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Guidance

Breast screening: quality assurance guidelines for breast pathology services

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Applies to England

Contents

This publication is available at https://www.gov.uk/government/publications/breast-screening-quality-assurance-guidelines-for-breast-pathology-services/breast-screening-quality-assurance-guidelines-for-screening-pathology-services

This document is an update to the quality assurance guidelines for breast pathology services (Cancer Screening Programmes publication No. 2). It includes advice and information on the requirements for laboratories providing a service to the breast screening programme. This includes guidance on quality assurance for handling and reporting both non-operative and surgical specimens.

This guidance should be read in conjunction with:

- Pathology reporting of breast disease in surgical excision specimens incorporating the dataset for histological reporting of breast cancer (Royal College of Pathologists publication G148) (https://www.rcpath.org/uploads/assets/7763be1c-d330-40e8-95d08f955752792a/G148_BreastDataset-hires-Jun16.pdf)
- Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening (Royal College of Pathologists publication G150) (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf)
- NHS Breast Screening Programme consolidated standards (https://www.gov.uk/government/publications/breast-screening-consolidated-programme-standards)

It also provides information on:

- methods to maintain high quality in the screening programme through participation in external quality assessment (EQA), education and training and regional pathology meetings
- the roles and responsibilities of:
  - breast pathologists
  - lead breast pathologists
  - professional clinical advisors (PCAs)
  - the national co-ordinating committee for breast pathology
- the aims, processes and logistics of the quality assurance (QA) visit

1. Introduction

The principal objective of these updated guidelines remains the drive for continued improvement in standards of pathology performance in the NHS Breast Screening Programme (NHS BSP). The quality of pathology services is central to the delivery of high-quality breast screening services because the definitive diagnosis of cancer and its subsequent classification are determined pathologically.

High-quality pathology is also required to distinguish cancer from benign conditions and report histological features of prognostic and predictive significance reproducibly and accurately. This makes sure patients are treated appropriately. However, the full significance of these pathological characteristics can be recognised only if they are reported consistently by all pathologists.

Consistency is optimised if guidelines are adopted by pathologists working in both breast screening and symptomatic breast services, as pathology data is a major element in the effective monitoring in both areas. Although the success of a breast screening programme is ultimately measured by a reduction in mortality in the invited population, statistically significant mortality data do not become available for many years. Other methods may therefore be used to monitor the effectiveness of programmes over the medium term. These include:

- the number of tumours detected
- the size of tumours
- nodal status
- other prognostic features such as histological grade

In addition to their role in monitoring the breast screening programme and supporting patients and their treatment, pathology data contributes to clinical and cancer standards audit as well as clinical research. The quality of this data depends on the expertise of pathologists and the techniques and reporting methods they employ.

Within the NHS BSP, specimens from screened women often make more demands on pathology resources and expertise than those from symptomatic women. Such samples can be macroscopically and histologically more complex and time consuming to examine. In particular, impalpable lesions may require specimen (and specimen slice) radiography, making the process of examining and reporting a specimen more intricate.

To generate high-quality pathological data and achieve the standards required by the NHS BSP, pathologists need:

- appropriate managerial and administrative support
- access to appropriate equipment and resources
- to rely on robust quality assurance (QA) processes, both internal and external

The pathology QA process is led and coordinated by the UK National Coordinating Committee for Breast Pathology (NCCBP) on behalf of Public Health England (PHE) and the Royal College of Pathologists (RCPath). It is part of the larger QA programme involving all professional groups working in the NHS BSP. The QA process for breast pathology operates and is managed on a regional basis. The regional pathology professional clinical advisors (PCAs) are members of the NCCBP.

This guidance is applicable to all laboratories and pathologists providing a breast screening pathology service. This includes those that are outsourced or handled and reported privately (such as third party providers).

2. Breast specimen handling and reporting

2.1 Standardisation of terminology, diagnostic criteria and use of proformas

A principal objective of the QA programme is to unify the terminology and diagnostic criteria employed in reporting breast lesions. This ensures accurate analysis of data sets. Central to this are the national breast screening system (NBSS) reporting forms that are used to enter pathological data for needle core biopsy and vacuum-assisted specimens (vacuum-assisted biopsies and excisions), surgical specimens and cytopathology.

Synoptic reports that include the RCPath minimum data set and NHS BSP pathology data set items must be used for reporting. This ensures comprehensive and consistent provision of pathology data and eases transcription for administrative and clerical (A&C) staff and accurate data transfer. This applies not only to NHS BSP systems but to cancer registry and audit data sets such as the National Cancer Registration and Analysis Service (NCRAS).

