



Public Health  
England



# NHS public health functions agreement 2019-20

Service specification No. 24  
NHS Breast Screening Programme

NHS England and NHS Improvement



# **NHS public health functions agreement 2019-20**

## **Service specification No. 24 NHS Breast Screening Programme**

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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement and NHS Improvement 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 due 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).

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## Service specification No.24

This is a service specification to accompany the 'NHS public health functions agreement 2019-2020 (the '2018-2019 agreement')'.

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 2019-2020 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-2020 agreement in accordance with the procedures described in Chapter 3 of the 2019-2020 agreement.

Please always refer to the service specification online to ensure you are using the latest version.

The 2019-2020 agreement is available at [www.gov.uk](http://www.gov.uk) (search for 'commissioning public health')

# 1 Purpose of the screening programme

## Purpose of the Specification

- 1.1 To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of breast screening as part of the NHS Breast Screening Programme.
- 1.2 The purpose of the service specification is to outline the service and quality indicators expected by NHS England and NHS Improvement for the population for whom it is responsible, and which meets the policies, recommendations and standards of the NHS Breast Screening Programme.
- 1.3 This specification is not designated to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. of the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.
- 1.4 This service specification should 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 website](https://www.gov.uk).

## The role of PHE Screening

- 1.5 Public Health England (PHE) advises the government and the NHS so England has safe, high quality screening programmes that reflect the best available evidence and the UK National Screening Committee recommendations. PHE also develops standards and provides specific services that help the local NHS implement and run screening services consistently across the country.
- 1.6 Providers should subscribe to the [PHE Screening blog](#) for the latest national news and updates. [National documentation and guidance](#) is published on GOV.UK.

## Personal informed choice

- 1.7 All screening is an individual choice. The UK NSC has published [guidance for screening programmes in the 4 UK countries](#) to follow. Everyone must be given the opportunity to make an informed choice about whether or not to be screened. The decision should be based on an understanding of:
  - why they are being offered screening
  - what happens during the test
  - the benefits and risks of screening
  - the potential outcomes (including types of result, further tests and treatment)
  - what happens to their screening records

If someone is provided with the above information about the programme and chooses not to attend screening, then this is a valid choice and must be respected.

## Opting out

- 1.8 Providers should respect the decision of any individual choosing to [opt out of screening](#), either on a single occasion or permanently. No pressure should be put on people to be screened and services should not require the individual to justify their decision.

## Public information

- 1.9 PHE Screening uses published best practice processes to develop public information leaflets. It also works with NHS Digital to ensure that information on the NHS.UK website for the public is accurate.

- 1.10 Providers must:

- use the public information leaflets from PHE Screening at all stages of the screening pathway
- involve PHE in the development of any local awareness campaigns
- involve PHE if they want to move from providing printed leaflets to online sources of information

Using the leaflets provided by PHE ensures accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening must be consulted and involved before developing any other supporting materials.

- 1.11 Providers must involve PHE 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 so that the national screening helpdesk is not overwhelmed with calls.
- 1.12 Local provider websites must not duplicate clinical information about screening but should be restricted to contact and logistical information. Links should be provided to the national information on NHS.UK (<https://www.nhs.uk/conditions/breast-cancer-screening/>) and GOV.UK (<https://www.gov.uk/topic/population-screening-programmes/breast>).
- 1.13 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.

## Ordering leaflets

- 1.14 Providers can order free [leaflets developed by PHE Screening](#) for core screening purposes.
- 1.15 Leaflets are regularly updated so providers should not order more than 3 months' supply, or stockpile leaflets, as they could become out of date and need to be



destroyed. Leaflets for non-core activities, such as local health promotion purposes, can be bought from the national print provider.

- 1.16 PHE can only provide one leaflet per person per screening episode. A screening episode is defined as an invitation (with any subsequent reminders) for a particular screening test. People who are referred for further assessment following a screen should get a single copy of the appropriate follow-up leaflet.

This means that duplicate copies should not be provided with reminder letters or if people lose or forget their leaflet. They should be signposted to electronic sources of information instead.

### **Addressing inequalities and ensuring equal access to screening**

- 1.17 Screening is offered to all individuals within the eligible population. One of the objectives of the NHS Screening Programmes is to help reduce health inequalities.

### **Sharing personal information**

- 1.18 Under the [2010 Equality Act](#), screening services are required to anticipate and prevent discrimination against people with learning disabilities.
- 1.19 The duty of care to share information can be as important as the duty to protect patient confidentiality. GPs and other health professionals should have the confidence to share relevant information with screening services with relevant information in the best interests of their patients. For example, a GP may know that an individual with a learning disability requires accessible information about screening in easy read format or needs a longer than normal appointment slot. Providers should actively seek information from GPs and other health professionals if individuals have a learning disability.

See [NHS England's information sharing policy](#) for more detailed guidance.

- 1.20 PHE Screening's [privacy notice](#) has more information about how screening data is shared within the legal requirements, including those of the General Data Protection Regulation (GDPR).

### **Reasonable adjustments**

- 1.21 Under the [2010 Equality Act](#), screening providers have a legal duty to make [reasonable adjustments](#) to make sure services are accessible to disabled people as well as everybody else.
- 1.22 Screening providers must follow the [Accessible Information Standard](#) by law. The standard aims to make sure that people who have a disability, impairment or sensory loss are provided with information they can easily read or understand with support, so they can communicate effectively with health and social care services.
- 1.23 As part of the Accessible Information Standard, screening providers must do 5 things:
- Ask people if they have any information or communication needs and find out how to meet their needs.
  - Record those needs clearly and in a set way.

