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4P. CYTOLOGY

4P.10 SAMPLE RECEPTION

Liquid base Cytology (LBC) samples are received in the laboratory sample reception area. The area is normally staffed by Health Care Support Workers, or higher-grade staff, under the direct supervision of a named qualified state registered biomedical scientist (BMS).

Clerical staff may also be involved in the sample reception process.

The process used in all laboratories providing the cervical screening service in Wales is the SurePath™ Liquid Base Cytology System (LBC).

4P.10.1 Staff Responsible

Primary responsibility:

Health Care Support Worker
Reception staff
Cytoscreener
Biomedical Scientist

Supervisory responsibility:

Biomedical Scientist
Supervisory Biomedical Scientist

Advisory responsibility:

Pathologist/Clinical Cytologist

4P.10.2 Quality Standards

BSCC Code of Practice
IBMS Patient sample and request form identification criteria
COSHH Regulations
Accreditation documents
Transportation guidance documents
Source Biosciences™ Belton Dickinson guidance documents

4P.10.3 Area of Application

Main Laboratory:

- Sample reception area

Operational requirements - Laboratory area:

- Appropriate laboratory garments must be worn
- This should include suitable hand protection where appropriate

4P.10.4 Policy and Procedure

Source of Smears

LBC samples are received at the laboratory in standard SurePath™ vials as unprocessed samples.

i. Primary Care, including:

General Practitioners and Sexual Health clinics and other External Sources.

ii. Hospital Clinic Samples, including:

Colposcopy clinics, Gynaecology Clinics, Sexual Health Clinics and other secondary and tertiary level sources.

Process:

- Samples are collected by the 'smear taker', in accordance with standard CSW procedures, and transported to the laboratory in the approved protective enclosures and packaging supplied with the LBC test consumables
- External Packaging may enclose samples taken from more than one woman, to a maximum of five samples
- Each individual sample will be enclosed in an individual sealed protective bag attached to the CSW-HMR request form. The bag is sealed by an integral sealing strip
- There should normally be only one LBC vial enclosed with each HMR request form
- HMR/bags containing more than one vial should be carefully checked prior to breaking the seal of the bag. Any discrepancies should be discussed with or referred to the sample-taker
- Samples transported by Royal Mail must conform to packaging requirements described in the Post Office guidance literature
- Due care must be taken to ensure that minimal risk procedures and good laboratory practice (GLP) are applied and properly controlled

LBC samples are considered to be highly unlikely to harbour viable pathogenic organisms.

Procedure

Note: External Packaging may enclose samples taken from more than one woman.

Sample receipt check

- The outer protective packaging is carefully unwrapped and the bagged samples are removed and checked

Sample Identification

- The identification details on the sample vial are immediately checked against the accompanying request form. This should be done before the seal is broken on the bag
- Only one sample should be opened at a time to reduce the possibility of sample crossover and laboratory mismatches
- If two sampling implements have been used this should have been recorded on the request form by the smear taker. This is checked and confirmed by examination of the vial
- If a request includes two sample vials this should normally be indicated by the smear taker. The receipt of multiple samples must be clearly noted on the request form
- The number of samples received and the sampling implements used should exactly match that indicated by the smear taker on the request form

Logging of Smears on the Laboratory Computer System

- Each case is logged onto the laboratory information management system (LIMS)
- All relevant details from the request form are entered onto the LIMS
- When entering data onto the LIMS, a check must be made that the identification details on the request form and sample match the individual's computer record being added to or created

Processing of Samples

- Samples are processed according to the LBC suppliers general guidance and instructions and CSW agreed procedures
- Care should be taken to ensure that request forms are kept in the same order as the samples

The exact procedure employed locally must be added to local copies of the Quality Manual as an appendix to this SOPP.

4P.10.5 Identification Process

To ensure that samples are correctly identified and recorded, specific identification criteria are applied.

Unlabelled samples should not be returned to the sender for labelling. A repeat sample should be requested and the Regional Nurse Coordinator informed. In exceptional circumstances follow the procedure under major discrepancies.

1) Essential Identifiers – Samples

- LBC samples must be correctly labelled by the smear taker using an indelible marker or a pre printed label
- The sample must be labelled with the following essential patient identifiers:
 - Patient's name: Surname, forename and initial/s
 - Date of Birth and/or NHS number

Optionally the patient's address may be included on the label, particularly where pre-printed labels are used by practices and clinics.

2) Essential Identifiers – Request Form (CSW HMR Form)

- Request forms must be legible and be both fully and accurately completed
- The minimum data requirements are:
 - Full name
 - Date of birth
 - Patient's address
 - NHS number*
 - Name and address of smear taker (sender)
 - Name and address of GP
 - Smear taker's personal ID code

All or most of the above data can also be received in barcode format. This is acceptable, provided that the bar coded label also includes an alpha numeric record of the patients name as a minimum.

*The NHS number may not be available to some hospital and sexual health clinics at the time of taking the smear. In these circumstances the smear may be accepted, provided that all other information criteria are met. The omission should be recorded under the procedure for minor discrepancies (see below).

3) Discrepancies

All discrepancies that result in the rejection of a sample must be reported to the Cervical Screening Administration Department (CSAD). This enables investigation of the discrepancy by the Regional Nurse Coordinator and activation of FailSafe procedures at the CSAD.

Major errors which include unlabelled vials and patient misidentification must be recorded in a separate booking-in area on the Laboratory Information Management System (LIMS). This will provide an audit trail but avoid inclusion in CSW monitoring data.

- All samples received must be recorded on the LIMS
- Any discrepancies between the labelling of the vial and the request form must be clearly noted on the form at the time of detection

- Discrepancies involving smears without request forms, or request forms without samples must be recorded and investigated (4P.10.6)
- The details written in by the smear taker on the request form or vial must not be altered under any circumstances
- It is essential that the correct computer record is identified and updated with current test information
 - If the woman has an existing record on the LIMS, any discrepancies between the data items on the request form and the data on the woman's existing laboratory computer system record must be investigated and resolved
 - Details of changes may be confirmed with the CSAD, through the National Health Application and Infrastructure Services (NHAIS)/Exeter system otherwise the woman's general practice must be contacted to determine which information is correct
- Failure to ensure that the most up to date information relating to the woman and her GP is included on the LIMS, and consequently on the final result form, could lead to the result not being received by the woman or her GP, especially when the smear taker is not practice based

Minor Discrepancies

- Minor discrepancies, such as a slightly misspelt name, may be acceptable if there is no question of a mislabelled sample. In such cases the discrepancy must be clearly recorded on the form for inclusion in the final report to the smear sender
- Acceptance of minor discrepancies must be authorised by the supervising biomedical scientist, and recorded in a discrepancy log
- It may be appropriate to verify details of the discrepancy with the sample source, before authorising acceptance; details of any contact made should be recorded in the discrepancy log

Major Discrepancies

- Unlabelled samples should not be returned to the smear taker. These must be disposed of in the laboratory and a repeat sample requested
- Samples and/or request forms must be returned to the sender if the essential identification criteria are not met
- The sender must be informed of the reason for the return of the sample and request form
- The smear taker is advised that a new sample must be collected from women whose sample has been rejected or returned
- Samples returned to the sender must be logged by the laboratory. The reasons for the return must be recorded in the discrepancy log. The discrepancy must be logged on the LIMS in a dedicated booking area, with a unique accession number

- information on discrepancies recorded against a LIMS accession number must be reported to the CSAD
- It is possible that the smear taker may re-submit samples to the laboratory with amended details:
 - The smear taker will be expected to note on the request form that this action has been taken. The alteration must have been confirmed and verified by the signature and ID code of the original smear taker. If this is not possible the sample must be rejected
 - If amendments have been made to the information on the vial, this should be clearly noted and reported in the final cytology report. In these circumstances the smear taker will be fully responsible for the attribution of the result received and correlation with the woman sampled; any consequences arising from the issue of the report will be the responsibility of the smear taker
 - Smear takers will be informed that amendments to vials may result in their being returned as unacceptable samples, if there is any further doubt over the woman's identity

Broken or Damaged Samples and packaging

- If the damage is minor and there is no doubt over the identity of the sample the laboratory may proceed to processing
- Irreparably damaged vials should be recorded and reported to the smear taker and a repeat sample requested

'Leaked' samples

Where there is evidence that a sample may have leaked or otherwise shows a loss of fluid, the sample may be processed for further viability assessment.

- **If there is less than 8 ml of fluid left in a leaked vial**, the specimen is processed for further assessment
 - If abnormal, the sample may be reported, although the report must record that there was a loss of sample fluid and consequently the cytology grade may not be truly representative of the woman's condition
 - If normal, the sample is reported as inadequate, as it cannot be ruled out that abnormal cells may have been lost with the spilled fluid

4) Sample Identification – Laboratory Numbers

- The sample and request form are allocated an unique laboratory accession number starting at 90,000 for the year concerned
- The accession number must be clearly marked on the request form
- If multiple samples on the same case are submitted as part of a single screening test, these should be identified with the same

accession number supplementary suffixes may be used to identify individual vials

- If local laboratory procedures require consecutive numbers, only one report must be issued. The exact local handling procedure must be documented in the laboratories operational manual and a copy of the variant procedure must be attached as an appendix to this SOPP
- As LBC processing is a multi-step procedure, arrangements must be in place to ensure that a 'chain of custody' is established to ensure that the processed slide is correctly identified
 - Internal control processes must include identity checks at each stage of the sample preparation process
- Laboratories are advised that any local handling procedures must be recorded in an appendix to this SOPP

5) Urgent requests

Screening tests are not usually considered urgent; however, laboratories may legitimately receive requests to urgently process some samples (eg anxious woman, woman moving or working abroad, etc). These requests should be handled sympathetically.

During periods when the turnaround time for smear tests exceeds CSW standards, consideration should be given to prioritising samples requiring an early report. Prioritised samples will include, in particular, samples received from colposcopy clinics.