Sample synoptic reports, definitions of terms, and more detailed guidance on using the forms are set out in the NHS BSP/RCPath publication G148 (https://www.rcpath.org/uploads/assets/7763be1c-d330-40e8-95d08f955752792a/G148_BreastDataset-hires-Jun16.pdf) and publication G150 (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf), and are therefore not duplicated here.

2.2 Frozen section of impalpable lesions

Frozen section examination has now almost entirely been displaced by effective non-operative diagnosis techniques. Rarely, diagnostic frozen section examination of palpable lesions may be justified. Only in exceptional circumstances should frozen section assessment be considered on impalpable lesions, and then only after detailed consultation and agreement between the pathologist and surgeon. If, in exceptional cases, diagnostic frozen section has been performed, the sections should be available for review at QA visits.

2.3 Quality assurance of non-operative diagnosis

Guidance on the principles and practical aspects of needle core biopsy and fine needle aspiration cytology (FNAC) is provided in RCPath publication G150 (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf). These recommendations should be adhered to when reporting such samples.

All specimens should be reported by a named NHS BSP breast screening consultant pathologist, or a trainee pathologist under a named breast screening consultant pathologist's supervision.

If an individual reports limited numbers of non-operative specimens per year, they should consider whether they are receiving sufficient exposure to maintain expertise. It is considered appropriate for any pathologist to report at least 30 non-operative specimens in a 3-year period. Analysis of results from individuals reporting fewer than this is impossible and in the national pathology audits those reporting less than 30 needle core biopsy cases in a 3-year period have been excluded.

B3 lesions should be managed in line with the NHS Breast Screening multidisciplinary working group guidelines for the diagnosis and management of breast lesions of uncertain malignant potential on core biopsy (B3 lesions) (https://pubmed.ncbi.nlm.nih.gov/29773220/).

The NBSS is able to generate QA statistical reports automatically from non-operative specimens and surgical histology data in the form of cytology quality assurance (CQA) routines and biopsy quality assurance (BQA) routines. These permit detailed examination of results both for an individual and a service.

The national pathology audit (produced by the Screening Quality Assurance Service (SQAS)) presents data on individual pathologist performance (for those reporting sufficient numbers of cases), as well as by service, on an annual basis. Pathologists should review their own results. SQAS and the regional pathology PCA can be approached for additional advice (for example, regarding outlier status).

For details of non-operative performance targets see RCPath publication G150 (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf).

2.4 Quality assurance of the macroscopic examination of specimens

Timely transfer of surgical pathological samples to the laboratory to enable appropriate and accurate fixation, dissection, processing, embedding, sectioning and staining procedures is mandatory.

Careful macroscopic examination of surgical specimens is a vital part of the screening process. Before undertaking macroscopic examination, the pathologist should make sure they are aware of all relevant clinical details (from the request form or electronic information systems).

Specimen handling should be undertaken only by:

- pathologists involved in the breast screening service (and who meet the requirements of a breast screening pathologist and are experienced in breast dissection)
- appropriately trained biomedical scientists (BMSs/Advanced Practitioners)
- trainee histopathologists under breast pathology consultant supervision

Detailed guidance on the macroscopic examination of diagnostic and therapeutic surgical biopsies, including wide local excisions, mastectomies and lymph node specimens, can be found in RCPath publication G148 (https://www.rcpath.org/uploads/assets/7763be1c-d330-40e8-95d08f955752792a/G148_BreastDataset-hires-Jun16.pdf).

Laboratory standard operating procedures (SOPs) for handling and reporting breast specimens must be well documented. A copy of the laboratory SOP for breast specimens must be provided as one of the supplementary documents attached to the pathology questionnaire as part of the QA visit.

2.5 Quality assurance aspects of specimen radiography facilities

Immediate specimen radiography of surgical specimens from impalpable lesions will be assessed in the operating theatre to confirm that they include the radiological abnormality.

While smaller specimens may then be all embedded and examined histologically, larger specimens may benefit from x-ray examination of the sliced tissue. Such further specimen (and specimen slice) radiography in the histopathology laboratory helps to make sure that the correct blocks of tissue are selected for examination.

Histopathologists must have ready access to digital specimen x-ray facilities or services and should be able to view these images in the department.

If x-ray facilities are located in the pathology laboratory, the quality of equipment must be maintained, and their safety and performance monitored by appropriately expert (radiation protection and physics) advisers. This will form part of breast screening quality assurance reviews.

It may be helpful in difficult cases to have radiological expert opinion available for the review of specimen slice x-rays and this should be available.

Written laboratory protocols should be in place for x-raying breast specimens and derivative slices and for using and monitoring the associated equipment.

