SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service name	NHS London Breast Screening Programme Clinical Services
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1. Introduction 4
1.1 Background 4
2. Population needs 4
2.1. National context and evidence base 4
2.2 Local context 5
2.3 London Breast Screening Service Model 5
3. Key service outcomes 6
3.1 NHS outcomes framework domains and indicators 6
3.2 Expected health outcomes 6
4. Clinical Service Description 6
4.1 Aims 6
4.2 Objectives 7
4.3 Service model summary 7
4.4 Routine Screening 9
4.4.1 Identification 9
4.4.2 Exclusion 10
4.4.3 Invite/offer 10
4.4.4 Self-referrers/opting in/withdrawal and ceasing 10
4.4.5 Inform 10
4.4.6 Out of Area 11
4.5 Round Length Planning 11
4.6 Very High-Risk Cohort 11
4.6.1 Invitation/offer 12
4.7 Test 12
4.7.1 Test – first stage screening 12
4.7.2 Test – second stage screening – assessment (routine and VHR) 13
4.8 Diagnose 14
4.9 Results giving, reporting, and recording 15
4.10 Treatment/intervention 15
4.11 Monitor outcomes 16
4.12 Transfer of, and discharge from, care obligations 16
4.13 Days/hours of operation 16
4.14 Programme board 17
4.15 Risk management 17
5. Failsafe arrangements 17
6. Workforce, Education and Training 18

6.1 Staffing 18
6.2 Training 19
7. Information Technology 19
7.1 New technologies 19
7.2 Paper Lite 20
8. Coverage and Uptake 20
8.1 Coverage 20
8.2 Uptake 20
9. Safety and safeguarding 20
10. Reducing Inequality 20
11. Reasonable adjustments 21
12. National accessible information materials 22
13. Personal informed choice 22
14. Sharing personal information 23
15. Governance and Policies 23
15.1 Governance Structure and Leadership 23
15.2 Clinical and corporate governance 24
15.3 Policies 24
16. User involvement 25
17. Equipment 25
18. Roles and accountabilities 26
19. Locations of screening delivery 26
20. Managing Risks and Incidents 26
21. Public / Patient Information 27
21.1 Public information 27
21.2 VHR 27
21.3 Digital Information Leaflets 28
22. Audit and Quality Assurance 28
22.1 Audits 28
22.2 Staff Survey and QA 28
22.3 Service User Survey 29
23. Sub-contracting 29
24. Applicable Provider standards 29
24.1 Data collection and monitoring 29
24.2 Key performance indicators 30
24.3 Service improvement 30
24.4 Research activities and participation 30

25. Applicable quality requirements and CQUIN goals 30
25.1 Applicable quality requirements 30
25.2 Applicable CQUIN goals 31
Appendix 1: Hub responsibilities 32
Appendix 2: VHR Pathway 33

1. Introduction

NHS England (NHSE) London region is responsible for commissioning breast screening services across the London region.
This document, the London Breast Screening Programme Clinical Services Specification sets the requirements and expectations for providers of the clinical functions of the London breast screening services and should be read in conjunction with national service specifications:
1. 2024-2025 NHS Breast Screening Programme Section 7A Service Schedule 4 Final Clean - Vaccinations and Screening - FutureNHS Collaboration Platform
2. 2024-25 NHS Breast Screening Programme Section 7A Service Schedule 2 v0.3 Final clean version - Vaccinations and Screening - FutureNHS Collaboration Platform

This document outlines the service requirements and quality indicators expected by NHSE (the commissioner) from the NHS BSP (the service providers) to ensure that a high standard of service is provided to the eligible population. It sets out the specific policies, recommendations, and standards that the service is required to meet.

This service specification is not designed to replicate, duplicate, or supersede any relevant legislative provisions which may apply, for example, the Health and Social Care Act 2008, or the work undertaken by the Care Quality Commission (CQC). In the event of new guidance emerging, the specification will be reviewed and amended, but, where necessary, both the commissioner and breast screening clinical service must work proactively to agree timely variations of contract ahead of the production of a revised specification.

This specification needs to be read in conjunction with NHS BSP guidance and standards as set out in the documents below:

- Breast screening: professional guidance
- Breast screening programme standards
- Breast screening pathway requirements specification
- Managing safety incidents in NHS screening programmes
- NHSE Serious Incident framework
- PHE screening inequalities strategy
- NHSE Equality and Health Inequalities Hub
- NHS England Standard contract

1.1 Background

Since 2016, breast screening in London has been delivered on a hub and spoke model. The breast screening clinical service providers are organised around one centralised administrative dedicated breast screening hub (Appendix 1).

2. Population needs

2.1. National context and evidence base

The purpose of the national breast screening specification is to ensure that there is a consistent and equitable approach to the provision and monitoring of the NHS Breast Screening Programme (BSP) across England.

The aim of breast screening is to reduce mortality from breast cancer by diagnosing cancer at an early stage when treatment is more successful.

In England, the NHS currently offers breast screening every three years to women aged from 50 up to their 71st birthday. Women aged 71 and over may self-refer every three years by contacting their local breast screening unit.

Women invited for breast screening have X-rays (mammograms) at a clinic or mobile breast screening unit. A female mammographer carries out breast screening, taking two mammograms of each breast. The appointment takes around 30 minutes, but the mammograms take only a few minutes.

Breast screening is a two-stage screening process involving mammography initially for all women, followed by further screening tests for a small proportion of women. The additional tests are to confirm the presence of breast cancer or to reassure women that they have no sign of cancer and can be discharged back to routine screening.

Women under 50 who have a Very High genetic Risk (VHR) of breast cancer, either because of a family history, because they are a carrier of a gene that puts them at a high risk of breast cancer (e.g. BRCA gene), or because they are on the Breast screening After Radiotherapy Dataset (BARD) database, may be offered regular screening as part of VHR screening.

2.2 Local context

This service specification has been developed to ensure that there is a consistent and equitable approach to the provision and monitoring of the NHS BSP across England. It will enable provision of the breast cancer screening pathway, including meeting the national cancer 28-day Faster Diagnosis Standard (FDS). The national specification is devolved down to each NHSE region for local management.

2.3 London Breast Screening Service Model

The NHS London Breast Screening Programme is organised and delivered on a hub and spoke model. There is a central Administrative Hub (Hub) and clinical providers must work in collaboration to ensure breast screening is delivered safely and in accordance with national and local guidance.

For the routine programme, the Hub is responsible for:

- co-ordination and delivery of each clinical services' Breast Screening Round Length Plan
- client booking (helpline)
- appointment booking/ amending/rebooking
- website update and maintenance
- screening invitations (including repeat invitations)
- communication of normal results to both the person screened and their GP

For the VHR clients, the Hub is responsible for:

- being central point of receiving VHR referrals
- ensuring the VHR are referred onto the appropriate clinical service

The clinical services providers must work with the Hub to ensure there is sufficient capacity and accessible locations for screening of their eligible population.

To support the collaboration of the Hub and clinical services, a Memorandum of Understanding (MOU) must be in place. It must contain, as a minimum:

- round length planning
- patient identification
- data collection
- reporting
- audits

3. Key service outcomes

3.1 NHS outcomes framework domains and indicators

The NHS Outcomes Framework (NHS OF) indicators provide national level accountability for the outcomes the NHS delivers. Indicators in the NHS OF are grouped around five domains, which set out the high-level national outcomes that the NHS should be aiming to improve. They focus on improving health and reducing health inequalities.