Prioritisation arrangements must be notified to the Regional Programme Coordinator.

The current local procedure for identifying and processing urgent smear tests must be appended to laboratory copies of the Quality Manual as an appendix to this SOPP. The category must include all colposcopy smears as priority samples

4P.10.6 Quality Control/Audit

A discrepancy report listing labelling errors and mismatches must be included in a regular information return sent to the Regional Nurse Coordinator.

Persistent problems will be addressed by the Regional Programme Coordinator and/or Regional Nurse Coordinator with the smear taker, following, where necessary, consultation with the laboratory.

4P.10.7 Further Information

Samples and forms with illegible details will be treated as inappropriately labelled, and cannot normally be accepted for processing.

The laboratory may choose to return the sample for verification by the smear taker, before accepting the sample for processing.

If a discrepancy is noted in a case where there has been difficulty in securing the attendance of the woman to take a cervical smear test, or she was hard to locate, or she may no longer be available for a repeat test, senior laboratory staff may sanction processing of the smear, providing that there is no significant doubt over the identity of the sample.

This action must be recorded and a disclaimer included in the laboratory's test report, detailing the fault in the identification of the sample or the request form.

The disclaimer must make it clear that the doctor responsible for the woman (GP/clinician) must take full responsibility for the result, and any consequences arising from the issue of the report.

4P.10.8 Risk Assessment

Employers are required by law to ensure that personnel involved in the handling of samples are appropriately trained and properly equipped to work safely without exposing themselves or colleagues to risk.

Physical Risks

- It is not practical to treat every individual sample as high risk, but the basic precautions of good laboratory practice, such as the wearing of gloves and appropriate laboratory protective garments, must be observed
- LBC processing can expose staff to a number of hazardous substances. A COSHH assessment must be completed for the process
- Processing must be conducted in accordance with the manufacturers and suppliers processes and recommendations and instructions detailed in their equipment operating manual
- Detailed procedure risk assessments must be completed locally, and the results appended to local copies of the Quality Manual
- The assessment of risk must be made by the person directly responsible for the item of work and must be recorded, in accordance with COSHH regulations, in order to prevent or control exposure to substances hazardous to health

- Risk assessments ensure that an informed judgement is made on the nature of any potential hazard posed by screening procedures. The assessment will identify the precautions necessary in relation to the risk
- The risk assessment must identify:
 - Specific hazards
 - Assessment of actual risk
 - Individuals affected
 - Areas affected
 - Assess and recommend control measures

Clinical Risks

There is a risk of sample mismatch, cross over, and transcription errors in the sample reception and processing procedures. This can result in a number of adverse outcomes, including false, negative and false positive results, inappropriate treatment and/or management and breaches of confidentiality.

The procedure must be carefully controlled at all stages to minimise the possibility of errors.

4P.20 RECEPTION OF HIGH RISK SPECIMENS

In relation to cervical cytology, specific high-risk pathogens include, in particular, the human immunodeficiency virus (HIV) and hepatitis viruses.

It is recommended that HIV positive women should be screened annually; these samples will usually be received from a Sexual Health Clinic. Annual recall is on the advice of the treating clinician, who will arrange any early recall of negative smear results.

The Liquid Base Cytology collection fluid is considered to be both bactericidal and viricidal, so high-risk samples should not present an increased risk of infection.

Known high risk samples should be specifically identified by the smear taker and special precautions taken in the submission of the sample.

The status of the sample may be indicated by a written or pre-printed notification, attached to the exterior packaging as well as labels attached to the sample and request form.

4P.20.1 Staff Responsible

- Staff working within the specimen reception area
- All staff handling samples must be made aware that any sample may potentially harbour infectious organisms

4P.20.2 Relevant Staff Groups

Administration and clerical staff
Health Care Support Workers
Cytoscreeners
Biomedical Scientists
Supervisory Biomedical Scientists
Clinical and Professional Staff

4P.20.3 Quality Standards

BSCC Code of Practice
COSHH Regulations
ACDP Guidelines on HIV
HSAC Safe Disposal of Clinical Waste
HSC Safe working and prevention of infection in Clinical Laboratories and PM rooms
RIDDOR Regulations

4P.20.4 Risk Assessment

The potential risk of infection from high-risk samples for health care workers is well recognised. Laboratory workers are mainly at risk from accidental inoculation by contamination of broken skin, or puncture wounds from sharps.

Employers are required by law to ensure that personnel involved in the handling of samples are appropriately trained and properly equipped to work safely without exposing themselves or colleagues to risk.

4P.30 PROCESSING AND STAINING PROCEDURE

Liquid Base Cytology samples for cervical screening are received by laboratories following sampling and collection in the primary and secondary care sectors in accordance with a standard protocol. Samples are subsequently processed by laboratories to produce a stained slide for cytological screening. The system used is the SurePath™ LBC system. The system includes a standard staining process using a modified Papanicolaou based staining procedure.

Staff involved with LBC processing must have completed an approved training programme delivered by the relevant company. This must be documented in staff training records.

The accurate interpretation of cervical smears depends on the quality of the preparation and staining procedures.

Sample processing and staining procedures are expected to meet the standards established and required by the CSW Technical External Quality Assurance Scheme (TEQA).

CSW promotes the adoption of common standard processes, although local conditions may require variations in system operating parameters to ensure that processing results are acceptable:

- Day to day variations in quality can be limited by well-controlled technical procedures
- Variations in staining results between laboratories can be limited, by the adoption of a consensus standard for routine staining procedures
- The UK NEQAS approved Technical External Quality Assurance Scheme promotes convergence towards a nationally agreed standard of preparation that should be acceptable to all laboratories working for Cervical Screening Wales

1. Coverslipping

Stained slides are mounted with a coverslip, which protects the preparation, and renders it translucent, enabling microscopical examination to be completed in the cytology laboratory. The coverslip may be glass or plastic tape:

- The coverslip is positioned to ensure that the stained area of the slide is fully covered
- The coverslip is affixed to the slide using the DPX mountant supplied in the SurePath laboratory processing kits
- Standard coverslips (size 22x22mm) are supplied in the SurePath laboratory processing kits, this size is the minimum standard

- Alternative coverslip sizes and systems, including plastic coverslip tape, applied by automated cover slipping machines, which exceed this minimum standard are acceptable

2. Labelling

During the preparation process, the slide identification must be re-checked against the request form and clearly labelled with the woman's name and accession number. Appropriately equipped laboratories will use bar-coded labels.

4P.30.1 Relevant Staff Groups

Primary responsibility:

Biomedical Scientist

Cytoscreener

Health Care Support Workers

Supervisory responsibility:

Senior Biomedical Scientist

Advisory responsibility:

Cervical Cytology Manager

Pathologist/clinical cytologists

4P.30.2 Quality Standards

Cervical Screening Wales TEQA scheme

UK NEQAS staining scheme

COSHH regulations

4P.30.3 Area of Application

Main Laboratory

- Sample reception and processing area

4P.30.4 Procedure

- It is important that identity checks are implemented at all stages of the processing schedule
- Smears are processed and stained on the SurePath™ LBC processing system according to the manufacturers protocol
 - Processing parameters may be adapted to address local conditions
- The protocol describes drying times, immersion times and other parameters for all stages of the process
- The working schedule for staining procedures must be regularly reviewed and updated as appropriate
- A record must be kept of routine maintenance procedures
- Stain quality must be monitored daily by a designated BMS

- Quality failures must be logged, the cause(s) must be investigated and the outcome recorded. System failure reports must be sent to the CSW LBC Coordinator

The laboratory's processing and staining protocol must be appended to the reference copy of the Quality Manual

4P.30.5 Quality Control/Audit

Local monitoring procedures
All-Wales TEQA scheme
Slide exchange scheme/feedback mechanism
UK NEQAS

Sub-optimally Stained Slides:

- Sub-optimal preparations should not be examined under normal circumstances
- The samples should be assessed to see if:
 - They can be re-processed to improve the final quality, or
 - They can be safely reported following careful screening
- Sub-optimal preparations that cannot be reprocessed should be double screened by a supervisor
- Irretrievably affected samples should be reported as technically unsatisfactory, and a repeat sample requested

The laboratory must indicate to the smear taker the reason for the inadequacy, particularly when the smear taking process is not considered faulty.

All processing laboratories are required to participate in the Cervical Screening Wales Technical EQA scheme.

4P.30.6 Risk Assessment

- Processing, staining and mounting processes can expose staff to a number of hazardous substances. Relevant COSHH assessments must be completed
- Employers are required by law to ensure that personnel involved in the handling of specimens are appropriately trained and properly equipped to work safely without exposing themselves or colleagues to risk
- Staff must be aware of their duty of care, and the requirement by law that they work in a safe manner, so as to minimise their personal risk and the risk to colleagues, by adhering to the established protocols
- A local assessment of risk must be made by the person responsible for the work and will be recorded, in accordance with COSHH

regulations, in order to prevent or control exposure to substances hazardous to health

The process must be subject to continuing risk monitoring.

The purpose of the risk assessment is to ensure that an informed judgement is made on the nature of any potential hazard posed by the procedure. The assessment will identify the precautions necessary in relation to the risk.

The risk assessment must identify:

- Specific hazards
- Assessment of actual risk
- Individuals affected
- Areas affected
- Assess and recommend control measures

Screening Sub-optimal samples

- The smear sender should be informed in the final report that technical problems may have affected the reliability of the test
- The sender must be advised to repeat the smear if the reporting cytologist has significant concern over the reliability of the result

4P.40 SCREENING PROCEDURE

The primary screening of cervical smear tests collected as liquid base cytology (LBC) samples is the single most important function in the cytology laboratory.

Every care must be taken to ensure that the screening environment and screening conditions are optimised, to promote a high quality screening service.