2.6 Quality assurance aspects of computers and monitors

All breast pathologists require adequate IT support, including computers and monitors.

Monitors should be of appropriately high quality to view digital x-ray images. Monitors and computers should be of sufficient standard to easily and adequately view, for example, web-based EQA and educational material.

The quality of IT support and equipment is likely to become more pertinent with the introduction of digital pathology in routine diagnostic reporting. Digital pathology is not currently approved for use within the NHS BSP.

Guidance on computer and monitor minimum specification, for example for the breast pathology EQA scheme, is available on the NCCBP website (http://www.nccbp.com/).

2.7 Quality assurance of histological examination

Details for standardisation of assessment of pathological prognostic factors and minimum data set items are described in RCPath publication G148 (https://www.rcpath.org/uploads/assets/7763be1c-d330-40e8-95d08f955752792a/G148_BreastDataset-hires-Jun16.pdf). Pathologists must be familiar with these guidelines and adhere to their recommendations for handling and reporting.

Recording histological features of invasive carcinomas that are of prognostic and predictive significance affects patient management. Accurate pre-operative assessment of grade and receptor status makes sure that the correct patients receive neoadjuvant therapy and access to appropriate clinical trials.

Assessment of histological features also allows comparison of cancers detected by screening and those presenting symptomatically, either as interval cancers or in unscreened women.

Pathologists must participate in the national breast pathology EQA scheme (see information on the pathology role, and the summary of information about the EQA scheme in section 6 of this document). They should be familiar, and practise in accordance, with the NHS BSP and RCPath guidelines on reporting breast specimens (both non-operative (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf) and surgical (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf) specimens.

2.8 Laboratory quality assurance

Minor variations in processing and staining methods from laboratory to laboratory do not significantly alter pathological interpretation. All laboratories involved in breast cancer screening must participate in general histology technical schemes and the national immunocytochemistry EQA scheme, if appropriate for the service they provide. Action must be taken if results of such schemes are sub-optimal.

For laboratories providing therapeutic predictive testing of patient samples, such as hormone receptor and human epidermal growth factor receptor 2 (HER2) assays, participation in a recognised EQA scheme is mandatory. Action must be taken if results of such schemes are sub-optimal.

Laboratories should ensure they are carrying out the minimum number of assays per year for oestrogen receptor (ER) (ideally 300 cases) and HER2 (250 cases for immunohistochemistry and 100 cases for in situ hybridisation), if they provide these services.

Regular and ongoing audit of ER and HER2 positivity rates should also be undertaken, in accordance with RCPath recommendations.

Turnaround times of breast pathology results (both non-operative and surgical specimens) are critical to the patient pathway and to facilitate meeting national treatment targets, and should be audited. The diagnostic report of 90% of non-operative specimens should be available within 5 working days and 90% of surgical specimen diagnostic reports should be available within 10 working days.

3. Achieving the pathology quality assurance objectives

3.1 External quality assurance - the UK National Breast Pathology Interpretive External Quality Assurance (EQA) Scheme

Participation in the UK National Breast Pathology Interpretive EQA scheme is mandatory for consultant pathologists working in the NHS BSP who provide a breast screening pathology service. It forms part of the contractual agreement for this service.

Participation is also recommended for all consultant pathologists who report breast specimens in the symptomatic service.

The scheme provides participants with a diagnostic assessment and personal performance appraisal. It also provides 3 educational cases, with a view to encouraging the development of further expertise.

Evidence of participation in the UK National Breast Interpretive EQA scheme is provided in the form of a certificate of participation. Submission of these certificates as proof of participation is required for all pathologists reporting breast screening cases as part of the evidence appended to the pathology questionnaire for the QA visit and provides evidence for consultant's annual appraisal.

Outline details of the EQA scheme are provided in section 6 of this document. Further scheme details, including documentation relating to its management and operation, can be accessed via the NCCBP website (http://www.nccbp.com/).

3.2 Education and training

Consultants taking on breast screening responsibilities should attend an appropriate breast pathology course within 6 months of appointment (or have attended one in the previous 6 months).

It is essential that pathologists gain an awareness of the roles of the other members of the multidisciplinary team (MDT) and of the problems which other specialities may encounter. This may be provided by attendance at a course or conference with a multidisciplinary component.

Pathologists must keep up to date and participate in the Royal College of Pathologists' continuing professional development (CPD) scheme. CPD activity should include regular, relevant, breast pathology-associated content

(at least 8 hours related to breast pathology per year or 24 points in 3 years). This is reviewed as part of the pathology questionnaire completed prior to the QA visit, which also requires attendance at regional QA meetings.