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

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

3.2 Expected health outcomes

Through the delivery of the Breast Screening Programme in London outlined in this service specification, the following is expected to be achieved by clinical services providers:

- reduce the number of service users in the eligible population who die from breast cancer by 20%
- achieve high coverage and uptake levels across all groups in society
- maximise detection of early breast cancer where breast cancer treatment is more successful
- refer service users promptly to treatment services
- minimise adverse physical/psychological/clinical aspects of screening (e.g. anxiety or unnecessary investigation)
- encourage early presentation of symptomatic cancers, which may develop between screening episodes

Reducing health inequalities, both in terms of access to services and health outcomes, is a major priority for the NHS. This specification aims to ensure that services are provided in an integrated way that seeks to reduce health inequalities where possible.

4. Clinical Service Description

4.1 Aims

The aim of the NHS BSP is to reduce mortality from breast cancer by diagnosing cancer at an early stage when treatment is more successful, leading to earlier detection, appropriate referral, and improved outcomes.

London Breast Screening clinical service providers must contribute to this aim by delivering a service that:

- provides the clinical mammographic screening, and MRIs for the VHR, and follow up assessment service with onward referral into breast cancer treatment services, where needed in line with the pathway and standards set out in [national breast screening service specification, Breast screening pathway requirements specification - GOV.UK (www.gov.uk)]
- works in partnership with the Hub to ensure equitable access, timely invitation, recall of all those eligible
- is safe, effective, of a high quality, externally and independently monitored, and quality assured
- detects cancer early and appropriately refers detected cases, in a timely manner and therefore improves patient outcomes
- is delivered by suitably trained, competent and qualified staff
- has audit embedded

4.2 Objectives

This will be achieved by delivering an evidence-based, population-based routine screening programme and VHR evidence-based programme that:

- works in collaboration with the Hub, as specified in the MOU, to identify the eligible population and ensure efficient delivery with optimal coverage
- is safe, effective, of a high quality, externally and independently monitored, and quality assured
- will be the first point of contact for the VHR referral
- receives appropriate referrals within the VHR programme from the Hub and confirms receipt of referrals
- authorises VHR referrals received from the Hub to ensure service users referred are effectively managed
- is delivered and supported by suitably trained, competent, and qualified clinical and non-clinical staff who, where relevant, participate in recognised ongoing continuing medical education (CME), continuous professional development (CPD), professional revalidation and external quality assurance (EQA) schemes
- has audit and service evaluation embedded in the service to maximise safety and accessibility of the service for all groups in the eligible population service
- maximises screening sensitivity and specificity and minimises the number of radiation - induced cancers by detecting early-stage cancers with the lowest practicable radiation dose
- minimises the referral and biopsy of service users who do not have breast disease to reduce the adverse impact (physical/psychological/clinical) of unnecessary investigations
- has a seamless pathway at the interface between the Hub, screening, diagnosis and a treatment pathway that ensures service users are referred promptly and safely to treatment services
- focuses on all aspects of screening pathway delivery with an emphasis to reduce inequalities experienced by the Core20PLUS5 population

4.3 Service model summary

In accordance with the national specification, guidance and programme quality standards, the

clinical services providers must provide all necessary steps required to diagnose or exclude breast cancer. This includes:

- breast screening mammography, subsequent assessment when needed with image guided tissue diagnosis as appropriate (including open biopsy) and MRI for VHR service users
- seamless links between 'screening responsibility' and 'treatment responsibility', so that service users at the end of the screening process are referred to treatment services once a diagnosis with breast cancer is made explicit
- all elements of the clinical services will be delivered by appropriately qualified staff, utilising suitable premises and equipment to national standards and guidelines
- all pathology laboratories dealing with screening programmes will be formally accredited by United Kingdom Accreditation Service (UKAS) or equivalent
- the clinical service providers must ensure screening service specific business continuity plans are in place to ensure resilience

To ensure national consistency in delivering the service, the clinical services providers must fulfil the following:

- work with the Hub in planning and maintaining the round plan and invitation rates
- ensure robust processes are in place and established with the Hub for very-high risk referrals
- work to national screening standards in accordance with programme and professional guidance as directed by the programme and relevant legislation
- working in collaboration with the Hub, as specified in the MOU, to provide data and reports as requested against programme standards, key performance indicators (KPIs) and screening outcomes to provide commissioners with assurance of effective operational delivery
- ensure appropriate governance structures are in place
- implement and monitor joint checks and audit mechanisms, where required, to ensure safe and timely processes across the whole screening pathway and to drive continuous quality improvement
- take part in quality assurance (QA) processes and implement changes in a timely manner as recommended by NHSE Screening Quality Assurance Service (SQAS), including urgent suspension of services if required following consultation with the relevant regional commissioners
- work with the commissioners, SQAS and the Hub in reporting, investigating, and managing screening safety incidents and serious incidents
- respond to nationally requested actions and lessons learnt, e.g. change of software, equipment or equipment supplier and new technologies, within recommended and agreed timescales
- ensure all health professionals access appropriate training to maintain continuous professional development (CPD) and competency
- use national resources e.g. patient information leaflets, letters, digital media and e-learning resources
- ensure services have business continuity plans in place to ensure resilience and continued service provision
- ensure that services prioritise improving screening uptake and coverage and reducing inequalities by undertake activities informed by the central screening team, on the FutureNHS platform, FutureNHS Collaboration Platform - FutureNHS Collaboration Platform, and utilising guidance available including recommendations from local health equity audits. It is recommended that services have designated staff with protected time to support this key function in services

- implement and support national IT developments

4.4 Routine Screening

The breast screening clinical services providers must be familiar with the NHS BSP screening pathway and associated timeframes for the routine breast screening cohort. The latest pathway can be found at: Breast screening pathway requirements specification

The screening process is divided into the following stages:

- identification of eligibility
- test
- diagnose
- giving abnormal results
- referral for treatment / intervention
- monitor outcomes

4.4.1 Identification

All the eligible population must be invited for routine breast screening.

To optimise coverage and uptake across their catchment area the clinical service providers must:

- obtain and agree annual estimates of the eligible population with the Hub for at least three years ahead, based on the current population database estimates using the Breast Screening Select (BS-Select) system to inform current and future service delivery requirements
- utilise the national round planning tool
- ensure that all eligible service users registered with a GP in the catchment area, and those resident in the area without a GP, are included in the service
- follow national guidance relating to the screening of transgender and non-binary people;
- ensure that episodes (routine and very high-risk) are closed as soon as possible following the second screening invitation or following assessment and not in excess of six months as per Breast screening: programme overview - GOV.UK (www.gov.uk) and national organising very high-risk guidance
- work with the Hub to ensure service users aged from 50 years up to their 71st birthday are invited for screening. In practice, the following age ranges will be used to identify the eligible population prior to invitation:
    - routine screening population: 49 years and >=8 months to 70 years, 364 days (up to the 71st birthday)
- work with the Hub to ensure screening will be offered to all eligible service users at a maximum interval of 36 months, according to the criteria specified by the NHS BSP
- plan to invite service users between 34 to 36 months of their last invitation. This will give time to accommodate unforeseen circumstances and reduce the risk of screening slippage
- commence screening of service users within three years of the specified starting age
- work with the Hub to ensure that all eligible service users are invited for their final routine screen within 34 to 36 months of their 68th birthday, this would mean that all service users will receive their final invite between the ages of 68 and 70 years and 364 days
- work with the Hub to identify service users who move into the screening catchment area from BS-Select, or who are registered with a GP in the screening catchment area
- work with the Hub to ensure that service users who are not on the Personal Demographics Service (PDS) have access to screening, and that local arrangements are made to cover residential institutions, including secure estates

