NHS public health functions agreement 2018-19

Service specification no.24 Breast Screening Programme
Promoting equality and addressing health inequalities are at the heart of NHS England’s values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic and those who do not share it (as required under the Equality Act 2010); and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).
Contents

Contents..............................................................................................................................................5
Service specification No.24......................................................................................................................7

1. Background and introduction ............................................................................................................8

   Purpose of the Breast Screening Specification..............................................................................8
   Aims, objectives and health outcomes.............................................................................................8
      Aims...........................................................................................................................................8
      Objectives...................................................................................................................................9
   Common Health Outcomes..............................................................................................................12
   Equality........................................................................................................................................12

2. Scope of the screening programme ................................................................................................13

   Description of the screening programme ......................................................................................13
   In this section of the document, the following terms are used:
   Activities Prior to Screening..........................................................................................................14
   Primary Screening..........................................................................................................................14
   Assessment, diagnosis, referral, follow-up.....................................................................................16
   Standards........................................................................................................................................16
   Administration, audit, SQAS, failsafe, IT .......................................................................................17
   Accreditation, training, guidance, research.....................................................................................18
   Care Pathway.................................................................................................................................19
   Failsafe arrangements......................................................................................................................20
   Roles and accountabilities...............................................................................................................20
   Commissioning arrangements..........................................................................................................21
   Links with the National Programme and ‘Do once and share’ .....................................................21

3. Delivery of the screening programme ............................................................................................22

   Service model summary ..................................................................................................................22
      Population coverage.....................................................................................................................23
   Programme Coordination..............................................................................................................23
   Clinical and corporate governance.................................................................................................24
   Definition, identification, and invitation of cohort/eligibility.........................................................25
   Location(s) of programme delivery.................................................................................................25
   Days/hours of operation....................................................................................................................25
   Working across interfaces...............................................................................................................26
   Information on test/screening programme......................................................................................27
   Testing (performance of tests by individuals)................................................................................27
Results reporting and recording.................................................................28
Providing results .........................................................................................28
Scope of cancer screening ........................................................................28
Transfer of, and discharge from, care obligations......................................28
Exclusion criteria .........................................................................................28
Staffing .........................................................................................................29
User involvement .........................................................................................29
Premises and equipment ............................................................................30
Key Performance Indicators .......................................................................31
Data collection and monitoring ..................................................................31
Data reporting ..............................................................................................31

4. Service standards, risks and quality assurance ....................................32
   Key criteria and standards .......................................................................32
   Risk assessment of the screening pathway ..............................................32
   Quality assurance ...................................................................................32
   Safety concerns, safety incidents and serious incidents ......................33
   Continual service improvement .............................................................34

5. Costs .......................................................................................................35

6. Teaching and research activities ............................................................35
Service specification No.24

This is a service specification to accompany the ‘NHS public health functions agreement 2018-19 (the ‘2018-19 agreement’).

This service specification is to be applied by NHS England in accordance with the 2018-19 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2018-19 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2018-19 agreement in accordance with the procedures described in Chapter 3 of the 2018-19 agreement.

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2018-19 agreement is available at [www.gov.uk](http://www.gov.uk) (search for ‘commissioning public health’).

All current service specifications are available at [www.england.nhs.uk](http://www.england.nhs.uk) (search for ‘commissioning public health’).
1. Background and introduction

Purpose of the Breast Screening Specification

1.1. The purpose of this specification is to ensure that there is a consistent and equitable approach to the provision and monitoring of breast screening across England.

1.2. This document is designed to outline the service and quality indicators expected by NHS England to ensure that a high standard of service is provided to NHS England’s responsible population. It therefore sets out the specific policies, recommendations, and standards that services are expected to meet.

1.3. The service specification is not designed to replicate, duplicate, or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008, or the work undertaken by the Care Quality Commission. In the event of new guidance emerging, the specification will be reviewed and amended with as much rapidity as possible, but where necessary, both NHS England and service providers should work proactively to agree speedy variations of contract ahead of the production of a revised specification.

1.4. This service specification needs to be read in conjunction with the current NHS Breast Screening Programme (NHSBSP) guidance and recommendations. These can be found on the population screening programmes pages of the [gov.uk](http://gov.uk) website.

Aims, objectives and health outcomes

**Aims**

1.5. The major aim of the NHS breast screening programme is to reduce mortality from breast cancer. This will be achieved by delivering evidence-based, population-based screening programmes that:

- identify the eligible population and ensure efficient delivery with optimal coverage;
- are safe, effective, of a high quality, externally and independently monitored, and quality assured;
- lead to earlier detection, appropriate referral, and improved outcomes;
- are delivered and supported by suitably trained, competent, and qualified, clinical and non-clinical staff who, where relevant, participate in recognized ongoing Continuing Medical Education, Continuous Professional Development, and EQA schemes;
- have audit and service evaluation embedded in the service.

**Objectives**

**Activities prior to screening**

1.6. In accordance with good management practice and experience, in order to ensure appropriate and efficient use of NHS resources, the programme as a whole should:
• identify and invite eligible women for screening at appropriate intervals

• use nationally developed and agreed letters and leaflets, so that the population of women invited are able to make an informed choice about whether or not to participate

• ensure that GPs are informed of screening in their area, and of the final outcomes of screening invitations for each of their patients

• Contribute to optimising acceptance by liaison with GP practices (by visiting, telephone calls or in writing) and by providing practices with up-to-date information about the Programme

• serve whole populations (all ages) numbering no less than 500,000 and up to about one million.

