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 is required from an NHSCSP approved CTC. Guidance for staff on return-to-work training is available from CTCs and should be tailored to the individual's needs.

4.12 Changing LBC technology / systems

All staff who wish to practise using an LBC collection and preparation system other than that in which they were trained (ThinPrep® or SurePath™) must undertake appropriate conversion training. This can only be delivered by an NHSCSP approved CTC and courses must be in line with national guidance:

<https://www.gov.uk/government/publications/cervical-screening-training-to-use-a-new-cytology-system/nhs-cervical-screening-programme-csp-liquid-based-cytology-system-conversion-training>.

4.13 Image assisted screening

Cytology screeners using imager assisted screening (currently only approved in Scotland) must have successfully completed formal training, validation and competency assessment in the use of the equipment provided by the manufacturer (Hologic®) on site, and have demonstrated the required competencies in interpreting imager stained and directed slides.

5. SAMPLE TRANSPORT, ACCEPTANCE AND PROCESSING

The laboratory must have a SOP to cover sample transport from source to laboratory, and, where appropriate, SLAs must be in place with partner providers. All laboratory transport, reception and processing must be in accordance with UKAS accreditation standard ISO 15189 <https://www.ukas.com/accreditation/standards/medical-laboratory-accreditation/> and <https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en> and must meet the contractual requirements for compliance with national turnaround targets (appendices 1B, 1G).

All 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.

There are currently two NHSCSP approved liquid-based cytology (LBC) technologies:

- Hologic ThinPrep® system (ThinPrep) <http://www.hologic.com/products/clinical-diagnostics/assays-and-tests/thinprep-pap-test>
- BD SurePath™ and BD PrepStain™ system (SurePath) <https://www.bd.com/en-us/offering/capabilities/cervical-cancer-screening/cervical-sample-collection/surepath-liquid-based-pap-test>

Note: only the Hologic® LBC technology is currently in use in the UK.

5.1 Transport of samples to the laboratory

Cervical screening samples are either transported from source directly to the screening laboratory or via other local laboratories. The objective is speedy, safe, and secure end-to-end transit conforming to ISO standard 15189.

5.1.1 Samples should be despatched from sample taker locations on the day of sample collection or, where this is not possible, the next working day

5.1.2 Courier/NHS staff must be made aware of the importance of the confidential nature of the samples being transported

5.1.3 Samples awaiting transport and when in transit should be stored at ambient temperature; there is no need to refrigerate LBC samples (see section 8)

5.1.4 Appropriate packaging such as self-seal specimen bags must be used for individual samples; for bulk transport between laboratories the specimen bags/boxes must be fit for purpose - sealable to avoid leakage, cross-contamination, and breakage, and must be clearly labelled with the delivery address

5.1.5 There must be equipment and procedures in place to deal with spillage and leakage at any point during the cervical sample transport pathways

5.1.6 Cervical screening samples may be sent by post if packaged according to Royal Mail requirements <https://www.royalmail.com/business/shipping/parcels/safebox>

5.1.7 To comply with the Data Protection Act 2018, which implemented General Data Protection Regulation (GDPR) in the UK, patient identifiable data must not be written on the outside of any transport packaging. There must, however, be appropriate labelling in line with the postal regulations specified above.

5.2 Sending slides out of the laboratory

5.2.1 There must be a SOP to cover the process for slides being sent out from a laboratory, such as for second opinions or for external reviews

5.2.2 Slides should be securely packaged, labelled as 'Fragile – glass slides', and sent using Royal Mail Special delivery (this tracks the package whereas recorded delivery does not).

Note that in Wales, only the dedicated CSW transport service is used to send slides to other sites

5.2.3 All slides sent out of the laboratory must be logged onto the LIMS as such by the sending laboratory, and their safe receipt must be confirmed by the recipient in compliance with NHS information and governance regulations and the ISO 15189 standard

5.2.4 When slides are returned to the originating laboratory they must be logged onto the system as having been returned

5.2.5 Periodic checks of the system should be made to identify any slides sent away but not returned, and any missing slides must be chased.

5.3 Receipt of samples in the screening laboratory

The main objective is to ensure prompt reception, booking in and accuracy of sample identity.

- Paper request forms received must be date-stamped promptly and an electronic record created within 24 hours, in accordance with contractual requirements
- Electronic requests received must be accessioned promptly and within 24 hours of sample receipt
- Sample vials and their corresponding requests must be checked for correlation prior to acceptance by the laboratory.

Cervical sample acceptance must be in line with standards outlined in the relevant CSPs guidance <https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories/guidance-for-acceptance-of-cervical-screening-samples-in-laboratories-and-pathways-roles-and-responsibilities>.

The laboratory must have a cervical sample acceptance policy conforming to ISO standard 15189 which outlines acceptable minimum patient identifiers; the SOP must also provide guidance on dealing with rejected samples or those samples accepted with minor discrepancies. Appropriate error logging and audit trails must be in place.

5.3.1 There must be a minimum of three unique patient identifiers on both sample and test request:

- Full name – surname, forename
- Date of Birth
- Unique patient number (e.g. NHS number, Community Health Index (CHI) number in Scotland, conforming to both CSP and IBMS requirements <https://www.ibms.org/go/media/publications/professional-guidance>)

5.3.2 Where there is a major discrepancy/mismatch, multiple minor discrepancies or the vial is out of date, the vial should be destroyed. It should NOT be returned to the sender. A record and audit trail of discarded vials must be kept, and a report issued to say that the sample has been rejected, stating the reason for the rejection

5.3.3 Minor discrepancies may be dealt with by telephone or by referring to Open Exeter/ the Scottish Cervical Call Recall System (SCCRS) to obtain the required clarification/confirmation; details must be clearly documented on the report and details recorded in the laboratory error log

5.3.4 It is acceptable to reject any samples received which do not satisfy NHSCSP screening intervals/age-related invitations in accordance with local commissioning agreements

5.3.5 Where electronic requests are used (such as Integrated Clinical Environment (ICE) requesting or via SCCRS in Scotland) and a sample arrives without a legible barcoded label, the sender should be contacted to inform them that there is one unlabelled sample which cannot be processed. The sample must be destroyed, and a record and audit trail must be kept

5.3.6 Wherever possible, data entry staff should use the unique patient NHS or CHI number as the preferred method of searching/creating an electronic entry, thereby avoiding multiple patient entries on LIMS and potential screening incidents arising from duplicate records.