- work with the Hub to utilise BS-Select and the National Breast Screening System (NBSS) to ensure that coverage is optimised and ensure that all GP practices and Defence Medical Service (DMS) practices are correctly identified
- ensure the inclusion cohorts of all eligible military and non-military personnel registered with a defence primary healthcare centre who are registered on the PDS (spine) within its responsible population boundaries

4.4.2 Exclusion

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

- service users below the current eligible age group who do not meet the criteria for very high-risk screening within the NHS BSP
- service users who have had bilateral mastectomy
- symptomatic referrals
- post diagnosis follow-up and management
- the treatment of breast cancer

4.4.3 Invite/offer

This function of the pathway is delivered by the Hub for the routine screening cohort.

4.4.4 Self-referrers/opting in/withdrawal and ceasing

Clinical services providers must:

- screen service users aged 71 or over who self-refer every three years
- routinely cease only those service users who have had bilateral mastectomies, who are excluded due to a best interests decision or who request to opt-out from screening to ensure that they no longer receive screening invitations
- support the Hub in providing evidence for any service user who is ceased from the programme. All supporting paper documentation must then be confidentially destroyed ensuring that all relevant policies and procedures are adhered to
- confirm with service users that phone numbers held on breast IT systems are accurate at each contact (either by phone or in person) to help support appropriate text messaging and screening uptake

4.4.5 Inform

Clinical service providers must:

- where clinical services are responsible for sending out letters, they must always use the national patient letter template, with links to the national patient information, at all stages of the screening pathway to allow personal informed choice
- ensure that clear directions and an up-to-date map to the screening site are available to be sent with the screening invitation via the Hub
- identify service users requiring reasonable adjustments to ensure they can be provided with appropriate support to enable them to understand all processes and results. The GP pre-screening pack informs how this process should work
- endeavor to ensure that a trained interpreter is present during assessment appointments for service users where requested whose functional language is not English, along with appropriate written information, and where this is not possible, a comprehensive translation service is available
- use information which is consistent with national policy for local NHS websites or social media. This must always link through 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);

- involve regional commissioning teams, the Hub, ICBs, Cancer Alliances, local authorities and central NHSE screening team, where appropriate, 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 and content and access to webpage links checked regularly for accuracy and access to links

4.4.6 Out of Area

If the service user wishes to be screened 'out of area', the clinical services should follow national guidance: Guidance for providers on 'out-of-area screening'

4.5 Round Length Planning

The clinical services:

- will be responsible for the creation and ownership of the round length plan
- must agree the round length plan and sign-off jointly with the Hub
- must agree with the Hub and commissioners on thresholds for escalation
- in case of breaches, provide mitigations and assurances on how these breaches will be resolved
- must review and update round length against varying demands

4.6 Very High-Risk Cohort

The Hub is responsible for receiving very high-risk referrals from clinical genetics and other referrers. It is responsible to send those referrals to the appropriate clinical service. [Depending on the service user's GP.]

Clinical service providers must accept referrals for service users fulfilling eligibility criteria for very high-risk screening via the Hub from the following sources:

- a genetics service by a consultant geneticist, genetic counsellor or an appropriately trained individual nominated by them
- the treating clinician (surgeon or oncologist) - for cancer patients found to carry a genetic mutation that meets the eligibility criteria for very high-risk screening
- an oncologist (in the case of service users treated with radiotherapy to sites involving breast tissue)
- the Breast screening After Radiotherapy Dataset (BARD) for service users treated with radiotherapy to sites involving breast tissue during treatment for lymphoma (BARD oncology consultant referral)

VHR Referrals can only be reviewed using the national referral proforma. The Director of Screening (or nominated representative) can then accept or reject the referral.

- the clinical services and the Hub must clarify the communications, via the MOU, confirming whether a referral has been accepted or rejected (with a rationale) to the service user's GP and the organisation the referral came from
- to ensure that referrals have been received for the VHR screening programme, the clinical service providers and the Hub must carry out as a minimum, an annual audit to reconcile the service users referred to screening by the VHR referrer (clinical genetics, BARD or oncology) and the cases received by the screening provider. This is in compliance with programme guidance and results should be reviewed by the local programme board
- once the client has been identified and is allocated, the ongoing communication and client care will be the responsibility of the accepting clinical service

- clinical service's VHR Screening should follow the latest guidance: Organising very high risk (VHR) screening
- the Director of Screening will be responsible for the oversight of escalation of any issues related to the VHR cohort

See Appendix 2, for the full VHR processes pathway.

4.6.1 Invitation/offer

Once a clinical service has accepted VHR referral it must:

- invite very high-risk women who require both MRI and mammography for imaging on the same day. Where this is not possible, mammography should be performed within 2 weeks of the MRI
- include SMS text message reminders as part of the invitation process. This is mandated. The requirement is a text message reminder for the initial invitation and at least one reminder for non-attenders. Further guidance can be found here: https://www.gov.uk/government/publications/nhs-population-screening-effective-text-message-use

4.7 Test

4.7.1 Test – first stage screening

4.7.1.1 Routine and VHR mammography

The clinical service providers must:

- ensure there is provision of reception staff in static screening clinics to improve the service user experience and maximise uptake, noting service users who do not speak or read English or have additional needs may have difficulty locating the clinic and interpreting signage and instructions. Any service user survey should include, but not limited to:
    - physical accessibility
    - access to information in the appropriate language and format
    - reasonable adjustment (see section 11)
- ensure that the service user's identity is confirmed in line with local protocols by an active 3-point procedure such as full name, date of birth and first line of the address in accordance with Ionising Radiation (Medical Exposure) regulations (IRMER)
- carry out mammography in a way that minimises the possible adverse aspects of screening (e.g. radiation dose, discomfort, anxiety) and that maximises the benefits (i.e. detecting abnormalities at an early stage)
- ensure that image quality and radiation dose are optimised in compliance with IRMER guidance, 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 CME, CPD and EQA schemes in fit for purpose facilities
- ensure that all Assistant/Associate Practitioners are working within the national scope of practice
- be encouraged to enable Assistant/Associate Practitioners to work under remote radiographic supervision within the NHS BSP, where the clinical service providers configuration permits, subject to the relevant provider obtaining the agreement of their commissioner. Commissioners will consider applications received in accordance with guidance which has been issued
- ensure that service users who are invited are not screened if they have had a previous mammogram in the past six months