Primary Screening

1.7. The provider should:

• provide women who attend for breast screening with a high quality, effective, and people-centred service

• carry out mammography in a way that minimises the possible adverse aspects of screening (e.g. radiation, discomfort, anxiety) and that maximises the benefits (i.e. detecting abnormalities at an early stage)

• ensure that women with implants are screened using routine mammography techniques including the Eklund technique and that all radiographers have training in this method as required by the programme. Where undertaken, this method should be recorded on the national breast screening computer system (NBSS)

• optimise attendance rates and maximise accessibility of the service for all groups in the community

• use only equipment which meets the NHSBSP standards of image quality and radiation dose

• allow women to opt out of the service, on a single occasion or permanently

• provide adequate numbers of appropriately trained, qualified, and competent staff to carry out high-quality screening mammography

• provide results within two weeks of attendance at screening as specified in the consolidated standards

Assessment, diagnosis, referral, follow-up

1.8 In accordance with NHSBSP standards and protocols, the provider should:
• undertake assessment and diagnosis of individuals with abnormal initial test results in appropriately staffed and equipped settings, to the standards expected within the NHSBSP

• invite women for assessment within the required interval from screening attendance

• accurately diagnose cancers, with reference to Multi Disciplinary Team (MDT) decisions, and refer women for treatment by appropriately trained and qualified specialists

• minimise the number of women placed on short term recall

• return individuals without breast cancer to routine recall as soon as possible

• ensure that assessment test results (whether normal, benign, or abnormal) are communicated clearly, accurately, and promptly, in person, by a member of the clinical team. Deviations are only acceptable in the following circumstances:
  - where there is a very strong suspicion that malignancy is not present the women may be offered results by clinic appointment or telephone
  - results by telephone can be given if specifically requested by the woman. This should not be routinely offered.

**Standards**

1.9. The consolidated standards should be achieved so that the programme as a whole should:

- maximise the number of cancers detected
- minimise the number of cancers presenting between screening episodes
- maintain acceptable standards of screening, whilst aiming for achievable standards
- participate in both approved national routine audits and ad hoc audits to evaluate overall programme performance

**Administration, failsafe**

1.10. The provider should:

- ensure effective and timely communication with the individuals who are invited, screened, assessed, or treated
- ensure effective and timely communication with the Young People and Adults screening programmes and Screening Quality Assurance Service (SQAS) teams within Public Health England, clinical multi-disciplinary teams, other screening centres, NHS England and the NHS Digital team
• work within a seamless and integrated pathway

• apply NHSBSP failsafe guidance at all stages of the pathway

• ensure that the NHSBSP recommendations for handling safety concerns, safety incidents and serious incidents are adhered to, in addition to local reporting procedures.

Audit and Quality Assurance

1.11. The provider and the quality assurance team within Public Health England should work collaboratively to:

• regularly audit and evaluate the programme to ensure that the service is delivered in a safe, effective, timely, equitable, and ethical way, in accordance with national policy and NHSBSP standards, guidelines, internal and external quality assurance arrangements and risk assessments

• monitor, collect, and report statistical data and other relevant information to relevant bodies, use it to promote continuous improvement in service performance and outcomes, give formal feedback to NHS England and the population served by the programme, and provide key information and models of good practice/innovation/achievement to those working in the area of breast screening

The provider should:

• participate willingly in multidisciplinary QA Visits organised by the cancer screening quality assurance service (SQAS) team within Public Health England.

• ensure that complete and accurate outcomes and results for all women are accurately entered onto the National Breast Screening System (NBSS) to allow national reports to be uploaded at prescribed intervals to the Breast Screening Information System (BSIS) for further analysis and audit by the SQAS

Information Technology (IT)

1.12. The provider must:

• use the programme's IT systems (NBSS) and Breast Screening Select (BS-Select)) and the Breast Screening Information System (BSIS) to manage women through the screening process, and to capture key screening data/outcomes promptly and accurately, supporting local and national SQAS, cancer registration processes and programme evaluation

• ensure the necessary hosting environment for NBSS is provided to the minimum standard specified by the current NBSS contractor including the connectivity necessary for the contractor to support the system
• comply fully with local NHS CSP and NHS information governance requirements relating to the confidentiality and disclosure of patient information and system/information security

• collaborate with the national Programme on an ongoing basis and for any new system developments, to produce system refinements to optimise the administration and reporting of outcomes of the screening programme.

**Accreditation, training, guidance, research**

1.13. The provider should:

• ensure that staff are appropriately trained and supported by national continuing professional development and skills frameworks, enabling them to develop their skills, competencies, and potential. Only approved/accredited training courses should be used, and these should be funded locally

• only contribute to research into the screening and diagnosis of breast cancer which have the necessary national approval, to inform screening practice and policy

• ensure that all pathology laboratories dealing with screening programmes are formally accredited by United Kingdom Accreditation Service (UKAS) or equivalent

• ensure that image readers and pathologists reporting images and material participate routinely in Personal Performance in Mammographic Screening (PERFORMS) and External Quality Assurance (EQA) schemes.