Update and refresher courses are provided by a number of centres to support ongoing breast pathology education. Where more individual tuition is needed, secondments to training centres can be facilitated (when possible) through pathology PCAs.

3.3 Regional pathology meetings

Regional PCAs play a major role in facilitating education and training within regions for all pathologists dealing with breast specimens. They host twice-yearly regional breast screening pathology meetings to include:

- discussion of slides circulated in the UK National Breast Pathology Interpretive EQA scheme, together with the analyses of consistency at each meeting
- feedback from the NCCBP committee meetings
- review of breast screening incidents relating to pathology (annually)
- presentation of the national pathology audit data (annually)

These meetings may also contain a seminar or lecture component.

Breast screening pathologists should attend at least one of the 2 regional meetings per year and at least one pathologist from each service must attend each meeting.

3.4 Research and development

Research is a vital component of pathology in breast cancer screening. It provides excellent opportunities to study the early stages of human breast cancer. All breast pathologists are encouraged to facilitate research in the breast screening programme and to support clinical colleagues. Local and national clinical trials recruitment depends on access to high-quality pathological data.

The research sub-group of the NCCBP actively identifies areas of research and development and provides updates and national guidance in new and emerging areas.

3.5 Local delivery of breast pathology quality

Laboratories involved in diagnosing screen-detected breast pathology (and also those diagnosing symptomatic disease) should be accredited by the UK Accreditation Service (UKAS) to International Organisation for Standardisation (ISO) standards.

All breast pathologists should provide a non-operative diagnosis service that meets the quality standards laid down in RCPath publication G150 (https://www.rcpath.org/static/4b16f19c-f7bd-456c-b212f557f8040f66/G150-Non-op-reporting-breast-cancer-screening.pdf) and in RCPath publication G148 (https://www.rcpath.org/uploads/assets/7763be1c-d330-40e8-95d08f955752792a/G148_BreastDataset-hires-Jun16.pdf).

All histological and cytological specimens must be reported by a consultant pathologist or a trainee under consultant supervision. The name of the reporting pathologist should be clearly identified in the synoptic report to facilitate data collection for the screening programme.

Pathology turnaround time targets relevant to the local breast service should be audited and met wherever possible, but these must not impact on the quality of pathological processing and reporting.

Provisional/preliminary and verbal reports should not be routine practice, as explained in NHS BSP guidance on issuing provisional or verbal pathology reports (https://www.gov.uk/government/publications/breast-screening-issuing-provisional-or-verbal-pathology-reports).

3.6 Second opinions and transfer of specimens between hospitals

Seeking second opinions on difficult cases is good practice and a useful educational exercise. This may be in the form of showing difficult cases (such as examples of atypical epithelial proliferations) to colleagues in the department as part of routine reporting practice, or as sending rare or more challenging cases for external expert second opinion.

Each department should have standard operating procedures (SOPs) for specimen transfer when sending cases away for second opinion or for other reasons such as external testing or clinical trials. Guidance for transport can also be found in Guidance for transfer of breast specimens between laboratories (https://www.gov.uk/government/publications/breast-screening-transferring-specimens-between-laboratories) and the Guidance on inter-departmental dispatch of cellular pathology material for referral and clinical trials (RCPath publication G137) (https://www.rcpath.org/uploads/assets/2ddb60aa-9003-4cd1-9a5a6bbe4d96a324/G137-Interdeptdispatch-Sep16.pdf).

3.7 Multidisciplinary team meetings

Attendance at regular multidisciplinary case management meetings by a pathologist providing a service to the breast screening service is mandatory.

Pre-MDT meeting case review practice is variable and should be adapted to local circumstances. This need not be the sole responsibility of the lead breast pathologist. There is no mandatory requirement for pathology slide review prior to MDT meetings, but this is regarded as good practice.

The local MDT pathologist is best placed to select any cases they feel may benefit from slide review, based on knowledge of the service's breast screening data (for example, B3 rates), experience of colleagues (for example, new consultants or locum staff) and other local circumstances.

There is no mandatory requirement for the projection of histology slides at the MDT meeting, although it is recognised to be best practice. It is valuable for clarity of explanation of pathological findings and for education, should logistics permit.

3.8 Local resource implications

The provision of high-quality pathology services depends on appropriate resourcing. This includes adequate staffing levels and funding to meet capital equipment and running costs.

The RCPath has guidance on appropriate workload for pathologists according to different specimen types (https://www.rcpath.org/uploads/assets/aaae5525-894f-472c-ae2dfa281829e3d1/g107_guidelinesstaffingworkload_sep15.pdf). This guidance will shortly be updated. Individual pathologists' workloads should be reviewed in line with these at annual job planning and appraisal meetings.