- ensure that service users 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 must be recorded on NBSS
- provide appropriate support for service users requiring reasonable adjustments, including service users with physical impairments. Where the equipment needed to support service users with physical impairments is not available, arrangements could be made with neighbouring screening units if appropriate. For example, some service users need a hoist to be lifted to be screened. Some screening units will use the hoist in general radiology departments where they are co-located
- provide appropriate advice and information to the service user, in line with programme guidance, where it has not been possible to obtain a complete set of images
- if national data recording ethnicity is not available, aim to collect ethnic origin information for all service users who attend on NBSS to identify whether certain ethnic groups are more or less likely to attend for screening. This can feed into health equity audits and uptake improvement planning
- have audit and service evaluation embedded in the organisation to maximise safety and accessibility for all groups in the eligible population
- ensure that all screening examinations are subject to double reading by readers fulfilling all requirements of the NHS BSP

4.7.1.2 VHR MRI

For women at VHR in the NHS BSP, Tests and frequency of testing for women at very high risk - GOV.UK (www.gov.uk). The clinical service providers must:

- ensure there is provision of reception staff MRI clinics to improve the service user experience and maximise uptake, noting service users who do not speak or read English or have additional needs may have difficulty locating the clinic and interpreting signage and instructions
- ensure that the service user's identity is confirmed in line with local protocols by an active 3-point procedure such as full name, date of birth and first line of the address
- carry out MRI in a way that minimises the possible adverse aspects of MRI (e.g. discomfort, anxiety) and that maximises the benefits (i.e. detecting abnormalities at an early stage)
- ensure MRI is undertaken and reported by suitably trained, competent, and qualified clinical and non-clinical staff
- provide appropriate support for service users requiring reasonable adjustments, including service users with physical impairments. Where the equipment needed to support service users with physical impairments is not available, arrangements could be made with neighbouring units if appropriate. For example, some service users need a hoist to be lifted
- provide appropriate advice and information to the service user, in line with programme guidance, where it has not been possible to obtain a complete set of images
- if national data recording ethnicity is not available, aim to collect ethnic origin information for all service users who attend on NBSS to identify whether certain ethnic groups are more or less likely to attend for screening. This can feed into health equity audits and uptake improvement planning
- have audit and service evaluation embedded in the organisation to maximise safety and accessibility for all groups in the eligible population

4.7.2 Test – second stage screening – assessment (routine and VHR)

In accordance with NHS BSP standards and protocols, clinical service providers must:

- refer service users to assessment with significant mammographic or magnetic resonance imaging (MRI) abnormalities
- offer service users an appointment to an assessment clinic as soon as possible and within three weeks (≤21 days) of their initial screen in line with achieving the FDS of 28 days
- notify service users in writing of their assessment clinic appointment and ensure that they have at least 24 hours' notice of the appointment
- ensure service users attending assessment have clear information about the assessment process
- ensure all service users 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 must see all service users 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 NHS BSP
- ensure adequate equipment and staffing levels are in place so that service users can be fully assessed during a single visit wherever possible. Repeat assessment visits must be kept to a minimum
- ensure that every service user'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 during the assessment clinic. This will be an accredited breast radiologist, consultant radiographic practitioner or breast clinician experienced in the full range of triple assessment
- ensure that before returning a service user to routine recall, when no biopsies have been undertaken, a second assessor must review these cases, where there is capacity
- ensure that biopsy specimen imaging is available while the service user is still positioned in the stereo X-ray equipment
- ensure that vacuum-assisted biopsy (VAB) and vacuum-assisted excision (VAE) is available and used for the investigation and excision of B3 lesions where indicated
- ensure that MR biopsy is available for MR only visible lesions, and where the unit does not perform MR biopsy that there is an agreement with an MR biopsy service to perform these
- ensure that service users are only placed on short-term recall from assessment in exceptional circumstances

To support effective use of assessment clinic capacity, service users with a screening result that requires them to have further tests can be contacted by screening centres before their assessment appointment, but this should only be done once there has been sufficient time for the letter to have been received. This should only happen:

- to support their screening pathway
- to offer an earlier clinic appointment date if extra capacity becomes available (this will help the patient by reducing the anxiety of waiting for an appointment and support the 28-day FDS)

4.8 Diagnose

At multidisciplinary team (MDT) meetings, clinical service providers must:

- discuss all service users undergoing biopsy with an outcome agreed by all disciplines. The outcome will be documented in one single, accessible record which clearly documents the future management of the service user
- accurately diagnose cancers, with reference to MDT decisions, and refer service users for treatment by appropriately trained and qualified specialists

- ensure that any localisations required are undertaken only in facilities that meet the NHS BSP standards
- refer service users for open surgical biopsy, if this is necessary to confirm or exclude malignancy, before discharge or onwards referral from the programme
- notify service users and their GPs on the outcome of assessment as soon as possible
- ensure that there is appropriate equipment and resource to allow robust connectivity if services operate virtual MDTs whilst maintaining patient confidentiality with regards to information governance

4.9 Results giving, reporting, and recording

The Hub is responsible for sending out normal results to routine service users and their GPs, for other eventualities and VHR, the clinical service 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 as soon as they become available
- 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 service user

  (This will not be routinely offered due to the possibility of a malignant outcome which will require an appointment in person with a member of the clinical team and CNS);
- ensure all malignant results are given to the service user by a member of the clinical team, in person, accompanied by the CNS who is the patient's advocate and offers support and information
- ensure that national cancer waiting times are adhered to along the screening pathway and that appropriate information for all service users invited to assessment (date of final image reading outcome and results) is transferred to the relevant waiting times department and recorded as coming from the NHS BSP to allow accurate reporting and continued monitoring e.g. FDS
- ensure that GPs are informed of the outcome of all their eligible population at the earliest opportunity

4.10 Treatment/intervention

The NHS BSP covers the period from identification of the eligible population to diagnosis. Service users who receive a diagnosis of breast cancer will continue to receive invitations for screening if they remain eligible. Clinical service providers must:

- ensure there is a seamless link between 'screening responsibility' and 'treatment responsibility', so that service users at the end of the screening process are referred promptly to treatment services once diagnosis with breast cancer is made explicit
- offer advice on future screening processes to service users who have received a diagnosis of breast cancer
- 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 service users 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 NHS BSP standards and policies
- agreeing jointly, between all agencies including the Hub, on the failsafe mechanisms that are required to ensure safe and timely processes across the whole screening pathway. The MOU should state the responsibilities of the Hub and the clinical services

4.11 Monitor outcomes

To maximise the effectiveness of the programme and provide ongoing service improvement and appropriate patient feedback, the clinical service providers must ensure:

- all clinicians audit their own work in comparison to their peers and in compliance with programme guidance, and that they demonstrate a willingness to alter their practice if the outcome reveals this to be necessary
- the results of audits are discussed in annual appraisals
- all cases are reviewed, within prescribed timescales, where service users 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. Service users have a right to know of this radiological review and request the outcome as part of the disclosure of audit process. To facilitate this process the clinical service providers must liaise with local symptomatic services
- service users are informed in writing of the offer to have the outcomes of radiology review where duty of candour applies
- timely engagement with staff from the SQAS to identify, and categorise, interval cancers and enter these onto NBSS within prescribed timescales
- work with symptomatic services to ensure that information on interval cancers, including results of radiological review, are given to service users in the most appropriate setting
- directors of screening or other delegated staff and CNS who undertake disclosure of audit or duty of candour consultations with service users, complete duty of candour e-learning training (as a minimum) and follow latest guidance: duty of candour

4.12 Transfer of, and discharge from, care obligations

The clinical services must have in place robust and clear decision-making process for the transfer of patients, to ensure that repeat screening is avoided.

