ORGANISING A BREAST SCREENING PROGRAMME

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1. INTRODUCTION

1.1 Purpose

This publication sets out the principles for the organisation of local breast screening programmes. It includes the essential criteria that must be met to enable quality assurance (QA) to be carried out to nationally agreed standards. It is aimed at commissioners, QA directors and directors of breast screening.

The publication replaces previous national guidance published as *Organising Assessment*.[1] It responds to QA directors' concerns about assuring the quality of some breast screening programmes that do not fit the typical model recommended in earlier guidance, in terms of either size or configuration. It also reflects the new arrangements for commissioning screening programmes following the implementation of *Shifting the Balance of Power within the NHS: Securing Delivery*.[2]

1.2 Current NHS Breast Screening Programme organisation

The current organisation of the NHS Breast Screening Programme (NHSBSP) is based on the advice of the Forrest report, which was published in 1986[3] in the context of the NHS structure in place during the late 1980s. Further guidance on the organisation of breast screening programmes, and in particular on the organisation of assessment, was set out in *Organising Assessment*, which was published by the NHSBSP in 1989.[1] Since this guidance was published, there have been changes to the role and size of health authorities along with the introduction of NHS trusts and commissioning by primary care trusts (PCTs). In 1996, the Calman-Hine report on cancer services (*A Policy Framework for Commissioning Cancer Services*[4]) introduced the concept of cancer centres and cancer units. This has now developed to the point where cancer networks have been formed, and they will play a key role in the delivery of *The NHS Cancer Plan*.[5] There have also been significant improvements in symptomatic breast services since the screening programme was set up.

The way in which QA for breast cancer screening is delivered has also changed. In some cases, the statistical return (the KC62 return) and the pattern of QA visits, both of which are used to monitor the breast screening programme, do not accurately reflect the true pattern of service delivery. This can occur if assessment and treatment take place at different sites and the multidisciplinary review of cases is carried out separately by teams at the different sites. This compromises the QA function. It is essential that the unit of quality assurance reflects the actual unit of service delivery: for example, the denominator used in determining the cancer detection rate must be the number of cases reviewed by a single team and not by a number of teams.

Further organisational changes to the NHS that were announced in *Shifting the Balance of Power within the NHS*,[2] and the extension of the age range for invitation for screening to women aged up to and including 70, also mean that revised guidance on the organisation of local screening programmes is needed in order that local commissioning and cancer networks can have a service that best reflects the needs of the local population and general patient flows.

Finally, improvements in mammography equipment and in assessment techniques and increasing expertise within the screening programme have meant that the assumptions about acceptance rates for screening and referral rates for assessment on which earlier guidance was based now need to be updated.

1.3 Commissioning breast screening

The principles for the safe and effective securing and delivery of population based screening programmes in the modernised NHS were set out in a discussion document that was circulated to regional directors of public health (RDsPH) on 15 April 2002.[6] The paper is called a 'discussion document' so that it can be revised to take into account any comments arising from its implementation.

The main points are:

- collaborative working by PCTs to commission screening programmes will be expected, probably with lead PCT arrangements
- a broader screening commissioning group involving all the parties concerned with commissioning and delivering a screening programme should be convened to work in conjunction with the lead PCT; the chair of that group would be accountable to the lead PCT for the work of the group
- each PCT and NHS Trust will need active involvement in the components of screening service delivery as appropriate to the programme
- the strategic health authority (StHA) will performance manage the commissioning and delivery of screening programmes by PCTs and NHS trusts
- quality assurance processes will remain independent from performance management of service provision; the RDPH responsibility for quality assurance of existing screening programmes will remain unchanged.