4P.40.1 Staff Responsible

Cytoscreeners
Biomedical Scientists
Supervisory Biomedical Scientists
Pathologists

4P.40.2 Equipment and Environment

1. Essential Equipment

- Microscopes equipped with x4, x10, x20* (or x25*), x40 objectives:
*It is strongly recommended that microscopes are equipped with an intermediary objective (x20 or x25)
 - Microscopes should conform to minimum ergonomic standards defined by the Medical Devices Agency (MDA)
- Dotting pens, marker pens or objective marker systems:
 - Alternatively, electronic marking systems associated with tracking systems and computer assisted screening devices may be utilised

2. Screening Environment

- The screening room should be in a dedicated area, separate from the reception, preparation, processing, general office, staff offices and slide/report storage areas
- Screening rooms should be appropriately furnished to the minimum standards recommended by the BSCC and the MDA:
 - Managers should pay particular attention to the different physical requirements of staff; furnishings should be sufficiently flexible to accommodate any physical variations
- Screening rooms should comply with BSCC recommendations, in particular:
 - Noise levels must be reduced to a minimum both within and adjacent to the screening area. All unnecessary equipment should be removed from the screening area
 - The area should ideally be carpeted to reduce noise and create a pleasant environment

- Temperature should be controlled at a constant and comfortable level
- Ventilation should not cause uncomfortable draughts
- Humidity should be controlled to prevent 'dry' eyes
- Screeners should be allocated sufficient space
- The BSCC recommends a minimum of 1.98 m/2.0m linear bench space
- Screeners will require additional space if they use a VDU at their work station
- Extraneous light and glare must be avoided. External windows should have blinds that are easy and safe to operate
- Where VDU equipment is used during the screening process, provision for the working area must comply with statutory requirements
- Microscopes should be properly positioned with due regard to physical requirements. The environment must be comfortable and enable screeners to vary their focal point during the screening process by looking at distant objects
- The microscope should be positioned to prevent unnecessary glare from windows
- Provision for heating and ventilation must be adequate and effective, to ensure comfortable working conditions

3. Microscopy Sessions

- Screeners should not sit for more than one hour without varying their focus in some way
- Periods of screening should be limited to no more than two hours continuous screening (maximum)
- Each period of screening should be interspersed with a change of practice or a short break
- Staff should not be involved in primary screening microscopy for more than five hours in one day. This includes any rapid screening procedures completed

4P.40.3 Quality Standards

Terminology in Gynaecological Cytopathology
Guidelines for Clinical Practice and programme Management
NHSCSP publication No 8, (1997)
ABC document - BSCC (1995)
Minimum Ergonomic Standards (MDA)
Display Screen Equipment Regulations (1992)
NHSCSP documents – laboratory organisation

4P.40.4 Area of Application

All areas associated with microscopy including:

- Screening rooms/areas

- Checking rooms/areas
- Reporting rooms/areas

4P.40.5 Procedure

- All processed LBC slides must be primary screened by qualified screening staff
- Prior to screening, the screener must check that the identification details on the slide match those on the request form
- Screeners must examine all of the sample area ensuring that the edges are carefully examined
- If cell drift is noted, screeners should screen outside of the process area, but should restrict this to no more than one field of view (FOV)
- If the cell drift exceeds one FOV, there may be a processing fault and the slide should be referred to a senior BMS for further assessment
- Slides should be screened in straight lines either horizontally or vertically
- Slides must be covered at a steady pace ensuring that the whole of the process area is examined
- Screeners must ensure an adequate overlap is allowed between fields of view - a 4/5 overlap is recommended
- Smears are reported according to the standard protocol (4P.60)
- Abnormal cells or equivocal cells are located by the primary screener, for reference to a checker, by marking the coverslip with a water resistant marker pen, objective marker or electronic marker, as described in a local protocol
- Slides that are considered to be abnormal or possibly abnormal by the primary screener are passed to a checker for further examination (4P.70)
- Screeners note their opinion on the request form, a reference sheet and/or laboratory computer system, when passing on smears for checking. Any additional written observations stored with the request form must be recorded on the electronic record system
- any additional written observations or notes stored with the request form must be clearly annotated with patient identity and sample number
- The screener must check that the identification details on the request form match the computer record
- Screeners should assess the degree of abnormality present, and record their opinion before referring on to a checker
- If there is doubt over the presence of an abnormality (an equivocal smear) the case may be described as ?borderline change by the screener and must be passed for checking

The local protocol for screening, locating and marking cells must be added to local copies of the Quality Manual as an appendix to this SOPP.

4P.40.6 Quality Control/Audit

CPA
Quality audit
Report validation
Feedback of opinions
Reflective practice

4P.40.7 Further Information

Reflective practice is an important tool in the maintenance of high standards of performance. Reflection and correlation cannot be implemented if all opinions expressed on the case are not recorded.

Accurate records of individual observer's opinions are necessary for the collection and definition of personal performance indicators for quality review processes. This applies to all grades of staff.

Further information on storage is available in 4P.150.

4P.40.8 Risk Assessment

- Vigilance decrement: the primary screening process is particularly vulnerable to disturbances, lapses in concentration and other interruptions. Screeners must ensure that they follow the recommendations for screening procedures (4P.40) to prevent this occurrence
 - Vigilance decrement is a potential source of false negative (F/N) results
- Transcription errors: can occur when recording opinions on request cards or when transferring information to the LIMS. Care must be taken to ensure the validity of all reports
 - Transcription errors are a potential source of F/N and false positive (F/P) reports
- Habituation: an accustomising process whereby expectancy is generated in the observer of a negative smear following the observation of a number of preceding similar smears
 - This is a potential source of F/N reports
- Anoesis: 'consciousness with sensation, but without thought'. A process whereby the screener consciously traverses the slide without actually observing the features of the sample
 - This is potentially, a significant source of F/N results

4P.50 INTERNAL QUALITY CONTROL - RAPID ASSESSMENT

All single screened negative and inadequate LBC samples, reported without further referral are subjected to a 'rapid assessment' quality assurance check.

Rapid quality control (RQC) assessments may be completed as a review or preview procedure.

Rapid review is a QC procedure, whereby the slide is scanned at normal speed, in a controlled method within a reduced screening time frame following completion of the primary screening process, prior to reporting and authorisation of the result.

It is not normally possible to fully review the whole of the preparation within the time allocated for rapid review - the process is not a rapid scan of the whole slide.

Rapid preview is a QC procedure, whereby the slide is scanned at normal speed, in a controlled method within a reduced time frame, prior to primary screening. Results are recorded, compared and reconciled against the final report, prior to authorisation of the result.

It is not normally possible to fully assess the whole of the slide preparation within the time allocated for rapid preview - the process is not a rapid scan of the whole sample.

Some laboratories may have the capacity to double screen samples. Where this is possible, this is an acceptable authorised alternative to Rapid QC procedures and the local protocol employed should be recorded as an appendix to this SOPP.

4P.50.1 Staff Responsible

Cytoscreeners
Biomedical Scientist
Supervisory BMS

4P.50.2 Quality Standards

NHSCSP Publications
ABC2 for Cervical Cytopathology - BSCC (2000)

4P.50.3 Area of Application

Microscopy areas:
▪ Screening rooms

4P.50.4 Procedure

Prior to Rapid QC the screener must check that the identification details on the slide match those on the request form.

The QC process must be completed before a final report is validated and issued by a laboratory.

It is important that Rapid QC procedures are completed when a screener is relatively fresh. It is recommended that the Rapid QC process is carried out before a screener starts a primary screening session.

The process is ideally carried out as the first task of the morning, or alternatively as the first task in the afternoon, following a refreshment break.

The pattern for Rapid QC screening of LBC samples is adapted from conventional cytology rapid screening.

An accepted adaptation is the 'sweep method' - looping back on completion with no overlap ensuring each sweep progresses across the sample so that the full area of the circle is viewed. This should take between eight to ten sweeps.

QC Procedure:

- The time taken may vary according to the cellularity and complexity of the sample, occasional slides may require slightly longer examination. Exceptionally the process may take up to two minutes
- The Rapid QC screen must be completed by a different person to the primary screener

Laboratories must describe the exact procedure employed in their laboratory for Quality Control - the procedure must be attached to this SOPP as an appendix.

Rapid review

- The primary screener's opinion should be available to confirm the rapid reviewer's opinion. This is especially important when there is an infection present or the sample is inadequate
- If a feature is noted which meets any of the criteria for referral for checking, as outlined in 4P.60 (page 4), then the feature should be marked/dotted and the rapid review of the smear terminated. The slide must then be referred to a checker for further examination (4P.70)
- A record must be kept of the number of slides QC checked by individual screeners, the number referred for full rescreen, and the

subsequent outcome of the checking process, including, if appropriate, the amended report issued

- A record should be kept to enable monitoring of the Rapid QC process and reviewer performance

Rapid preview

- The rapid previewer's opinion should be checked against the primary screener's opinion before the report is issued
- If a feature is noted which meets any of the criteria for referral for checking, as outlined in 4P.60 (page 4), the feature should be recorded and the pre-view of the smear terminated
- A record must be kept of the number of slides QC checked by individual screeners, the number for referral re-screen, and the subsequent outcome of the checking and reconciliation process

Double Screening

Some laboratories may have the capacity to double screen samples. Where this is possible, double screening is an authorised alternative to Rapid QC procedures.

The individual screening processes should be conducted independently as a parallel blind assessment. Specific screening protocols must be developed by individual laboratories and agreed and recorded as an appendix to this SOPP.

4P.50.5 Quality Control/Audit

It is important to review the circumstances surrounding the need to amend a primary screening report following QC checks, and to discuss where appropriate, the outcome of the process, with the primary screener.

Any discussions must be approached sensitively; the procedure must not pose any 'threat or discomfort' for the primary screener.