Service users who receive a diagnosis of breast cancer will continue to receive invitations for screening if they remain eligible. The clinical service providers must:

- offer advice on future screening processes to service users who have received a diagnosis of breast cancer
- transfer service users efficiently to treatment services on diagnosis. Any post-treatment follow-up will be the responsibility of the treatment service

4.13 Days/hours of operation

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. Clinical service providers must therefore be able to demonstrate efficient and effective use of resources.

4.14 Programme board

Clinical service providers must attend the NHS England local programme boards at a schedule agreed with the commissioners. As a minimum, clinical service providers must ensure attendance from the screening director, programme manager, office manager and host organisation managers. It may be helpful to include the superintendent or lead radiographer.

Clinical service providers must:

- ensure co-operation with and representation on the local screening oversight arrangements and/or structures
- ensure that robust, organisational oversight and governance is in place to support the screening programme
- ensure that there is regular monitoring and audit of the screening service and as part of the organisation's clinical governance arrangements, the local programme board is assured of the quality and integrity of the screening service
- ensure that in accordance with good practice, feedback on services provided is gained, and to public involvement is in place
- ensure that any service improvements required are adhered to in compliance with contractual requirements
- produce an annual report of screening services, which is signed off by the local board

4.15 Risk management

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

Clinical service providers must have internal QA and risk management processes in operation always and be able to demonstrate to the commissioner that those processes are commensurate to the risks, QA issues and best practice of the services documented and other evidence to support this must be in place.

On a quarterly basis, high scoring risks will be identified and agreed between the clinical service providers and the commissioners at the local programme board, and plans put in place to mitigate against them.

5. Failsafe arrangements

Quality A within the screening pathway is managed by the inclusion of failsafe processes. Failsafe 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.

Clinical service providers must:

- review and respond to any instances requiring action as identified by the national assurance dashboard on a monthly basis
- run monthly failsafe batches to ensure that all eligible service users are invited for screening
- select monthly auto batches to make sure that all eligible service users are invited for screening
- run regular housekeeping reports supporting failsafe routines on NBSS and BS-Select in compliance with NHS BSP guidance
- ensure appropriate failsafe mechanisms are embedded across the whole screening pathway as detailed in the NHS BSP guidance. This will include the laboratory receipt of correctly identified needle samples and surgical specimens

- ensure that the NHS BSP recommendations for handling safety concerns, safety incidents and serious incidents are adhered to, in addition to local reporting procedures and 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 commissioners to develop, implement, and maintain appropriate risk reduction measures in conjunction with SQAS
- review and risk assess local screening pathways
- 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 will be documented into the IT system according to NHS BSP 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. This audit will be done with active participation from the Hub. Evidence will be produced for SQAS visits and reviews
- ensure that appropriate links are made with internal provider governance arrangements, such as risk registers and linked actions plans
- agree jointly with the other agencies at pathway interfaces failsafe mechanisms that are ensure robust and timely processes across the whole screening pathway
- ensure routine staff training and ongoing development take place

6. Workforce, Education and Training

6.1 Staffing

Clinical service providers must:

- ensure that there are adequate numbers of trained, qualified, and competent staff in place to deliver a high-quality service, in line with best practice guidelines and NHS BSP national guidance
- explore the recruitment of apprentices where mammographic shortages exist and advanced practice where consultant shortages exist
- 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 service, especially where an increase in the eligible population is predicted (generally this is the case until 2027), where initiatives to increase uptake are successful and go beyond capacity, and/or where there are difficulties in the recruitment of appropriately qualified healthcare staff
- support and implement recommendations from NHSE, and other systems, to maximise innovative solutions to workforce shortages and retention and recruitment issues across the screening pathway
- consider the feasibility of a named Practice Educator/Mentor post within the service to promote clear leadership to support trainees and less experienced staff within the workforce. The specific role would focus on safe ergonomic practice to prevent and reduce repetitive injuries within the workforce and promote health and wellbeing within the team
- ensure that professionals involved in the NHS BSP 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 external quality assurance (EQA) schemes as appropriate

6.2 Training

Clinical service providers must:

- ensure all staff groups engaged in providing screening are trained and complete continual professional development in accordance with guidance and in accordance with national programme requirements
- ensure training has been completed satisfactorily and recorded and that there is a system in place to assess ongoing competency for all staff in line with organisational requirements
- allow staff to have protected time to undertake training activities and continued professional development. The requirement to provide protected time for learning and development should be actively communicated to staff, and they should be kept informed about training opportunities as they arise
- provide adequate numbers of appropriately trained, qualified, and competent staff to carry out high-quality screening mammography to NHS BSP 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 are used, these are funded locally
- ensure that all readers reporting breast images participate in 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

7. Information Technology

Clinical service providers must:

- use the programme's IT systems, NBSS, BS-Select and the Breast Screening Information System (BSIS), to manage service users 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
- local commissions of IT initiatives will not be implemented where national procurement is being developed by the Digital Transformation of Screening (DToS) programme. Any proposed initiatives should be discussed with the BSP IT team in the first instance to ascertain support and required access to system changes, if deemed appropriate
- ensure the necessary hosting environment for NBSS (e.g., the appropriate version of Windows) is provided to the minimum standard specified by the current NBSS contractor including the connectivity necessary for the contractor to support the system
- ensure the alignment and adoption of a shared cloud service for the breast screening system when made available
- 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 commissioner on any new national system developments, to produce system refinements to optimise the administration and reporting of outcomes of the screening programme

7.1 New technologies

New technologies will not be used for screening unless approved by the UK National Screening Committee, following full evaluation of the technology.

7.2 Paper lite

Paper lite working within the NHS BSP is defined as the reduction in printed paper documentation used in the screening pathway. There is no alteration to former working practices (prior to the introduction of paper lite implementation) and no requirements for workarounds in the IT system to support the pathway.
Clinical services are encouraged to adopt paper lite.

8. Coverage and Uptake

8.1 Coverage

Cohort information will be provided to clinical service providers through BS-Select.
Clinical service providers must work in collaboration with the Hub to optimise coverage and uptake across their catchment area.

8.2 Uptake

Clinical service providers, in conjunction with the Hub, must:

- work with local authorities, Cancer Alliances, integrated care boards (ICBs), commissioners and third sector organisations to understand and collaboratively develop plans to address local uptake and inequalities. The co-ordinated plan should support the uptake of screening, particularly with regards to the socially excluded and underprivileged (Core20PLUS5). Local community engagement is encouraged when producing resources, or designing initiatives to improve uptake
- discuss these plans at local programme board meetings or via other locally agreed forums. SQAS visits and review should include an assessment of the process to develop such plans and their implementation at a local level
- plan, pilot, execute and evaluate local solutions to address inequalities of access. Before piloting, these local proposals will be agreed with the commissioner to ensure consistency of message with nationally agreed resources
- share uptake initiatives undertaken including methodology and outcomes on the FutureNHS platform to allow sharing of best practice, including initiatives which have not achieved expected outcomes. Results should be published, preferably in peer reviewed journals
- 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 access for all. Suitable guidance is available, NHS population screening: access for all - GOV.UK (www.gov.uk), that supports siting screening services in convenient locations, including community diagnostic centres
- collaborate with commissioners to use mechanisms such as CQUIN to improve programme acceptability, where appropriate
- have a robust process in place for follow up of service users who do not attend (DNA) or do not book their appointment. Direct phone contact with non-attenders in areas of low uptake is recommended to ascertain barriers to attendance and support uptake improvement strategies

9. Safety and safeguarding

Clinical service providers must refer to, and comply with, the safety and safeguarding requirements as set out in the NHS Standard Contract.