Pathologists should have protected time in their job plan to support CPD, audit and MDT meetings, as set out in the RCPath guidelines.

High-quality histology and cytology services rely on adequate secretarial support.

Breast screening pathology also makes particular demands on technical time. For example, it may require a large number of blocks, specimen (and specimen slice) radiography and examination of extra levels to identify microcalcification in vacuum-assisted cores and surgical resection specimens. Adequate laboratory staffing is therefore required.

High-quality specimen radiography equipment is vital for all laboratories handling breast specimens. Resources should be allocated for its maintenance and timely replacement, and it should be subject to a physics quality control programme.

Access to suitable facilities, including projection of microscopic images, is needed for MDT meetings.

4. Roles and responsibilities

This information is applicable to pathologists providing a breast screening pathology service and to those working in outsourced and/or private (third party) providers. To optimise consistency, the NCCBP recommends that these standards are also adopted by pathologists in the specialist breast symptomatic service.

4.1 Breast screening pathologist

The recommended minimum standards for all pathologists providing a service to the NHS BSP are that the pathologist:

- must participate in the UK National Breast Pathology Interpretive EQA scheme
- must report a minimum of 50 primary breast cancer resection specimens each year*
- must have protected time in their job plan to support CPD, audit and MDT meetings, as set out in the RCPath guidelines
- should attend an appropriate breast pathology course within 6 months of appointment (or have attended one in the previous 6 months)
- must participate in relevant CPD for each round (the recommendation is at least 8 hours related to breast pathology per annum)
- should participate in relevant and regular departmental audit
- should regularly attend regional QA pathology meetings (at least one of the 2 per annum)
- should be a member of a specialist breast service MDT and participate regularly in clinical multidisciplinary team meetings

- must ensure multidisciplinary case discussion meetings are attended by at least one pathologist of consultant level
- must participate in NHS BSP QA visits

*Such a workload will involve handling additional specimens, including non-cancer and cancer-related non-operative and diagnostic specimens and those relating to follow-up and subsequent treatment episodes. If they report limited numbers of non-operative specimens per year, they should consider whether they are receiving sufficient exposure to maintain expertise and to report breast screening non-operative pathology samples. The RCPath has guidance on appropriate workload for pathologists according to different specimen types (https://www.rcpath.org/uploads/assets/aaae5525-894f-472c-ae2dfa281829e3d1/g107_guidelinesstaffingworkload_sep15.pdf). Each individual pathologist's workload should be reviewed in line with these at annual job planning and appraisal meetings.

4.2 Lead breast pathologist

Each laboratory is required to have a nominated lead and deputy lead pathologist with responsibility for breast screening pathology. The lead breast pathologist requires adequate time in their job plan to perform this role.

The roles and responsibilities of the lead pathologist are to:

- comply with all other requirements of a breast screening pathologist
- review breast pathology data for the service
- act as nominated point of contact for SQAS
- provide evidence for QA visits
- advise the director of breast screening regarding pathology-related issues

4.3 Professional clinical advisor (PCA)

Professional clinical advisors (PCAs) are appointed regionally by PHE. Their roles and responsibilities are to:

- provide ongoing, ad hoc advice to the regional QA service
- advise on areas of concern or potential incidents
- participate in delivery of QA visits
- support education and training in the regional professional group
- support national work to develop the screening QA service
- support the revision of targets and guidance relating to the programme – they encourage the participation of peers and lead or delegate this work as appropriate, in collaboration with the PHE national programme lead and programme manager
- be a source of advice to the national programme lead and programme manager
- assist in the development and or delivery of education and training resources as required

4.4 National Co-ordinating Committee for Breast Pathology (NCCBP)

The NCCBP is responsible for coordinating QA procedures and guidance, in particular reviewing and recommending standards. It also provides guidelines and advice on pathological examination of breast tissues to achieve a high level of accuracy and consistency in reporting breast lesions.

The group comprises:

- the regional PCAs to the breast screening programme in England

- representatives of PHE
- the Royal College of Pathologists' specialty advisor in breast pathology
- co-opted pathologists with specialist expertise in breast pathology including representatives from Scotland, Wales, Northern Ireland and the Republic of Ireland
- representatives of equivalent surgical and radiological associations

Members of the EQA scheme secretariat and management are in attendance. Information on the terms of reference of the committee and current membership and contact details can be found on the NCCBP website (http://www.nccbp.com/).