**Safety and Safeguarding**

1.14. The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract.

**Common Health Outcomes**

1.15. The programme as a whole aims:

• to reduce the number of women in the target population who die from breast cancer by 20%

• to maximise detection of breast cancer at stages 1 and 2 (PHE domain 2)

• to refer women promptly to treatment services

• to achieve high coverage levels across all groups in society

• to minimise adverse physical/psychological/clinical aspects of screening (e.g. anxiety, unnecessary investigation)

• to encourage early presentation of symptomatic cancers, which may develop between screening episodes.
Equality

1.16 The objectives of the screening programme should include:

- Help reduce health inequalities through the delivery of the programme

Key deliverables:

- Screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary

- A Health Equity Impact Assessment should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations

- The service should be delivered in a culturally sensitive way to meet the needs of local diverse populations

- User involvement should include representation from service users with equality characteristics reflecting the local community including those with protected characteristics

- Providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow both equality, health inequality and screening guidance when making such decisions

The provider will be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

The provider will have procedures in place to identify and support those persons who are considered vulnerable/hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such persons.

Providers are expected to meet the public sector Equality Duty which means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees

https://www.gov.uk/equality-act-2010guidance

It also requires that public bodies:

- have due regard to the need to eliminate discrimination
- advance equality of opportunity
- foster good relations between different people when carrying out their activities
All screening programme providers should ensure they have included members of the armed forces who are registered with Defence Medical Centres within their responsible population boundaries.
2. Scope of the screening programme

Description of the screening programme

In this section of the document, the following terms are used:

- **NHSBSP** – This describes the entire programme, from identifying individuals to be invited to referral for treatment/return to routine screening as applicable.
- **Breast screening unit** – There are 79 breast screening units in England, which are responsible for the delivery of breast screening programmes locally to a defined population.
- **Provider** – This is the NHS Trust or private provider that is contracted to provide screening centre activities. If a breast screening unit comprises more than one provider, one will be the lead and hold the contract with NHS England.
- **Eligible population** – Women are eligible for screening if they are in the screening age range or in a specified high risk category and are not ineligible due to bilateral mastectomy.

Activities Prior to Screening

2.1. In accordance with agreed management and professional best practice in the breast screening guidelines, the provider should:

- invite women who move into the screening catchment area, or who are registered with a GP in the screening catchment area, to attend for screening before their 53rd birthday. (This becomes their 50th birthday if they are included in the programme extension trial)
- ensure that women who have already been invited for screening are offered screening again within 36 months of their previous screen until they reach the age of 71. (This becomes their 74th birthday if they are included in the programme extension trial)
- enable those who have received their final routine invitation to continue to be screened at 3-yearly intervals on request or as part of the programme extension trial
- ensure that women who are not on NHS lists have access to screening, and that local arrangements are made to cover residential institutions, including prisons and defence medical practices
- contribute to optimising acceptance by liaison with GP practices (by visiting, telephone call, or in writing) and by providing practices with up-to-date information about the Programme
- ensure that referrals for high-risk screening are only taken from specialised services e.g. Genetics or Oncology. The screening programme is not expected to carry out risk assessments for these cases
- ensure that screening is provided to women who are eligible for higher-risk breast screening to NHSBSP protocols and standards.

**Primary Screening**

2.2. The provider should:

- encourage attendance by ensuring that the process of changing appointments is straightforward for those women who request this
- invite women who are eligible for higher risk breast screening to be screened with appropriate modalities, at appropriate ages and intervals, according to NHSBSP protocols
- use nationally developed and agreed letters and leaflets to allow informed choice of whether to attend for screening
- send women who do not attend a second appointment a letter, with a timed appointment
- send letters to women with normal results and further timed appointments for women requiring further assessment
- inform women of their right to request screening if they are over the age where routine invitations are sent, and have not received an invitation as part of the age-extension trial
- keep supporting documentary evidence for any woman who is ceased from the programme for an indefinite time period. This information should be held by the screening service which would otherwise be responsible for her screening
- routinely cease only those women who have had bilateral mastectomies
- carry out annual audits on ceased women
- develop and regularly review the screening Round Plan to ensure that the appropriate population is covered and that invitations are sent promptly, in accordance with the timescales outlined above
- accommodate women who request to be screened at an alternative screening centre according to agreed systems and protocols, which should ideally include undertaking their assessment to minimise the risk associated with transfer of patient information across organisations
- send results of basic screening to the woman within two weeks of her screening attendance
- ensure that image quality and radiation dose are optimised, with technical repeats minimised
- ensure that all equipment used complies with national equipment standards, and is tested routinely by appropriately trained staff and medical physics services, in accordance with NHSBSP guidelines
• ensure that all mammography X-ray systems used in the screening programme are Full Field Direct Digital Mammography systems, and that image quality and radiation dose meet acceptable standards

• ensure that all screening examinations are subject to double reading

Assessment and diagnosis

2.3. In accordance with NHSBSP standards and protocols, the provider should:

• refer women to assessment with significant mammographic or Magnetic Resonance Imaging (MRI) abnormalities, or significant screen-detected breast cancer signs or symptoms.

• offer women an appointment to an assessment clinic within three weeks of their initial screen.

• notify women in writing of their assessment clinic appointment and ensure that they have at least 24 hours’ notice of the appointment.

• ensure women attending assessment have clear information about the assessment process.

• ensure all women attending an assessment appointment meet a clinical nurse specialist (CNS) in breast screening, at the start of assessment to manage any anxiety. Women undergoing needle biopsy should speak with a CNS at assessment.

• ensure that every woman’s management in assessment is overseen by a responsible assessor (RA) who is named on NBSS, to ensure that all appropriate investigations have been adequately performed and documented. This must be an accredited breast radiologist, consultant radiographer or breast clinician.

• utilise triple assessment for further investigations (needle test/ additional imaging/ clinical examination).

