

## Breast screening programme specific operating model QA process

Pathway element: Call and recall breast screening (BS) select	SQAS activities	Frequency
Provided under a separate contract by NHS Digital (NHSD)	Monitor follow up of recommendations	Annually

Pathway element: Identifying cohort	SQAS activities	Frequency
Allocating general practitioner (GP) group	Review as part of the failsafe activities at the quality assurance (QA) visits, monthly assurance reports and NHSD annual audits	At QA visits/monthly
GP lists	Internal QA process to be checked/verified at QA visits and breaches reported to programme boards/incident reporting	Annually
Identification of high risk clients/supradiaphragmatic radiotherapy and specific risk factors (SRTs)	** To be developed, awaiting guidance. Next test due date (NTDD) late and missing picked up through assurance work	**To be decided (TBD)/monthly
Round planning <ul style="list-style-type: none"> <li>• age extension/NTDD</li> <li>• breast screening service (BSO) that can call by date of birth (DoB)</li> </ul>	Measuring screening round length (SRL) performance <ul style="list-style-type: none"> <li>• exception reports for units failing the standard</li> <li>• action plans for units failing the standard for 3 consecutive months as a minimum</li> <li>• round plan checked at the visit</li> </ul>	Monthly

<b>Pathway element: Identifying cohort</b>	<b>SQAS activities</b>	<b>Frequency</b>
• * location of mobiles to support attendance		
Batch specification	Assurance reports	Monthly
Call and recall functions	NHSD annual visits/monthly assurance	Assurance is monthly
Ceasing	Process reviewed at visits.  **National ceasing audit and reporting process being developed	** Annually
Failsafe	Monthly assurance and checked at QA visits	Monthly and at QA visits
* Out of catchment women	** Once national guidance is finalised, will include this within the QA visit process. Hard to reach groups will be picked up as part of the breast inequalities toolkit	**TBD
* Prisons	** Once national guidance is finalised, will include this within the QA visit process. Hard to reach groups will be picked up as part of the breast inequalities toolkit	**TBD
* Travellers	**Once national guidance is finalised, will include this within the QA visit process. Hard to reach groups will be picked up as part of the breast inequalities toolkit	**TBD
* Asylum seekers	**Once national guidance is finalised, will include this within the QA visit process. Hard to reach groups will be picked up as part of the breast inequalities toolkit	**TBD

<b>Pathway element: Identifying cohort</b>	<b>SQAS activities</b>	<b>Frequency</b>
** Ministry of Defence (MoD)	** Once national guidance is finalised, will include this within the QA visit process. Hard to reach groups will be picked up as part of the Breast inequalities toolkit	**TBD
Information governance	At visits identifies if the provider organisation has submitted a data security protection toolkit return in the past year	At QA visits

\*Public health system leadership and commissioning function (please refer to pre visit questionnaire for complete list of functions for peer review)

\*\* Under development

<b>Pathway element: Invitation</b>	<b>SQAS activities</b>	<b>Frequency</b>
Cohort identification	Monthly assurance with in-depth review at QA visits	Monthly/at QA visits
Booking of slots	Discussion at QA visit if indicated	At QA visits
* Identification of special needs appointments	Breast inequalities toolkit	At QA visits
Use of national letters and leaflets	Check at QA visits	At QA visits
Clarity and accuracy of maps	Breast inequalities toolkit	At QA visits
* Did not attend (DNAs)	Administration of DNAs will be reviewed as part of the 'right results' process	At QA visits
Second timed appointments	Check at QA visits; admin and clerical (AandC) and breast inequalities toolkit	At QA visits

<b>Pathway element: Invitation</b>	<b>SQAS activities</b>	<b>Frequency</b>
SMART clinics	Check at QA visits (NBSS SEXA report analysis)	At QA visits
** Time from invitation to screen	** An area to be introduced due to current wide variability and impact on attendance	At QA visits
* Cancelled screening clinics	Reported to the programme boards; SQAA to pick up any trends reactively.  ** National crystal report in development	Variable
* Location of screening mobile/statics	Breast inequalities toolkit; At QA visits	Variable/at QA visits
* Health promotion on activities (texts, phone calls)/client satisfaction surveys/DNA questionnaire	Check at the QA visits what activities are undertaken to increase uptake (Breast inequalities toolkit)	At QA visits
Self referral rates	Data included in the KC62	Reported annually
Uptake	Quarterly monitoring key performance indicator (KPI), data provided to NHSE, raise at QA visits.	Quarterly monitoring
Coverage	Annual calculations by Health and Social Care Information Centre (HSCIC) (NHSE report it monthly), and now by breast screening office (BSO) raise at QA visits.  ** Developing more contemporaneous metric to ensure all eligible women are invited	Reported annually