- Highlight or flag the person's file or notes so it is clear that they have information or communication needs and how to meet those needs.
- Share information about people's information and communication needs with other providers of NHS and adult social care, when they have consent or permission to do so.
- Take steps to ensure that people receive information which they can access and understand and receive communication support if they need it.

### **National accessible information materials**

- 1.24 PHE Screening has published national easy read versions of screening information leaflets and screening appointment letter templates. Local screening providers should use these national materials when inviting individuals for screening who have been identified as needing information in an easy read format.
- 1.25 Large print and audio (MP3) versions of standard information leaflets are also available to download from GOV.UK for people with sight loss.
- 1.26 Local screening providers should send any individual requests for hard copy Braille versions of PHE Screening leaflets to the [screening helpdesk](#).

### **Education and training**

- 1.27 PHE screening provides a variety of education and training for NHS screening staff. Evidence based, up-to-date e-learning resources, study days and courses can be accessed here <https://www.gov.uk/guidance/nhs-population-screening-education-and-training>
- 1.28 In addition, each screening programme will have specific guidance for the initial training and ongoing learning for screeners. This learning should be facilitated, supported and monitored by local screening providers. In line with professional regulations individuals have a responsibility to ensure their practice is up-to-date and evidence based. Local programmes can use the national programme training guidance and resources to support this.

### **Equality**

- 1.29 Delivery of the screening programme contributes to reducing health inequalities and should include the following deliverables:
  - screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary a Health Equity Audit should be undertaken as part of both the commissioning and review of a screening programme when there is a change of service provider. This should include monitoring of 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 equality, health inequality and screening guidance when making such decisions

- 1.30 The provider will demonstrate they have systems in place to address health inequalities and make sure there is equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to make sure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the [2010 Equality Act](#).
- 1.31 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 traveler 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.
- 1.32 Providers are expected to meet the public sector Equality Duty which means that public bodies must consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees.

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

## 2 Outcomes

### NHS Outcomes Framework Domains & Indicators

2.1 This specification will meet the following domains in the NHS Outcomes Framework

|          |   |   |
|----------|---|---|
| Domain 1 | <b>Preventing people from dying prematurely</b>   | X |
| Domain 2 | <b>Enhancing quality of life for people with long-term conditions</b>                               |   |
| Domain 3 | <b>Helping people to recover from episodes of ill health or following injury</b>                    |   |
| Domain 4 | <b>Ensuring that people have a positive experience of care</b>                                      | X |
| Domain 5 | <b>Treating and caring for people in a safe environment and protecting them from avoidable harm</b> | X |

## 3 Scope

### Aims and objectives of the programme

#### Aim

- 3.1 The major aim of the NHS breast screening programme is to reduce mortality from breast cancer by diagnosing cancer at an early stage when treatment is more successful. This is achieved by delivering an evidence-based, population-based screening programme. Continuous monitoring and evaluation by an expert quality assurance process ensures screening services meet standards and continuously improve the quality of their service.

#### Objectives

- 3.2 The key objectives of the NHSBSP include:
- identifying the eligible population and ensure efficient delivery with optimal coverage
  - delivering and supporting the programme with suitably trained, competent, and qualified, clinical and non-clinical staff who, where relevant, participate in recognised ongoing Continuing Medical Education, Continuous Professional Development, professional revalidation and External Quality Assurance schemes in fit for purpose facilities
  - having audit and service evaluation embedded in the service to maximise safety and accessibility of the service for all groups in the eligible population
  - maximising screening sensitivity and specificity by detecting early stage cancers with the least possible radiation dose and minimising the biopsy and referral of women who do not have breast disease to minimise the adverse impact (physical/psychological/clinical) of unnecessary investigations
  - having a seamless pathway at the interface between screening and diagnosis and the treatment pathway to ensure women are referred promptly and safely to treatment services

### Service description and care pathway

- 3.3 The screening process is divided into the following stages:
- Identification
  - Invitation
  - Inform
  - Test
  - Diagnose
  - Treatment/intervention
  - Monitor outcomes

