**Trust Procedure**

Plymouth Hospitals NHS
NHS Trust

# Breast Screening Programme Standard Operating Procedure

| Date | Version |
|---|---|
| **June 2015** | **V1.1** |

## Purpose

This standard operating procedure is designed to support the process of requesting, undertaking, verifying and communicating the results of the Breast Screening Programme. Its purpose is in enabling all staff to ensure that the Breast Screening Programme is managed to minimise the risk to patients and to improve patient outcomes and quality of care.

## Who should read this document?

All medical, nursing and other support staff involved directly or participating in the management of the Breast Screening Programme, within or on behalf of Plymouth Hospitals NHS Trust.

## Key messages

Clear pathways must be in place that identify how, when and to whom results should be communicated.

## Accountabilities

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| **Production** | Director of Breast Screening |
| **Review and approval** | Breast Imaging Management Team |
| **Ratification** | Director of Breast Screening |
| **Dissemination** | Director of Breast Screening |
| **Compliance** | Director of Breast Screening |

## Links to other policies and procedures

Policy for the management of diagnostic testing and screening procedures
West Devon and East Cornwall Breast Screening Quality Screening Manual

## Version History

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| **V1.0** | May 2012 | Document developed in response to the requirements of the NHSLA Risk Management Standards. It is designed to supplement the procedures documented within the Breast Screening Quality Screening Manual. |
| **V1.1** | June 2015 | Document updated to include updated competencies for Advanced Practitioner. |

| Last Approval | Due for Review |
|---|---|
| June 2015 | May 2018 |

*PHNT is committed to creating a fully inclusive and accessible service.*

*Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff.*

*We will treat people with dignity and respect, actively promote equality and diversity, and eliminate all forms of discrimination regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/ maternity.*

*Throughout this document references to gender reflect current incumbents and in no way imply future desired genders for roles.*

**An electronic version of this document is available on the Trust Documents Network Share Folder (G:\TrustDocuments). Larger text, Braille and Audio versions can be made available upon request.**

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Plymouth Hospitals NHS
NHS Trust

# Standard Operating Procedure (SOP)

# Breast Screening Programme

## 1 Purpose and Scope

This standard operating procedure is designed to support the process of requesting, undertaking, verifying and communicating the results of the Breast Screening Programme. Its purpose is in enabling all staff to ensure that the Breast Screening Programme is managed to minimise the risk to patients and to improve patient outcomes and quality of care.

### Background

There are 80 breast screening units across England, each inviting a defined population of eligible women (aged 50 to 70) through their GP practices. Women are invited to a specialised screening unit, which can be hospital based, mobile, or permanently based in another convenient location such as a shopping centre. In Plymouth, women can be invited to attend the mobile unit, the unit based in the Guildhall in Plymouth city centre or the Primrose Unit at Derriford Hospital.

The NHS Breast Screening Programme is nationally coordinated. It sets national standards which are monitored through a national quality assurance network.

### Key Duties

### Breast Imaging Management Team

The Breast Imaging Management Team: The Director of Screening, Office Manager/Programme Manager, Lead Radiographer and QMS Lead who between them represent line management for every member of staff within the imaging section of the breast unit. This group meets on average every fortnight for formally convened and minuted meetings.

The Management Team is responsible for overview of performance, and for planning and communication of interventions designed to deal with issues noted from this. The team review the staffing issues, finance and budgetary issues, adherence to governance, guidelines and policy including review of the QMS system itself, and address specific concerns reported to any member of the team by the staff.

### Effective Care Group

The Effective Care Group is responsible for:

- ensuring that it receives assurance of the appropriate delivery of screening and diagnostic tests, through receipt of periodic performance and exception reports from clinical directorates, seeking

assurance that risks identified in relation to screening and diagnostic tests are managed and mitigated appropriately and escalated where required, in accordance with the Trust's Risk Management Framework.

- seeking assurance that incidents, including legal claims and inquest findings are managed appropriately and that any lessons to be learned from incidents are taken into account in future delivery of the service.

**Lead Clinician/Director of Screening**

The Director of Screening is responsible for local clinical, technical, assessment and other protocols in accordance with national guidelines. He must ensure, with the assistance of the QMS lead and other staff, to whom he may delegate individual policy writing, that such guidance is appropriately drafted and consulted upon, and represents the true practice of the unit. He must review audits performed to ensure this.