<b>Pathway element: Invitation</b>	<b>SQAS activities</b>	<b>Frequency</b>
** Outsourcing providers including information on governance issues and robust auditing	** Review of contracting arrangements and escalation	At QA visits
Transfer previous screening images/packets	Checked through the 'right results' process at the QA visit	At QA visits

<b>Pathway Element: Primary screening</b>	<b>SQAS activities</b>	<b>Frequency</b>
Transfer of patient identifiable information to the van	'Right results' walkthrough and QA visit	At QA visits
Training of staff	Trust responsibilities; at visits access to continuous personal development (CPD) to be checked	At QA visits
National breast screening service (NBSS) management a. transfer of data files to/from mobiles	'Right results' walkthroughs	At QA visits
Checking of identification (ID)	'Right results' walkthroughs	At QA visits
Consent a. process for women where English is not their first language. b. before and during examination	'Right results' walkthroughs a. breast inequalities toolkit b. breast inequalities toolkit	At QA visits

<b>Pathway Element: Primary screening</b>	<b>SQAS activities</b>	<b>Frequency</b>
Recording of signs and symptoms	'Right results' walkthroughs and QA visit process (radiology)	At QA visits
Recently screened (less than 6 months)	'Right results' walkthroughs	At QA visits
Imaging the augmented breast	Question re review of the digital versatile disc (DVD) and implementation of the Eklund technique by radiographers in the QA visit questionnaire	At QA visits
Imaging women who've had previous breast surgery		
Proportion of cases where more than 4 views taken	** Part of the QA visits; data process to be developed	At QA visits
Partial mammography a. special needs	National annual audit. Question in the right result process – required to tick appropriate box on NBSS a. breast inequalities toolkit	At QA visits
Process for management of women who attend without an appointment	'Right results' walkthroughs	At QA visits
Picture archiving and communication systems (PACS) a. transfer of data files from mobiles b. backup	Dedicated QA visit questionnaire (a and b)	At QA visits

<b>Pathway Element: Primary screening</b>	<b>SQAS activities</b>	<b>Frequency</b>
Technical recall and technical repeat (TCTP) rates	'Right results' walkthroughs and quarterly data	Monthly, quarterly and annually
Quality of images achieved by the mammographers	Image review by radiography professional clinical advisors (PCA) at visits, indirectly by radiology PCA at case reviews and discussion with team re image quality audits. TCTP rates	At QA visits
Ergonomics and musculoskeletal (MSK) risk assessments	National guidance on ergonomics. Not part of QA's remit – Trust responsibility. May include in observations from the visits	At QA visits, if applicable
Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) knowledge and local rules	Incorporated under medical physics	At QA visits

<b>Pathway element: screening test equipment performance</b>	<b>SQAS activities</b>	<b>Frequency</b>
Equipment/specification approved for use in the NHS breast screening programme (NHSBSP) a. mobiles b. X-ray c. ultrasound (US)	Review at the QA visit a to e  ** QA of high risk including MRI outstanding pending new national guidance	At QA visits

Pathway element: screening test equipment performance	SQAS activities	Frequency
d. tomosynthesis e. monitors f. ** Magnetic resonance imaging (MRI)		
Competence of staff to the use the equipment in the clinical setting.	Review at the QA visit	At QA visits
** Equipment tested by medical physics to NHSBSP standards	** Central collation of data; to be used locally at sub-regional level	At QA visits
Routine and comprehensive user quality control (QC) processes in place a. appropriate time allocated for user QC b. identified user QC radiographer c. process for taking action based on results d. routine testing of biopsy guns in the clinical setting e. ultrasound QC f. monitors QC (acquisition and reporting monitors)	Review at the QA visit (a to g)	At QA visits



<b>Pathway element: screening test equipment performance</b>	<b>SQAS activities</b>	<b>Frequency</b>
g. Faxitrons/specimen cabinets		
Effective handover processes between clinical and medical practitioners (MP)/engineers	Review at the QA visit	At QA visits
Appropriate radiation protection - for example, lights	Review at the QA visit	At QA visits
Fault reporting a. locally b. nationally	Review at the QA visit	At QA visits