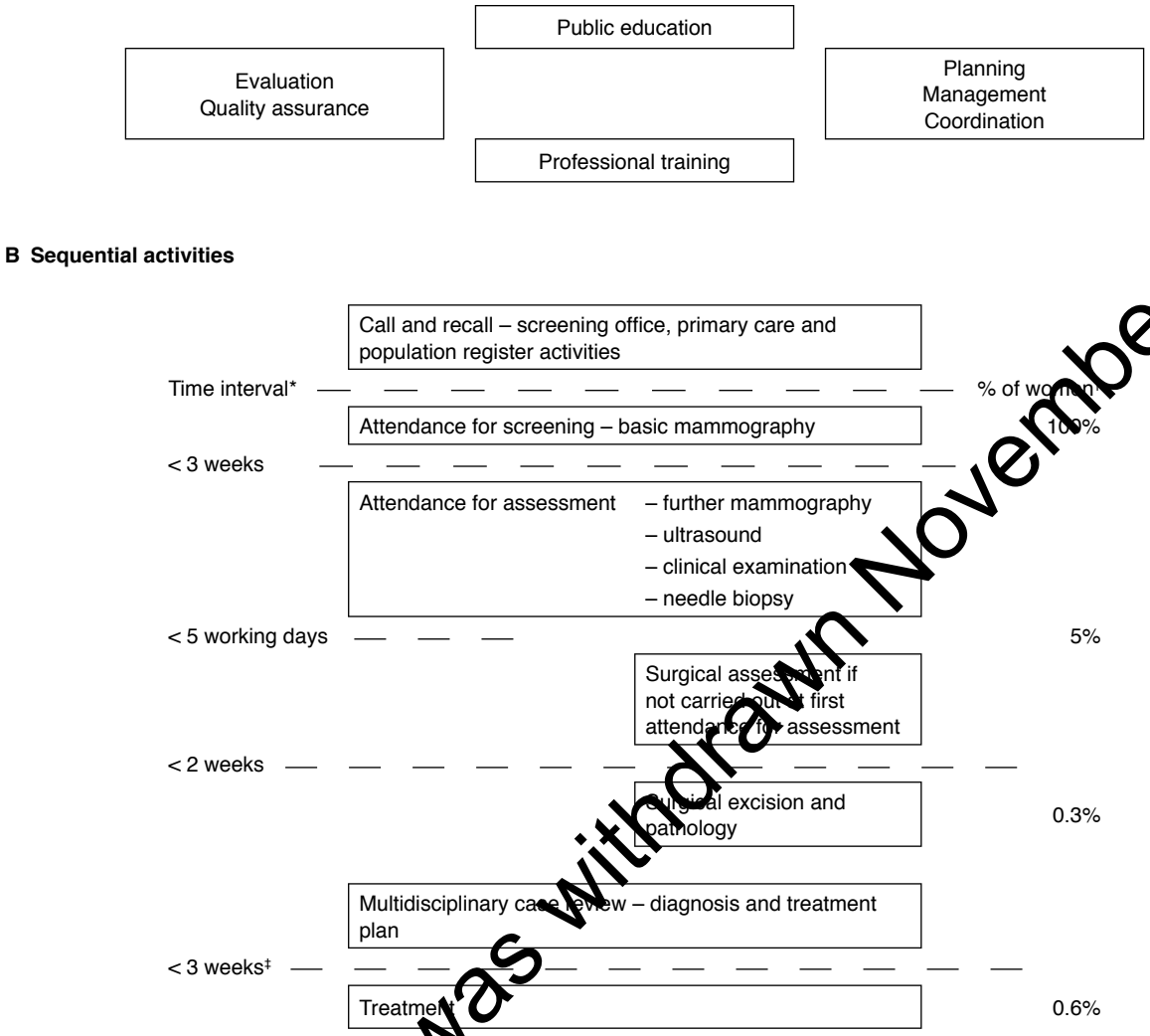
1.4 Breast screening process

The main activities in the breast screening process are shown in Figure 1.

1.4.1 Call and recall

Originally, women aged 50–64 were routinely invited for screening every three years. Arrangements are in progress to extend routine invitations by 2004 to all women up to and including the age of 70. Women older than the invited age range are entitled to screening every three years on request. One-third of women in the eligible age range are invited for screening each year. Currently, 75% of invited women attend for screening, although there are local variations between and within programmes.[7] The national minimum standard for attendance is 70%.[9] About 95% of women screened are returned to routine recall after basic screening.[7] The routine recall interval is three years. Exceptionally, a very few women are recalled at a shorter interval (short-term or early recall).[8] The national minimum standard for early recall is < 1% of women screened, with a target of ≤ 0.25%.[9]

Each breast screening programme has a screening office, which administers the programme. Some breast screening programmes share a



*Taken from NHSBSP minimum standards.[9] †Taken from NHS Breast Screening Review.[7] ‡100% within 4 weeks.[5]

Figure 1 Main activities in the breast screening process.

single screening office. The screening office sends out invitation letters to women eligible for screening, based on lists derived from the local register of individuals who are registered with NHS GP practices. These registers are known as the 'Exeter' system.

1.4.2 Basic (or first stage) screening

Basic screening by mammography can take place either at a static breast screening unit or on a mobile breast screening unit. Film processing usually takes place at the static unit, where the films are also read and reported.