## Screening pathway for the NHSBSP

3.4 Figures 1 and 2 outline the NHSBSP pathway for routine screening and for very high risk screening.

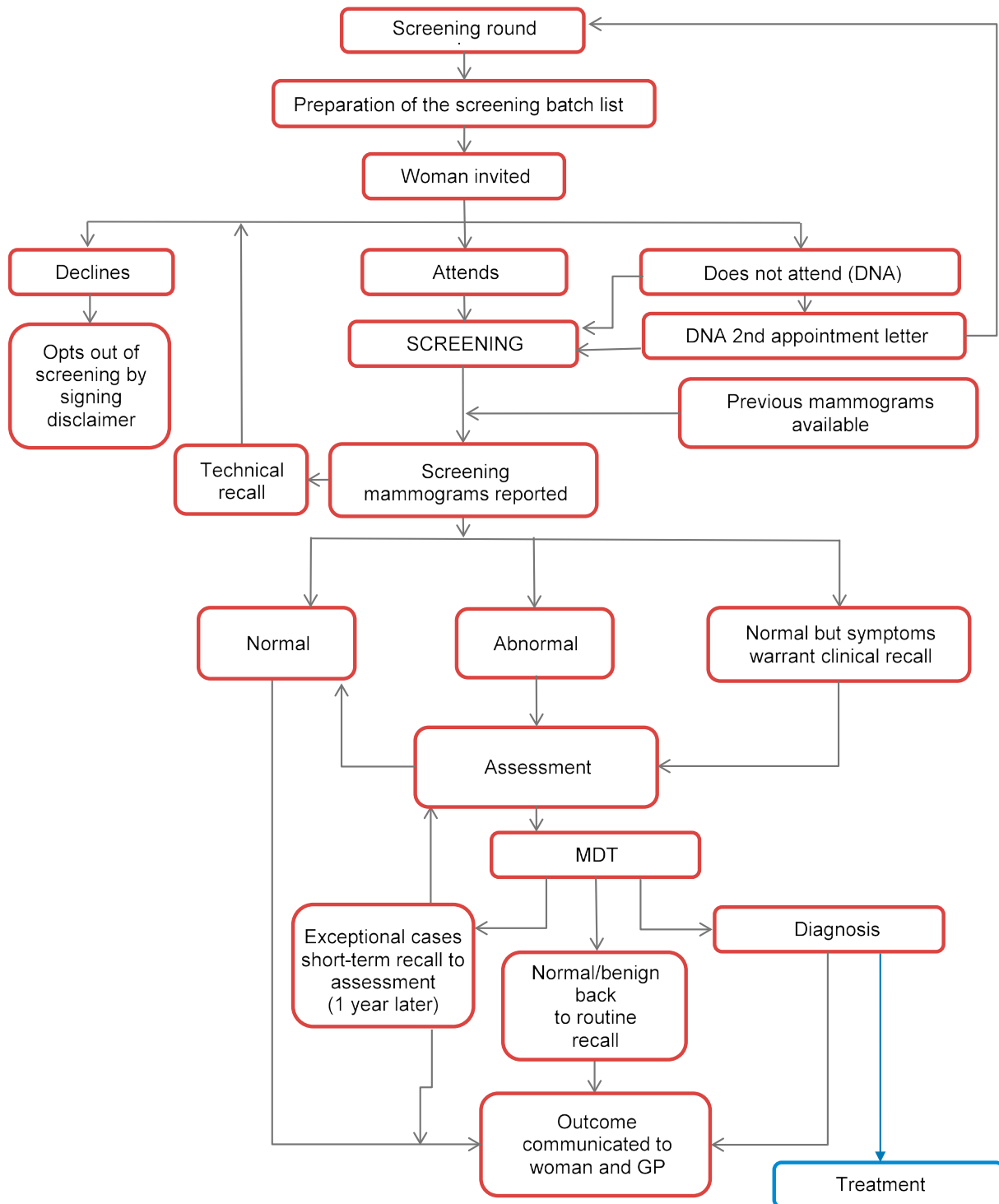


Figure 1: Routine Screening pathway

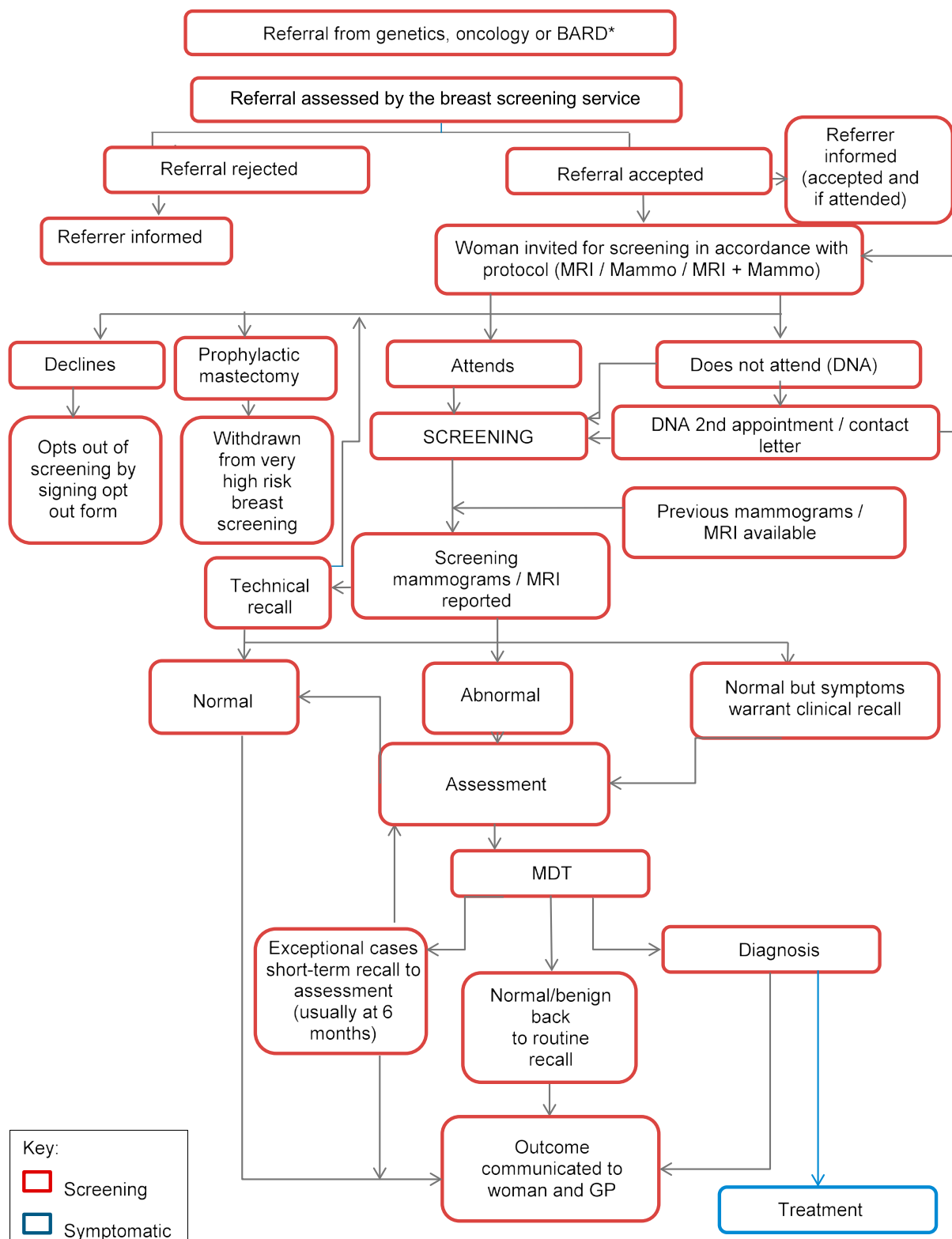


Figure 2: Very High Risk Screening Pathway (\*Breast after radiotherapy dataset – a database established to actively identify all women in England treated with radiotherapy to sites above the diaphragm involving breast tissue below the age of 36 who are eligible for very high risk screening)