<b>Pathway element: Reading</b>	<b>SQAS activities</b>	<b>Frequency</b>
Appropriately trained and registered	Employer responsibility not checked by SQAS	N/A
Minimum number of reads (1500 first reads/4000 screening/5000 total)	Caseload monitoring by reader, discussed at visits	6 monthly and annual
Double reading	A question on the QA visit proforma	At QA visits
Technical recalls	TCTP rates	Monthly, quarterly and annually
** Arbitration of consensus process a. transfer of images	** To be developed a. right results process	A and b at QA visits

<b>Pathway element: Reading</b>	<b>SQAS activities</b>	<b>Frequency</b>
b. previous images	b. 'right results' process	
Sensitivity/specificity	Film reader quality assurance (FRQA) rates and unit level radiology outcomes measures for example, recall to assessment rates	Annually
Time to normal result	Monthly monitoring time from screen to normal results letters	Monthly, quarterly and annually
Interval cancers a. radiological classification	Screening histories identified using screening histories information management (SHIM) and interval cancer (IC) rates calculated as per the IC manual with details of the classification  ** National data to be developed	Annually
Personal performance in mammographic screening (PERFORMS)	Participation checked at QA visits	At QA visits
Locums a. appropriate orientation regarding processes; paperwork and safe use of equipment	FRQA rates for locum available  a.** To be developed	Annually

<b>Pathway element: Assessment</b>	<b>SQAS activities</b>	<b>Frequency</b>
Right woman comes to assessment a. cover hub and spoke model	** 'Right results' walkthroughs  a. process reviewed at all assessment sites	At QA visits

<b>Pathway element: Assessment</b>	<b>SQAS activities</b>	<b>Frequency</b>
Timely invitation to assessment	Monitoring time from screen to first offered assessment appointment and exceptions for non-compliance	Monthly, quarterly and annually
Time to attend	Monitoring time from screen to attendance at assessment and exceptions for non-compliance	Monthly, quarterly and annually
DNAs from assessment	Process discussed at visits	At QA visits
* Cancellation of assessment clinics	Not routinely audited but may be picked up through screen to assessment exception reports and question included at visits. Included as a reporting requirement in the specification	At QA visits
Appropriate leadership of assessment clinic	** Responsible assessor audit to be developed	At QA visits
Induction of staff a. locums b. new substantive staff c. returners from long absence	Not included in current remit. If included in new guidance, will need to revisit	At QA visits
Maintenance of skill set a. radiographer b. consultants & Advanced practitioners c. radiologists	b and c – number of continuing medical education (CME) points or equivalent asked at visits	At QA visits
** TCTPs of images taken at assessment	** To be developed as indicated	At QA visits

<b>Pathway element: Assessment</b>	<b>SQAS activities</b>	<b>Frequency</b>
** Clinical nurse specialist (CNS) present as assessment	** To be developed as indicated	At QA visits
** effective assessment practice a. ** Tomosynthesis b. ** axilla c. ** number of assessment visits	** Process to collect data to be developed. C included in NHSBSP and association of breast surgery (ABS) audit	At QA visits
Women who had a biopsy leave the clinic with an appointment to get their results	** To be developed, as indicated Discussed at visits	At QA visits
Internal audit of relative risk (RR) from assessment without a biopsy	Discussed at QA visits	
** Accurate completion of NBSS record by the responsible assessor for each part of the assessment process	** To be developed	At QA visits
Communication of assessment findings to the multi-disciplinary meetings (MDT) and identification of discrepant cases	Paperwork reviewed at case review element of the QA visit	At QA visits
Short term recall from assessment a. repeat imaging on both sides	Short term recall rates and QA visits process	At QA visits
Short term recall from short term recall	STR from STR rates	At QA visits
** Previously assessed cancers	QA visits process a. previously assessed cancers returned to SQAS	Annually

<b>Pathway element: Assessment</b>	<b>SQAS activities</b>	<b>Frequency</b>
	b.** Annual audit process to be developed	
** Process for MRI guided biopsy	** To be developed	At QA visits, annually