4P.50.6 Further Information

- Rapid QC will not detect all cases of false negative cytology
- Detecting a missed dyskaryosis is the prime objective of Rapid QC
- Individual screeners may require further training before they are involved in the Rapid QC process
- Individual screeners should be encouraged to explore their review pattern options to find the variation they are most comfortable with, before being included in the Rapid QC process
- The time a screener spends on Rapid QC is not considered to be part of the normal primary screening workload. The task may be completed in addition to the maximum five hours screening time

4P.50.7 Risk Assessment

- The Rapid QC process is not a substitute for high quality screening. Care must be taken to ensure that the process is not seen as a safety-net by primary screeners, building a false sense of security into screening
- Rapid QC may require the acquisition or development of different screening skills; it is possible that not all staff are suited to the role. Managers should satisfy themselves that staff are sufficiently competent to be involved in the process, prior to their inclusion
- The Rapid QC process may be particularly susceptible to habituation, and fatigue can seriously reduce a screener's powers of concentration. For this reason it is recommended that the process is not carried out at the end of a screening session

4P.60 REPORTING: PRIMARY SCREENING PROCEDURES

4P.60.1 Staff Responsible

Cytoscreener
Biomedical Scientist
Supervisory Biomedical Scientist
Pathologist
Clerical officers
Office Manager

4P.60.2 Quality Standards

Terminology in Gynaecological Cytopathology
Guidelines for Clinical Practice and Programme Management - NHSCSP
publication No 8 (1997)
ABC2 for Cervical Cytopathology - BSCC (2000)
NHSCSP Publications

4P.60.3 Area of Application

Primary screening

4P.60.4 Policy and Procedure

- All Liquid Base Cytology (LBC) slides are primary screened by qualified screening staff (4P.40)
- The ascription (identity) of the slide must be double-checked against the request form and accession number before screening
- Results are recorded on the CSW/HMR request/report form, or other formats approved by Cervical Screening Wales
- The woman's identification on the slide and the slide accession number must be rechecked against the identity and accession number on the form and/or laboratory computer system before the screener records her/his opinion

iii. Categorisation of Smears

- LBC slides are categorised by primary screeners as:
 - Negative
 - Negative with infection
 - Inadequate
 - Inadequate with infection
 - Refer for checking - ?abnormal
 - Refer for checking - mandatory rescreen
 - Abnormal refer for checking
- At the time of reporting, the woman is assigned a recall period which defines when the next smear is due

The routine recall period is defined by CSW policy as 3 years from the date of sampling; this applies:

- If the smear is negative and the woman has no previous history of abnormality
- Or, there is no indication for a reduced screening interval
- The routine recall period may be adjusted (early repeat) according to a number of factors, which include the grade of the result and the woman's previous screening history
 - The appropriate recall period is described in 4P.80
 - The appropriate recall period must be included in the report
 -

iv. Reporting of Smears

Smears are reported according to the following protocol:

Negative Smears

- Slides which show no abnormality may be classified as negative (box-22) and signed out by the primary screener, without further referral, except as specified below
- Slides which show no abnormality but have evidence of specific infections may be classified as negative (box-22), with a specified infection reported (box-23), then signed out by the primary screener with no further referral, except as specified below
- Certain specifically designated conditions associated with a negative smear must be referred for checking and if confirmed, reported by a pathologist/clinical cytologist as they may require recommendations for the clinical management of the woman (see 'Refer for Checking' below, 4P.70 and 4P.71)

Inadequate Smears

Samples reported as inadequate must be coded appropriately on the LIMS. The code must accurately reflect reasons for inadequacy. The appropriate codes are listed in the CSW Pathology Data Dictionary.

- It is the responsibility of the smear taker to sample the whole of the transformation zone (TZ). The cervix must be seen at the time the smear is taken and the full circumference of the cervix must be sampled. A sample can only be adequate if the cervix was seen and adequately sampled
- For a sample to be adequate for cytological interpretation it must contain sufficient numbers of well preserved cells. Full criteria for judging the adequacy of a smear are listed
- The absence of Transformation Zone (TZ) sampling indicators is not in itself a reason for calling a sample inadequate. This includes negative samples examined as part of follow-up for cervical intraepithelial neoplasia (CIN)
- In some cases following treatment, cervical stenosis may make it impossible to sample the transformation zone. In such cases the smear

taker may ask the laboratory to comment on the cellular content of the smear. Further follow-up in such cases should be decided on clinical judgement, and may require clinical reporting with special management recommendations (SOPP 4P.71)

- Samples taken from women with a previous history of cervical glandular intra-epithelial neoplasia (CGIN), or taken as part of follow-up procedures following treatment for CGIN, or taken from women under surveillance following an untreated 'borderline' glandular abnormality, which do not contain endocervical cells, must be reported as inadequate
- Samples taken as part of follow up procedures for CGIN or an untreated borderline glandular lesion may be sampled using both a Cervex™ brush and an endocervical brush. Both sampler heads should be collected into one vial and must be present in the LBC vial when submitted
- A sample will be classified as inadequate if:
 - It is insufficiently cellular, taking into account the woman's age and hormonal status
 - Entirely composed of separated superficial cells, suggesting a vaginal origin
 - Entirely composed of endocervical cells, indicating a probable endocervical brush sample only - not taken as part of a multiple sample
 - It was taken as part of follow-up after treatment for CGIN, but contains no endocervical cells
 - It contains no endocervical cells and was taken during surveillance following an untreated glandular abnormality
 - The cervix is reported by the smear taker as 'not completely visualised'
 - The smear taker reports that a full sample was not completed
 - The smear was taken less than 12 weeks post natal or less than 12 weeks after a miscarriage or termination of pregnancy
 - If the smear is a repeat sample taken less than six weeks after the previous sample
- Samples which are considered inadequate for screening, in accordance with the specified categories, and show no abnormality are classified as inadequate. These may be signed out by the primary screener without further referral, unless the inadequate result will result in referral for colposcopy (see 'Refer for Checking' below and 4P.80)
- Samples which are considered inadequate for screening, in accordance with the listed specifications and show no abnormality, but have evidence of one of the listed specific infections, may be classified as inadequate. The identified infection must be specified in the report, and signed out by the primary screener where appropriate without further referral, unless the inadequate result will result in

referral for colposcopy or clinical management recommendations (see 'Refer for Checking' below and 4P.80)

- Where referral for colposcopy will result, the sample must be referred for checking (4P.70) and if still considered inadequate referred to a pathologist/clinical cytologist for reporting (4P.71)
- In all cases the reason for inadequacy must be stated on the report

Technically Inadequate Samples

If a slide is considered to be 'technically' inadequate and is reprocessed and the reprocessed slide is confirmed as adequate, the original slide may be discarded without being screened.

Referral for Checking

- The following result categories must be referred to a checker (senior BMS) for further examination (see 4P.70):
 - Slides considered to be abnormal or possibly abnormal
 - Slides where there is doubt about classification
 - Inadequate samples that will result in a referral for colposcopy or clinical management recommendations (see 4P.80)
 - Specified conditions associated with a negative smear (see below)
- The following conditions associated with a negative sample must be referred for clinical reporting by a pathologist or clinical cytologist, as there may be a requirement for clinical management recommendations:
 - Clinical symptoms that will lead to a negative result being accompanied by a disclaimer (informing the woman's GP/smear taker that the cervical smear is an inappropriate test for women with clinical symptoms) (see 4P.90)
 - Follicular cervicitis
 - Herpes infection
 - Other conditions specified for clinical reporting may be defined in a local protocol
- Inappropriate endometrial cells in menopausal women (see guidance on reporting 4P.71)
- Screeners must attempt to assess the abnormality and note their opinion on the request form or reference sheet when passing smears on for checking
- The outcome of samples referred for checker or clinical reporting will be notified to the initial screener. The screener should be given an opportunity to discuss the result with the senior BMS

Any case where the checker consider the slide to be abnormal should be passed to a consultant BMS or medical consultant for reporting

Records

- The opinion and observations of all staff who have examined the sample must be recorded in a permanent, identifiable and retrievable manner

- When entering data onto the laboratory computer system, a check must be made that the identification details on the request form match the computer record accessed

4P.60.5 Quality Control/Audit

- Identification: All samples and forms are subjected to identity checks before issuing reports
- Authorisation: All reports must be authorised by a senior BMS or pathologist before they are validated
- Validation: All reports must be validated by a senior BMS or a delegated senior member of administration staff before issue

4P.60.6 Further Information

- The presence or absence of transformation zone indicator cells should be recorded on the laboratory information management system (LIMS)
- The recording of TZ status does not form part of the cytology report but must be separately recorded. This information is categorised as a 'soft' quality indicator, and is used in the overall assessment of the effectiveness of the screening programme and in the assessment of performance of individual smear takers
 - Observer variability in the reporting of TZ sampling within a laboratory may indicate interpretational issues, eg conflict between the identification of immature metaplasia versus parabasal cells
 - This may be remedied by close performance monitoring coupled with appropriate training

4P.60.7 Risk Assessment

- There is potential for both false negative and false positive results to be generated at this stage of the screening process
- The procedure may be particularly susceptible to transcription errors
- The procedure must be carefully monitored, controlled and validated at all stages

4P.70 CHECKING PROCEDURES

Specified preliminary results and mandatory categories are referred to a checker by primary screeners for further evaluation.

4P.70.1 Staff Responsible

Senior BMS and above

4P.70.2 Quality Standards

Terminology in Gynaecological Cytopathology
Guidelines for Clinical Practice and Programme Management, NHSCSP
publication No 8, (May 2000)
ABC2 for cervical cytopathology - BSCC (2000)
NHSCSP Publications

4P.70.3 Area of Application

Screening/Checking rooms/areas

4P.70.4 Policy and Procedure

1) Slides Checked

The categories of samples referred to a checker following primary screening or Rapid Quality Control assessment are specified in 4P.60 and 4P.50.

2) Checking Procedure

Prior to screening, the checker must verify that the identification details on the slide match those on the request form.