1.4.3 Assessment

About 5% of women screened are recalled for further investigation because their basic screening mammogram shows some abnormalities or because other signs or symptoms were noted when they attended for basic screening.[7] The aim of assessment is either to return women to routine recall or to reach a definitive diagnosis of breast cancer and

agreed referral for treatment. In a very small number of cases, women may be placed on early recall for further assessment.

Assessment takes place at a specialist assessment clinic, usually held at a hospital site, and is based on a triple approach (further imaging, clinical examination and needle biopsy). Clinical protocols for the assessment process are published in *Clinical Guidelines for Breast Cancer Screening Assessment*.[8] The assessment clinic is run by a core team of a consultant radiologist, a clinician with skills in clinical examination (who might be the radiologist, a breast clinician or a breast surgeon), a radiographer, a clinical nurse specialist in breast care and an appropriate administrative support. A pathologist needs to be available during the clinic session if immediate reporting of biopsies is required.

Seven out of eight women who attend for assessment are returned to routine recall.[7] They may be given the result at their first attendance at the assessment clinic or they may attend a subsequent clinic to be given their result.

Women who have a provisional diagnosis of breast cancer usually attend a subsequent clinic to be given their result. The majority of breast cancers are diagnosed non-operatively on the basis of triple assessment, but some women are referred for open biopsy (a biopsy obtained during a surgical excision) before a definitive diagnosis can be made (see below). If the surgeon who will have care of the woman does not attend the assessment clinic, the minimum standard is that the interval between the first visit to the assessment clinic and examination by the surgeon is less than or equal to 5 working days.[9]

1.4.4 Surgical assessment

About 0.3% of all women screened require an open biopsy (a biopsy obtained during a surgical excision) to enable a definitive diagnosis to be made.[7]

1.4.5 Multidisciplinary case review

All cases that are not returned to routine recall at the woman's first visit to the assessment clinic must be discussed at a multidisciplinary team (MDT) meeting attended by the assessment team. The purpose of the meeting is to reach a definitive diagnosis and agree treatment.

1.4.6 Treatment

About 0.6% of all women screened are diagnosed with breast cancer and referred for treatment to a specialist breast surgeon.[7]

2. SIZE OF PROGRAMMES

2.1 Forrest units

The Forrest report recommended a basic screening unit to serve a population of 471 000.[3] The report estimated that this would give a target population of 41 150 women aged 50–64 years. Assuming that 70% of women invited accept the invitation, and including an allowance for repeat films and for self referrals, this gives an estimated total number of screening attendances of 12 000 per year. Forrest estimated that this would result in 696 referrals for assessment per year. Details are shown in Table 1.

There is considerable variation in the size of actual screening programmes, although the average serves a population of women aged 50–64 years of 45 000. This equates to an eligible population of 63 000 women aged 50–70 years. Table 1 shows estimates of numbers of women at the various stages of the screening process, based on current rates for acceptance of screening invitations and referrals for assessment, in an average size programme.

Table 1 Annual throughput of a typical breast screening programme

Forrest report assumptions*	Forrest screening unit (women aged 50–64) 70% uptake	Average size screening unit (women aged 50–64) 75% uptake	Average size screening unit (women aged 50–70) 75% uptake	Minimum size screening unit (women aged 50–70) 75% uptake	Minimum size screening unit (women aged 50–70) 60% uptake
Target population	41 150	45 000	63 000	36 000	45 000
One-third invited for screening annually	13 716	15 000	21 000	12 000	15 000
Attend for screening	9600	11 250†	15 750	9000**	9000**
Repeat films (technical recalls)‡	1200	–	–	–	–
Self referrals	1200	1125§	–	–	–
Total screening attendances	12 000	13 275	15 750¶	9000¶	9000¶
Referred for assessment	696	619†	788	450	450
No assessed per week††	17	14	18	10	10

*Forrest report, Figure 8.4.[3]

†NHS Breast Screening Review.[7]

‡Not identified as a separate screening attendance by NHSBSP.

§Assuming self referrals are an additional 10% of attendances in response to invitations, ie self referrals are 9% of total screening attendances.

¶The majority of current self referrals typically are women aged 65–70. Therefore, until evidence about patterns in women over 70 can be established, no assumptions can be made.

**Small programme, as defined by Blanks et al.[11]

††Assuming 45 working weeks per year.