## Identification

3.5 To optimise coverage and uptake across their catchment area the provider will:

- obtain annual estimates of the eligible population for at least three years ahead, based on the current population database estimates using the Breast Screening Select (BS-Select) system. This will help inform current and future service delivery requirements
- ensure all eligible women registered with a GP in the catchment area, and those resident in the area without a GP, are included. English services bordering Scotland or Wales should accommodate women who request to be screened elsewhere adhering to the [Out of area Guidance](#). The service will invite women aged from 50 up until their 71<sup>st</sup> birthday. In practice, the following age ranges will be used to identify the eligible population prior to invitation:
  - routine screening population: 49 years and  $\geq 8$  months to 70 years, 364 days (up to the 71<sup>st</sup> birthday)
  - age extension trial ([AgeX](#)) younger cohort: 46 years and 10 months to 49 years and  $< 8$  months
  - age extension trial ([AgeX](#)) older cohort: 71 years and 0 months to 73 years and 364 days (up to the 74<sup>th</sup> birthday)
- all eligible women will be invited to their final routine screen within 36 months of their 68<sup>th</sup> birthday
- identify women who move into the screening catchment area from BS-Select, or who are registered with a GP in the screening catchment area
- 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
- routinely cease only those women who have had bilateral mastectomies, women who are excluded due to a [best interests decision](#) or who request to opt-out from screening to ensure that they no longer receive invitations for screening
- keep supporting documentary evidence for any woman who is ceased from the programme for an indefinite time period. This information should be copied onto BS-Select when this function is available so that there is an indefinite record if the woman moves screening services
- carry out annual audits on ceased women to ensure that women have been ceased appropriately in compliance with programme [guidance](#)
- utilise BS-Select and the national breast screening system (NBSS) to ensure that coverage is optimised and ensure that all GP practices are correctly identified

## Referrals of very high-risk women

3.6 Women fulfilling eligibility criteria for [very high risk screening](#) must be referred into the programme using the national referral proforma via the following routes:



- a genetics service by a consultant geneticist or an appropriately trained individual nominated by them
- an oncologist (in the case of women treated with radiotherapy to sites involving breast tissue)
- the Breast screening After Radiotherapy Dataset (BARD) for women treated with radiotherapy to sites above the diaphragm involving breast tissue below the age of 30 (BARD oncology consultant referral)

The referral form should be reviewed by the director of screening (or nominated representative) to accept or reject the referral. The referrer and GP should be informed of the outcome (if accepted) and reason for rejection (if the referral is not accepted).

## Invitation

### 3.7 All breast screening services must:

- offer breast screening to eligible women at a maximum interval of 36-months, according to the criteria specified by the [NHSBSP](#)
- develop and regularly review the screening round plan to ensure that the appropriate population is covered and that invitations are sent promptly
- ensure all women are invited to attend for their initial (prevalent) screen within the 3 years after their 50<sup>th</sup> birthday. Women may be invited from the age of 47 as part of the age extension trial until 2026
- use national letter templates ([Appendix 1](#))
- send timed invitations by letter and where women do not attend their first invitation, a second timed appointment letter should be sent
- post initial invitation letters at least 2 weeks before the appointment date
- ensure women are invited to screening at accessible screening sites to ensure efficient screening delivery to optimise coverage and screening uptake. Screening sites should take account of the public transport links and car parking arrangements and provide appropriate support for women with additional needs
- encourage attendance by ensuring that the process of changing appointments is straightforward for those women who request this
- accommodate women who request to be screened at an alternative screening centre according to [guidance](#), which should ideally include undertaking their assessment to minimise the risk associated with transfer of patient information across organisations
- inform women of their right to request screening if they are aged 71 years or over and have not received an invitation as part of the age-extension trial. The Programme will screen women aged 71 or over who self-refer or refer via their GP every three years

- ensure results letters and invitations for screening assessment are sent within [national standards](#)

3.8 In relation to women eligible for very high risk screening, providers must:

- issue invitations without delay and first contact at the initial screening invitation must be made within 2 weeks of the referral being made to the provider
- invite women who are eligible for higher risk screening at appropriate ages and screened with appropriate modalities and screening intervals according to [NHSBSP protocols](#)
- ensure results letters and invitations for screening assessment are sent within [national standards](#)
- ensure the service has [adequate equipment](#) to screen the very high risk population

3.9 The service provider is encouraged to use a variety of prompts and reminders to maximise screening attendance where this is possible. This may include:

- text reminders
- GP endorsement letters

## Inform

3.10 Providers must:

- always use the patient information leaflets from PHE Screening at all stages of the screening pathway to allow informed choice ([Appendix 2](#)). This ensures 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
- ensure that clear directions and a map to the screening site are sent with the screening invitation and leaflet
- ensure that women with learning disabilities are provided with support to enable them to understand all processes and results
- ensure that a trained interpreter is available during assessment appointments for women where requested whose functional language is not English, along with appropriate written information
- not develop their own information about screening for local NHS websites which is inconsistent with national policy and should always link through to the national information on NHS Choices (<https://www.nhs.uk/conditions/breast-cancer-screening/>) and GOV.UK (<https://www.gov.uk/topic/population-screening-programmes/breast>)
- 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