- The checker examines the screener's dots and fully rescreens the slide
- The checker rescreens referred slides in accordance with the screening guidelines (4P.40)
- Slides that are considered to be abnormal are graded by the checker according to the degree of dyskaryosis present
- Screeners should be discouraged from submitting slides that do not have a referral opinion. If there is doubt over the presence of an abnormality (an equivocal slide) the case may be labelled ?borderline changes
- Senior staff have an important role in supporting and encouraging screening staff; on some occasions screeners may wish to have a negative slide checked by a senior member of staff (eg baseline inadequacy or '6th sense' cells, etc)
 - Screeners should never be discouraged from seeking the help and advice of supervisory staff, it is, therefore, not appropriate to record these checks as borderline changes

- Recording equivocal opinions inappropriately could also skew performance indicators. In these circumstances primary screener opinions should legitimately be recorded as negative on the case record
- The use of this option should however be carefully monitored as over-use may indicate a potential screening or interpretative problem

3) Reporting of Checked Slides

- If the checker confirms any abnormality or an inadequate sample that will result in referral for colposcopy, the smear is referred for clinical reporting to a pathologist or clinical cytologist for confirmation and/or further assessment and reporting (4P.71)
 - An appropriate repeat interval or management suggestion must be included in the report (4P.80)
- If the sample is an equivocal negative and the checker agrees that the sample is negative the case may be signed out without further referral
- If the slide has been referred as dyskaryotic, but the checker considers it to be negative, the checker should seek further confirmation of this opinion from another senior BMS
 - If subsequent checker opinion concurs, the smear may be signed out
 - Borderline changes should not normally require further checking
 - If the 2nd and 3rd opinions do not agree, the case should be referred for clinical reporting (4P.71). If there is subsequent agreement that the smear is negative it should be signed out by the reporting clinician
- Any case where the checker consider the slide to be abnormal should be passed to a consultant BMS or medical consultant for reporting
- The following conditions associated with a negative sample must be reported by a pathologist/clinical cytologist if confirmed at checking, as they may require recommendations for the clinical management of the woman:
 - Clinical symptoms that will lead to a negative result being accompanied by a disclaimer (informing the woman's GP/smear taker that the cervical smear is an inappropriate test for women with clinical symptoms) (see 4P.90)
 - Follicular cervicitis
 - Herpes infection
 - Other conditions specified by the pathologist/clinical cytologist, previous Cytology
 - Inappropriate endometrial cells in menopausal women (see guidance on reporting)
- If the current case shows high-grade dyskaryosis, and the previous sample was negative or unsatisfactory, the previous slide must be reviewed:

- This may be done immediately, at the time of reporting or:
 - Deferred for review as part of a regular organised QA process
- The review should include all slides submitted within the last recall interval, especially in the case of inadequate slides or, in the case of a poor attender - the last available smear(s) within the preceding ten years)
- If the original report is not confirmed or the slide considered to be underreported, the slides should be retained for an indefinite period
- Precise arrangements for this review must be described in an appendix to this SOPP

4P.70.5 Quality Control/Audit

- Identification: all slides and forms are subjected to identity checks before issuing reports
- Authorisation: all reports must be authorised by a senior BMS, clinical cytologist or pathologist before they are validated
- Validation: all reports must be validated by a senior BMS or a delegated senior member of administration staff before issue

4P.70.6 Further Information

In exceptional circumstances, such as temporary staffing problems, following prior approval and agreement by CSW, it may be permissible for a limited range of specified checking duties to be carried out by an appropriately experienced BMS, for a pre-defined limited time period.

Such an arrangement would require:

- Close monitoring by senior staff
- must conform to agreed time limits
- be subject to periodic review

The precise duties undertaken must be identified and recorded. The arrangement should normally:

- only extend to six months and
- must be reviewed at least quarterly, and
- should not exceed a period of twelve months

4P.70.7 Risk Assessment

- The checker is subject to the same or similar pressures and risk factors as a primary screener – habituation, vigilance decrement, anoesis and transcription errors are all potential sources of false positive and false negative cytology
- A checker must observe the maximum microscopy limitations relevant to primary screeners: No more than five hours should be spent at the microscope for the purposes of primary screening and/or associated checking

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- Any involvement in quality control procedures including rapid review QC procedures may be conducted in addition to primary screening and checking duties. No upper limit has yet been defined for this task; checkers should ensure that they are involved in no more Rapid QC than is expected of primary screeners
- The duties undertaken must be limited to those within the individuals area of competence (see 4P.61)

4P.71 CLINICAL REPORTING

All samples that require clinical reporting must be examined and reported by a suitably experienced and appropriately qualified pathologist or clinical cytologist

Staff involved in the reporting of samples must maintain and demonstrate their personal competence by undertaking CPD relative to this area of activity

4P.71.1 Staff Responsible

Pathologist or clinical cytologist

4P.71.2 Quality Standards

Terminology in Gynaecological Cytopathology
Guidelines for Clinical Practice and Programme Management - NHSCSP
publication No 8 (1997)
ABC2 for Cervical Cytopathology - BSCC (2000)
NHSCSP Publications

4P.71.3 Area of Application

Clinical reporting

4P.71.4 Policy and Procedure

The following result categories must be 'clinically reported' by a pathologist or clinical cytologist:

- Abnormal samples, including borderline changes
- Samples deemed equivocal at checking (see below)
- Inadequate samples that will result in a referral to colposcopy (see 4P.80)
- Specified conditions associated with a negative sample (see below).
- Equivocal results ie: those referred on, following primary screening, where the opinions of two checkers do not agree
- Where the medical consultant or BMS wishes to report a sample coded as high grade dysk or glandular neoplasia by a primary screener or checker as negative or inadequate, the BSCC recommend that the slide be shown to a second medical consultant or consultant BMS before reporting
- The following conditions associated with a negative sample must be reported by a pathologist if confirmed at checking, as they may require recommendations for the clinical management of the woman:
 - Clinical symptoms that will lead to a negative result being accompanied by a disclaimer (informing the woman's GP/smear

taker that the cervical smear is an inappropriate test for women with clinical symptoms) (see 4P.90)

- Follicular cervicitis
- Herpes infection
- Other conditions specified by the pathologist/clinical cytologist, previous Cytology
- Inappropriate endometrial cells in menopausal women (see guidance on reporting)
- Other identified conditions confirmed by the pathologists/clinical cytologist.

All locally specified conditions reported by a pathologist/clinical cytologist must be defined in an appendix to the laboratory's reference copy of the Quality Manual

Reporting of Endometrial Cells:

The presence of normal endometrial cells need not be reported for pre-menopausal women regardless of:

- Day of cycle
- Hormonal therapy
- Pregnancy status

For post menopausal women on hormonal treatment :

- the presence of normal endometrial cells need not be reported
- the reporting pathologist should exercise clinical judgement in relation to specific cases taking into account all data reported such as the presence and frequency of accompanying bleeding etc

For post menopausal women who are more than one year post menopausal and not on hormone treatment:

- The presence of normal endometrial cells must be reported accompanied by a recommendation for further investigation
- The presence of normal endometrial cells in a sample does not affect the woman's recall by CSW

Abnormal endometrial cells of any grade should always be reported with a recommendation for direct referral to colposcopy.

All samples that require clinical reporting.

Additional rubric relating to reporting procedures/WRP requirements.

4P.71.5 Risk Management:

External Referral Procedures, Advice and Support

In occasional circumstances a specialist, confirmatory, or supportive second opinion on cervical samples or screening cases may be

necessary where an interpretational difficulty or a difficult diagnostic decision exists prior to final reporting. This process addresses a need and risk identified in consultations with the Welsh Risk Pool.

An external referral system has been defined following indications in specific cases of difficulty, which present a particular risk to the screening programme if not adequately reported. Specific areas of difficulty include the recognition of marginal 'apparent' low grade disease, or poorly or under-recognised dyskaryotic changes.

4P.71.6 CSW Cervical Cytology External Referral Service

- In most cases supportive opinion for clinical reporting should be available on site through colleagues.
- Difficult cases that do not reach consensus should be referred on through the CSW secondary external referral system
- The need to refer samples for external advice should be relatively infrequent; unusual cases in particular should be referred for second and external opinion prior to reporting
- Organisational arrangements in laboratories should ensure that no pathologist or clinical cytologist should be reporting cervical cytology if working unsupported in permanent isolation
- The CSW External Referral Service may be particularly useful where there is local difficulty in securing a second opinion even for more routine cases, due to a temporary unavailability of clinical or diagnostic support
- Reporting staff are particularly encouraged to use the reference panel if there is equivocal evidence of abnormality.

Reference Process for Diagnostic Support:

- CSW has established and will maintain a small panel of advisors. The current reference panel is listed in 2R.100 appendix 4
- The originating (reporting) clinician should arrange a review directly with an appropriate panel member. The reviewing clinician consulted should be in practice outside of the originator's area.
- The breadth of the panel membership will ensure that immediate referral of slides can be arranged at short notice to ensure a timely response to queries
- The panel includes recognised specialist and/or expert advisors in the field of cervical cytology working within the cervical screening programme in Wales

4P.71.7 External Slide Referral – Transfer of Slides:

Slides referred for second/confirmatory opinion are considered to be unique material, especially where only very scanty or discrete cells or

groups are being queried, so care must be taken in ensuring safe transfer between laboratories

- The receiving clinician/laboratory must be contacted prior to dispatch to be informed of transfer details and carrier used.
- Care must be taken to ensure that all sample transfers are conducted in a secure fashion
- Care must be taken to ensure that identity protection and confidentiality are maintained
- Slides must be securely packaged in appropriate protective containers, with adequate external protective packaging, together with supporting or relative documents
- Double wrapping should be used to protect against loss through damage.
- External packaging should include dispatcher's details to enable return of mis-delivered packages.
- The internal package should also include separate sender return details to guard against loss through damage
- Transport of slides/samples must be carried out through specialist couriers, Royal Mail special delivery or registered mail, or personal delivery by known staff
- Full sample tracking processes must be in place
- Documented hand over of samples must be completed and retained. This will include signature acknowledgement by both the dispatching and receiving parties
- This advice applies to both forward and return dispatches.