2.2 Small screening programmes

Recent research carried out by the NHSBSP has found that smaller screening programmes perform less well than larger programmes.[10] The research project compared the performance of the smallest 25% of screening programmes with those of larger programmes. The size of a programme was measured by the number of screening attendances between 1 April 1999 and 31 March 2000 of women routinely invited (KC62 returns, Tables A, B and C1). According to this criterion, a small programme is one with a total annual screening attendance of fewer than 9000 routinely invited women. The results showed that the performance of small programmes is poorer than medium and large programmes in that they detected fewer cancers, referred more women for assessment and had a lower positive predictive value (PPV) for assessment. The reasons for this difference in performance are not clear: it may be that staff in smaller programmes have less opportunity to gain expertise in screening and assessment than those in larger programmes, or it may be that smaller programmes are subject to less rigorous quality assurance because of the inherent difficulty of identifying underperformance when small numbers of women are screened. Either way, the evidence supports the original 'Forrest' view that larger units are preferable to small screening programmes.

2.3 Quality assurance

Quality assurance of breast screening takes two main forms: the QA visit, which takes place at least once every three years, and the monitoring of statistical returns. The QA visit provides an opportunity to examine many aspects of quality assurance, including team working and the physical facilities available. QA visits are described in *Guidelines for Quality Assurance Visits.*[10] For statistical QA purposes, the number of women invited, screened and referred for assessment needs to be large enough for QA data to be statistically significant over a single three-year screening round. Random fluctuations in the numbers of small cancers detected may disguise poor performance by the programme. Ideally, meaningful figures should be obtained on an annual basis since a problem could then be identified and remedied more quickly. Other forms of QA surveillance, for example increased frequency of visits, are not likely to compensate effectively because of the difficulty of measuring any impact on performance.

2.4 Viability

A programme needs to be viable in terms of staffing in order to provide cover for planned and unplanned staff absences. There also needs to be sufficient throughput of women to justify the provision of the specialised equipment and facilities for screening and assessment. Experience suggests that the number of women who can be seen at a typical assessment clinic is between 8 and 10.[12] Fewer than this does not represent an effective use of clinic staff or facilities.

2.5 Programme configuration

Factors that determine programme configuration include travelling times for staff and for women and referral patterns. The pattern of professional links and patient flows within cancer networks may also be an influence. Many breast screening programmes use mobile screening units to deliver basic screening services that minimise travelling times and distances for women. Evidence suggests that many women prefer to attend a mobile unit for screening rather than to travel to an acute hospital site, and accept-

ance of screening invitations is generally higher when mobile units are used.[13] However, for assessment, the Forrest report recommended that the need to concentrate expertise in order to maintain and develop it was more important than minimising travelling times for the small proportion of women who may require it. This principle still holds, although it is important to emphasise that best practice is to carry out all investigations at a single assessment visit for women with long travelling distances.

The development of cancer networks will lead to closer alignment between breast screening services and symptomatic breast services, and cancer networks should review arrangements for breast screening to ensure that the best use is made of expertise and facilities and that breast screening services are integrated with the wider provision of breast cancer services.[14] However, assessment clinics for women referred through the screening programme and clinics for symptomatic women should not be held in the same place at the same time (although they may use the same staff and facilities). Optimal arrangements should be determined locally, but it is important to recognise that women who have been referred from the screening programme have different expectations for the outcome of assessment from women who have been referred symptomatically.[3] It is also important to be able to statistically identify screened and symptomatic women separately in terms of treatment and the outcomes of treatment in order to evaluate the screening programme.

2.6 Minimum size of programmes

The latest evidence concerning the impact of size on the effectiveness of a breast screening programme is consistent with the Forrest guidelines. Local factors, for example the configuration of treatment and constructive services, will determine the final service size and configuration. Where small units are unavoidable because, for example, of the distribution of population in rural areas, the findings of the recent research should guide local planners. The minimum size for a breast screening programme is 9000 screening attendances per year of routinely invited women aged 50–70. The size of the target population needed to achieve this screening workload will depend on the screening uptake for the local programme. For programmes with an uptake level of 75% (the national average), the minimum target population is 36 000. Programmes that have a lower uptake, for example those in inner cities, need to invite women from a larger target population to achieve the same minimum throughput. Programmes that have higher levels of uptake can achieve the minimum throughput with a smaller target population. However, if uptake fluctuates, the viability of small programmes may be called into question.