- 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

## Test – First stage screening – mammography

3.11 Screening by mammography is the initial screening test in the NHSBSP. Services are required to do the following:

- 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 image quality and radiation dose are optimised, with [technical repeats minimised](#)
- ensure mammography is undertaken and reported by suitably trained, competent, and qualified, [clinical and non-clinical staff](#) who, where relevant, participate in recognised ongoing Continuing Medical Education, Continuous Professional Development, and External Quality Assurance schemes in fit for purpose facilities
- 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 NBSS
- ensure that women who are invited are not screened if they have had a previous screen in the past 6 months
- provide appropriate support for women with additional needs
- have audit and service evaluation embedded in the service to maximise safety and accessibility of the service for all groups in the eligible population
- ensure that all screening examinations are subject to double reading by readers fulfilling all [requirements of the NHSBSP](#)

## Test – Second stage screening - assessment

3.12 In accordance with NHSBSP standards and protocols, the provider must:

- refer women to assessment with significant mammographic or Magnetic Resonance Imaging (MRI) abnormalities, or presenting with significant 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 assess anxiety and offer appropriate support. The CNS should see all women undergoing needle biopsy procedures
- undertake triple assessment (needle test/additional imaging/clinical examination) and diagnosis of individuals with abnormal initial test results in appropriately staffed and equipped settings, to the [standards expected within the NHSBSP](#)
- 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
- 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 practitioner or breast clinician experienced in the full range of triple assessment
- before returning a woman to routine recall, when no biopsies have been undertaken, a [second assessor](#) is recommended to review the case
- ensure that biopsy specimen imaging is available whilst the woman is still positioned in the stereo x-ray equipment
- ensure that [vacuum assisted excision](#) (VAE) is used for re-biopsy of the same lesion and the [investigation of B3 lesions](#)
- ensure that women are only placed on short term recall from assessment in exceptional circumstances
- carry out localisations only in facilities that meet the NHSBSP standards

## Diagnose

3.13 At a multi-disciplinary team (MDT) meeting services should:

- discuss all women undergoing biopsy with an outcome agreed by all disciplines. The outcome should be documented in one single, accessible record which clearly documents the future management of the woman
- accurately diagnose cancers, with reference to MDT decisions, and refer women for treatment by appropriately trained and qualified specialists
- refer women for open surgical biopsy, if this is necessary to confirm or exclude malignancy, before discharge or onwards referral from the programme
- notify women and their GPs on the outcome of assessment as soon as possible

## Results giving, reporting and recording

3.14 All providers must:

- 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

- ensure that conclusive results are recorded on the appropriate information systems for the whole screened population
- send results of basic screening to the woman and GP within two weeks of screening attendance
- 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:
  - only offer the option of results by clinic appointment or telephone where there is a very strong suspicion that malignancy is not present
  - only offer results by telephone if specifically requested by the woman

This should not be routinely offered due to the possibility of a malignant outcome which will need an appointment in person with a member of the clinical team and CNS.

- ensure all malignant results are given to the women by a member of the clinical team, in person, accompanied by the CNS who is the patient's advocate and offers support and information
- results of breast screening will be automatically sent from the NBSS system to BS-Select to determine future call/recall management. The system runs national returns showing screening coverage (KC63)
- ensure that national cancer waiting times are adhered to along the screening pathway and that appropriate information (date of final image reading outcome) is transferred to the relevant waiting times department to allow continued monitoring
- ensure that the GP is informed of the outcome of all their eligible population at the earliest opportunity

## Treatment/Intervention

3.15 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:

- ensure there is a seamless link between 'screening responsibility' and 'treatment responsibility', so that women at the end of the screening process are referred promptly to treatment services, once diagnosis with breast cancer is made explicit
- advise women who have received a diagnosis of breast cancer to contact the screening office for advice about screening in their particular case
- ensure that any post-treatment follow-up will be the responsibility of the treatment service
- ensure there are systems in place to support timely and seamless referral of women to treatment services by:

- 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

## Monitor outcomes

3.16 To maximise the effectiveness of the programme and provide ongoing service improvement and appropriate patient feedback, it is important 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. The results of audits should be discussed in annual appraisals.
- providers 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. To facilitate this process screening services should liaise with local symptomatic services
- all breast screening services 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 within prescribed timescales
- 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)

## Service model summary

- 3.17 All elements of the screening pathway must be delivered by appropriately qualified staff, utilising suitable premises and equipment to national standards and guidelines.
- 3.18 Where sub-contracts and/or service level agreements are in place this should be made explicit to SQAS and local commissioning teams. These should only be

undertaken with providers who meet national standards and guidance for the breast screening programme

- 3.19 All pathology laboratories dealing with screening programmes should be formally accredited by United Kingdom Accreditation Service (UKAS) or equivalent.
- 3.20 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 very high risk of breast cancer may involve MRI.
- 3.21 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.
- 3.22 Services must 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.
- 3.23 Business continuity plans must be in place where required to ensure resilience.
- 3.24 Commissioners should approach PHE to assess whether service reorganisations are feasible where redesign has implications with regards to breast screening IT. This should be done in a timely way to ensure the quality and safety of the programme.