The functions of the group are to:

- advise PHE, RCPath and other medical organisations on breast pathology-related issues
- advise PHE on aspects of programme pathway delivery and support the programme by providing professional advice as required, for example in the support of incident management
- monitor and have oversight of the performance of pathology services in the breast screening programme, including the national pathology audit
- provide support and information for PCAs and thus to regional pathologists
- identify educational needs of pathologists and organises training, including national courses
- monitor the adequacy of data provided by pathologists
- promote the timely uptake of quality issues and standards
- regularly review the pathology information system for the breast screening programme
- act as the steering committee for the UK National Breast Pathology Interpretive EQA scheme
- establish and maintain close working relationships with other breast pathology associations, to ensure standardisation of advice and to avoid duplication of effort and responsibilities
- support the exchange of information and quality issues with other professional groups
- support the exchange of information between pathologists and NCRAS

- support the exchange of information and pathological material between pathologists and the wider research community

5. Regional delivery of breast pathology quality and quality assurance (QA) visits

The QA process is operated and managed on a regional network basis. It is coordinated by regional SQAS with regionally appointed PCAs in each professional discipline. Clinical and professional advice is important in supporting effective assurance of the quality of screening services and includes peer review, education and training, and advice. The regional pathology PCAs play a major role in supporting the QA process and are integral members of the regional QA teams. They also support education and training initiatives, for example by holding the regular twice-yearly regional breast screening pathology meetings with managerial and educational components.

QA visits usually occur at least once in the agreement period. As part of the visit, pathology departments involved in the screening programme are visited every 3 to 5 years by regional QA teams who inspect local facilities and ensure that performance meets agreed standards. The QA visit is primarily a means of providing support and enabling improvement rather than an inquisitorial process. Only if a significant issue is identified will immediate action be recommended. QA visit outcomes are currently reported to the host trust and the commissioner. Appropriate guidance regarding remedial actions and required changes and actions are advised when facilities, resources, protocols or performance are assessed as sub-optimal.

5.1 Objectives of the QA visit

The QA visit is to:

- ensure the pathology service provided to the local breast screening service is of a high standard and performs in accordance with national guidelines and standards
- identify areas of underperformance and to make recommendations as to where improvements should be made
- determine or resolve multidisciplinary working issues

5.2 Process of the QA visit

The visiting pathology PCA meets with the local pathologist(s) and determines if the performance, organisation and resourcing of the service meets national pathology guidelines and standards and quality standards in breast pathology. This is done through:

- review of a completed, detailed QA questionnaire
- discussion
- observation
- examination of data, slides and reports

The QA visit aims to support the local service to achieve a high-quality service through identification of any areas of deficiency. Should problems be identified the QA team will suggest mechanisms to support the local pathologists and the screening service to achieve the necessary standards.

Pre-visit
A pre-visit by the pathology PCA allows potentially important issues to be discussed at an early stage. It may be undertaken for the histopathology slide review component of the visit. At the pre-visit the pathology PCA may meet with the lead breast pathologist, attend an MDT meeting, visit the pathology laboratory and or other relevant staff.

Main QA team visit

At the main QA team visit the pathology PCA meets with the lead breast pathologist, all other pathologists reporting specimens for the local breast screening service (ideally) and, if necessary, with other members of the local team.

The meeting includes a discussion of the completed pathology questionnaire, as well as clarification and more detailed discussion of any issues raised. The pathology PCA provides feedback from the review of data, slides and reports. Any significant diagnostic discrepancies should be discussed at one of the 2 visits to the department. The pathology PCA may provide preliminary verbal feedback to the lead pathologist prior to feedback to the full QA team.

5.3 Data required for QA visit

The following data is required and provided to the visiting pathology PCA by the local SQAS before the QA visit (usually available from the PHE Screening division IT system, ‘MARVIN’). The data includes:

- pathology questionnaire(s), completed by the relevant lead breast pathologist(s) in conjunction with colleagues reporting breast pathology specimens, with relevant supplementary documents for all laboratories providing a service to the screening service (for example, all pathologists’ breast EQA certificates, relevant National External Quality Assessment Service (NEQAS) data, departmental SOPs and details of attendance at regional pathology meetings)
- KC62 cohort needle core biopsy (BQA) and cytology (CQA) data from NBSS for the previous 3 years – this information should be provided for the service as a whole and also for individual pathologists
- a breakdown of the histological characteristics of benign and malignant lesions (HQA data) for the previous 3 years
- service data from the national breast pathology audit and Association of Breast Surgery (ABS) audit, for example histological invasive grade distribution, node positivity rates, ER and HER2 positivity data and information relating to completeness of data recording (other data may be requested in specific instances)

- the previous QA report and details of outstanding pathology recommendations, plus an update on all other recommendations
- the pre-visit data booklet
- any requested policies, patient information and audits where provided
- the MDT questionnaire
- the MDT attendance records

5.4 Peer review of slides and reports

Peer review of slides and reports forms part of the quality assurance process. Review of histological reports is undertaken to confirm adherence to NHS BSP reporting categories, use of proformas or templates and completeness of minimum data set provision. Ten histology reports should be reviewed for each reporting pathologist but the number of histology reports (and nature of lesions) requested will be based on the pathology questionnaire and the data received from the SQAS.