The target population may be calculated by:

$$\text{Target population} = (\text{Minimum size} \times 3 \times 100)/\text{Uptake (\%)}$$

For a programme of minimum size (9000 invited women screened) with 60% uptake:

$$\text{Target population} = (9000 \times 3 \times 100)/60 = 45\,000$$

For a programme of minimum size (9000 invited women screened) with 75% uptake:

$$\text{Target population} = (9000 \times 3 \times 100)/75 = 36\,000$$

Examples are shown in Table 1. This table also shows the implications for numbers of women attending assessment clinics. A screening throughput of 9000 women per year gives an assessment workload of 10 women per week, assuming an assessment rate of 5%. Experience shows that this is viable in terms of resources.[12] If the assessment rate is slightly higher, two assessment sessions per week may be needed on some occasions.

2.7 Self referrals

At present, the majority of self referrals are from women aged 65–70. Women in this age range will be invited routinely in the future. The number of self referrals are in addition to the numbers used in the calculations above. Routine quality assurance monitoring also excludes self referrals.

3. LOCAL BREAST SCREENING PROGRAMMES

3.1 Essential conditions

All breast screening programmes should be the minimum size (see section 2.6). In addition, they should meet the essential conditions described below.

The preferred organisation for a breast screening programme is to have a single assessment centre with all members of the assessment team being based at the same site as the assessment centre. However, this is not always possible in practice. The need to ensure that a programme serves a large enough population to enable it to be properly quality assured and achieve the NHSBSP minimum standards may mean that assessment will take place at several sites, or that referrals for surgical assessment and treatment are made to breast surgeons at one or more peripheral hospitals. The following conditions must be satisfied for the service to be considered as a single programme whatever configuration is used:

1. All screening units must work to the same clinical protocols, and there must be suitable arrangements to cover staff absences across all screening and assessment sites.

2. There must be a single clinical lead covering all assessment sites.

3. A single MDT must be formed which meets at least once a week. All screen detected abnormalities not returned to routine recall at a woman's first assessment visit must be reviewed at the MDT meeting. In large programmes, there may be a need for the MDT to meet more frequently. If long travelling times to attend the MDT are involved, contributions to the MDT session may be made via teleconferencing.

4. It is not essential, but may be desirable, for all members of the assessment team to attend every MDT meeting **provided** that, as a minimum:
   a. films and slides from the assessment clinic are available for review at the MDT meeting
   b. the meeting is attended by a radiologist (this should ideally be the same radiologist who read the assessment films)
   c. the lead screening radiologist attends all possible MDT meetings and provides the link between meetings where several are held within one programme
   d. the meeting is attended by a pathologist experienced in interpreting slides from breast screening needle biopsies
   e. the meeting is attended by a specialist breast surgeon whenever his or her patients are discussed

f. there are clear protocols for sharing experience from MDT meetings with all members of the assessment team across all assessment and treatment sites; these protocols will be audited by the QA team
g. at least two-thirds of all MDT meetings in a year must be covered by each individual MDT member or his/her designated deputy. The MDT member must attend personally at least half of all MDT meetings in a year. Cover can be arranged for the remainder. Attendance in person is preferable; however, if teleconferencing is used, there should still be regular attendances in person on a less frequent basis.

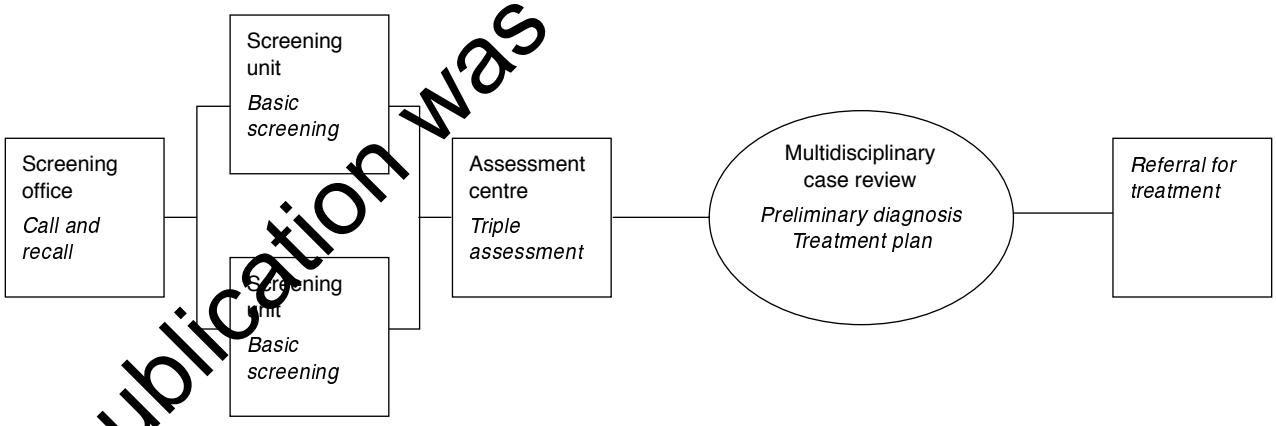
Unless these conditions are met, separate assessment centres must be regarded as separate programmes for QA and performance monitoring purposes.