5.4 Sample preparation

5.4.1 HPV Processing

- The screening programmes in England, Scotland and Wales have now fully implemented HPV primary screening (HPVPS) so all samples must first have an HPV test in accordance with CSP guidance

<https://www.gov.uk/government/publications/cervical-screening-laboratory-testing-for-human-papillomavirus>

- Only HPV testing platforms/assays that have been approved by the NHSCSPs should be used, and in accordance with the manufacturers' guidelines
<https://www.gov.uk/government/publications/cervical-screening-acceptable-hpv-tests>
- Laboratories must participate in an EQA scheme for HPV detection – see section 10.

5.4.2 Cytology Processing

All samples testing positive for HPV must have a LBC slide prepared according to CSP and manufacturers' published protocols.

- LBC slides must be stained using a Papanicolaou based method
- Staining quality must be checked and recorded daily and after every new batch of stains, by appropriately trained screening staff, to ensure consistency and reliability for either human or machine screening
- Any issues arising from the stain check must be investigated promptly, and once resolved, the staining quality must be rechecked
- Laboratories must participate in the national EQA scheme for the preparation and staining of LBC samples – see Section 10.

6. ASSESSMENT AND REPORTING OF CERVICAL SCREENING SAMPLES

HPVPS is now performed on all cervical screening samples* and cytology is used as a triage test in women where the HPV test is positive.

**Except in Northern Ireland, where HPV primary screening implementation is planned for 2022/23. Until then, cytology primary screening will continue with HPV testing for triage of low-grade cytology samples and test of cure in women who have had treatment for histologically proven Cervical Intraepithelial Neoplasia (CIN), and so the previous version of the BAC CoP (2017) should be referred to.*

6.1 HPV test results

Samples which have a negative or unavailable HPV test result must be reported in accordance with programme guidelines

<https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-and-cytology-services-in-the-nhs-cervical-screening-programme>

- Where a routine screening test is HPV negative (infection code 0) the individual will be returned to routine recall
- The BAC supports the use of automatic authorisation of HPV negative test results on routine screening samples, to improve efficiency and reduce errors compared with manual systems
- Where a routine screening test is HPV unavailable (infection code U) the test should be repeated in no less than three months
- Samples which test positive for HPV (infection code 9) must have an LBC slide made for cytology screening.

In Scotland, cytological assessment is performed as a co-test on samples from women on certain follow up pathways, regardless of the HPV result. Algorithms are detailed in SCCRS nationally agreed procedures [Laboratory – SCCRS \(scot.nhs.uk\)](https://www.scot.nhs.uk/scotnhs/services/cervical-screening/laboratory-sccrs)

The rest of this section of the CoP concentrates on the screening and reporting of LBC slides.

6.2 Primary cytology screening

Cytology slide 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 guidance [Cervical screening: laboratory HPV testing and cytology services - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services)

6.2.1 Manual Primary screening - all the cellular material on the slide must be examined. Screening should be carried out using a 10x microscope objective lens. Cells of interest must be examined at higher magnification. Whatever screening

technique is used, individual screeners must overlap fields by at least 30%⁶. Potentially abnormal cells identified by the primary screener should be marked for checking according to agreed laboratory protocols

6.2.2 Computer assisted primary screening - only Scotland currently uses computer assisted primary screening⁷.

Primary screeners must adhere to the screening protocol as described by the manufacturers. Further information about the ThinPrep Imaging System® can be found at <http://www.hologic.ca/products/clinical-diagnostics-and-blood-screening/instrument-systems/thinprep-imaging-system>

6.3 Criteria for adequacy

Current NHSCSP guidance states that laboratories must follow the published criteria for the assessing the adequacy of LBC slide preparations, which is a minimum of 5,000 cells for ThinPrep® and 15,000 cells for SurePath™

https://www.ncbi.nlm.nih.gov/books/NBK279881/#_ncbi_dlg_citbx_NBK279881

The BAC recommends that laboratories do not have limits lower than these, given the evidence that sensitivity for detection of abnormal cells is reduced in low cellularity samples^{8,9}.

A cell count should only need to be performed if the adequacy of a preparation is uncertain, as detailed in CSP guidance <https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-and-cytology-services-in-the-nhs-cervical-screening-programme>.

The Scottish CSP recommendation for adequacy is 10,000 cells (Laboratory Quality Assurance group 2013, 2015) and there is a national agreed procedure for estimating cellularity <http://www.sccrs.scot.nhs.uk/wp-content/uploads/2021/11/NAPs-revised-version-July-2020.docx>

Under no circumstances should LBC samples be reported as inadequate if they contain any evidence of a cytological abnormality.

Additional points with respect to sample adequacy:

- A sample must be reported as inadequate if the sample taker has not completely visualised the cervix, if the sample has been taken with a sampling device not approved by the NHSCSP³, or with an approved sampling device not used appropriately
- A sample may be deemed inadequate for morphological reasons such as the epithelial cells being obscured by mucus, blood, non-recommended lubricant or where the cells show marked cytolysis. Samples containing so much blood or mucus

that the cell count is below the recommended minimum threshold should be reprocessed and treated, according to the LBC manufacturers guidelines, as this may produce an adequate sample for cytological assessment

- Laboratories should monitor both their overall and individual screeners' inadequate rates and ensure that these remain within expected upper and lower ranges, investigating reasons for unexpectedly high or low inadequate rates.