4P.80 SUGGESTED MANAGEMENT

The suggested management for all cervical screening samples is recorded at the laboratory on the CSW modified HMR request form or authorised alternate format and entered onto the Laboratory Information Management System (LIMS) at the time the sample is reported.

The recall date, repeat interval, or management advised is dependent on the microscopical appearance of the sample, its cellular content (cellularity), the cellular grading of the sample, the woman's previous history, and any other relevant clinical data.

4P.80.1 Staff Responsible

Negative cytology:

Cytoscreener

Biomedical Scientist

Clinical Reporter:

Pathologist/Clinical Cytologist

Abnormal Cytology:

Clinical Reporter:

Pathologist/Clinical Cytologist

4P.80.2 Quality Standards/References

CSW Standards

ABC2 for cervical cytopathology - BSCC (2000)

NHSCSP publications

4P.80.3 Area of Application

Cytology laboratory:

- Screening/checking rooms
- Reporting rooms

4P.80.4 Quality Control/Audit

Comparative assessment

Feedback from CSAD

Recommendations based on CSAD information

Feedback from Colposcopy and MDTs

4P.80.5 Procedure

The suggested management (HMR box 24) must be completed in accordance with extant CSW policy. The specified or recommended management actions and recall intervals are described in 2R.31 Management of the Abnormal Cervical Sample.

4P.80.6 Risk Assessment

Women may receive an inappropriate management suggestion or recall date if accurate patient information and clinical history is not available to the laboratory at the time of reporting.

This may lead to the issue of a report, which may later require a change, resulting in a risk of possible conflicting advice being given to the woman.

It is important that the laboratory appends a 'default' management recommendation to the final report, which is recorded in the laboratory computer system (LIMS), to ensure that laboratory FailSafe procedures function.

In occasional instances, the laboratory data may be more complete than the CSAD data. Correct coding at the CSAD for these women may, therefore, depend upon the accuracy of the management suggestions by the laboratory. It is, therefore, essential that management recommendations entered by the laboratory are based upon the best information available to them at the time.

4P.81 SMEARS FROM WOMEN WITH SYMPTOMS

Cervical cytology is a screening test and should never be considered a diagnostic test. The taking of a cervical smear, as an investigation of symptomatic women, is never clinically justified.

Samples taken from women with clinical symptoms that are not due under current screening policy will, nonetheless, continue to be screened and reported by the laboratory in accordance with the relevant SOPP (4P.90). An appropriate disclaimer must accompany the cytology result; the disclaimer informs the woman's smear taker and GP that the cervical smear test is not appropriate for women with clinical symptoms and that her management must not be based on the result – it is expected that the woman will be treated for her clinical symptoms and managed accordingly or referred if appropriate to a gynaecologist.

SAMPLES TAKEN INAPPROPRIATELY INCLUDING THOSE FROM SYMPTOMATIC WOMEN

Cervical Screening Wales is committed to offering a high quality cervical screening programme in Wales. Smear takers submitting samples to the service are expected to recognise the distinction between a screening service and a diagnostic service (See also 2R.20.10).

Samples outwith the current screening policy will be recorded at the Cervical Screening Administration Department (CSAD) and reported to the Regional Nurse Coordinator for appropriate action to be taken in informing and advising the smear taker about current screening policy.

Any grade of abnormality in a smear from a woman, who has been previously ceased following hysterectomy/Manchester Repair or treatment for cancer of the cervix, will be directly referred to colposcopy by the CSAD. The woman will be re-ceased from screening and further management will be determined by her colposcopist.

Any grade of abnormality detected in women aged 65 and over will be directly referred to colposcopy, but further management will depend upon the outcome of the colposcopy.

- If negative or no abnormality is found, recall is ceased
- If CIN is diagnosed follow up will be as CSW protocol

Samples taken outside of the current screening policy will continue to be screened by the laboratory in accordance with the relevant SOPPs. Where indicated the Regional Nurse Coordinator will enquire into the circumstances of the request, and discuss with the smear taker

Where samples have been taken from women with suspicious symptoms, the guidance in this SOPP should be followed.

4P.81.1 Staff Responsible

All staff

4P.81.2 Quality Standards

All-Wales Cervical Screening Policy

4P.81.3 Area of Application

Cervical Screening Administration Department
Cytology Department

4P.81.4 Procedure

- Although random tests are discouraged, any samples taken inappropriately, outside of the current policy will be accepted and screened by laboratories, and the results passed to the CSAD for action
- Women sampled outwith the current policy should be recommended for routine recall, unless the symptoms, or cytology, or a combination of both indicate otherwise. The routine recall date will be defined by the last acceptable negative test completed
- When it is indicated on the request form that a woman exhibits clinical symptoms, an appropriate disclaimer must be included in the cytology report
- The presence of clinical symptoms evident at the time of examination in the course of taking a legitimate screening smear test will not preclude the sample from the screening programme, but may affect the ability of the laboratory to adequately examine the sample, possibly resulting in an inadequate result. Laboratories will append a standard 'clinical symptoms disclaimer' to appropriate samples
- In this instance, it is the duty of the smear taker to make a judgement as to whether or not the symptoms may have materially affected the quality of the sampling process. Consideration should be given to the option of referring the woman for colposcopic assessment at this point
- The doctor responsible for the woman's health must be aware that;
 - The receipt of a negative result in this situation does not mean that the woman is necessarily free from disease
 - The receipt of a low grade result in this situation does not mean that the woman is free from high grade disease
- The disclaimer informs the woman's GP/smear taker that the 'cervical smear' is an inappropriate test for women with clinical symptoms and that subsequent management decisions must not be made on the basis of the smear result and the woman's subsequent

management is the responsibility of the her GP and/or smear taker.
A suitable disclaimer is reproduced below:

IMPORTANT NOTE: A cervical smear is not a reliable diagnostic test in a symptomatic patient. Patient management should not be determined by this result, which may not reflect the severity of any disease that may be present.

- These smears must be reported by a pathologist/clinical cytologist (4P.71)
- Slides submitted for examination that fall outside current screening policy will be recorded and may be reported to the Regional Nurse Coordinator for further action if appropriate

4P.81.5 Quality Control/Audit

Practices and clinics will be monitored by the Regional Nurse Coordinator, initially through information gathered by the CSAD and, where necessary, supplementary evidence supplied by the laboratory.

4P.81.6 Further Information

A call or recall smear test that is taken whilst a woman exhibits clinical symptoms, or when she is less than 12 weeks post-natal, could result in a genuine screening smear being unreliable or unrepresentative within the context of the screening programme.

The pathologist/clinical cytologist should assess symptomatic cases individually and may consider it appropriate to suggest that the sample be repeated following successful treatment of the woman's symptoms or condition.

Post Natal Samples:

In the case of a post-natal sample a repeat smear is requested no sooner than 12 weeks post partum allowing sufficient time for 'normal' cytological appearances to re-establish; this guidance also applies to miscarriages and termination of pregnancy.

4P.81.7 Risk Assessment

The acceptance of inappropriately referred smear tests may result in the issue of an accurate report, which is nonetheless an unrepresentative result. If the result is viewed out of context, the woman may receive inadequate or inappropriate treatment and/or follow-up. This can result in an undermining of confidence in the screening programme.

In instances of inter menstrual bleeding (IMB) or post coital bleeding (PCB) in particular, there is a significant risk that the woman's subsequent management may be inappropriately based solely on the result of the

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smear test. It is vital, therefore, that inappropriate smear test referral is properly controlled.

4P.82 VAULT SMEARS FROM WOMEN FOLLOWING TOTAL HYSTERECTOMY OR MANCHESTER REPAIR (MR)
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Women who have a sub-total hysterectomy will continue to be included in the cervical screening programme as their cervix is still present.

The following guidance applies to women who have undergone a total hysterectomy or a Manchester Repair (which involves amputation of the cervix).

Women who have had a total hysterectomy/Manchester repair (MR) more than 5 years ago and not had follow up will be ceased from recall.

For specific guidance see 2R.20.10

4P.83 MANAGEMENT FOLLOWING DIAGNOSIS OF INVASIVE CERVICAL CANCER

Women who are diagnosed as having invasive disease will not be further treated or managed within the cervical screening programme except those women who have conservative management of early invasive disease (Ia1).

For specific guidance see 2R.33

Exceptions and Special Management

In exceptional circumstances, the pathologist or clinical cytologist may suggest a management action that is outwith the standard CSW policy or defined recall period.

- This action will be based on an assessment of the clinical information provided by the smear taker, and/or on the cytological appearance of the smear
- The result will clearly indicate in box 21 (written report) the reason for this action
- The result will be clearly annotated 'Special Management Recommended', to indicate to the CSAD, GP and/or smear taker that the standard recommended action does not apply and an alternative recommendation is made
- The Regional Programme Coordinator will contact the laboratory if the result or details of the suggested management require further clarification

Clear and timely communication between the laboratory and the CSAD will minimise the risk of conflicting results being issued to the GP and the woman.

4P.84 CODING QUERIES

All coding queries are referred back to the pathology laboratory by the CSAD, and if not resolved will be referred to the Regional Coordinator for discussion with the laboratory.