• ensure that biopsy specimen imaging is available whilst the woman is still positioned in the stereo X-ray equipment.

• ensure that VACB is used for re-biopsy of the same specimen and the investigation of B3 lesions.

• notify women and their GPS on the outcome of assessment.

• discuss all women undergoing biopsy at a multidisciplinary team meeting and all disciplines agree the outcome, in one single, accessible record which clearly documents the future management of the woman.

• refer women for open surgical biopsy if this is necessary, to confirm or exclude malignancy, before discharge or onwards referral from the programme.

• carry out localisations only in facilities that meet the NHSBSP standards.

• ensure that results of assessment are reported to the woman in person, by a
member of the clinical team or where benign and at her request, by telephone. Cancer diagnoses should be provided in person, by the clinician leading the care of the woman.

- ensure adequate equipment and staffing levels are in place so that women can be fully assessed in the course of a single visit wherever possible (repeat assessment visits should be kept to a minimum).

Standards

2.4 In addition to meeting the minimum standards in Appendix 1, the provider should:

- ensure that all staff working in the NHSBSP are familiar with relevant and current Programme guidance.

- ensure that all staff maintain minimum standards, and also adhere to NHSBSP guidance and recommendations via internal audit and external quality assurance monitoring.

- take prompt action where standards are lower than expected to identify the causes and improve the service.

- agree early warning systems and triggers with the local screening quality assurance service (SQAS) team within Public Health England.

- manage failures to provide services to the level specified in the NHSBSP guidelines according to NHSBSP.

- ensure that all programmes have a multidisciplinary SQAS visit at a timetable determined by SQAS.

Administration, audit, quality assurance failsafe, IT

2.5. Batches of eligible women are called from BS-Select by the screening provider. Regular failsafe batches are requested by the breast screening offices to ensure that no individual is missed. In addition, women who have had a bilateral mastectomy, or who request cessation from screening are ceased from this system to ensure that they no longer receive invitations for screening.

2.6. Results of breast screening will be automatically sent from the NBSS system to the BS-Select to determine future call/recall management. The system runs national returns showing screening coverage (KC63).

2.7. The provider should:

- utilise the BS-Select/NBSS system to ensure that coverage is optimised and the care pathway is managed to its planned conclusion.

- specify failsafe batches and run these at least once every month to ensure that all eligible women are invited.

- maintain, comply with, and regularly audit the Quality Management System and accompanying documentation. This will ensure that the right results are given,
that the screening pathway is safe and seamless, that safety concerns, safety incidents and serious incidents are minimised, and that the programme’s performance is optimised. The screening process should be entered into the IT system according to NHSBSP protocols (including direct entry of results).

- undertake a ‘Right Results’ audit annually as an in-house “walkthrough” to demonstrate compliance with QMS protocol and work instructions. Evidence will be required at SQAS visits.

- ensure that all clinicians audit their own work in comparison to their peers and that they demonstrate a willingness to alter their practice if the outcome reveals this to be necessary.

- review all cases, within prescribed timescales, where women present with breast cancer between screening episodes (interval cancers) or following a previous assessment appointment which resulted in a routine recall outcome but later presented as an interval cancer or cancer at the next screening episode.

- work with staff from the screening quality assurance service (SQAS) team within Public Health England to identify, and categorise, interval cancers and enter these onto NBSS in a timely manner.

- review, on an annual basis, the number of women who have requested screening or assessment at an alternative service.

- provide statistical analyses of uptake and coverage, and of individual, professional and team performance on request to both NHS England and screening quality assurance service (SQAS) teams within PHE.

**Accreditation, training, guidance, research**

2.8 The provider and the screening quality assurance service (SQAS) team within Public Health England should:

- ensure that all screening service staff regularly participate in screening quality assurance service activities (including SQAS formal and ad-hoc visits, the EQA scheme (pathologists), PERFORMS (film readers) and that all professionals meet CPD/CME requirements.

The provider should:

- encourage eligible women to participate in appropriate clinical trials or studies.

- ensure that only Clinical Pathology Accreditation CPA accredited labs or Labs accredited by the UK Accreditation Service (UKAS) with ISO accreditation (ISO 15189) are used for analysis of breast tissue material.
Care Pathway

2.9 The flow diagram below shows the pathway from development of a three year plan to the final outcome of the screening examination.

Screening round

Preparation of the screening batch list

Woman invited

Declines

Options out of screening by signing disclaimer

Attends

SCREENING

Does not attend (DNA)

DNA 2nd appointment letter

Previous mammograms available

Technical recall

Screening mammograms

Normal

Abnormal

Normal but symptoms warrant clinical recall

Assessment

MDT

Exceptional cases short-term recall to assessment (1 year later)

Normal/benign back to routine recall

Outcome communicated to woman and GP
Failsafe arrangements

2.10 Quality assurance within the screening pathway is managed by the inclusion of fail-safe processes. Fail-safe are a back-up mechanism, designed to ensure that, where something goes wrong, processes are in place to identify: what is going wrong; and what actions are necessary to ensure a safe outcome.

2.11. The provider is expected to:

- include appropriate fail-safe mechanisms across the whole screening pathway. Details of appropriate procedures are embedded in the guidance and recommendations on the NHSBSP’s website (See, for example, the advice on second appointments, Right Results, MDT discussion of all needle tests, and the running of regular fail-safe batches)
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the national office (PHE)
- work with NHS England and screening quality assurance service (SQAS) teams within PHE to develop, implement, and maintain appropriate risk reduction measures
- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report safety concerns, safety incidents and serious incidents (see Appendix 4)
- ensure that appropriate links are made with internal provider governance arrangements, such as risk registers
- ensure routine staff training and ongoing development take place.