## Failsafe Procedures

- 3.25 Quality assurance within the screening pathway is managed by the inclusion of failsafe processes. Failsafe systems must be able to identify, as early as possible, people that may have been missed or where screening results are incomplete. To help ensure that all women receive the right results at the right time, the following should be undertaken by services:
  - [monthly failsafe](#) batches must be run by the breast screening office to ensure that all eligible women are invited for screening
  - regular housekeeping reports supporting [failsafe routines](#) must be run on NBSS and BS-Select in compliance with NHSBSP guidance
  - ensure appropriate failsafe mechanisms are embedded across the whole screening pathway as detailed in the [NHSBSP guidance](#). This should include the laboratory receipt of correctly identified needle samples and surgical specimens
  - ensure that the screening programme recommendations for handling [safety concerns, safety incidents and serious incidents](#) are adhered to, in addition to local reporting procedures ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report safety concerns, safety incidents and serious incidents
  - work with NHS England and NHS Improvement and SQAS teams within PHE to develop, implement, and maintain appropriate risk reduction measures



- review and risk assess local screening pathways in the light of guidance offered by quality assurance processes or the Young Peoples and Adult team (YPA) within PHE. YPA produces national guidance for the breast, bowel, cervical, aortic aneurism and diabetic eye screening programmes.
- maintain, comply with, and regularly audit the Quality Management System (QMS) 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 documented 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 appropriate links are made with internal provider governance arrangements, such as risk registers
- where multiple organisations undertake screening, it is important to agree jointly, between all agencies, on the failsafe mechanisms that are required to ensure robust and timely processes across the whole screening pathway
- ensure routine staff training and ongoing development take place
- ensure effective and timely communication with the YPA and SQAS teams within PHE, clinical multi-disciplinary teams, other screening services, NHS England and NHS Improvement and the NHS Digital team as required

### Roles and accountability throughout the pathway

3.26 The breast screening programme depends on systematic, specified relationships between screening services and stakeholders (which include treatment services, histopathology, genetics services, external diagnostic services, primary care representatives). 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 require:

- a programme manager and a named [director of breast screening](#) to be 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
- the director of breast screening and the programme manager to be given adequate resources to carry out their roles effectively
- the director of breast screening to be a consultant breast radiologist, consultant practitioner or [breast clinician](#) experienced in the full range of triple assessment. Alternatively, they can be a breast screening consultant (for example a breast surgeon or histopathologist) within the breast service but they will need the additional support of a radiology advisor



- a deputy screening director should be appointed where the service population is large (over 100,000 eligible women)
- 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 failsafe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway
- contributing to any initiatives led by NHS England and NHS Improvement 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

### Competencies and ongoing training

3.27 Training and education for all staff groups must be conducted as required by the breast screening programme. The provider shall ensure all staff groups engaged in providing the service are trained and complete continual professional development in accordance with guidance and in particular in accordance with the [relevant programme requirements](#). The provider should ensure training has been completed satisfactorily and recorded and that there is a system in place to assess ongoing competency.

3.28 All providers must:

- provide adequate numbers of appropriately trained, qualified, and competent staff to carry out high-quality screening mammography to NHSBSP standards
- 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
- ensure that only approved/accredited training courses should be used, and these should be funded locally 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 readers reporting breast images participate in external quality assurance activities (EQA schemes) the results of which will be used to compare with real life performance annually
- ensure all pathologists reporting breast specimens participate in the EQA scheme

### Information technology, call and recall

3.29 The provider must:

- use the programme's IT systems (NBSS), 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
- work in a collaborative and timely manner with the NBSS contractor with regards to NBSS changes, releases and security patch management
- comply fully with NHS information governance requirements relating to the confidentiality and disclosure of patient information and system/information security
- collaborate with the national YPA team within PHE 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

### Population covered

3.30 The provider will serve whole populations (all ages) numbering no less than 500,000 and up to about one million. Cohort information will be provided to the provider through BS-Select.

### Acceptance criteria

3.31 All the eligible population should be invited for screening. Information on the eligibility of the lesbian, gay, bi-sexual and trans gender people are [available online](#).

### Exclusion criteria

3.32 This specification does not include the following activities, or any work or cost associated with them:

- women below the current eligible age group who do not meet the criteria for higher-risk screening within the NHSBSP
- women who have had bilateral mastectomy
- symptomatic referrals
- post diagnosis follow-up and management
- the treatment of breast cancer

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.

### Interdependence with other agencies, services and providers

3.33 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.

3.34 The provider will ensure that there are clear, named lines of clinical responsibility at all times, and particularly where there is handover of care.

### Increasing uptake

3.35 It is recommended that:

- commissioners and providers work with external organisations (such as sustainability and transformation partnerships (STPs), cancer alliances and 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
- providers and commissioners are encouraged to pilot, evaluate and publish 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
- services 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
- services collaborate with commissioners to use mechanisms such as CQUIN to improve programme acceptability

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

## 4 Applicable service standards

### Applicable national standards

- 4.1 PHE, through the national screening programmes, is responsible for leading high-quality, uniform screening and providing accessible information to both the public and health care professional and developing and monitoring standards. It is also responsible for the delivery of national quality assurance, based at regional level, and for ensuring training and education for all those providing screening is developed, commissioned and delivered through appropriate partner organisations.
- 4.2 [Programme standards](#) are available online. The standards should be achieved so that the programme as a whole should:
- maximise the number of cancers detected whilst minimising the number of women recalled to assessment
  - minimise the number of cancers presenting between screening episodes
  - maximise screening sensitivity and specificity by detecting early stage cancers with the least possible radiation dose and minimising the biopsy and referral of women who do not have breast disease to minimise the adverse impact (physical/psychological/clinical) of unnecessary investigations
  - participate in both approved national routine audits and ad hoc audits to evaluate overall programme performance
- 4.3 The provider will meet the [acceptable, and work towards the achievable, programme standards](#). Where acceptable standards are not met, the provider will be expected to indicate in service plans what changes and improvements will be made over the course of the contract period. This is in compliance with schedule 4 of the NHS E standard contract.
- 4.4 The provider shall develop a contractual services development plan in line with key performance indicators (KPIs) and the results of internal and external quality assurance checks. The plan will respond to any performance issues highlighted by the commissioners, having regard to any concerns raised via any feedback from women, family or carers. The plan will contain action plans with defined timescales and responsibilities and will be agreed with the commissioners. This is in compliance with schedule 4 of the NHS E standard contract.