<b>Pathway element: MDT</b>	<b>SQAS activities</b>	<b>Frequency</b>
Referral pathway to the linked MDT	Reviewed at QA visits	At QA visits
Pre MDT preparation time	Questioned at QA visits	At QA visits
Breast screening radiologist present	Reviewed at QA visits; MDT attendance sheet	At QA visits
Appropriate equipment including monitors and video conferencing	Questions at QA visit re monitors & video conferencing facilities observed as part of the pre-visit MDM attendance	At QA visits
Appropriate communication regarding the cases to be discussed	Can be raised by services if there is a perceived issue. Nothing proactive in current processes	At QA visits
Timely transfer of images and paperwork	Images and final reports available at MDT	At QA visits
Frequency. Should be held a minimum of weekly	Frequency questioned at the QA visit	At QA visits
Appropriate record keeping of attendance	MDT attendance sheet submitted as QA visit evidence	At QA visits
MDT discussion a. pre-operative and/or post-operative b. all biopsy and STR cases	Questioned at QA visits	At QA visits

<b>Pathway element: MDT</b>	<b>SQAS activities</b>	<b>Frequency</b>
c. real time completion of projected MDT record and clarity regarding next steps d. projection of imaging and pathology to increase educational value of meetings e. identification of appropriate trials		
Effective and timely process for repeat biopsies a. recording on NBSS	NHSBSP and ABS audit of screen detected (SD) cancers	Annually
Feedback of outcomes data to the services	Annual data reports provided by SQAS to services	Annually

<b>Pathway element: Localisation</b>	<b>SQAS activities</b>	<b>Frequency</b>
Localisation should be undertaken of impalpable masses	Localisation pathway discussed at visit and failed localisations reviewed	At QA visits
Placement of clips at non-op biopsy	Discussed at QA visits	At QA visits
Placement of wire within 10mm of the lesion a. when patients have to travel that these are securely placed	Review of failed localisation as part of the pre-visit image review and surrogate data measures included in surgical data set	At QA visits and annually
Accurate communication of the placement to the treating surgeon	Review of case notes by surgeons as part of the visit process	At QA visits

<b>Pathway element: Localisation</b>	<b>SQAS activities</b>	<b>Frequency</b>
Check images done on NHSBSP tested equipment	QA visit process; medical physics	At QA visits
Wires placed by NHSBSP consultants/advanced practitioners	No specific review at present	At QA visits
Achieve right site surgery in all instances	QA visit; discordant case review and surgical data	At QA visits

<b>Pathway element: Surgery</b>	<b>SQAS activities</b>	<b>Frequency</b>
Results and treatment plan discussed with patient following MDT discussion and within one week of the biopsy	QA visit question	At QA visits
Caseload	NHSBSP audit of screen-detected breast cancers	Annually
Timeliness to first operation	Trust waiting times data; part of the requested pre-visit evidence	At QA visits
Treatment appropriate to a. invasive status b. whole size	Operation type and rates (NHSBSP audit of SD cancers)	Annually
Patients choice regarding intervention including watch and wait	NHSBSP audit of screen-detected breast cancers/entry into the (low risk (LORIS) trial question asked at visits	At QA visits
Appropriate assessment of the axilla	NHSBSP audit of screen-detected breast cancers. Availability of sentinel lymph node biopsy (SLNB) discussed at visits	Annually

<b>Pathway element: Surgery</b>	<b>SQAS activities</b>	<b>Frequency</b>
Accurate recording of neo-adjuvant treatments	Neo-adjuvant treatment included in visit data booklet. May be raised if data looks atypical.	Annually
Number of operations/repeat operation	Number of diagnostic and therapeutic procedures recorded. NHSBSP audit of screen-detected breast cancers	Annually
Access to immediate reconstruction	Rates presented in QA visit data booklet	Annually
Review of understaging of the disease	B5a to invasive rates reviewed in visit data booklet	Annually
Review of cases with benign surgery	B5 to normal rates reviewed	Annually
Review of cases with disease present at margins	NHSBSP audit of screen-detected breast cancers	Annually
Review of open biopsies	Benign and open biopsy rates reviewed annually and discussed in depth at QA visits	Annually
Accurate recording on NBSS and validation of audit data	NHSBSP audit of screen-detected breast cancers and QA visits	Annually

<b>Pathway element: Pathology</b>	<b>SQAS activities</b>	<b>Frequency</b>
Workload; reporting of 50 primary specimens	QA visit question	At QA visits
Safe transfer of biopsy specimens a. NHS laboratories b. private providers	Opportunity for staff to raise any issues at the QA visits  Review any incidents	At QA visits