Roles and accountabilities

2.12 The breast screening programme depends on systematic, specified relationships between screening services and stakeholders (which include treatment services, the laboratory, genetics services, external diagnostic services, Primary Care representatives, etc). The provider will be expected to take the lead in ensuring that inter-organisational systems are in place to maintain the quality of the whole screening pathway. This will include, but is not limited to:

- providing coordinated screening across organisations, so that all parties are clear about their roles and responsibilities at every stage of the screening pathway, and particularly where responsibility for a patient is transferred from one party to another
- developing joint audit and monitoring processes
- agreeing joint fail-safe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway
- contributing to any initiatives led by NHS England or Public Health England to develop the screening pathway in line with the NHSBSP expectations
• maintaining robust electronic links with IT systems and relevant organisations across the screening pathway
• agreeing links with primary care, and with secondary and/or tertiary care.

Commissioning arrangements

2.13 Breast screening services will be commissioned by NHS England alongside commissioning of cancer services. Minimum data requirements for NHS England are shown in Appendix 1, 2 and 3.

Links with the National Programme and ‘do once and share’

2.14 Certain functions of English national cancer screening programmes are managed from PHE by the national office of the cancer screening programmes. National guidance documents can be accessed via the NHSBSP websites.

PHE, through the national screening programmes, is responsible for leading high-quality, uniform screening, providing accessible information to both the public and health care professionals, and developing and monitoring standards. It is also responsible for the delivery of national quality assurance, based at regional level, and for also ensuring that training and education for all those providing screening is developed, commissioned and delivered through appropriate partner organisations.

Education and training:

2.15 Providers must facilitate screener training in line with programme requirements/standards as detailed in each NHS screening programme specification. Providers should ensure training has been completed satisfactorily and recorded, and that they have a system in place to assess on-going competency.

Providers must allow appropriate annual CPD in line with programme and requirements, for example a screening study day or completion of e-learning.

Public information:

2.16 Providers must always use the patient information leaflets from PHE Screening at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening should be consulted and involved before developing any other supporting materials.

• Providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.

• Providers must not develop their own information about screening for local NHS websites but should always link through to the national information on
NHS Choices (http://www.nhs.uk/Livewell/Screening/Pages/screening.aspx or the relevant programme page) and GOV.UK (https://www.gov.uk/topic/population-screening-programmes or the relevant programme page).

- To support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, providers are encouraged to send PHE Screening the results of any local patient surveys which contain feedback on these national resources.
3. Delivery of the screening programme

Service model summary

3.1. In accordance with the national standards, the service will provide all necessary steps required to diagnose or exclude breast cancer. This includes breast screening mammography and subsequent assessment for those women who require recall after their initial screen, and open biopsy (where required). Screening a woman identified to be at high risk of breast cancer may involve MRI.

3.2. The screening programme will be offered to eligible women at a maximum interval of 36-months, according to the criteria specified by the NHSBSP. Screening of women will commence within three years of the specified starting age.

3.3. All women registered with a GP in the catchment area, and those resident in the area without a GP but eligible for NHS care, are included. Particular arrangements will be made for women in border areas who have Scottish or Welsh GPs. The service will invite women aged from 50 to 70 years of age. It will screen women aged 71 or over who self-refer every three years.

3.4. Women who have been assessed by specialised services and categorised as having a higher risk of developing breast cancer, and who meet the eligibility for screening within the NHSBSP will be included in the screening programme at a younger age and according to different protocols, following an appropriate referral from a Genetics or Oncology service.

3.5. There must be seamless links between ‘screening responsibility’ and ‘treatment responsibility’, so that women at the end of the screening process are referred to treatment services, once diagnosis with breast cancer is made explicit.

3.6. All elements of the screening pathway must be delivered by appropriate staff, to national standards and guidelines.

Population coverage

3.7. NHS England and screening service providers will work together to:

- ensure that up-to-date population registers and lists of GP registered populations are maintained and cleaned to guarantee accuracy and completeness
- optimise coverage and uptake across their catchment area
- cooperate with regular analysis of breast screening coverage to identify groups of women who either access breast screening at lower levels, or do not access services at all
- deliver screening and assessment from agreed accommodation, which is appropriate to house the equipment needed for full-field digital mammography (FFDM), and ensure that the number and location of pieces of screening equipment meet the needs of the resident screening population and also national and regional screening guidelines

3.8. Annual estimates of the eligible population for at least three years ahead, based on the current population database will be produced using the BS-Select
Increasing Uptake

3.9 It is recommended that:

- Commissioners and providers work with local authorities and third sector organisations to understand and develop plans to address uptake and inequalities. QA visits include an assessment of the process to develop such plans and their implementation at a local level.
- Commissioners work with providers to ensure that letters and invitations have been endorsed by GPs (where the GP agrees), timed first and second appointments are offered and appointment reminders are used.

Providers, commissioners and local authorities are encouraged to pilot, evaluate and publish (preferably in peer reviewed journals) local solutions to address inequalities of access. Before piloting, these local proposals must be agreed with the PHE screening team to ensure consistency of message with nationally agreed letters.

PHE screening team will share new and emerging knowledge via the screening inequalities network and blogs.