Slide review includes:

- a selection of specimens from the previous year
- cases from all reporting pathologists
- at least 5 cases for each pathologist which include a range of pre-operative specimens, therapeutic surgical cases, potential false positive cases and open diagnostic surgical specimens
- histology from cases with malignant core biopsy and normal/benign excision in the absence of neoadjuvant therapy – these should all be reviewed (for example, where the tumour is believed to have been removed by core or vacuum-assisted biopsy)
- all histology reports from potential false positive cases (cases with a malignant core biopsy diagnosis and a benign outcome at surgery) – the slides for all of these must be available for examination but histological

sections from patients who have received neoadjuvant chemotherapy will be examined at the pathology PCA's discretion (see NHS BSP guidance on managing B5 core malignant biopsies (https://www.gov.uk/government/publications/breast-screening-managing-b5-core-malignant-biopsies))

- frozen sections from screen-detected excision cases should be available for review – any diagnostic frozen section (such as for diagnosis of a specific lesion) should be reviewed while those, for example from nipple shave margins, will be examined at the PCA's discretion
- an additional selection of cases for review, based on knowledge of the screening service, national pathology audit and questionnaire or if a specific issue is identified from review of the QA statistics

If in exceptional cases frozen section has been performed on a screen-detected breast lesion, the sections should be available for review at the QA visit .

The total number of slides reviewed is at the discretion of the pathology PCA. It will depend on the number of histopathologists within a service that are reporting breast screening specimens.

For all cases selected, the department being visited should provide all sections and matched histology reports.

5.5 MDT review

The pathology PCA (along with other members of the visiting QA team) will observe a live breast MDT meeting to enable comment on the adequacy of facilities, clarity of inter-professional communication, arrangements for pathology case review and approaches to discrepancies in diagnosis.

5.6 QA report

The pathology section of the written QA report should be provided to SQAS by the PCA within 7 days of the QA visit. This is submitted to the director of breast screening within 6 weeks and should be available to the lead breast pathologist (via the director of screening) to check for factual accuracy and returned within 2 weeks.

The report will include comment on aspects of:

- organisation and leadership
- workload, staffing and laboratory accreditation
- communication
- laboratory processes
- pathology reporting and data collection
- training and CPD
- quality assurance and audit
- slide and report review
- MDT meetings

Recommendations will include anticipated timescales with required evidence and be categorised as:

- immediate concern
- high priority
- standard priority

Issues for shared learning are also highlighted in the report.

The screening service provider is responsible for developing an action plan in collaboration with the commissioners to complete the recommendations contained in the report.

SQAS works with commissioners to monitor activity and progress in response to the recommendations made for a period of 12 months after the report is published. After this point SQAS sends a letter to the provider and the

commissioners summarising the progress made and outlines any further action(s) needed.

5.7 QA process for breast pathology services for varying laboratory configurations

Whilst a single QA visit process has been developed for England which includes standardised pre-visit activities, questionnaires and rationales for evidence requested, it is clear that there is increasing variability in configuration of delivery of pathology services for the breast screening programme.

Some screening services are served by more than one laboratory. Other cellular pathology departments may provide a service to more than one screening service. Frequently, even if non-operative specimens are reported in a ‘main’ laboratory serving the screening service, subsequent surgical samples may be processed and reported in another.

The following information outlines how the standardised QA visit process can be applied to these settings. This ensures QA is maintained without excess duplication of activity for the SQAS, PCAs and the laboratories involved.

The models of delivery are:

A) One screening service and one pathology laboratory (on the same or another site)
B) One screening service and one ‘main’ histology laboratory, but some specimens (often surgical samples) are received in other pathology laboratories
C) One screening service and multiple pathology laboratories
D) Several screening services served by one pathology laboratory
E) Complex situations, such as one screening service submits specimens to multiple laboratories which also receive samples from other screening services

As a principle, when a QA visit is being undertaken for any one screening centre, all pathology laboratories providing the service to that screening service should be included in the QA review, whether that is one single

('main') cellular pathology department, or multiple histology departments.