6.4 Rapid re-screening/pre-screening

Rapid screening is the mandatory NHSCSP method⁹ for routine quality control of primary screening and can be either a pre-screen or re-screen, both of which are acceptable by the CSPs. Pre-screening entails a rapid screen of all slides prior to a full primary screen and re-screening entails a rapid screen of all slides considered to be negative or inadequate on primary screening.

Key points of rapid screening are:

- A rapid screen should take approximately 60 to 90 seconds
- Rapid screening must only be carried out by qualified members of screening staff who have undergone training and been assessed as competent to undertake rapid screening
- The rapid screener must be a different individual from 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
- Laboratories should regularly audit the method of rapid review to validate its effectiveness
- The number of rapid screens that individuals undertake is expected to be proportionate to the number of primary screens. Any individual undertaking primary screening should rapid screen no 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>
- If rapid pre-screening is used, then the laboratory must ensure that any abnormal samples identified on rapid pre-screening are not removed from the routine primary screening workload or marked in any way
- The pre-screen opinion must be blinded to the primary screener.

6.5 Checking

The lead consultant for the screening laboratory 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 and have been assessed as being competent in this role.

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.

The checker should examine the whole slide, paying particular but not exclusive attention to any areas marked by the primary screener. Ideally, the checker should form an opinion before noting the primary screener's opinion as this minimises any interpretation bias.

Where the checker agrees with the primary screener that an abnormality is present the slide must be passed to a consultant for reporting and recommendation of appropriate patient management.

Where the primary screener has indicated that the sample shows a high grade abnormality or borderline changes in endocervical cells and the checker considers the slide to be negative or inadequate, then the slide should be passed to either a second checker or consultant to review the slide before reporting it as such.

The BAC acknowledges that consultants may from time to time perform a "checker" role. Where this occurs, slides considered to be abnormal can be directly reported by the consultant without a third opinion, although individual screening programme policy, such as in Wales, mandates the checking step.

However, the BAC does not support the use of consultant staff as checkers on a permanent basis as this is an inappropriate use of resources. The BAC recommends that laboratories maintain the checker role as it 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.

6.6 Reporting abnormal cytology

All slides considered to contain abnormal cells by the primary screener and checker must be passed to a consultant for reporting. The consultant must be a suitably qualified consultant pathologist or consultant biomedical scientist. The whole slide must be examined, paying particular, but not exclusive, attention to any marked areas on a slide.

Where a consultant wishes to report a sample as high grade dyskaryosis or glandular neoplasia, which has been referred to them as either negative or inadequate, then the BAC recommends that it is best practice to show the slide to a second consultant before reporting.

Similarly, if a consultant considers a slide to be negative but it has been referred to them as high grade dyskaryosis by a checker, then it is best practice to show the slide to a second consultant before reporting.

The BAC also recommends that it is good practice that all cases of borderline changes in endocervical cells are double reported to try and minimise the overcalling of reactive or benign changes.

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

Feedback from consultants on discrepant slides should be given to checkers and primary screeners on a regular basis.

6.7 Reporting categories and patient management recommendations

NHSCSP guidance <https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-and-cytology-services-in-the-nhs-cervical-screening-programme> details the cytology classification and reporting codes to be used on all cervical screening tests in England, Wales and Northern Ireland, whether just an HPV result or a combination of HPV and cytology results.

In Scotland, there is separate guidance for reporting and management recommendations according to nationally agreed procedures <http://www.sccrs.scot.nhs.uk/lab.html>

6.8 Referral for colposcopy

The BAC endorses the requirement in the NHSCSP professional guidance ‘Cervical Screening; programme and colposcopy management’ <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 and Northern Ireland, the CSPL is responsible for ensuring that procedures are in place in both the screening laboratory and all associated colposcopy units to support the direct referral process, particularly a robust failsafe mechanism.

In Wales, the responsibility for direct referral and follow-up of abnormal cytology lies with the Cervical Screening Administration Departments (CSADs).

In Scotland the SCCRS system generates direct referrals to colposcopy.

6.9 Colposcopy MDTs

MDTs are important to enable discussion of individual patient cases and to agree a consensus management plan. Colposcopy MDTs should be held at least monthly, and more frequently if the case load per meeting is too large for the supporting cytology laboratory.

Consultants from cervical screening laboratories are required to participate in the MDT meetings of all the colposcopy units to which they make direct referrals, but it is the responsibility of the Colposcopy unit to arrange the meetings and to chair them.

Cytology slide review opinions presented at the MDT must be noted in laboratory records and the MDT minutes, but a cytology report must not be amended as a result of the MDT review.

Cases for MDT discussion can be identified by colposcopy, histology or cytology, and the reason for inclusion in the meeting must be given in the MDT paperwork. Cases for discussion should include:

- All cases where a high-grade cytology opinion is not confirmed by histology
- All cases of a cytological endocervical abnormality (borderline or ?glandular neoplasia)
- Cases where clinical management or follow up requires clarification
- All cases of invasive cervical cancer (for audit purposes)
- All cases of CIN2 for consideration of conservative management
- All cases where further management of individuals who have had 2 previous cervical treatments is required

The following cases do not need MDT discussion:

- Cases with high grade CIN where the referral cytology was low grade
- Cases where a previous biopsy confirmed CIN but a subsequent excisional sample is negative; the BAC recommends that a review of the previous biopsy should be undertaken and commented upon in the excisional sample report
- Cases of incomplete excision of CIN on a large loop excision of the transformation zone (LLETZ) where this would not affect clinical management

There should be regular audit of cases put onto the MDT discussion list to check for appropriateness of discussion and to ensure that unnecessary cases are not being included.