3.2 Options

Some of the ways in which local breast screening programmes may be organised are described below:

Option a

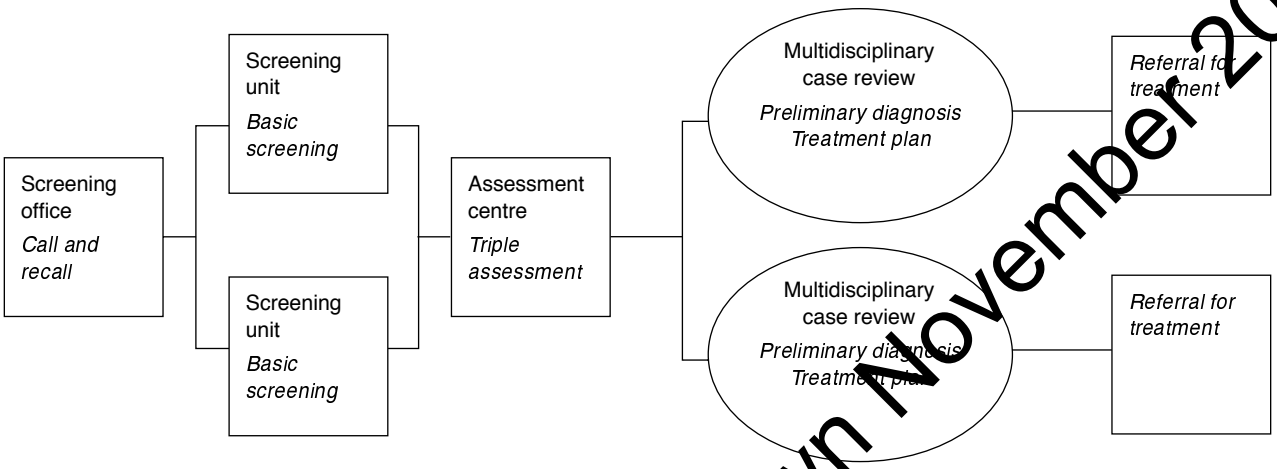
One or more basic screening unit (static or mobile), with a single assessment centre. Cases are reviewed at a weekly MDT meeting at the same site. There is a single clinical lead, and a single clinical protocol for the programme. A screening radiologist attends the case review meeting, which is also attended by the pathologist who reported the specimens and the surgeon who will be treating the women.



This is a single programme and a single QA visit and a single KC62 return is required.

Option b

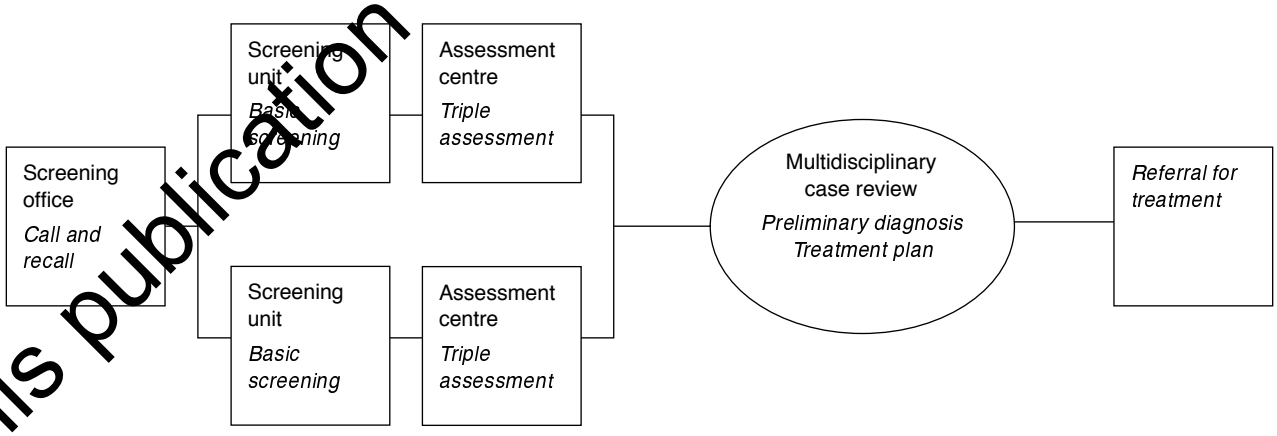
One or more basic screening unit (static or mobile), with a single assessment centre. Cases are reviewed at several weekly MDT sessions at the same site or at the hospitals where the women will be treated. There is a single clinical lead, and a single clinical protocol for the programme. A screening radiologist attends each case review meeting, which is also attended by the pathologist who reported the specimens and the surgeon who will be treating the women.