10. Reducing Inequality

See the NHS England Standard Contract Service Condition 13 (SC13) for the contractual requirements for equity of access, equality, and the avoidance of discrimination.

Clinical service providers must make sure systems are in place to address health inequalities and ensure equity of access to screening, and where relevant, subsequent diagnostic testing and any treatment or interventions for everyone invited for screening. Clinical service providers must be able to demonstrate evidence of how this has been done and present this to the local programme board.

Clinical services providers must:

- take a systematic approach to identifying and addressing screening inequalities by conducting a health equity audit (HEA) that includes equality characteristics, socioeconomic factors, local vulnerable populations, and geographical variation
- deliver the service in a way that addresses local health inequalities, tailoring and targeting interventions when necessary
- deliver the service in a culturally sensitive and appropriate way to meet the needs of local diverse populations
- involve service users in developing and evaluating the service
- apply high levels of diligence when considering excluding people with protected characteristics from screening and follow equality, health inequality and screening guidance when making such decisions

The HEA will result in a screening inequalities action plan which is monitored at the local programme board. Action plans must contain specific, measurable actions and goals and services should evaluate their performance against them. The following resources may be of use:

- NHS population screening: a health equity audit guide
- PHE Health Equity Assessment Tool

Service user involvement in service development and evaluation must include representation from service users reflecting the local community, including those with protected characteristics. Please see https://www.legislation.gov.uk/ukpga/2010/15/section/4.

Clinical service providers must have procedures in place to identify and support people who are considered vulnerable or underserved, including but not exclusive to:

- those who are not registered with a GP
- homeless people and rough sleepers
- asylum seekers
- Gypsy, Roma and Traveller communities
- those in secure estates
- those with mental health conditions
- those with drug or alcohol harm issues
- those with learning disabilities, physical disabilities, neurodiversity or communication difficulties
- transgender and non-binary people
- non-English speakers

Clinical service providers must comply with safeguarding policies and good practice recommendations for such people.

11. Reasonable adjustments

Under the 2010 Equality Act, clinical service providers have a legal duty to make reasonable adjustments to make sure services are accessible to everyone, including people with disabilities.

The provider must follow the Accessible Information Standard by law. The standard aims to make sure 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.
As part of the Accessible Information Standard, clinical service providers must:

- ask people if they have any information or communication needs, and find out how to meet those needs
- record those needs clearly in line with programme guidance
- highlight or flag the person's file or notes so it is clear that they have information or communication needs and how these are met (see more information on the reasonable adjustment flag https://digital.nhs.uk/services/reasonable-adjustment-flag)
- share information about people's information and communication needs with other providers of NHS and adult social care, when it has consent or as permitted by law
- take steps to ensure people receive information which they can access and understand, and communication support if they need it (Public Health England (PHE) provides many information resources https://www.gov.uk/government/collections/nhs-population-screening-access-for-all nationally to help meet this requirement)

Clinical service providers must use appropriate interpreter services at assessment for people who have specific communication needs, for example if English is not their first language or if they have a hearing impairment.

Longer appointments should be planned, usually at a static site, with adequate space for carers/supporters should be made available for service users who may have additional needs. Services should understand and comply with NHSE's guidance relating to reducing and identifying inequalities in the breast screening programme.

12. National accessible information materials

National easy guide versions of screening information leaflets and screening appointment letter templates are available for people with learning disabilities, people with low levels of literacy, English as a second language and others who find easy read information helpful. Clinical service providers must use these national materials when inviting individuals for screening who have been identified as benefiting from information in an easy read format.

People with sight loss can access the digital web page versions of standard information leaflets on GOV.UK using screen reader technology. Providers can also advise people with sight, hearing, motor, or cognitive impairments that they can adjust settings on mobile devices to make it easier to read digital publications. Step-by-step instructions are available on the AbilityNet website https://mcmw.abilitynet.org.uk/.

Clinical service providers must ensure all materials sent to service users requiring reasonable adjustments, are provided in the appropriate format, including braille for people with visual impairments.

Every effort should be made to screen service users with a physical disability and to produce images of diagnostic quality. However, this may not always be possible for service users who have limited mobility in their upper bodies or who are unable to support their upper bodies unaided. In these cases, service users should be given the information provided by the programme.

13. Personal informed choice

All screening is an individual choice. Clinical service providers must refer to the UK National Screening Committee (UK NSC) guidance for screening programmes: https://www.gov.uk/government/publications/uk-national-screening-committee-information-development-guidance
Clinical service providers must ensure that everyone is be given the opportunity to make an informed choice about whether to be screened. The decision will 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 have screening, then the provider must respect this decision as a valid choice.

14. Sharing personal information

The duty of care to share information can be as important as the duty to protect patient confidentiality. GPs and other health professionals must have the confidence to share relevant information with screening services 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.

See NHS England's information sharing policy for more detailed guidance: https://www.england.nhs.uk/publication/information-sharing-policy/

NHS England's 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: https://www.gov.uk/government/publications/patient-confidentiality-in-nhs-population-screening-programmes

15. Governance and Policies

15.1 Governance Structure and Leadership

Clinical service providers must:

- co-operate with and have representation on local oversight arrangements as agreed with the commissioner
- identify a trust director (or equivalent in a private provider) who is responsible for the operational oversight of the screening programme
- identify a named director of screening with accountability for the providing service and where the eligible population is large (over 100,000 eligible service users), a deputy will be appointed in accordance with programme guidance. Clinical service providers must ensure that the screening director has the required competencies, capability, and experience to take overall responsibility
- appoint a programme manager who is actively involved in service delivery, planning and management
- provide documented evidence of clinical governance that includes:
    - compliance with the provider and commissioner 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 https://www.gov.uk/government/publications/patient-confidentiality-in-nhs-population-screening-programmes;
- ensure that there is regular monitoring and audit of the service, and as part of the organisation's clinical governance arrangements, the local programme board is assured of the quality and integrity of the screening programme
- produce an annual provider report of screening performance, which is signed off by the local programme board
- ensure the programme is delivered by trained and competent workforce that meet national requirements in accordance with the Leading a breast screening service guidance

15.2 Clinical and corporate governance

Clinical service providers must ensure:

- an appropriately skilled and competent executive officer within its organisation is accountable for, and oversees, the breast screening service
- the trust's board of directors is part of the clinical governance procedures and are 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 multidisciplinary 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

15.3 Policies

Clinical service providers 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 and mitigation plans
- duty of candour

Clinical service providers must agree the governance framework with the commissioner prior to the services commencement date and annually thereafter.