Programme Coordination

3.10 The provider will:

- be responsible for ensuring that the programme it delivers is coordinated. Where collaboration is necessary, each part of the programme should interface seamlessly with others, particularly in the areas of timeliness and data sharing. This will ensure that the aims and objectives of the NHSBSP are met.
- ensure that one or more named individuals are responsible for the coordination of planning and delivery. This individual should be given appropriate administrative support to ensure timely reporting and response to requests for information.
- ensure that a Programme Manager and a named Director of Breast Screening are appointed. Both must be actively involved in the screening programme, and the latter must be an individual possessing suitable competencies, capability and experience who can take overall responsibility and accountability for the service and its quality.
- Both the Screening Director and the Programme Manager must be given adequate resources to carry out their roles effectively. If the screening director is not a clinician, a non-medic appointed to the role will require a lead radiologist to be in post at the service. This will also be required if the screening director is a medic but not a consultant radiologist or breast physician. The lead radiologist will provide expert advice on the radiology
aspects of performance to the director of screening.

- ensure that adequate cover arrangements are in place to guarantee the sustainability and consistency of the programme.
- meet with NHS England at regular intervals (at least biannually). The meetings will include representatives from programme management, clinical services, laboratory services, and service management.

**Governance and leadership**

3.11 The provider will:

- cooperate with and have representation on local oversight arrangements as agreed with NHS England commissioners
- identify a Trust director (or equivalent in a private provider) who is responsible for the screening programme
- identify a named screening director with accountability for the service and where the service population is large (over 100,000 eligible women), a deputy should be appointed
- provide documented evidence of clinical governance that includes:
  - compliance with the NHS Trust and NHSE information governance/records management
  - user involvement, experience and complaints
  - failsafe procedures
  - risks and mitigation plans
  - Compliance with the NHS cancer screening programme confidentiality and disclosure policy
- ensure that there is regular monitoring and audit of the screening programme, and as part of the organisation’s clinical governance arrangements, the board is assured of the quality and integrity of the screening programme
- produce an annual report of screening services, which is signed off by the board
- ensure the programme is delivered by trained workforce that meet national requirements

**Location(s) of programme delivery**

3.12 The provider will:

- ensure that screening takes place in suitable and appropriate mobile or static locations, which take account of the public transport links and car parking arrangements.
- Programmes are responsible for providing suitable premises and equipment
for the screening programme which meets NHSBSP standards.

Days/hours of operation

3.13 The days and hours of operation will be locally determined and suitably accessible for the target population. However, timeliness of screening and assessment is essential, and this is a key criterion of quality along all parts of the screening pathway. The provider should therefore be able to:

- demonstrate efficient and effective use of resources

Working across interfaces

3.14 The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway. Accurate and timely communication and handover across these interfaces are necessary to reduce the potential for errors and ensure a seamless pathway for service users. The provider will

- Ensure that there are clear, named lines of clinical responsibility at all times, and particularly where there is handover of care.
- State these lines of clinical responsibility in an operational policy within the programme.

3.15 The provider will ensure that appropriate systems are in place to support timely and seamless referral to treatment services, including but not limited to:

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- providing strong clinical leadership and clear lines of accountability
- developing joint audit and monitoring processes
- working to agreed NHSBSP standards and policies agreed by PHE
- agreeing jointly, between all agencies, on the failsafe mechanisms that are required to ensure safe and timely processes across the whole screening pathway

3.16 The provider must ensure that procedures at interfaces follow these guidelines:

- invitation and reminder letters should be sent to women with timed appointments
- where women do not attend a first appointment, a second timed appointment should be sent by letter
- a Radiographer/Assistant Practitioner should provide diagnostic quality mammograms to the expert readers and must meet NHSBSP standards for training and experience
- readers should recall appropriate women for further assessment
• a failsafe system should ensure laboratory receipt of correctly identified needle samples
• Symptomatic services should inform screening services about interval cancers
• Genetics services should send only appropriate referrals as specified in higher-risk breast screening guidance and should be informed of screening outcomes after each subsequent attendance (see Appendix 3 and 4).

In addition, see section in Chapter 2 on the Care Pathway.

Information on test/screening programme

3.17 The provider will

• ensure that, at relevant points throughout the screening pathway, women are provided with approved information on breast screening and breast cancer treatment.

• ensure that a trained interpreter is available during appointments for women whose functional language is not English, along with appropriate written information

• provide appropriate support for women with physical disabilities

• ensure that women with learning disabilities are provided with support to enable them to understand all processes and results

Testing (performance of tests by individuals)

3.18 The provider will ensure that:

• screening units follow policy guidance and standards for screening mammography with regards to undertaking regular user quality control testing (and MRI, where appropriate) (see all Appendices).

• screening units enter routine data onto the National Breast Screening Information System (NBSS) in a timely manner and in the required format, as specified in NHSBSP manuals and guidance

• equipment faults should be reported without delay to the National Coordinating Centre for the Physics of Mammography (NCCPM) and dose surveys completed within timescales for national collation and QA purposes

Results reporting and recording

3.19 The provider will ensure that

• All images from the initial screening examination are reported directly onto the NBSS system promptly by the reader who is directly responsible for those results.

• The Programme records conclusive results on the information system for the
whole screened population.

Providing results
3.20 The provider will ensure that

- women are notified of a normal result from the screening process within two weeks of the initial examination by letter, and that their GP is also informed.
- the results of needle tests undertaken at an assessment visit are given by a clinician.
- a Clinical Nurse Specialist must be available to support the women as required after a benign diagnosis or a diagnosis of cancer.
- all screening women should be given information on radiological review of interval cancers in the symptomatic setting (where this applies).
- screening services must inform women, in writing, of the offer to have the outcomes of radiology review where duty of candour applies.
- Directors of screening or other delegated staff and clinical nurse specialists who undertake disclosure of audit or duty of candour consultations with women, must complete PHE duty of candour e-learning training (as a minimum).