He must ensure that decisions made at MDT meetings are documented (this task will normally be delegated to the MDT co-ordinator), and that decisions are consistent with screening policy. He is responsible for accepting such authority as delegated to him by senior trust management for budgets relating to screening and symptomatic breast imaging, and for liaison/accountability to the commissioners of screening. He must ensure regular staff and reading team meetings and adhoc meetings as the need arises to allow staff to raise issues of concern, and be made aware of any particular issues known to the Breast Imaging Management Team but not widely disseminated otherwise.

He is responsible for maintenance of the screening targets, implementation of the central policies, compliance with the instructions from the Quality Assurance Reference Centre and from the central steering groups of the breast screening programme, according to the NHS BSP mandates for such a role (see NHSBSP No. 52, Organising a Breast Screening Programme). He is responsible for overseeing investigations into complaints, ensuring good liaison with charities and patient groups, and for overseeing Health Promotion.

The Director of Screening is directly accountable to the Chief Executive, and to the Medical Director, and should work with the Directorate Manager and Clinical Director to ensure optimum efficiency, financial viability and quality for patients in the breast unit and wider directorate.

**The Lead Radiographer** is responsible for the day to day management of the unit. With the unit director she is responsible for the smooth running of the Department, management of the service line budget, responding to incident reports on Datix, line management of radiography staff and screening office manager and planning of the screening round. She is accountable to the Director of Screening, and to the Directorate Manager.

**Radiographers** are responsible for maintaining professional competency, practising to a high standard, following standard operating procedures as documented in the QMS policy documents, including aspects relating to radiation protection, confidentiality, safeguarding and infection control. A team of radiographers are responsible for quality assurance of the radiological equipment and ultrasonographic equipment. Radiographers are also

responsible for supervising Assistant Practitioners. They are accountable to the Lead Radiographer.

**Radiologists** are responsible for maintaining professional accreditation and competency and continued personal development (CPD), meeting the standards in the NHS BSP publication number 59, quality assurance guidelines for breast cancer screening radiology, for high-quality training of junior staff, and have overreaching responsibilities regarding radiation protection, confidentiality, safeguarding and infection control. They are responsible for those aspects of medical care that pertain to imaging and diagnosis, covering colleagues at times of absence, for representation of clinical scenarios at the multidisciplinary meeting, and for their parts of the patient pathway as documented in the local QMS documentation. They are accountable to the Director of Screening

**Advanced practitioner radiographers**, are responsible for maintaining professional accreditation and competency and continued personal development (CPD). According to their role, are responsible for the quality of their reporting, or biopsy within the NHS breast screening programme or in symptomatic radiology, for those roles in the same way in which a Radiologist would be. They are accountable to the Director of Screening.

**Assistant practitioners** are responsible for production of high-quality mammography, maintaining their accreditation and continuous professional development, audit of their own work, and ensuring that the work is supervised by radiographers at times as required Society of Radiography accreditation. They are accountable to the Lead Radiographer.

**Clinical Departmental Assistants** are responsible for chaperoning, ensuring smooth flow of patients during clinics including cleaning up probes, preparing the room, assisting patients during clinics, as well as responsible for assisting administrative staff where required in various routine tasks specified in the QMS documentation. They are accountable to the Lead Radiographer.

The **Office Manager** line manages all of the other office staff, including breast secretaries and screening office administrative staff. She is responsible for production of audits, training administrative staff, data quality, liaison with the QARC as the primary contact. She is expected to maintain her level of knowledge and adapt as and when required to new expectations from the NHS BSP central office regarding data returns or other means of audit. With the director of screening and Lead Radiographer she forms an important part of the management of the unit, and has a place in the Breast Unit Management Team. She is accountable to the Director of Screening, the Lead Radiographer who appraises her and the Directorate Manager.

**Screening Office Administrative Staff** are responsible for ensuring the smooth running of the administrative aspect of breast screening. This includes answering telephone queries from members of the public, arranging appointments for screening and, arranging failsafe appointments, audits as required by the Director of Screening or by any other member of his/her staff. They assist in managing paperwork, requesting old films from other centres, liaising with Synertec and other companies, downloading images from the van or static site into our PACS system, and any other administrative tasks

required by the screening programme. They are accountable to the Office Manager.