QA visit to a screening service serviced by more than one pathology laboratory

Of note, significant differences between results (for example, audit data) from laboratories serving one screening service are likely to be related to that cellular pathology department and not radiological aspects of the programme. It is therefore important that all laboratories are included in the QA process to maintain consistency of a high-quality service (technical and medical) and ensure standardisation of application of both diagnostic criteria and terminology.

When multiple laboratories serve one screening service, attention should also be paid to adequacy and timeliness of transport and fixation of specimens.

For pathology QA visits in this setting, see (models A, B, C and E):

- a pathology questionnaire should be completed for all laboratories
- slide and pathology report review should be undertaken for all laboratories, ensuring samples from all reporting pathologists from each centre are included
- audit data by pathologist should be reviewed – great care should be taken in the evaluation of data from those reporting only small numbers of cases, while conversely noting the guidelines set for numbers of resections (50 cases per annum) for specialist breast pathologists
- all reporting pathologists should have undertaken adequate CPD and provide evidence of participation in the breast EQA scheme and regional pathology meetings, as detailed in the visit questionnaire
- the pathology PCA should meet with reporting breast pathologists from all laboratories, ideally visiting the different laboratories in person, particularly if numbers of specimens are other than minimal – this may require multiple visits (a degree of pragmatism is required) but the lead breast pathologist for each laboratory (at a minimum) should be interviewed
- multiple breast MDT meetings will be in place – the format of these will vary according to local protocol (it may not be feasible for the pathology PCA to be present at an MDT meeting for every combination of screening service and laboratory service, but one of the visiting QA team should assess staff interactions as well as adequacy of facilities, which may include video-links)

QA visit to a screening service serviced by one pathology laboratory, which has been visited by the QA team within the previous year

Given the increasing complexity of breast screening pathology provision, a pragmatic approach to QA visits is sensible. For example, if one laboratory provides a service to more than one screening service (as in models D and E), it is possible that the pathology department has been visited by the Breast QA team within the previous cycle.

In such cases, so as not to duplicate assessment and cause unnecessary work for the laboratory and the PCA (particularly if no significant issues were recorded), pathology QA should include:

- review of the previous QA visit pathology questionnaire with confirmation of ongoing EQA and CPD by the reporting pathologists and confirmation of an absence of change in facilities, staffing and management (this is considered adequate if completed and satisfactory (without any outstanding issues) within the previous year) – re-review of laboratory protocols (SOPs) and technical audit results are not required
- identification of issues of specimen transport and fixation (case review of representative cases is good practice) – adequacy of pathology sampling and reporting will have been evaluated previously, however, as the laboratory is also receiving specimens from the screening service now under review, specimens may be affected by delayed transport and fixation (such as mastectomies) should be considered
- assessment of audit data for the screening service under review – it may prove useful to compare this with data for the previously reviewed screening service, as well as national data, if issues are identified
- a visit between the pathology PCA and (ideally) all the pathologists reporting breast specimens to determine if there are any issues relating to the screening service presently under review, for example regarding specimen fixation and transport, attendance and logistics of MDT meetings (including video conferencing, if used) and personnel

6. Summary overview of the UK National Breast Pathology Interpretive EQA scheme

The National Breast Pathology EQA scheme was started in 1990, primarily to investigate the level of consistency that pathologists involved in the breast screening programme could achieve in reporting breast lesions. The scheme used the data gathered to devise improvement initiatives. The success of these could be evaluated in further rounds of the scheme. Subsequently, the scheme was opened to non-screening pathologists and adapted to be used for individual assessment and collective performance review.

The scheme is hosted by Nottingham University Hospitals NHS Trust and overseen by the NCCBP.

The scheme presents 2 assessments per year, each comprising 13 mandatory cases and one unusual or rare educational case. The assessment form incorporates multiple reporting features as defined in relevant breast pathology reporting guidance. While the scheme is considered primarily educational, performance appraisal is also a component of the scheme. Performance is assessed on overall diagnosis only.

To participate, individuals must register with the scheme. Once registered, you will be issued a user name and password which let you access the tools and materials available.

The scheme provides guidance for participants about the computer hardware, browser and network specifications required to optimise participation in the breast EQA scheme. Scheme guidance on IT technical requirements is published on the NCCBP website (http://www.nccbp.com) or can be obtained via direct enquiry using the contact details below.

Additional information about the scheme is contained in the scheme management documentation and in the participants' manual which is available either on request or on the EQA Scheme website (http://www.nccbp.com).

All UK National Breast Pathology Interpretive EQA scheme enquiries should be directed to:

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