Scope of cancer screening
3.21 The NHSBSP includes all investigations necessary to confirm or rule out a diagnosis of breast cancer.

Transfer of, and discharge from, care obligations
3.22 The screening programme covers the period from identification of the eligible population to diagnosis. Women who receive a diagnosis of breast cancer will continue to receive invitations for screening if they remain eligible. The provider should:

3.23 advise women who have received a diagnosis of breast cancer to contact the screening office for advice about screening in their particular case.

3.24 transfer women efficiently to treatment services on diagnosis. Any post-treatment follow-up will be the responsibility of the treatment service.

Exclusion criteria
3.25. This specification does not include the following activities, or any work or cost associated with them:

- Women below the current eligible age group (unless they meet the high-risk criteria)
- Women who are not eligible for NHS care
- Women who have had bilateral mastectomy
- Symptomatic referrals
- Post diagnosis follow-up and management
- The treatment of breast cancer
- Women who do not meet the criteria for higher-risk screening within the NHSBSP.

3.26. See Clause 54 of The Standard Terms and Conditions for Acute Hospitals (Gateway Reference 15458) for the contractual requirements for equity of access, equality, and the avoidance of discrimination. This is now detailed in the Standard NHS Contract.

**Staffing**

3.27 The provider will:

- ensure that there are adequate numbers of trained, qualified, and competent staff in place to deliver a high-quality breast screening programme, in line with best practice guidelines and NHSBSP national guidance (see Appendix 4).
- ensure that all staff demonstrate competence in their area, linked to training (qualifications will be specific to the groups of staff delivering the service across the care pathway).
- have in place a workforce plan designed to maintain a sustainable programme, especially where an increase in the eligible population is predicted (generally this is the case until 2027) and/or where there are difficulties in the recruitment of appropriately qualified healthcare staff.
- ensure that professionals involved in the NHSBSP screening programme are aware that they are required to keep up-to-date with nationally approved training programmes and CPD/CME etc. and to participate in educational schemes such as PERFORMS and histopathology EQA as appropriate.
- ensure that arrangements are in place so that Assistant Practitioners are given adequate clinical supervision by a registered healthcare professional who is working with them in the imaging or treatment room or immediately accessible for support and advice (telephone supervision is not appropriate). Providers must ensure that all Assistant Practitioners are working within the national Scope of Practice.

**User involvement**

3.28 In accordance with good practice, to gain feedback on services provided, and to have public involvement on service provision, the provider will collect the views of service users via a survey. This should:
• demonstrate that they have collected the views of service users, in respect of the services they provide (for women screened in static and mobile locations if the service provides screening in both facilities)

• demonstrate how those views will influence service delivery for the purposes of raising quality

• show that all women are given information about how to provide feedback about services they receive, including the complaints procedure.

Premises and equipment

3.29 The provider will ensure that:

• suitable premises and equipment are provided for the screening programme.

• only mammography equipment evaluated and found suitable by the NHSBSP is used for screening.

• full-field direct digital mammography is the only modality used for routine screening. MRI may be used for higher-risk women according to NHSBSP protocols (see Appendix 3).

• MRI screening is only carried out by services that meet the MRI Technical Guidelines developed by the NHSBSP (see Appendix 4).

• only technologies and protocols that have been evaluated and recommended by the national office of the Cancer Screening Programmes within PHE are used in the programme, and that the manner of their use accords with national guidelines. The provider must make all staff aware that unorthodox use of approved technologies or used of unapproved technologies is prohibited within the NHS Breast Screening Programme, except as part of a formal national evaluation, or a properly constituted and nationally approved research project. The definition of ‘technology’ here is an inclusive one, but normally refers to mammography equipment.

• appropriate policies are in place for equipment calibration, maintenance, and replacement.

• the NBSS database is able to support the programme and to supply data for the purpose of national standards and Key Performance Indicators.

• failsafe routines are run on NBSS.

Key Performance Indicators

3.29. The provider will adhere to the requirements in the consolidated standards.

Data collection and monitoring

3.30. The Quality Assurance service, in liaison with the providers, will provide validated data for the following purposes:
• provide routine data to NHS England, Public Health England and the Health and Social Care Information Centre in a timely manner to monitor performance

• contribute to national data collection exercises where required for national analysis

• provide annual data measuring performance against both standards and the Key Performance Indicators to monitor performance and measure trends

Data reporting

3.31. The Quality Assurance service, in liaison with the providers, will:

• report data to NHS England and Public Health England on a regular basis as documented in Appendices 1 and 2.