- If an amendment to the woman's recommended management is required a CSW 'change of management form' will be issued to the GP by the CSAD
- A copy of the CSW 'change of management form' which confirms the action and the reason for the change will be issued to the laboratory by the CSAD for record purposes and data amendment
- The laboratory will issue a supplementary report to the GP, CSAD and, if appropriate, the smear taker. The text of the supplementary report must be clearly marked to indicate that the suggested management has been altered eg - 'Supplementary Report'
- The CSAD will record the change of management on the administration copy of the laboratory report
- The laboratory will alter its database to record the amended recall interval

4P.85	MANAGEMENT OF WOMEN FOLLOWING FERTILITY PRESERVING TREATMENT FOR EARLY STAGE CERVICAL CANCER
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The treatment of early invasive cervical cancer (FIGO stage Ia1, Ia2, Ib1, Ib2 and IIa) is outwith the responsibility of Cervical Screening Wales and consequently the outside the general scope of the colposcopy SOPPs. However, the following specific guidance applies.

If early invasive disease is detected, the lead colposcopist and the consultant responsible for the care of the woman should be informed as soon as possible.

For specific guidance see 5C.145

4P.86 EXCEPTIONAL REPORTS

Cases of vaginal intra epithelial neoplasia (VaIN)
Smears taken on women with a history of VaIN are reported by the laboratory. The management will be decided by the gynaecologist/colposcopist/oncologist responsible for her care.

4P.100 LABORATORY FAILSAFE PROCEDURES

The Cervical Screening Wales (CSW) FailSafe procedures have been designed to ensure that appropriate action is taken when a woman fails to attend an appointment for a routine cervical smear test, an early repeat cervical smear test, colposcopy appointment or follow-up cervical smear test. The term FailSafe encompasses all of the procedures designed to ensure that appropriate action is taken.

For each category of missed appointment, the FailSafe arrangements are proportionate to the degree of risk for the woman who does not attend.

The FailSafe procedures involve CSADs, laboratories, colposcopy services and general practices. Wherever possible, should one element of the system fail, another element will ensure that a woman does not become lost to follow up.

The Regional Programme Coordinator in each CSW Screening Region has primary responsibility for FailSafe within their division, supported by the Regional Nurse Coordinator and the Cervical Screening Administration Department (CSAD). The process is implemented by the local CSAD through the NHAIS call/recall system (Exeter System).

Each CSAD uses the Exeter system and the FailSafe/Safety-Net system to ensure that appropriate action is taken when a woman fails to attend an appointment for a routine smear, repeat smear, colposcopy appointment or follow-up smear.

Information to support FailSafe is also generated by the Colposcopy Highlight Rules (CHR).

The CSAD sends appropriate information to relevant women, GPs, laboratories and colposcopy services and, in specified circumstances, refers women into the Cervical Screening Wales Non-Responder Scheme. The CSAD relies on information provided by GPs, laboratories and colposcopy services to support the process.

The laboratory supports and backs up the CSAD FailSafe procedures, through the operation of a separate computerised laboratory FailSafe system.

The laboratory enters the details of women onto their Laboratory Information Management System (LIMS) whenever a result is issued; this includes any management recommendation for the woman including any early repeat smears and referral for colposcopy.

The laboratory uses the LIMS to produce a weekly list of women for whom no subsequent smear or biopsy (where relevant) has been received within specified time periods; this list is sent to the CSAD. The laboratory is not responsible for contacting women or GPs.

Women remain on the laboratory FailSafe list until an adequate smear test or biopsy is received or until they are advised that entries may be removed, when:

- Woman is not due for a repeat test (with explanation)
- Repeat test reported by another laboratory
- Woman has received treatment
- Woman has moved out of Wales
- Woman has become a non responder for a third time
- Woman has completed a CSW 'opt-out form'

4P.100.1 Staff Responsible

Cervical Cytology Manager

4P.100.2 Quality Standards

CSW FailSafe Procedures

4P.100.3 Area of Application

Laboratory

4P.100.4 Procedure

When a cervical cytology report is issued with the suggested management of an early repeat smear or referral to colposcopy, the woman must be included on the computerised laboratory FailSafe list. The laboratory FailSafe system must ensure that:

- In cases where a repeat smear is awaited, the woman is identified on a weekly list six months after the due date for the repeat smear, if a repeat smear has not been received by the laboratory
- In cases where a colposcopy referral was recommended, the woman is identified on a weekly list six months later if no confirmation of attendance is received from the colposcopy service (eg a histology or cytology request)
- The CSAD is provided with a copy of the weekly list by the laboratory. The information detailed on the list must include:
 - Full name and address
 - Date of birth
 - NHS number
 - Date of test, grade of result, and recommended management
- If no repeat smear or confirmation of attendance from the colposcopy service (as appropriate) is received and no request is received from the Regional Programme Coordinator to remove the

woman from the laboratory FailSafe system, the woman is identified on the weekly list a further 12 months later. This cycle is repeated at 12 month intervals for as long as necessary (in practice, almost all women will have been removed from the laboratory FailSafe system before a third 12 month period has elapsed)

- The woman is included on only one weekly list after every 12 month period

CSAD Action Following Notification of FailSafe Action by a Laboratory

When the laboratory notifies the CSAD that a follow up smear or confirmation of attendance from the colposcopy service has not been received, the woman's records are checked to determine whether the woman is due to have a repeat smear or a colposcopy appointment.

If the woman is due to have a repeat smear or colposcopy appointment, further checks are made to determine if the woman's details are correct and to verify details if there is an information mismatch between laboratory and CSAD data. The CSAD will contact the GP for clarification and notifies the laboratory of the outcome. Appropriate changes are then made to the laboratory and/or Exeter systems:

- If the Exeter data was incorrect, the invitation cycle may need to be restarted or a colposcopy referral reissued using correct data. In such cases, the CSAD notifies the laboratory so that the data used by the laboratory FailSafe system can be amended.

Information checks should show:

- For repeat smears, whether the woman has had a repeat smear reported at another laboratory, has had treatment or has moved out of the area
- For colposcopy referrals, whether the woman has attended a colposcopy service sending histology or cytology requests to another laboratory
- Whether, the appropriate action has been taken by the CSAD. If not, this is rectified and the reasons identified and reported to the Regional Programme Coordinator and CSAD Manager

When the above action has been taken by the CSAD, the Regional Programme Coordinator must notify the laboratory in writing of the result of the checks and, in specified cases, request that the woman be removed from the laboratory FailSafe system.

One of the following criteria must be specified for each woman to be removed from the laboratory FailSafe system:

For all women:

- Woman has moved out of the area
- Woman has completed a CSW 'opt-out form'

For repeat smears:

- Woman is not due for a repeat smear (with explanation)
- Woman has had a repeat smear reported by another laboratory
- Woman has received treatment
- Woman has become a final non responder for a third time

For colposcopy referrals:

- Woman is not due for a colposcopy appointment (with explanation)
- Woman has attended a colposcopy service sending histology or cytology requests to another laboratory
- Woman enters CSW Colposcopy Defaulters Scheme (ColpSafe)
Woman has been placed on the Exeter system 'special invitation cycle'

4P.100.5 Quality Control/Audit

Audit of FailSafe Procedures
Colposcopy Highlight Rules

4P.100.6 Further Information

CSW FailSafe Procedures
CSW Administration Quality Manual
CSW Colposcopy Quality Manual

4P.100.7 Risk Assessment

The risk of women becoming lost to follow up is minimised through the use of multi-track FailSafe in defined circumstances, involving laboratories, CSADs, general practices and colposcopy services, as appropriate.

Failure to follow FailSafe procedures may result in women who are at relatively high risk becoming lost to follow up

4P.120 TRANSFERRING REPORTS TO CSAD

To ensure that the screening process is completed, it is essential that all cervical screening reports are safely transferred to the Cervical Screening Administration Department (CSAD) for appropriate action.

Negative reports will not be subject to FailSafe checks through any other pathway other than routine recall procedures. The CSAD must, therefore, be able to verify that all reports have been safely received.

4P.120.1 Staff Responsible

Clerical Staff
Office Manager
Supervisory Biomedical Scientist

A named individual within each laboratory will be responsible for the safe transfer of reports to the CSAD. Deputising arrangements, covering periods of absence, must be in place.

4P.120.2 Quality Standards

CSW service standards
NHSCSP publications
Record retention/storage RCPATH/IBMS
Accreditation standards

4P.120.3 Area of Application

Laboratory Office

4P.120.4 Procedure

Computer Generated Hard Copy Reports:

Administration copies of reports are generated for the CSAD following completion of the validation/reporting process and recording of results on the laboratory information management system (LIMS):

- Copy reports are normally sorted by clerical staff
- If the laboratory handles requests from more than one screening region, the reports are sorted into separate CSAD batches
- Reports which require further action by the smear taker ie abnormal reports and unsatisfactory or inadequate reports are secured in a separate bundle to negative reports; the reports in each separate bundle are counted and the total numbers recorded
- The two bundles are inserted into an envelope; each envelope is uniquely identified with the laboratory identification and a consecutive numbering system, which has been previously established in consultation with the CSAD. It is recommended that 'double bagging' is used in the transfer process

- Each envelope will display the following information:
 - Laboratory Identity
 - Dispatching Officer Identity
 - Total number of negative reports
 - Total number of 'action required' reports
 - Date of dispatch
- A record of the envelope details described above is recorded by the laboratory in a dispatch log
- At the end of each week a list of the laboratory reference accession numbers of all reports sent to the CSAD during that week is produced and sent to the CSAD

Receipt at the CSAD

- The details on the envelope are checked and the contents confirmed as correct on opening, by the receiving officer
- Any discrepancies must be notified immediately to the laboratory for investigation
- The receiving officer will telephone the dispatching officer or named deputy (or a laboratory manager/senior BMS if the appointed officer is not available) to confirm receipt of the package. The identity of the dispatching officer or deputy should be clearly indicated to the receiving officer

Details of the call will be logged by the CSAD

- The receiving officer:
 - Must clearly identify her/his self to the laboratory
 - Must clearly identify the batch number received
 - Must clearly confirm that batch contents are correct
- The dispatching officer will record the safe receipt of the envelope on the dispatch log. The entry should include:
 - The date of confirmation
 - The identity of the receiving officer
- Acknowledgement of receipt will be expected by the laboratory within one working day; non-response will be addressed with the CSAD, by telephone, for immediate investigation. This action will be recorded in the dispatch log
- The weekly list of accession numbers provided by the laboratory is checked by the CSAD two weeks after receipt to confirm that all report forms received have been entered onto the Exeter system by the CSAD
- e-mail notification process – automated e-mails are generated by the 'Exeter' system. Checks are made against authorised reports and discrepancies are referred and discussed

4P.120.5 Further Information

Refer to CSAD SOPP 6A.30

The transfer of reports to the CSAD is an important administrative task that should be supervised by the Office Manager.