This is a single programme and a single QA visit and a single KC62 return is required.

Option c

One or more basic screening units (static or mobile), with two assessment centres. Cases are reviewed at a weekly MDT meeting at the hospital where the women will be treated. There is a single clinical lead, and both assessment centres work to the same clinical protocol. The lead screening radiologist attends the case review meeting, which is also attended by the pathologist who reported the specimens and the surgeon who will be treating the women.

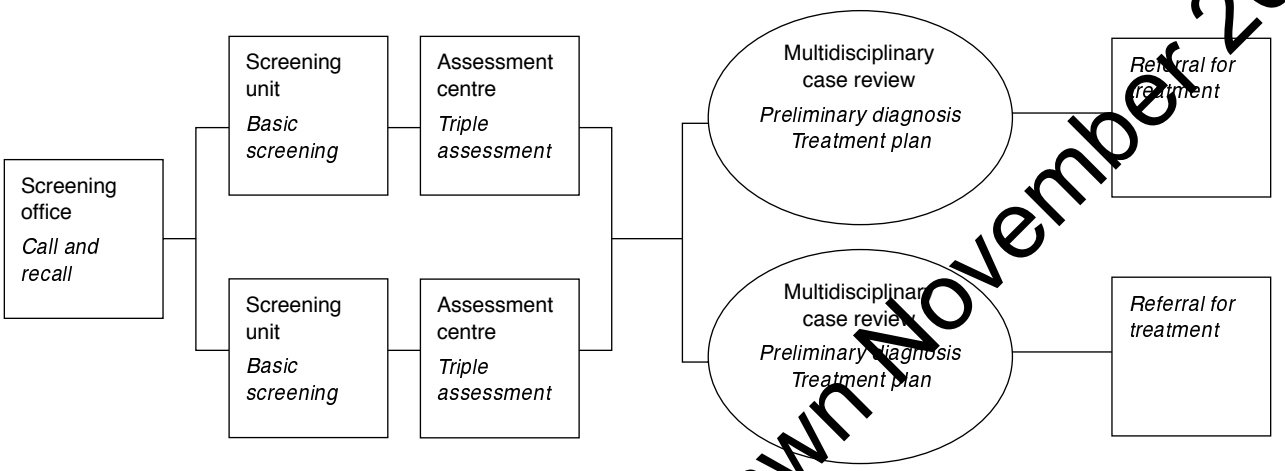


This is a single programme and a single KC62 return is required, but the QA team will visit both assessment centres.

If the QA team identifies differences between the performance or quality of the two assessment centres that cannot be resolved, the QA team may recommend treating the arrangement as two separate programmes with two KC62 returns.

Option d

One or more basic screening unit (static or mobile), with two assessment centres. The two assessment centres may share a common screening office, teams of radiographers and specialist equipment or may have some members of the assessment team in common. Cases are reviewed at separate weekly multidisciplinary case review meetings at each assessment site. Each assessment site has its own clinical lead and works to its own clinical protocol.



The results from each assessment centre must be monitored separately with separate KC62 returns for QA and performance management purposes.

3.3 Management arrangements

There should be a clear distinction between screening and symptomatic services with separately identifiable budgets, staff allocations and clinic sessions. Accountability for the screening service should be clearly defined in terms of clinical and programme management. Clinical management means the management of the clinical aspects of screening and assessment. Programme management means the day-to-day organisation of the programme, including planning of screening rounds, call and recall, and procedures to ensure that all eligible women are invited and receive the correct results. The director of breast screening is responsible for both clinical and programme management, but programme management may be delegated to a designated programme manager.