<b>Pathway element: Pathology</b>	<b>SQAS activities</b>	<b>Frequency</b>
Safe transfer to laboratories undertaking additional tests, for example HER2	Not part of the QA process	N/A
Appropriate fixation	Would be raised if noted at slide review and/or if raised by MDT	When necessary
Accurate orientation marking	Opportunity to be raised at the QA visit	At QA visits
Accurate reporting of biopsy specimens	Wide bore needle (BQA) stats and QA visit slide review	At QA visits
Accurate reporting on NBSS	Routine audit activity including NHSBSP audit of screen-detected breast cancers and routine pathology audit data	Annually
Clear communication of results, supplementary reports and changed reports	Review reports and copy of policies at QA visits	At QA visits
Clear process for getting second opinion	Can be discussed at QA visits if necessary	At QA visits
Discussion of benign biopsies in MDT setting	QA visit question	At QA visits
Accurate final histology	Histology QA report (HQA) stats and QA visit slide review	Annually and at QA visits
Turnaround times a. biopsy b. final specimens c. receptor status	QA visit questions	At QA visits
Participation in national breast external quality assurance (EQA) scheme	QA visits and SQAS monitoring	Annually and at QA visits

<b>Pathway element: Pathology</b>	<b>SQAS activities</b>	<b>Frequency</b>
Participation in breast MDT	At QA visits	At QA visits
False negatives	Identified in national audit but non-specific	At QA visits
False positives	Identified in national audit but non-specific	At QA visits

<b>Pathway element: Clinical nurse specialist (CNS)</b>	<b>SQAS activities</b>	<b>Frequency</b>
Supporting the patient in assessment	QA visit questioning	At QA visits where covered
Managing anxiety	QA visit questioning	At QA visits
Provision of appropriate information	QA visit questioning	At QA visits
Present at results	QA visit questioning	At QA visits
Environment for counselling; privacy and dignity	QA visit questioning	At QA visits
Accessibility of the CNS, for example telephone numbers provided in advance	QA visit questioning	At QA visits
Aspects of advanced practice a. nipple tattoo	Question regarding advanced practice at visit	At QA visits
Wound drain management	Not a QA responsibility	N/A
Prosthesis provision	Not a QA responsibility	N/A

<b>Pathway element: Clinical nurse specialist (CNS)</b>	<b>SQAS activities</b>	<b>Frequency</b>
Role in health promotion	Questions in management questionnaire	At QA visits
Patient advocate at MDT	Observation at a live MDT	At QA visits
Clinical supervision	QA visit question	At QA visits

<b>Pathway element: Programme management and governance</b>	<b>SQAS activities</b>	<b>Frequency</b>
Identified director of breast screening (DoBS) with time and job description (JD) to cover the role	QA visit evidence request	At QA visits
Appointed programme manager, if applicable, with clearly defined scope of practice	QA visit evidence request	At QA visits
Lines of accountability within and between trusts Hub and Spoke models i. incident Management ii. media enquiries iii. professional performance issues iv. SLA for sub contracted elements	QA visit evidence request	At QA visits
Organisational chart for the programme	QA visit evidence request	At QA visits

<b>Pathway element: Programme management and governance</b>	<b>SQAS activities</b>	<b>Frequency</b>
Risk assessment and management a. business continuity – disaster recovery plan	QA visit questions	At QA visits
Clinical governance, escalation processes and integration into Trust systems	QA visit questions	At QA visits
Information governance	QA visits question with regard to the information governance (IG) toolkit	At QA visits
* Financial governance	Not part of the QA process	N/A
Staffing current and projected needs	Discussed at the QA visit	At QA visits
Population current and projected changes	Discussed at the QA visit	At QA visits
* Annual report to commissioners a. presentation to Trust(s) boards	QA visit evidence request	At QA visits
Equipment replacement programmes	Discussed at QA visits	At QA visits
Maintenance contracts	Discussed at QA visits	At QA visits
Incidents	Managed in line with national guidance, discussed/closed at programme board meetings (PBMs), Quarterly and annual reports on themes, discussed at joint action meetings (JAM) and process discussed at QA visit	Monthly, quarterly and at QA visits

<b>Pathway element: Programme management and governance</b>	<b>SQAS activities</b>	<b>Frequency</b>
Complaints – complaints received by patients/clients as via the patient advice and liason service (PALS)	Question asked at QA visit and performance/programme board meetings	At QA visits
Facilities/accommodation	Reviewed at the QA visit	At QA visits
* Client satisfaction	Discussed at visit, breast inequalities toolkit	At QA visits
* Health promotion	Discussed at visit, breast inequalities toolkit	At QA visits
* Programme development for example Tomosynthesis	Discussed at the QA visit	At QA visits
* Service specifications and commissioning	Discussed at visit within QA of commissioning	At QA visits