Laboratories are expected to have adequate clerical staff to cover administrative functions, as recommended in the BSCC Code of Practice. This recommendation is adopted as policy by CSW.

4P.120.6 Quality Control/Audit

- Feedback between separate offices - CSAD and Laboratory
- Audit of dispatch/receipt logs

Note: The retention by the laboratory of a list of results requiring action will facilitate the immediate replacement of these reports if an envelope is identified as missing.

4P.120.7 Risk Assessment

- Missing reports:
 - Are a significant potential source of error
 - Are a potential source of under-treatment for the screened woman
 - Can seriously undermine the performance of the cervical screening programme
 - May cause a breach of confidentiality for women in the cervical screening programme

4P.120.8 Electronic reporting and transfer of requests

- Electronic transmission has been considered for the transfer of results from the laboratory to the CSAD. CSW's advisor for the 'Exeter System' has advised that the control processes available for electronic transfer are not sufficiently robust to guarantee the integrity of information transferred in this way
- Laboratories should ensure that specifications for their LIMS include provision for electronic transfer. Further advice should be sought from CSW before final specifications are agreed
- The electronic transfer of CSW reports to GPs has not yet been approved
- When laboratories undertake electronic transfer to GPs, this must be in addition to and not replace the issue of paper reports
- Specifications for planned systems under development should, include provision for this enhancement of procedures

4P.121 TRANSFERRING REPORTS TO GPs/SENDERS

It is essential that a report of every cervical screening result is sent to the woman's GP and to the sender of the sample (sample taker) if different.

All laboratories use standard CSW format computer generated report forms in place of the NCR-HMR report.

4P.121.1 Staff Responsible

Clerical Staff
Office Manager
Supervisory Biomedical Scientist

A named individual within each laboratory will be responsible for the transfer of reports to GPs and senders.

4P.121.2 Quality Standards

CSW service standards

4P.121.3 Area of Application

Laboratory Office

4P.121.4 Procedure

Computer Generated Hard Copy Reports:

Duplicate reports are generated for the GP and sender (if different), following completion of the validation/reporting process and recording of results on the laboratory computer system:

- Copy reports are sorted for dispatch by clerical staff
- Reports may be batched if several reports are to be sent to the same GP or sender
- Each report or batch is inserted into an envelope and sealed prior to dispatch. It is recommended that printed address envelopes, or printed address labels are used for all reports
- Regardless of the addressing method used, it is essential that a check is always made, prior to dispatch, that the destination address is correct and corresponds with the reports contained within the envelope
- Results should not be sent to the CSAD before they are dispatched to GPs and senders, this will ensure that they have the result available should the woman make contact following receipt of her result letter
- A record of all results or batches sent is recorded by the laboratory in a dispatch log

The exact procedures employed by the laboratory must be documented in an appendix to the laboratory's reference copy of the Quality Manual.

4P.121.5 Quality Control/Audit

Audit of dispatch/receipt logs

4P.121.6 Risk Assessment

- Missing reports:
 - Are a significant potential source of error
 - Are a potential source of under-treatment for the screened woman
 - Can seriously undermine the integrity of the cervical screening programme
 - May cause a breach of confidentiality for women in the cervical screening programme

4P.150 STORAGE OF SLIDES AND REPORTS

The Laboratory has a duty to ensure that samples and slides are kept confidentially, safely and securely, to guard against accidental or non-accidental loss, damage or mishap.

The epidemiology of cervical cancer indicates that there is normally an extended pre-malignant development phase in the progress of the disease. It is important therefore that smear test slides and the cervical screening history are retained long enough to ensure that audit of the service can be completed.

To ensure effective internal monitoring procedures, quality control and audit of the screening procedure it is essential that previously reported slides are available for review, for a specified period.

The Long Term Storage of Records

The Royal College of Pathologists (RCPATH) advises that cervical smear test slides should be kept for a period of ten years; this includes all grades of abnormal, negative, and inadequate reported samples

Storage beyond 10 years is not recommended, slides greater than ten years post sample-date must be destroyed according to standard guidance.

4P.150.1 Staff Responsible

Head of department
Laboratory manager

4P.150.2 Quality Standards

BSCC Code of Practice

The Retention and Storage of Pathological Records and Archives – RCPATH

4P.150.3 Area of Application

Laboratory processing and storage areas

Long term storage facilities

4P.150.4 Equipment Required

Metal slide filing cabinets

Slide archive boxes

Appropriate shelving

4P.150.5 Policy and Procedure

Stained Slide Preparations

- Normally only one slide preparation is made from each liquid base cytology (LBC) sample. If multiple slides are produced and examined in the process of producing a screening result, these should all be retained
- Multiple slides produced for other purposes, such as teaching or quality control should only be retained for as long as the specific procedure is active. Wherever possible, slides used in teaching or QA procedures should be duplicated preparations. These preparations should preferably be anonymised or alternatively pseudonymised
- Multiple slides produced following technical problems need not be retained if a reportable slide is eventually produced. The retained slide must be the slide assessed for the report to be issued; however, if the additional slides have been used in defining the final report this must be noted and the slides retained
- Where samples have to be repeated due to technical problems, a representative slide must be retained. This includes samples where a reportable slide was not identified; the slide retained should be representative of the technical problem encountered
- All screening slides should be stored in dry, light free conditions in appropriate containers. The storage arrangements should provide ready access for retrieval of slides
- Slides should be stored in numerical order, by year of processing; this is determined by the date of receipt at the laboratory
- At least one full normal recall period of negative slides should be available in the laboratory, or a readily accessible adjacent storage area
- Smears reported by a pathologist or clinical cytologist may be separately stored in a dedicated 'abnormal' file. This may conveniently include slides referred to pathologists and reported as negative. This is not a mandatory requirement
- Laboratories may wish to re-file slides that have been extracted from the archive files for review purposes (as described in 4P.60 and 4P.70) with the current case if it has been referred to a pathologist. This is not a mandatory requirement
- Slides are disposed of at the ten year interval (post sampling date) as three consecutive screening recall periods will have been completed in that time
- Proof of destruction must be retained (eg certificate of disposal). It is expected that records will be destroyed by incineration
- There is no legal requirement to store screening slides longer than ten years (nb see 4P.150.7)

Request Forms

- The request form is a medico-legal document, recording important information about the woman at the time that the smear was taken. It is important that the document, or an exact facsimile of it, is securely stored and readily retrievable
- Completed request/report forms, should be filed in a retrievable form either alphabetically or by accession number, by year of receipt and processing. For pre-LBC samples this copy is usually the back copy if multi-part forms were used
- Careful attention must be paid to the storage conditions of archived HMR forms and records, as NCR copies are particularly prone to fading
- Facsimile copies, such as electronic filing systems including hard drives and CD or microfiche storage are recommended for archiving files
- If microfiche or electronic storage is used the record should include all comments and opinions noted on the form by all laboratory staff, and any relevant separate ancillary notes relating directly to the reporting of individual cases
- Where electronic filing systems are available and full and legible details of the complete record are made, CSW authorises the disposal of paper copies following filing/archiving of the electronic record
- Reporting records must be stored for at least 10 years; this includes negatives, inadequates and abnormal cases
- Following disposal, proof of destruction must be retained (eg certificate of disposal). It is expected that records will be destroyed by incineration

4P.150.6 Quality Control/Audit

- Periodic inspection of storage facilities
- Environmental monitoring
- Identifiable tracer systems for slides removed from file
- Tracer records and audit trail for referred slides

4P.150.7 Special Information

It should be noted that if a laboratory is aware that there is a reasonable expectation that legal proceedings may be likely, are about to commence or have already commenced, any archive destruction relating to the case/individual in question should be halted in relation to medical notes, records and documents relevant to that matter.

This caveat extends to all archive material, including the cytology slide, as permanent or semi-permanent preparations are considered to be part of the patient record.

Laboratories must immediately inform Cervical Screening Wales of any potential cases or enquiries received.

Cervical Screening Wales will notify the service of any investigations in progress.

4P.150.8 Risk Assessment

Physical Risk

A number of physical risks are associated with the archiving process. Due care must be taken when handling archive material.

- H&S - Fire hazards
- H&S - manual handling techniques
- CoSHH assessment
- Xylene hazards
- Glass

Clinical Risk

- Stored slides and reports contain confidential patient details. Every care must be taken that the integrity of files is maintained especially when a laboratory is using remote storage facilities, or an external agency for storing or microfiche reports
- When laboratories dispose of slides and reports the process must be fully documented and the complete destruction of all of the material must be warranted by the disposal agency
- A certificate of destruction must be obtained from the contractor responsible for securely disposing of the records. It is expected that records will be destroyed by incineration

4P.150.9 Retention and storage periods

- Slides are retained for a maximum of ten years from date of sampling
- Request forms are retained for a maximum of ten years from date of sampling
- Request records must include any 'examination notes' made during the reporting process
- The retention of records need not be the paper or 'hard copy' an exact and complete facsimile in electronic or microfiche media may be retained as the 'permanent record'
- Where alternative storage systems (e-records) are used the system must have a physically separate but identical back-up copy. This is usually achieved by storing the information on a remote back-up unit

4P.150.9 Disposal of Samples, Procedure and Records