Further guidance on colposcopy MDTs can be found in the following programme guidance documents:

<https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management/3-providing-a-quality-colposcopy-clinic>

and

<https://www.gov.uk/government/publications/cervical-screening-histopathology-reporting-handbook>

and

<https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-and-cytology-services-in-the-nhs-cervical-screening-programme>.

7. CERVICAL SCREENING LABORATORY INFORMATION TECHNOLOGY (IT)

7.1 Principles of IT systems used in cervical cytology laboratories

No CSP laboratory should be providing a service without a suitable IT system that conforms to the data requirements of NHSCSPs, IG, and data protection and to UKAS ISO 15189 standards. All laboratory IT systems must have the ability to interface securely, either directly or via middleware, and comply with the requirements of and IT data and security guidance.

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 UK there may be several systems operating in an integrated or semi-integrated way. LIMS are often not focused on cervical cytology, and it is vital that senior cytology professionals have input into the choice of system so that it meets CSP needs as well as those of the wider pathology services. In the absence of any general IT guidance in the CSPs, the following points must be considered in the implementation or upgrade to any existing IT system within the CSP.

The systems must:

- be capable of interfacing with HPV testing platforms
- be able to offer auto-authorisation of most HPV negative samples
- have flexibility built in by design to accommodate projected changes in the screening programme such as the facility to record HPV vaccination status and self-sampling requests and results
- be capable of interfacing with other IT systems such as national screening programme systems and ideally HPV vaccination databases
- have access to legacy data as it is essential for the call, recall and management of women
- undergo rigorous user acceptance testing (UAT) to ensure data integrity and appropriate recall dates are retained where there is any transfer of data between systems
- have robust back-up facilities between the hardware and networking infrastructure to remote servers
- have all back up processes regularly tested and validated, and any remedial actions required must be recorded
- be able to retain data for long as legislation/guidance requires (see section 8)
- have a clear audit trail of all data entry for every record which must be easily accessible
- have controlled access to data; hardware must be stable, regularly monitored, and secure as the security of data is paramount
- have patient identifiable data stored only on systems that meet all NHS requirements, and data protection policies must be strictly adhered to

- ensure users have access appropriate to their role
- have entry screens containing fields for all essential data items on the request form in a logical sequence
- have rule based systems to prevent the entry of illogical or inappropriate decisions
- use only IT providers with a broad support and development base to ensure continuing support and development.

Ideally the systems should:

- have HPV testing platforms and cytology laboratory LIMS interfaces that can identify samples for cytology triage and work lists
- be capable of interfacing with other testing platforms such as imaging systems
- where possible, have single systems incorporating all elements of the screening programme to be used. Interfaces with related systems can be difficult to design and may be a source of error or system failure.

Points to consider for future system upgrades/replacement should be:

- paper free electronic requesting and reporting for all new systems
- the use of barcodes where possible instead of manual entry of data.

7.2 Specific requirements of a cervical screening laboratory IT system

7.2.1 Sample receipt and data entry

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 that inadequately identified requests are rejected. 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.

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.

7.2.2 Reporting cervical screening tests

The system must permit entry of HPV results through an interface with the HPV testing platform.

Reporting of HPV test and cytology results on the same report must be supported.

All reports which include a cervical cytology result must have a primary screener opinion and at least one other opinion entered, and the identity of all individuals who gave an opinion on the cytology slide sample must be recorded.

Samples with results of HPV not detected or HPV unavailable/unreliable may be automatically authorised by the LIMS in line with appropriately set algorithms and national guidance <https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-and-cytology-services-in-the-nhs-cervical-screening-programme>.

Each microscopy workstation should have a personal computer linked to the LIMS to enable result entry, authorisation, and patient enquiries.

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. HPV results must be available, and ideally HPV vaccination status too. A facility for patient notes to describe the background in complex cases or to provide additional information to explain management decisions should be available.

The system must use diagnostic codes as agreed by the national screening programme. The codes used must be able to be easily updated to reflect any changes in terminology.

Validation and authorisation of reports must be controlled by setting appropriate access levels which reflect the hierarchy of reporting as described in section 6.

7.2.3 Internal quality control (IQC) of primary cytology screening

Whichever method of IQC is used, whether rapid pre-screen or re-screen, the 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 the rapid pre-screen method for IQC must ensure that the system design “blinds” the pre-screen opinion to the primary screener opinion.

7.2.4 Issuing reports

Reports must be computer generated as a single integrated report containing both the HPV test result and cytology result where applicable, and must contain the following information:

- Name of reporting laboratory
- Date of sample receipt and sample taken
- HPV status
- Clear text cytology report where applicable
- Clear management advice
- Name of individual who authorised the final report
- Date of report.

7.2.5 Amended results

A clear audit trail must be retained to show:

- The original report
- The amended result
- An explanation of why the result was amended
- The name of the individual who authorised the amended report.

7.3 Transfer of results to call/recall databases

In England and Northern Ireland, the system must facilitate mapping of laboratory codes to the standard national result and action codes for the NHSCSP. This must be an automatic function. Transfer of results to call/recall databases must be electronic; the sending of results by e-mail is not permitted. There must be a failsafe audit in place to check that the number of results sent equals the number of results received in each file transferred.

In Wales, results for women resident in England but tested in Wales will go from the laboratory to the Wales CSAD who scan and send onto Cervical Screening Administration Service (CSAS) in England to enter onto the Open Exeter system. CSAS send the result to the woman, and CSW send the result to the GP.