**Radiology secretaries** are responsible for typing clinics where voice recognition fails, managing postal queries where possible, assisting with "personal assistant" functions for consultant breast radiologist and Advanced Practitioner, assisting during one-stop clinics and other clinical sessions by providing documentation for biopsy, for example. They are responsible for co-ordinating/booking of imaging appointments on CRIS. They are also responsible for ensuring that requests to the Department of Health are managed in a timely fashion and bring them to the attention of a relevant clinician. They are responsible for completing audits as required and taking minutes of meetings. They are accountable to the Office Manager.

**Duties External to the Organisation**

**The Quality Assurance Reference Centre**. This body, which is national with a regional base, quality assures the breast screening programme on behalf of the NHS BSP. They are accountable to the central screening office and Prof Dame Julietta Patnick. They produce quality assurance reports on a three yearly basis following inspection

**Shared Business Services:** this organisation is responsible for specifying batches of women based upon GP registration as requested by the screening units. They are accountable to the SHA

**Staff competencies**

- Consultant radiologists practising within the breast screening programme must meet the requirements of NHS BSP publication number 59 (most recent edition March 2011, 2nd Edition)
- Advanced practitioners must possess a Masters level post graduate certificate or diploma relating to their advanced practice skill in breast imaging, and have trained for at least two years within an NHS breast screening programme training centre before they can practice as above.
- A Master's degree would be expected for an advanced practitioner or consultant radiographer practicing multiple imaging skills. In addition they must have a certificate of competency in mammography and have completed a degree course or equivalent in radiography.
- Radiographers must possess a degree course in radiography (or equivalent), and a mammography competency certificate.
- We require that all staff involved in all stages of the screening procedure have read and understood this SOP and comply with it
- We require staff to maintain competencies, through attending relevant training, development and awareness sessions when required. Achievement of required competencies should be evidenced and recorded, in accordance with the Trust's relevant workforce policies. This is monitored through appraisal and revalidation for doctors, through appraisal and records kept by the superintendent radiographer for staff

groups which she line manages, and by appraisal and records kept by the office manager for administrative staff.

### Monitoring and assurance

The NHS Breast Screening programme (NHSBSP) is inspected every three years by the Quality Assurance Reference Centre (QARC) with onsite inspection where the “right results” protocols will check the whole screening process from beginning to end. This documents the administrative functions of the service. The clinical aspects of the service are inspected by individual service specialists. Monthly audits of data directly entered during the film reading process and assessment process are performed at the quality assurance reference centre, and regular tables of performance against other centres on key performance indicators are produced. The KC 62 table, for example, assesses cancer detection rate, uptake of screening appointment, non-invasive and small cancer detection, biopsy rate, and looks at trends against time against the region and against national performance.

In addition, real-time monitoring of the database is possible at QARC regional level and national level. This facility is used to produce monthly performance reviews against targets for sending of results and recall to assessment. The QARC produce these monthly reviews and distribute them to the management of all screening units in their region, and the public health and commissioning team associated with breast screening.

Φ An audit program is normally performed locally as directed by the QMS manager and performed by the staff trained to audit, who are selected from each of the main staffing groups which includes all areas of performance described above on a yearly rotation of inspection and audit, which is internal, and the reports are brought to the QMS meeting which is held monthly[1]. Issues identified would be prioritised and addressed through the normal management process via the Management Meeting or via the leads in each area as appropriate, monitored by documentation at the QMS meeting and the audit loop closed there. Feedback to staff would occur as an integral part of addressing the issues, but also through the staff meetings or internal Email as appropriate. We are a small team, and many minor issues can be effectively communicated by the lead in each area talking directly to staff, which is always part of the process, independent of the more formal and documented approach. Where issues represent risk to patients or staff, these are always raised through the trust DATIX system, would be automatically included in the unit management meeting, and would be addressed and delegated as appropriate by the Superintendent, who receives the DATIX output for the unit.

## 2 Procedure to Follow

### Process for Requesting Screening Procedures

[1] *Between August 2013 and June 2015 due to staff shortages and sickness this role was only partially performed, but is planned to recommence in full from July 2015.*

The screening office in the Primrose Unit will request of the Devon and Cornwall Practitioner and Patient Services Agency (PPSA) that they specify a batch of women within the eligible age group to us. This happens once every 3 years for each GP surgery, and approximately every 3 to 4 weeks for our screening programme.