Clinical service providers 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 Code of Practice on Confidential Information: NHS Digital Code of Practice on Confidential Information
- comply with the best practice guidance on the management of screening records set out in the Records Management Code of Practice: Records Management Code of Practice–- NHS Transformation Directorate (england.nhs.uk)
- achieve, or have in place an improvement plan to achieve, at least the 'good' performance standard for the NHS Digital Data Security and Protection Toolkit: https://www.dsptoolkit.nhs.uk/
- only access screening records held in NHSE-controlled IT systems for direct care of patients and local quality assurance or local service evaluation. Approval from NHSE is

required for processing identifiable data, controlled by NHSE, for multicentre audit, research or planning purposes. Any queries regarding this matter should be sent to england.screening.research@nhs.net

16. User involvement

In accordance with good practice, to gain feedback on screening provision, and to have public involvement on service provision, clinical service providers must collect the views of service users via a survey, at least annually.

Clinical service providers must:

- demonstrate that they have collected the views of service users, in respect of the services they provide (for service users screened in static and mobile locations if the service provides screening in both facilities)
- develop a service user survey and agree content with commissioners and SQAS, incorporating national guidance as appropriate
- demonstrate how the views collated from service users will influence service delivery for the purposes of improving quality and uptake
- show that all service users are given information about how to provide feedback about services they receive, including the complaints procedure
- publicise findings in waiting rooms

17. Equipment

Clinical service providers must:

- have an equipment replacement schedule in place for all equipment used within the programme, which is reviewed on a regular basis. Mammography X-ray equipment should be scheduled for replacement as a maximum every 10 years and ultrasound every 4 to 6 years following installation. Liaison with the organisation's Estates Department and Finance team may support this process
- ensure that there is adequate MRI capacity to support the VHR programme either locally or where outsourced to another provider, mindful of potential increased capacity demands from BARD and NHS BRCA testing programme future roll-out
- 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 NHS BSP guidelines
- adhere to national guidelines: Guidelines for medical physics services, which include regulatory requirements for employers that work with ionising radiation
- 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 NHS BSP and that image quality and radiation dose meet acceptable standards
- ensure full-field direct digital mammography is the only modality used for routine screening. MRI may be used for higher-risk service users according to NHS BSP protocols
- ensure MRI screening is only carried out by services that meet the MRI technical guidelines developed by the NHS BSP
- follow policy guidance and standards for screening mammography with regards to undertaking regular user quality control testing (and MRI, where appropriate)
- ensure new technologies are not to be used for screening unless approved by the UK National Screening Committee (UK NSC)
- ensure equipment faults are reported immediately to the National Co-ordinating Centre for the Physics of Mammography (NCCPM)
- ensure dose surveys and physics data as requested by NCCPM are uploaded within timescales for national collation and QA purposes

- follow national guidance on tomosynthesis, Digital breast tomosynthesis, when using this form of advance mammography

18. Roles and accountabilities

The NHS BSP depends on systematic, specified relationships between screening services and stakeholders (which include treatment services, histopathology, genetics services, external diagnostic services, primary care representatives, and Admin Hub). Clinical service providers must take the lead in ensuring that inter-organisational systems are in place to maintain the quality of the whole screening pathway.

Clinical service providers must ensure:

- a programme manager and a named director of breast screening are in place. Both will be actively involved in the screening programme, and the latter will be an individual possessing suitable competencies, capability and experience who will take overall responsibility and accountability for the service and its quality
- the director of breast screening and the programme manager are given adequate resources to carry out their roles effectively
- the director of breast screening is a consultant breast radiologist, consultant radiographic 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 have the additional support of a radiology lead
- a deputy screening director is appointed where the eligible population is large (over 100,000 eligible service users)
- a co-ordinated approach is in place 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
- joint audit and monitoring processes are in place
- joint failsafe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway are in place
- robust electronic links with IT systems and relevant organisations across the screening pathway are maintained
- links with primary care, and with secondary and/or tertiary care providers are in place

19. Locations of screening delivery

Clinical service providers must:

- 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 adhere to national and regional screening guidelines
- 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 and safety considerations such as street lighting and visibility
- be responsible for supplying suitable premises and equipment for the screening programme which meets NHS BSP standards
- ensure workstations have full desktop integration with NBSS and PACS and the provider must ensure that there is liaison with the local PACS teams to resolve any operational issues where the need arises

20. Managing Risks and Incidents

Failsafes are a back-up mechanism to ensure that things that are going wrong are identified and actions taken to ensure a safe outcome. In breast screening most of the failsafes are built into NBSS/BS Select.

Where manual intervention is required, the clinical servcies must use the reports that NBSS/BS Select produces. The provider must have protocols for the management of the information in the reports.

The clinical services must:

- include appropriate failsafe mechanisms across their section of the screening pathway
- review and risk assess local screening pathways in light of guidance offered by QA, NHS BCSP or the commissioner
- ensure that appropriate links are made between the clinical service and internal provider governance arrangements, such as incident reporting and risk registers
- work with the commissioner and SQAS teams to develop, implement and maintain appropriate risk reduction measures
- ensure that mechanisms are in place for implementation and regular audit of risk reduction measures and reporting of safety concerns, safety incidents and serious incidents.
- ensure that the NHS BSP recommendations for handling safety concerns, safety incidents and serious incidents are adhered to, Managing safety incidents in NHS screening programmes - GOV.UK (www.gov.uk), in addition to local reporting procedures

21. Public / Patient Information

21.1 Public information

Clinical service providers must always use the national patient information 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. The regional commissioning teams and national breast screening team must be consulted and involved before developing any other supporting materials.

Clinical service providers must involve the regional commissioning teams and national breast screening team 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 will be used.

Clinical service providers are encouraged to work with the Hub to develop web content and resources to encourage screening uptake on a variety of social media. The messaging must align with national available resources and should be reviewed regularly by the local programme board. Clinical services and the Hub should engage with their service users, using techniques such as surveys, user groups and market research, to support this work.

People who are referred for further assessment following a screen must receive information to help them understand the screening assessment process from the clinical service providers.

21.2 VHR

In the case of VHR cohort, the clinical service providers should only provide one printed leaflet per Service User at the prevalent invitation or until a service user attends for screening. Thereafter, service users do not receive the NHS BSP invitation leaflet.

21.3 Digital Information Leaflets

The government's digital by default policy, as well as user expectations, means that most people will receive screening information in digital form rather than as physical leaflets. All NHS national screening information leaflets for the public are now available in accessible HTML digital format for reading on screens. The only exceptions are the easy guides for people who may require this format, which are available in PDF format for printing out by providers. Only the national screening invitation leaflet remain as an orderable print resource.