7.4 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.

Laboratory reports must be available to allow the calculation of the following:

- Laboratory workload by source
- HPV reporting profile
- Cytology reporting profile
- Combined cytology and HPV reporting profile
- Individual cytology reporting profiles

- National statistical returns such as KC61
- PPV, TPV and APV reports (see section 10.3)
- Turnaround time reports
- Sample taker performance reports
- PPV and RV by individual Colposcopy unit

Ideally these reports will be generated directly by the LIMS.

7.5 Failsafe

The system must have a function to identify women who have been referred for colposcopy and are therefore subject to failsafe. Automated identification of women who have not had subsequent colposcopy and biopsy should ideally be available. The system may be used to generate standard failsafe enquiry letters where appropriate (see section 9).

8. STORAGE AND RETENTION OF DATA AND SAMPLES

The main UK general reference guidance for slide, request form and sample retention is the joint RCPATH & IBMS publication 'The retention and storage of pathological records and specimens (5th edition) (2015)' <https://www.rcpath.org/uploads/assets/049ea966-df5c-4a9f-9353ba24a69bb808/The-retention-and-storage-of-pathological-records-and-specimens-5th-edition.pdf> and <https://www.ibms.org/resources/documents/the-retention-and-storage-of-pathological-records-and-specimens/>

(Note - these documents are currently in the process of being updated).

Each laboratory must have a SOP to describe 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 should be local guidance 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>

8.1 Current specific requirements pertinent to the storage and retention of cervical screening, samples and data are as follows:

Item	Storage time
Request forms (HMR 101 or other)	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 any handwritten opinions, and kept for 30 years
Daily work logs	8 years from specimen receipt
Protocols / Standard Operating Procedures	At least 30 years for both current and outdated versions
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 any communications 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, to ensure availability through two accreditation cycles
LBC vials	Minimum 48 hours after final report has been issued, maximum in line with manufacturers' recommendations* See below for HPV testing requirements**
Equipment records	Lifetime of instrument plus 4 years
Invasive cancer audit records	Forwarded electronically to regional Screening Quality Assurance Service (SQAS) and retained locally for 30 years
Documents relating to legal cases	Minimum of 10 years after the case has closed
Screeener and laboratory performance records	8 years minimum, ideally 10 years
Staff training records	Retained according to employing organisation's human resources policy

* Cytological samples in PreservCyt® Solution for ThinPrep® testing can be stored at between 15°C (59°F) and 30°C (86°F) for up to 6 weeks, and the rules for storage of flammable liquids apply. Information is available from the ThinPrep Material Safety Data Sheets (MSDS):

<https://msds.hologic.com/WebView/private/document.aspx?prd=PRESERVCYT-SOLN%7E%7EPDF%7E%7EMTR%7E%7EHOL2%7E%7EBE%7E%7E2019-08-12%2013%3A15%3A06%7E%7ETHINPREP%AE%20PRESERVCYT%20SOLUTION%7E%7E& VI EWSTATEGENERATOR=CD1C98A3&CUSTOM2=d ThinPrep&language=d BE>

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.

**** Samples for HPV testing**

As per the manufacturer's guidance:

Cytological samples in PreservCyt® Solution for HPV testing on the Hologic Aptima® system must be HPV tested within 30 days or within 60 days if the sample is transferred to an Aptima® tube.

Samples for HPV testing on the Roche 4800® system must be tested within 6 months; testing on the 6800 or 8800 systems must be done within 3 months.

The BAC recommends that data arising from the cervical screening programme such as request forms, reports, work logs, reporter opinions and patient correspondence should ideally be stored electronically, either by being entered directly onto the laboratory/hospital IT system or by scanning and uploading of paper records (see section 7).

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 as above.

8.2 Legacy data and materials

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

9. CSP LABORATORY FAILSAFE

Cervical screening laboratories are responsible for operating a failsafe system for women referred to colposcopy. In England and N. Ireland the CSPL for the organization is responsible for ensuring that an effective laboratory failsafe system is in operation (see Appendix 2).

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 'Cervical screening: cytology reporting failsafe (primary HPV)', July 2019 <https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe>.

In Scotland, the laboratory component of failsafe is incorporated in SCCRS; in Wales, failsafe actions for the follow up of cytology reports are carried out by the CSADs.

10.QUALITY ASSURANCE

10.1 Key principles

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

- The lead consultant (<https://www.rcpath.org/uploads/assets/81dcaa1f-23db-48af-ae6f1f00b4727adf/BPR-Clinical-responsibility-for-cytology-services.pdf>) 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 scientists
- Departments must have a named quality manager in line with UKAS ISO 15189 requirements
- There must be internal quality control (IQC) systems to ensure that 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. Trend analysis must be carried out to identify any persistent issues and all remedial actions recorded.
- All potential quality issues that arise must be documented, fully investigated and action taken as required to address any shortfalls which are identified.

10.2 External quality assessment (EQA) schemes

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

- All individuals reporting cervical cytology must participate in the national gynaecological cytopathology EQA scheme, details of which can be found in NHSCSP professional guidance <https://www.gov.uk/government/publications/cervical-screening-gynaecological-cytopathology-external-quality-assessment/gynaecological-cytopathology-eqa-background-aims-and-governance>
- All laboratories must participate in the national technical EQA scheme. Protocols and procedures for this are included in NHSCSP professional guidance: <https://www.gov.uk/government/publications/cervical-screening-cytology-samples-external-quality-assessment>
- All laboratories must participate in an approved EQA scheme for HPV detection , such as <https://uknegas.org.uk/programmes/result/?programme=molecular-detection-of-hpv> or <https://www.qcmd.org/index.php>
- In Scotland, laboratories use the Hologic® imager stain and will participate in the manufacturer’s EQA scheme
- Any performance issues identified at either laboratory or individual level must be documented and investigated, with any associated corrective actions recorded.