• participate in data reporting for consolidated annual reports KC62 (activity) currently published by NHS Digital for the purpose of service comparison.
4. National standards, risks and quality assurance

4.1 The provider will:

- meet the acceptable national programme standards and work towards attaining and maintaining the achievable standards
- adhere to specific professional standards and guidance
- maintain a register of risks, working with NHS England and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and ensure that these points are reviewed in contracting and peer review processes
- participate fully in national quality assurance (QA) processes which includes:
  - submitting agreed minimum data sets and reports from external quality assurance schemes
  - undertaking ad-hoc audits and reviews as requested
  - completing self-assessment questionnaires / tools and associated evidence
  - responding to SQAS recommendations within agreed timescales providing specified evidence
  - producing with agreement of commissioners of the service an action plan to address areas for improvement that are identified in recommendations
- operate and evidence
  - check points that track individuals through the screening pathway
  - identify, as early as possible, individuals that may have missed screening, where screening results are incomplete or where referral has not happened
  - have process in place to mitigate against weakness in the pathway
- have arrangements in place to refer individuals to appropriate treatment services in a timely manner and these should meet programme standards
- demonstrate that there are audited procedures, policies and protocols in place to ensure the screening programme consistently meets programme requirements
- comply with guidance on managing safety incidents in national screening programmes and NHS England serious incident framework
- ensure business continuity - business continuity plans must be in place where required
• ensure sub-contracts and/or service level agreements with other providers meet national standards and guidance

4.2 Service improvement:

Where national recommendations and acceptable/achievable standards are not fully implemented the provider is expected to indicate in service plans what changes and improvements will be made over the course of the contract period. The provider shall develop a CSIP (continual service improvement plan) in line with the standards and key performance indicators and the results of internal and external quality assurance checks. The CSIP will respond to any performance issues highlighted by the commissioners, having regard to any concerns raised via any service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with the commissioners.

4.3 New technologies:

New technologies should not be used for screening unless approved by the UK National Screening Committee.

5. Costs

5.1. The age expansion randomisation trial will be funded directly from PHE for the length of the trial. Amounts will be calculated according to the Age Expansion Implementation Guide.

6. Teaching and research activities

6.1. Screening programmes will participate in the age extension trial if they have approval from PHE and the triallists.

6.2. Any research activities undertaken by the provider must have the appropriate ethical approvals and the Breast Screening programme Research Advisory Committee must be consulted.
Appendix 1: Additional data requirements for programme boards

<table>
<thead>
<tr>
<th>Data requirements</th>
<th>Reporting period</th>
<th>Source of report</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Results of a local client satisfaction survey</td>
<td>Annual</td>
<td>Service provider</td>
</tr>
<tr>
<td>13. List of completed medical physics surveys</td>
<td>Annual</td>
<td>Service provider/SQAS</td>
</tr>
<tr>
<td>14. Screening services to provide tables summarising the number of eligible women in each year of the 3 year screening round and details of the 3 year screening programme including the location and timing of mobile screening</td>
<td>Annual</td>
<td>Service provider</td>
</tr>
<tr>
<td>15. Annual report (including a report against measures in consolidated standards)</td>
<td>Annual</td>
<td>Service provider and annual performance report from SQAS service</td>
</tr>
<tr>
<td>16. Summary of complaints</td>
<td>Tabled at programme board meetings</td>
<td>Service provider</td>
</tr>
<tr>
<td>17. Number and proportion of clinics cancelled</td>
<td>Tabled at programme board meetings</td>
<td>Service provider</td>
</tr>
<tr>
<td>18. Details of any safety concerns, safety incidents and serious incidents</td>
<td>Tabled at programme board meetings</td>
<td>Service provider/SQAS</td>
</tr>
</tbody>
</table>
Appendix 2: PROFESSIONAL BEST PRACTICE GUIDANCE

Quality Assurance Guidelines for Pathologists. NHSBSP Publications No 2, July 2011 (2nd edition)


Guidelines on Quality Assurance Visits Publication No 40, October 2000

Guidelines for Managing Incidents in the Breast Screening Programme Publication No 44, June 2009

Quality Assurance Guidelines for Administrative and Clerical Staff. NHSBSP Publication No 47, November 2000


Organising a Breast Screening Programme Publication No 52, December 2002 (revision forthcoming)

Information and Advice for Health Professionals in Breast Screening. NHSBSP Publication No 53, December 2002 (revision forthcoming)

The Right Results – Guide to the Correct Processing and Issuing of Results. NHSBSP Publication No 55, May 2003, (revision forthcoming)

External Quality Assessment, Scheme for Breast Screening Histopathology. NHSBSP Publication No 57, October 2003


Quality Assurance Guidelines for Mammography including Radiographic Quality Control. NHSBSP Publication No 63, April 2006:

Improving the Quality of the Written Information sent to Women about Breast Screening: Evidence-Based Criteria for the Content of Letters and Leaflets. NHSBSP Publication No 64, August 2007

Improving the Quality of the Written Information sent to Women about Breast Screening: Guidelines on the Content of Letters and Leaflets. NHSBSP Publication No 65, August 2007.

Uncertainties in the Management of Screen-detected Ductal Carcinoma In Situ. NHSBSP Publication No 66, July 2008


Guidance notes for the installation and testing of ultrasound scanners for use in the NHSBSP Publication No 70, April 2011


Guidelines on organising the surveillance of women at higher risk of developing breast cancer in an NHS Breast Screening Programme. NHSBSP Publication 73, March 2013

Protocols for the Surveillance of Women at Higher Risk of Developing breast cancer; NHSBSP Publication 74; Version 4, June 2013


Consent to Cancer Screening Cancer Screening Series No. 4, Second Edition, January 2009

Routine quality control tests for full field digital mammography systems 4th Edition 2013 (NHSBSP Report 1303)
Routine quality control tests for breast tomosynthesis (Radiographers) 2014 (NHSBSP Report 1406)

The commissioning and routine testing of full field digital mammography systems 2009 (NHSBSP Report 0604, version 3)

Routine quality control tests for breast tomosynthesis (Physicists) 2015 (NHSBSP Report 1407)