3.4 Director of breast screening

A breast screening programme must have a single director of breast screening. The term 'director of breast screening' should be used in preference to 'clinical director', which is used in many trusts for clinicians who have direct accountability to the trust board for a wider group of clinical services. In many trusts, the director of breast screening is responsible to the clinical director of breast services. The director of breast screening must be a clinician and is the person responsible for the management and performance of the breast screening programme. Accountability and responsibility must be clearly defined and documented, with the ultimate responsibility for breast screening (as with all other services) resting with the chief executive of the trust in which the programme is based. If screening or assessment takes place in more than one trust, clear lines of

accountability must be agreed with the chief executives of all the trusts as part of their arrangements for clinical governance. Similarly, if the director of breast screening is employed by a trust other than that in which the breast screening programme is based, clear lines of accountability for the management of the programme must be agreed.

3.5 Clinical management

The clinical management role of the director of breast screening is to:

- agree local clinical, technical, assessment and other protocols for the programme in accordance with national guidelines
- ensure that these local protocols are agreed and implemented in accordance with national guidelines
- ensure that clinical policy is maintained through regular MDT meetings and that decisions taken at MDT meetings about patient management are consistent with that policy
- be responsible for documenting decisions taken at MDT meetings about diagnosis and referral for treatment
- agree clear lines of accountability for the organisation and management of the programme and for budgets
- have regular multidisciplinary programme management meetings
- monitor the performance of the programme against national NHSBSP standards
- make sure that each component part of the programme meets national and local standards (including those for equipment and mobile vans)
- ensure that appropriate measures are taken (including running failsafe batches at least every 3 months) to ensure that all eligible women are invited for screening.

3.6 Programme management

Programme management describes the management of the non-clinical aspects of the programme.

These include:

- managing the call and recall system, including procedures for sending the correct results to women and running failsafe batches
- planning the screening round
- liaison with other organisations such as cancer networks, strategic health authorities, PCTs, the QA reference centre and cancer registries
- managing the budget
- managing staff
- staff development
- site management
- maintenance of equipment and facilities
- responsibility for the quality management system
- collecting performance data.

The director of breast screening is responsible for programme management, but some or all of the duties may be delegated to the programme manager (where appointed), superintendent radiographer or the screening office manager. The responsibilities of each should be clearly defined

in job descriptions and adequately resourced. Accountability for programme management is to the director of breast screening, who, in turn, is responsible to the chief executive of the trust in which the programme is based.

REFERENCES

1. Murray-Sykes K. *Organising Assessment.* Oxford, NHS Breast Screening Programme, 1989.
2. *Shifting the Balance of Power within the NHS: Securing Delivery.* London, Department of Health, 2001.
3. *Breast Cancer Screening.* Report to the Health Ministers of England, Wales, Scotland and Northern Ireland by a working group chaired by Professor Sir Patrick Forrest. London, Department of Health, 1986.
4. *A Policy Framework for Commissioning Cancer Services.* A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales. London, Department of Health, 1996.
5. *The NHS Cancer Plan.* London, Department of Health, 2000.
6. *Securing and Delivering Population Based Screening Programmes in a Modernised NHS.* Discussion document for the UK National Screening Committee (unpublished).
7. *Reducing the Risk.* NHS Breast Screening Review. Sheffield, NHS Cancer Screening Programmes, 2000.
8. Wilson R, Asbury D, Cooke J, et al (eds). *Clinical Guidelines for Breast Cancer Screening Assessment.* Sheffield, NHS Cancer Screening Programmes, 2001 (NHSBSP Publication No 49).
9. *Standards for the NHSBSP* (updated May 2000). Sheffield, NHS Cancer Screening Programmes, 2000 (unnumbered publication).
10. *Guidelines for Quality Assurance Visits*. Sheffield, NHS Cancer Screening Programmes, 2000 (NHSBSP Publication No 40).
11. Blanks RG, Bennett RL, Wallis MG, et al. Does individual programme size affect screening performance? Results from the United Kingdom NHS Breast Screening Programme. *Journal of Medical Screening* 2002, 9: 11–14.
12. Caseldine J. *Survey of Assessment Clinics in the NHS Breast Screening Programme.* Sheffield, NHS Breast Screening Programme, 1998 (unnumbered publication).
13. *Breast Screening Acceptability: Research and Practice. Report of the UKCCCR/NHSBSP workshop.* Sheffield, NHS Cancer Screening Programmes, 1993 (NHSBSP Publication No 28).
14. *Improving Outcomes in Breast Cancer. Manual Update.* London, National Institute for Clinical Excellence, 2002.