10.3 Performance monitoring

The lead consultant is responsible for performance monitoring of the laboratory as a whole and of individual staff, although national CSPs may vary with respect to governance and monitoring arrangements.

Laboratory sample turnaround times must be monitored and reviewed as these are a required element of CSP performance targets (see appendices 1B, 1G).

10.3.1 Laboratory Performance

A detailed description of performance monitoring criteria for evaluating cervical cytology is provided in the relevant NHSCSP professional guidance documents: <https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services> and <https://www.gov.uk/government/publications/cervical-screening-programme-standards/cervical-screening-programme-standards-valid-for-data-collected-from-1-april-2018> (updated annually).

The mandatory key performance indicators (KPIs) currently in use by the CSPs for England, N. Ireland and Wales are:

- inadequate/unsatisfactory rates
- positive predictive value (PPV)
- referral value (RV)

with the standards for these KPIs being set as the 5th to 95th percentiles.

KPI data should be produced at least quarterly with an annual summary.

Other parameters that may be useful in determining laboratory performance are:

- total predictive value (TPV)
- abnormal predictive value (APV)
- PPV/APV plot diagram
- mean CIN score

It should be noted however, that these indicators may be influenced by histology and colposcopy as well as cytology performance.

Overall laboratory sensitivity and specificity for primary screening must be calculated and reported at least annually. It should be noted that the implementation of HPVPS will lead to a change in monitoring data and performance indicators, but these have yet to be finalised by NHSEI.

In England, all laboratory results and an overview of programme performance are published in the NHSCSP Statistical Bulletin <https://digital.nhs.uk/data-and-information/publications/statistical/cervical-screening-annual/england---2020-21> and also in the NHSEI CSP standards report

<https://www.gov.uk/government/publications/cervical-screening-standards-data-report-2020-to-2021> (appendix 1J).

In Wales, annual statistical reports are produced by Cervical Screening Wales.

<https://phw.nhs.wales/services-and-teams/cervical-screening-wales/information-resources/programme-reports/csw-annual-statistical-reports/csw-annual-statistical-report-2018-19/>

In Scotland, laboratory profiles are produced quarterly by SCCRS and formally reviewed at national laboratory quality assurance meetings. Parameters routinely reviewed include:

- turnaround times (which must conform to the Health Improvement Scotland standard)
https://www.healthcareimprovementscotland.org/our_work/standards_and_guidelines/stnds/cervical_screening_standards.aspx
- PPV and APV
- sensitivity and specificity for primary screening
- colposcopy referral rates.

Screening programme statistics are published by NHS Scotland Information and Statistics Division: <https://www.isdscotland.org/Health-Topics/Cancer/Cervical-Screening/>.

The Healthcare Improvement Scotland Cervical Screening Standards, published in 2019, have been aligned to the current NHSCSP standards and been developed to work alongside HPV testing which was implemented in 2020. All NHS health boards in Scotland with responsibility for delivery of cervical screening have implemented these standards.

In Northern Ireland, the Public Health Agency (PHA) produce annual statistical reports. Laboratory performance is formally reviewed at annual laboratory visits.
<https://cancerscreening.hscni.net/1827.htm>

10.3.2 Individual performance monitoring

Screeener 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 their individual performance profile at least quarterly, with the opportunity provided to discuss issues arising with a senior member of staff. There must be a mechanism detailed in a SOP for identifying and managing persistent poor performance and instigating remedial action where required.

10.3.3 Managing substandard performance

Underperformance of an individual can be identified through IQC or EQA and must be managed in accordance with the laboratory's SOP on managing substandard performance and/or appropriate employer policies.

The workload and reporting profile of the individual should be reviewed and an action plan agreed with the individual detailing the support required. This may include double screening of their work for an agreed time period. Further advice may be sought from the CTC manager and a suitable plan devised which may include attending a relevant formal training course/courses.

10.4 Audit

10.4.1 Invasive Cancer Audits

The audit of invasive cancers of the cervix is an integral component of the understanding of cervical cancer development. All laboratories in the UK must participate in these audits.

In England, the CSPL (see appendix 2) is responsible for undertaking the audits of invasive cervical cancers as described in NHSCSP professional guidance, updated September 2021 <https://www.gov.uk/government/publications/cervical-screening-auditing-procedures>.

Where cervical cytology and histology have been reported in different laboratories there should be a SOP covering transfer of required information and a process for slide review. Separate guidance exists for the review of SurePath™ slides <https://www.gov.uk/government/publications/cervical-screening-auditing-procedures/reviewing-historic-surepath-slides>.

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

In Scotland, each Health Board undertakes a comprehensive audit of invasive cervical cancers, led by the Screening Co-ordinators. A national invasive cervical cancer audit (NICA) protocol was implemented in 2015 and data is analysed centrally by the Information Services Division.

In Northern Ireland, there is the Framework for the Audit of Invasive Cervical Cancers and disclosure of findings. This is managed by the Health & Social Care Public Health Agency (HSC PHA) Northern Ireland Cervical Screening Programme (NICSP) <https://cancerscreening.hscni.net/2161.htm>

10.4.2 Other audits

Although not mandatory, the BAC recommends that laboratories undertake cytology review and additional audit of their own practices for educational purposes and as part of external quality assurance. Review of cases requiring discussion at the MDT meeting can provide ideas and an opportunity for audit and education. Examples of such audits could include the audit of the outcomes of:

- glandular abnormalities / suspected invasive disease reported on cytology
- borderline changes reported on cytology
- referrals for third HPV positive / cytology negative samples.