We will specify the batch required both by age and by GP surgery, to achieve universal coverage in our screening area. The NHAIS (National Health Authority Information System) or Exeter system contains the live database of GP registrations, and the PPSA will interrogate this database to provide the list. GP surgeries are alerted that we are about to screen so that they can inform us of women who should not be screened (double mastectomy, terminal illness, very severe disability which would prevent mammography) and can alert us as to those with special needs who can then receive tailored invitations and extra community support, and dedicated appointments allowing more time for the test. Disabled eligible women who are, for example, wheelchair bound would be alerted if the van cannot use the lifting tailgate in its screening site so that they can be redirected to Derriford or to the site within the Guildhall, both of which have excellent screening access. After vetting of the list by GP surgeries, and after removing cases that have previously opted out ("ceased" in screening parlance) from the programme, we send a request to Synertec, a company to whom we have outsourced the printing of screening requests. The letters of invitation would be sent out to the standards of the NHS Breast Screening Programme (reference NHS BSP publication number 60, June 2005, consolidated guidance on standards for the NHS breast screening programme (second edition)).

**How the clinician treating the patient is informed of the result, including timescales**

All GP surgeries receive a formal feedback letter containing the results of breast screening on their population. This lists by name all women who participated in screening and those that did not, and gives each result (of the final process) which will be either that they were normal, or had breast cancer or other abnormality necessitating surgery. This report is produced every week and lists all patients screened that week.

The GP receives a letter following assessment clinic where all suspicious screening cases are reviewed. The letters are sent within 5 working days.
The GP also receives a copy of the screening services referral letter to breast surgeons where appropriate, after the patient has attended for results.

**How the patient is informed of the results, including timescales**

All images obtained are double read. Where there is a concordant normal result a "normal" letter is sent to the client's home address within 14 days of the screening test. Where there is a concordant abnormal test result, all women will receive an invitation to the breast assessment clinic within 14 days, and will attend the clinic within 21 days of screening, even if they cannot make the first appointment offered, except by patient choice (the NHSBSP standard is that 90% should meet this goal). Assessment letters are

generated by the NBSS computer system automatically following the outcome of reading. Where the first 2 readers do not agree, a third reader will arbitrate, and that final opinion will determine the course of action taken next within the timescales above

### How the patient is followed-up or referred, including timescales

Where an abnormality is believed to be present after extra views in the assessment clinic, patients will have a biopsy or be referred to surgery directly if biopsy is impossible or declined (very rare to do the latter). All biopsies are discussed in the Multidisciplinary meeting and referral noted in the minutes of that meeting and monitored by cancer services within the trust for 62 day targets. Immediately after the meeting, in addition, formal referral letters are written. The appointment system to ensure that these women are told their results is administered by the Breast Care Nurses who keep a “pending” list of cases, to act as a first failsafe. The NBSS computer programme will also flag any unreferred case. Any unreferred cases which are exceptionally rare would be referred to the Director of Screening to action.

### Process for documenting the Screening Process

The NBSS is a UK wide database that tracks all stages of the patient pathway in breast screening. Data entry at film reading and at assessment is directly into this system, and the system will flag failure to do any of the above processes. Audit of the time to sending results, attending for assessment, and time to referral is performed directly on the live dataset by the external monitoring authority, the Quality Assurance Reference Centre.

## 3 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Breast Imaging Management Team and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated author. These must be ratified by the Medical Director and should be reported, retrospectively, to the Breast Imaging Management Team.

Significant reviews and revisions to this document will include consultation with the Breast Imaging Team. For non-significant amendments, informal consultation will be restricted to the Breast Imaging Management Team or members of the Breast Imaging Team who are directly affected by the proposed changes.

### *Dissemination and implementation*

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

## 4 Reference material

Listed below are some useful sources of reference material:

National Patient Safety Agency (NPSA). (2004). *Right Patient Right Care*. London: NPSA. Available at: www.npsa.nhs.uk

UK National Screening Committee. (2010). *Managing Serious Incidents in the English NHS National Screening Programmes*. Available at: www.screening.nhs.uk

Department of Health. (2007) *Collaborative Commissioning of National Screening Programmes*. London: DH. Available at: www.dh.gov.uk

Department of Health. (2000). *Second Report of the UK National Screening Committee*. London: DH. Available at: www.dh.gov.uk

http://www.cancerscreening.nhs.uk/breastscreen/publications/numbered-index.html