### Oversight and monitoring of pathway standards

- 4.5 PHE Screening Quality Assurance Service (SQAS) systems support commissioners and the provider in the quality and clinical governance aspects of the services so that core processes are robust, and the programme achieves better outcomes
- 4.6 The provider shall at all times cooperate and participate fully in national quality assurance processes, co-operate in undertaking ad-hoc audits and reviews as requested and as may be directed by the commissioner, from time to time. The provider shall act upon and implement recommendations made as a result of SQAS visits or reviews within a timeframe and in accordance with a plan that has been agreed by the commissioner.

- 4.7 The provider shall ensure that it submits the following to SQAS within the timescales laid out in [guidance](#) or otherwise as directed by SQAS:
- data and reports
  - minimum data sets as required
  - self-assessment questionnaires / tools and associated evidence
  - audits or data relating to nationally agreed internal quality assurance processes incidents and serious incidents as they occur in accordance with [policy](#)
- 4.8 Where SQAS believe there is a significant risk of harm to the population, they will recommend to commissioners to suspend a service.
- 4.9 SQAS, in liaison with the providers, will provide validated data for the following purposes:
- provide routine data to NHS England and NHS Improvement, PHE and NHS Digital 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 KPIs to monitor performance and measure trends
- 4.10 SQAS, in liaison with the provider, will:
- report data to NHS England and NHS Improvement and PHE on a regular basis as documented the [NHSBSP standards](#)
  - participate in data reporting for consolidated annual reports KC62 (activity) currently published by NHS Digital for the purpose of service comparison
  - 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 NHS Improvement 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
- 4.11 The provider will:
- ensure that complete and accurate outcomes and results for all women are accurately entered onto the 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
  - 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 SQAS team
- manage failures to provide services to the level specified in the [NHSBSP guidance](#).

4.12 The provider will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.

4.13 The provider shall, at all times comply with the UK NSC guidance '[Managing Serious Incidents in the English NHS National Screening Programme](#)' (or updated version) as referred to in the Quality Requirements in Schedule 4 and the NHS England and NHS Improvement guidance for the management of incidents.

### [Applicable standards set out in guidance and/or issued by a competent body](#)

4.14 The provider will :

- review, on an annual basis, the number of women who have requested screening or assessment at an alternative service
- produce statistical analyses of uptake and coverage, and of individual, professional and team performance on request to both NHS England and NHS Improvement and SQAS teams within PHE

4.15 Information on training and development for providers are available [online](#)

### [Clinical and corporate governance](#)

#### **Accountability and oversight**

4.16 The provider shall ensure that:

- an appropriately skilled and competent executive officer within its organisation is accountable for, and oversees, the breast screening service
- the provider's board of directors is part of the clinical governance procedures and must be responsible for receiving assurance on the quality of the service
- there is appropriate internal clinical oversight of the service with its own management and internal governance of the service
- an internal multi-disciplinary operational group is established, that meets monthly as a minimum. This group will ensure robust operational processes are in place between individuals delivering the services

### [Programme board](#)

4.17 A screening programme board must meet at a minimum of every 6 months and at a schedule agreed with commissioners. As a minimum, meetings must include, the

screening director, programme manager, the screening and immunisation lead, and SQAS representative. The programme boards must consider service user engagement and involvement.

4.18 The provider must:

- ensure co-operation with and representation on the local screening oversight arrangements / structures
- ensure good governance of the screening programme
- ensure that service improvements required due to the advice of SQAS to screening commissioners are adhered to in compliance with contractual requirements
- produce an annual report of screening services, which is signed off by the board
- ensure that there is regular monitoring and audit of the screening service and as part of the organisation's clinical governance arrangements, the programme board is assured of the quality and integrity of the screening service
- ensure that 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 ([Appendix 3](#)). 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
  - include feedback from women with additional needs or from disadvantaged groups wherever possible

## Risk management

4.19 The provider must have an internal risk management process to manage the risks of running the service. The risk management process must be reviewed and agreed at the programme board and form part of the assurance to the provider's board of directors.

4.20 The provider shall have internal quality assurance and risk management processes in operation always and be able to demonstrate to the commissioner that those processes are commensurate to the risks, quality assurance issues and best practice of the services documented and other evidence to support this must be in place.

4.21 On a quarterly basis high scoring risks will be identified and agreed between the provider and the commissioners and plans put in place to mitigate against them. It is expected that providers will investigate anything outside the acceptable levels.

## Governance policies

4.22 The provider must have an appropriate governance framework in place that has been approved by the commissioner, covering the following aspects of the services:

- information governance/records management
- equality and diversity
- user involvement, experience and complaints
- failsafe procedures
- risks & mitigation plans

4.23 The provider shall seek the commissioner's approval of the governance framework prior to the services commencement date and annually thereafter.

4.24 The provider must:

- comply with the statutory data protection requirements of the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 (DPA 2018)
- comply with the best practice guidance on collecting, analysing and disseminating confidential patient information set out in the NHS Digital (previously the Health & Social Care Information Centre) Code of Practice on Confidential Information
- comply with the best practice guidance on the management of screening records set out in the Information Governance Alliance Records Management Code of Practice for Health and Social Care 2016
- achieve, or have in place an improvement plan to achieve, at least the 'good' performance standard for the NHS Digital Data Security & Protection Toolkit
- only access screening records held in PHE-controlled IT systems that are to be used for multi-centre audit, evaluation and research purposes through the PHE Office for Data Release



## 5 Location of provider premises

- 5.1 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.