10.5 Quality assurance of cervical screening programmes

Responsibility for quality assurance (QA) of screening programmes in England transferred from PHE to NHSEI's medical directorate on 1st October 2021. The SQAS is organised and delivered nationally, primarily through four dispersed QA teams - North, Midlands & East, London, and South. For further information see

<https://www.gov.uk/government/publications/nhs-population-screening-regional-quality-assurance-teams-in-england> and <https://www.gov.uk/government/publications/cervical-screening-programme-specific-operating-model>.

The SQAS will quality assure how NHSCSP services meet national standards and guidance in England, provide expert advice on quality and safety in screening programmes and support quality improvement. This includes monitoring the quality of the programme using information gathered through data collection and validation, regular multidisciplinary visits by quality assurance representatives and a variety of other means, including the provision of the EQA schemes across the UK for gynaecological cytology and the staining of cervical cytology preparations. 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.

Equivalent QA structures and functions are in place in Scotland, Wales, and Northern Ireland. Appendix 1(I) provides links to all current national QA arrangements.

APPENDIX 1

Four nation and UK professional body links

A	Cervical screening programme websites
	<p>England: https://www.gov.uk/topic/population-screening-programmes/cervical</p> <p>Wales: https://phw.nhs.wales/services-and-teams/cervical-screening-wales/ http://howis.wales.nhs.uk/screeningprofessionals/cervical-screening-wales</p> <p>Scotland: http://www.sccrs.scot.nhs.uk/ https://www.nss.nhs.scot/specialist-healthcare/screening-programmes/cervical-screening/</p> <p>Northern Ireland: https://cancerscreening.hscni.net/1827.htm</p>
B	Service specifications
	<p>England: Service specification 25 https://www.england.nhs.uk/wp-content/uploads/2017/04/Service-Specification-No.25-Cervical_Screening.pdf</p> <p>Wales: Welsh Statutory Instruments: 2009 No. 2058 (W.177). NHS Wales The Public Health Wales National Health Service Trust (Establishment) Order 2009 https://www.legislation.gov.uk/wsi/2009/2058/made SLAs are in place with all health boards for delivery of colposcopy and histology services</p> <p>Scotland: No published service specification. Each processing laboratory has an SLA with NSD.</p> <p>Northern Ireland: No published service specification.</p>
C	UK Standards and Professional Guidance
	<p>UKAS ISO 15189: https://www.ukas.com/accreditation/standards/medical-laboratory-accreditation/</p> <p>IBMS professional guidance: https://www.ibms.org/resources/professional-guidance/</p> <p>Royal College of Pathologists: Key performance indicators – proposals for implementation (July 2013) https://www.rcpath.org/profession/guidelines/kpis-for-laboratory-services.html https://www.rcpath.org/uploads/assets/24572f2b-b65f-4a4b-b9e4d0f526dbac55/G181-Key-assurance-indicators-for-pathology-services.pdf</p>

D	Protocols and practice guidance for HPV testing
	<p>England: Cervical screening: primary HPV screening implementation https://www.gov.uk/government/publications/cervical-screening-primary-hpv-screening-implementation</p> <p>Cervical screening: laboratory testing for human papillomavirus https://www.gov.uk/government/publications/cervical-screening-laboratory-testing-for-human-papillomavirus</p> <p>Cervical screening: cytology reporting failsafe (primary HPV) https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe</p> <p>Wales: Cervical screening Wales quality manual http://howis.wales.nhs.uk/screeningprofessionals/hpv</p> <p>Scotland: NSD/SCCRS standard operating procedure http://www.sccrs.scot.nhs.uk/wp-content/uploads/2021/11/NAPs-revised-version-July-2020.docx</p> <p>Northern Ireland: https://cancerscreening.hscni.net/2161.htm NHSCP 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</p>
E	Terminology and reporting guidelines
	<p>UK: NHSCP professional guidance – Cervical Screening: laboratories providing HPV testing and cytology services in the NHSCSP, Sept 2021 https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services/cervical-screening-guidance-for-laboratories-providing-hpv-testing-and-cytology-services-in-the-nhs-cervical-screening-programme and https://www.journalslibrary.nihr.ac.uk/hta/hta19220/#/full-report</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>

F	Career Framework
	<p>UK: National job profiles for biomedical scientist and clinical support workers https://www.healthcareers.nhs.uk/explore-roles/healthcare-science https://www.nhsemployers.org/articles/annual-pay-scales-202122</p> <p>Key elements of the career framework https://www.skillsforhealth.org.uk/?option=com_mtree&%3Bamp%3Btask=att_download&%3Bamp%3Blink_id=163&%3Bamp%3Bcf_id=24</p> <p>IBMS position statement on role requirements and banding for scientists undertaking reporting within cellular pathology departments https://www.ibms.org/resources/documents/position-statement-role-requirements-and-banding-reporting/</p>
G	Turnaround times
	<p>England: 14-day turnaround (from sample taken to receipt of result letter) for 98% of women NHSCSP professional guidance – Cytology improvement guide: achieving a 14 day turnaround time in cytology (2009) https://www.gov.uk/government/publications/cervical-screening-cytology-improvement-guide</p> <p>Wales: Overall – 4 weeks from date sample taken to result received by the patient. Laboratory – 3 weeks from receipt of sample to issue of result.</p> <p>Scotland: A minimum of 80% of individuals to receive their screening results within 14 days from the date of the sample being taken.</p> <p>N. Ireland The N. Ireland Department of Health has endorsed the English standards stated above. Cervical screening programme: standards - GOV.UK (www.gov.uk)</p>
H	CPD Schemes
	<p>RCPATH: Continuing Professional Development (CPD) (rcpath.org)</p> <p>IBMS: CPD - Institute of Biomedical Science (ibms.org)</p> <p>BAC CEC Scheme: http://www.britishcytology.org.uk/go/education/continuing-education-certificate</p>
I	Quality Assurance
	England:

Cervical screening: programme specific operating model (2021)

<https://www.gov.uk/government/publications/cervical-screening-programme-specific-operating-model>

Wales:

Cervical screening Wales, Quality manual

<http://howis.wales.nhs.uk/screeningprofessionals/quality-manual>

Scotland:

<http://www.nsd.scot.nhs.uk/services/screening/index.html>

N. Ireland

<https://cancerscreening.hscni.net/2161.htm>

APPENDIX 2

The role of the Cervical Screening Provider Lead (CSPL)

The concept of the CSPL role was introduced into the NHSCSP in 1997, when the role was referred to as the Hospital Based Programme Coordinator (HBPC). The role has since expanded to encompass changes and additional responsibilities introduced in subsequent NHSCSP publications, and the title changed to CSPL in 2018 following publication of updated guidelines <https://www.gov.uk/government/publications/cervical-screening-role-of-the-cervical-screening-provider-lead>

These guidelines include information for CSPLs on:

- requirements of the role
- accountability
- working relationships and continuity of services across organisational boundaries
- roles and responsibilities
- meetings.

All organisations (NHS or private and standalone services) must have a CSPL in place if they provide one or more services for:

- cervical cytology and high-risk human papillomavirus (hrHPV) testing
- colposcopy
- cervical histopathology.

The role of the CSPL is to oversee and co-ordinate the quality and effectiveness of the NHS Cervical Screening Programme (NHSCSP) services provided within their organisation. CSPLs also play a vital role in the audit of invasive cervical cancers and in ensuring that the individual elements of local programmes work together to provide the best possible service and outcomes for women.

Accountability for the CSPL 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 CSPL role must be undertaken by someone in a position to be able to discuss all aspects of the role covered.

The CSPL must have identified time in their job plan to fulfil the role, a minimum of 1 programmed activity or 1 half day per week.

There must be a named deputy to cover periods of annual leave and sickness absence.

Tasks that considered to be administrative by the CSPL may be delegated to appropriate individuals and this must be formally recognised in their job description.

A minimum of 0.2 WTE administrative / secretarial support should be provided. The CSPL is responsible for maintaining close working relationships between all parts of the provider's cervical screening activities and with NHS England and other stakeholders. The CSPL should also ensure close working relationships are maintained with other CSPLs across the screening pathway to provide continuity across the programme.

Core responsibilities of the CSPL role are to:

- monitor the quality and effectiveness of the services provided by the organisation according to NHSCSP standards and guidelines and take appropriate action to address any shortfalls or escalate appropriately
- report to the appropriate screening and immunisation team(s) (SITs) and local cervical screening programme boards any aspects of the programme which do not meet nationally and locally agreed standards
- report to clinical governance committees on the performance, achievements and significant issues related to the cervical screening programme within the organisation
- produce an annual performance report and 6 monthly update to cover all NHSCSP services provided for the organisation's main clinical governance committee
- ensure all new cases of invasive cervical cancer diagnosed in women referred to the provider for investigation (from any source) are registered and audited in accordance with current NHSCSP guidelines
<https://www.gov.uk/government/publications/cervical-screening-auditing-procedures>
- play a lead role in the SQAS visit process for all aspects of the programme that are provided by the organisation, ensuring that any recommendations are addressed in a timely manner and responding with evidence of achievement to SITs and SQAS
- ensure all screening safety incidents are notified to SQAS and recorded and investigated according to NHS screening and local organisational policy
- attend local cervical screening programme board meetings chaired by the SIT and feed back to provider colleagues
- attend regional SQAS meetings for CSPLs and feed back to colleagues
- organise and chair a quarterly provider cervical screening management meeting
- be responsible for ensuring that multidisciplinary case discussion meetings take place according to NHSCSP guidance, in organisations providing a Colposcopy service
- oversee effective failsafe systems for all women referred to colposcopy, in

line with the requirements set out in NHSCSP guidance

<https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe>

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

REFERENCES

1. BAC Code of Practice (2017 update)
http://www.britishcytology.org.uk/resources/BAC_Code_of_Practice2015_-_2017_update.pdf
2. British Society for Clinical Cytology, 2010: Recommended Code of Practice for Laboratories Participating in the UK Cervical Screening Programmes (available on the BAC website) <http://www.britishcytology.org.uk/>
3. NHSCSP professional guidance - Cervical screening: laboratory HPV testing and cytology services, September 2021
<https://www.gov.uk/government/publications/cervical-screening-laboratory-hpv-testing-and-cytology-services>
4. NHSCSP publication 14 - Laboratory organisation: a guide for laboratories participating in the NHS Cervical Screening Programme (2003)
<http://webarchive.nationalarchives.gov.uk/20150506150512/http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp14.html>
5. NHSCSP publication 12
<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf>
6. Gill, GW. Pap Smear Risk Management by Process Control. *Cancer Cytopathology* 1997 81;198- 211
7. Kitchener H, Blanks R, Cubie H, Desai M, Dunn G, Legood R, Gray A, Sadique, Z and Moss S, on behalf of the MAVARIC Trial Study Group. MAVARIC – a comparison of automation-assisted and manual cervical screening: a randomised controlled trial. *Health Technology Assessment* 2011;15: No 3
8. A study of cellular counting to determine minimum thresholds for adequacy for liquid-based cervical cytology using a survey and counting protocol. *Health Technology Assessment* 2015; 19: No 22.
<https://www.journalslibrary.nihr.ac.uk/hta/hta19220/#/full-report>
9. Dudding, N. Rapid rescreening of cervical smears: an improved method of quality control. *Cytopathology* 1998;6: 95–99