The clinical service provider must ensure:

- people are directed to the appropriate nationally developed information resources to comply with national service specifications
- printed screening invitation leaflets are enclosed only with prevalent screening invitations until a service user attends for screening. They are not sent out with future invitations once service users have attended screening
- orders of free printed leaflets are limited to one copy per individual, for each screening episode until the client attends for screening
- people are directed to the appropriate digital information leaflets with all incident invitations and positive screening test results
- printouts of digital information are provided for the small minority of people who cannot access online information
- they follow the national easy read guidelines: Easy guide, for those that may find information presented in an easy read format helpful, such as people with learning disabilities, people with low levels of literacy and non-English speakers

22. Audit and Quality Assurance

22.1 Audits

Clinical service providers must work collaboratively with the Hub, commissioners and SQAS 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 NHS breast screening standards, guidelines, internal and external quality assurance arrangements, and risk assessments
- monitor, collect and report statistical data and other relevant information in a timely manner to relevant bodies, and use this to:
    - promote continuous improvement in service performance and outcomes
    - give formal feedback to the commissioner and the population served by the provider
    - provide key information and models of good practice/innovation/ achievement to those working in breast screening
- ensure that any local audits which are mandated nationally are tabled at the local programme board on completion (see Schedule 4)

22.2 Staff Survey and QA

Clinical service providers must:

- ensure that all screening staff regularly participate in screening quality assurance service activities (including SQAS formal and ad hoc visits, the EQA scheme (pathologists and image readers) and that all professionals meet CPD/CME requirements
- ensure that all readers reporting breast images participate in external QA schemes, the results of which will be used to compare with real life performance annually

- ensure that complete and accurate outcomes and results for all service users are accurately entered onto the NBSS to allow national reports to be uploaded at prescribed intervals to the BSIS for further analysis and audit by the SQAS

22.3 Service User Survey

Clinical service providers must collect the views of service users via a survey which will:

- demonstrate the collection of views of service users, in respect of the services they provide (for service users screened in static and mobile locations if the provider provides screening in both facilities)
- demonstrate how those views will influence service delivery for the purposes of raising quality
- show that all service users are given information about how to provide feedback about services they receive, including the complaints procedure
- include feedback from service users with additional needs or from underserved groups wherever possible

23. Sub-contracting

Clinical service providers must not subcontract any element of the service without the prior discussion and agreement with the regional commissioner and SQAS, and only with providers who meet national standards and guidance for the NHS BSP. Clinical service providers must have robust formal subcontracting arrangements using the NHS Standard Contract subcontracting template or equivalent, for any agreed subcontracted elements of the service. Clinical service providers must regularly review and monitor subcontracted elements and maintain overall responsibility and accountability. Clinical service providers must ensure that subcontracted elements do not deviate in omission or addition from the service as described in this specification.

It is the director of breast screening's responsibility to 'provide assurance that all internal and outsourced or subcontracted services meet NHS BSP guidance and associated quality, safety and performance standards.' The provider must ensure that subcontracted elements do not deviate in omission or addition from the service as described within this specification.

24. Applicable Provider standards

The consolidated standards https://www.gov.uk/government/publications/breast-screening-consolidated-programme-standards will be achieved so that the programme as a whole will:

- maximise the number of cancers detected (screening sensitivity)
- minimise the number of cancers presenting between screening episodes
- minimise the number of unnecessary recalls to assessment (screening specificity);
- 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

24.1 Data collection and monitoring

Clinical services must:

- enter routine data onto the NBSS in a timely manner and in the required format, as specified in NHS BSP manuals and guidance
- work in collaboration with the Hub to provide routine data to the commissioner, SQAS and NHS England in a timely manner to monitor performance in line with Schedule 2 and 4 of the contracts

- provide annual data measuring performance against both standards and the key performance indicators (KPIs) to monitor performance and measure trends
- work with partners to deliver the FDS to ensure that patients find out within 28 days whether or not they have cancer NHS England » Faster diagnosis and provide annual data measuring performance against both standards and the KPI to monitor performance and measure trends
- contribute to national data collection exercises where required for national analysis
- report equipment faults (including ultrasound equipment) without delay to the National Co-ordinating Centre for the Physics of Mammography (NCCPM)
- ensure surveys and physics data, as requested by NCCPM- are uploaded within timescales for national collation and QA purposes
- collect outcome data (surgical, pathology and oncology)

National and local standards and KPI for the clinical service providers are detailed in Schedule 4. These include the national 28-day FDS.

24.2 Key performance indicators
The descriptions of the KPIs are in Schedule 4.
Current standards for the NHS Breast Screening Programme are available at:
https://www.gov.uk/government/publications/breast-screening-consolidated-programme-standards

24.3 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. Clinical services providers must develop a service development improvement plan (SDIP) in line with the standards and key performance indicators and the results of internal and external quality assurance checks. The SDIP will respond to any performance issues highlighted by the commissioner, having regard to any concerns raised via any service user feedback. The SDIP will contain action plans with defined timescales and responsibilities and will be agreed with the NHSE commissioner.

24.4 Research activities and participation
For the avoidance of doubt this service is not commissioned by the commissioner and information is included here to make clear funding arrangement.

The research must have appropriate ethical approvals and should seek input from the NHS Breast Screening Programme Research, Innovation and Development Advisory Committee (RIDAC) and support for the research and access to programme data and programme resources must have been obtained. The commissioner must be notified of any planned research activities undertaken by the provider which may impact on delivery of the screening service.

Clinical service providers have a responsibility to promote opportunities to take part in health and social care research by service users in appropriate clinical trials or studies.

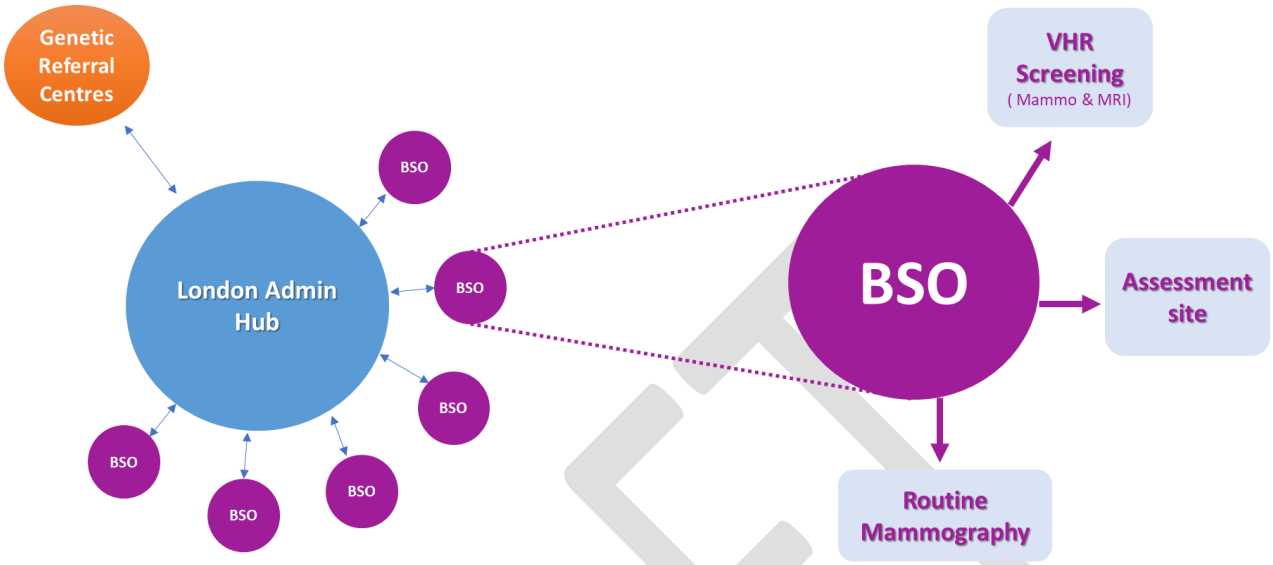
25. Applicable quality requirements and CQUIN goals

25.1 Applicable quality requirements
Clinical service providers are required to meet the acceptable (threshold) and work towards the achievable standards in Schedule 4.

25.2 Applicable CQUIN goals

This section is to be populated by regional commissioning teams.

Appendix 1: Hub responsibilities



Appendix 2: VHR Pathway