## 6 Equipment specification

- 6.1 The provider will:
- ensure that all equipment used complies with national equipment standards, has been approved for use in the programme 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, are accredited for use within the NHSBSP and that image quality and radiation dose meet acceptable standards
  - 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.
  - MRI screening is only carried out by services that meet the MRI [technical guidelines](#) developed by the NHSBSP
- 6.2 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)
  - new technologies should not be used for screening unless approved by the UK National Screening Committee
  - equipment faults must be reported immediately to the National Coordinating Centre for the Physics of Mammography (NCCPM) and dose surveys completed within timescales for national collation and QA purposes

## 7 Transfer of the discharge from care protocols

- 7.1 Active inclusion in the screening programme ends when:
- women have been diagnosed with cancer or received confirmation that they have a normal or benign outcome after mammography or following screening assessment

## 8 Safeguarding policies

- 8.1 The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2013/14 NHS Standard Contract:

<http://www.england.nhs.uk/wp-content/uploads/2013/03/contract-service.pdf>

17-19 NHS Standard Contract

<https://www.england.nhs.uk/publication/standard-contract-provisions-primary-and-secondary-care-implementation-toolkit/>

- 8.2 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.
- 8.3 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 traveler 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.

## 9 Research activities and participation

- 9.1 The screening service participates in the [age extension trial \(AgeX\)](#) if they have approval from PHE and the age extension trial team based at the University of Oxford. Funding for screening activity as part of the AgeX trial is separate to the routine screening contract between NHS England and NHS Improvement and provider. Funding for AgeX comes directly from the DHSC via PHE to the screening provider.
- 9.2 Any research activities undertaken by the provider must have the appropriate ethical approvals and the breast screening programme Research Advisory Committee (RAC) must be consulted.
- 9.3 Providers should encourage eligible women to participate in appropriate clinical trials or studies.

## Appendix 1: Standard NHSBSP letter templates

| Letter type                         | Notes  |
|-------------------------------------|--|
| Screening invitation                | Sent within 36 months of previous screen or previous first offered invitation where the woman did not attend.  |
| Second timed appointment            | Must give a specific time and date to all women who do not attend their first timed appointment.   |
| Open second appointment             | An open appointment following a non-attendance may be issued by a service only in agreement with the screening commissioners and SQAS.   |
| Easy read letter                    | <p>To be sent as an alternative to the standard invitation letter where the GP has identified to the service that a woman has additional needs. These women would be identified on NBSS as having a special appointment type.</p> <p>The letter can also be sent where the service are aware that the woman prefers this easy read format.</p>       |
| Technical recall (first)            | Women should be sent a technical recall letter with a timed appointment where the images were not of diagnostic quality.   |
| Technical recall (second)           | If women fail to attend for the technical recall appointment, they must be sent a second timed technical recall appointment.   |
| Technical recall for non-attenders  | Woman must receive a letter to explain that her screening episode is not completed. The letter must be scanned and saved onto NBSS.  |
| Recall to assessment                | <p>Offer women an appointment to an assessment clinic within three weeks of their initial screen.</p> <p>Notify women in writing of their assessment clinic appointment and ensure that they have at least 24 hours' notice of the appointment and notification is not received at a time when women cannot contact the service for advice.</p>      |
| Recall to assessment (non-attender) | Must give a specific time and date to all women who do not attend their first timed assessment appointment. Failure to attend the second timed appointment should result in a letter contacting the woman and her primary care team to agree on appropriate further management. This may include identifying the level of concern directly to the GP |
| Short-term recall                   | Must give a time and date for an assessment invitation at least 12 months following screening assessment.  |
| Short-term recall (non-attender)    | Must give a specific time and date to all women who do not attend their short-term recall appointment. Failure to attend the second timed appointment should result in a letter contacting the woman and her primary care team to agree on appropriate further management. This may include identifying the level of concern directly to the GP.     |

## Appendix 2: Standard NHSBSP leaflets to enable an informed choice

| Leaflet  | Notes  |
|--|--|
| <a href="#">Helping you Decide</a>   | Should be sent with all first timed appointment letters every screening round (36 months)<br><br>Available in various formats and languages for easy accessibility |
| <a href="#">An easy guide to breast screening (easy read)</a>                  | Should be sent to all women receiving the first timed easy read invitation letter  |
| <a href="#">Age extension trial</a>  | Should be sent to all women with all routine invitations (not required for second timed appointments or any non-routine screening invitation)                      |
| <a href="#">Breast implants and breast screening</a>                           | Should be given following a screen where it is known that the woman has implants   |
| <a href="#">Breast screening for women aged 71 or over</a>                     | Should be available in the service (static or mobile sites) for women following their last NHSBSP screen on request  |
| <a href="#">Partial or incomplete mammography</a>                              | Should be given to the woman at the end of the screening appointment where this applies  |
| <a href="#">Breast screening for women with a higher risk of breast cancer</a> | Should be sent out with all invitations for high risk screening  |
| Information for trans-gender and non-binary people                             | Should be available within the service as required   |

## Appendix 3: Additional data requirements for programme boards

| Data requirements  | Reporting period                   | Source of report          |
|--|------------------------------------|---------------------------|
| Results of local client satisfaction surveys   | Annual                             | Service provider          |
| List of completed medical physics surveys  | Annual                             | Service provider          |
| 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 | Annual                             | Service provider          |
| Annual report (including a report against measures in consolidated standards)  | Annual                             | Service provider          |
| Summary of complaints  | Tabled at programme board meetings | Service provider          |
| Number and proportion of clinics cancelled (screening and assessment)  | Tabled at programme board meetings | Service provider          |
| Details of any safety concerns, safety incidents and serious incidents   | Tabled at programme board meetings | Service provider/<br>SQAS |