Determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHSScotland

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1 EXECUTIVE SUMMARY

Breast cancer is the most common cancer affecting women, with approximately 3,600 new cases being diagnosed in Scotland each year. While the disease is not yet preventable, early detection and treatment reduces mortality. The Scottish Breast Screening Programme (SBSP) was established in 1988, and uses mammography to detect breast cancer at an early stage. Screening for breast cancer by mammography has been shown to reduce mortality by up to 25% among women aged 50–70 years.

The SBSP currently provides a high standard, quality-assured service using conventional film-screen mammography (FSM) which records an X-ray image of a woman’s breast on a film in a cassette. Digital technology is now available, offering several benefits and is starting to be used for breast screening programmes elsewhere, including the United Kingdom (UK) and Europe and for other types of radiology in NHS Scotland.

Objectives

The aim of this Health Technology Assessment (HTA) is to explore the most clinically and cost-effective way to implement digital technology for breast screening in Scotland, without compromising the quality of the existing service.

Methods

Scientific literature was systematically searched to identify evidence of the clinical and cost-effectiveness of digital mammography. Experts, professional groups and other interested parties were also invited to submit evidence. All evidence was critically appraised. A working group was convened to identify the specific organisational issues relating to the introduction of digital technology to the SBSP and experiences from other breast screening programmes were considered.

Results and conclusions

The evidence shows that digital mammography technology is available which meets national dose and image quality standards and suggests there is no difference in diagnostic accuracy between FSM and digital mammography. Reported benefits of digital mammography include:

- a reduction in radiation dose with some digital mammography technologies
- immediate access to images, resulting in fewer return visits for technical repeats
- a reduction in repetitive tasks for mammographers with some digital mammography technologies
- the opportunity to trial innovative working patterns, such as remote reporting and distributed reporting
- a quieter, cleaner working environment.

Before digital mammography is implemented, it is highly desirable that the necessary information management and technology (IM&T) infrastructure is in place. This comprises: the image capturing equipment (modality); a Breast Screening Information System (BSIS) for administration, data entry at reading and compiling statistics; and a Picture Archive and Communications System (PACS) on which to store and retrieve images.

Although physically separate, it is essential that PACS and BSIS are compatible and fully integrated. Ideally, all components would be implemented and linked at the same time, but it is recognised that, given the timescales and need to replace equipment, interim measures may be needed.

Computed radiography (CR) and direct digital radiography (DDR) are the two main digital mammography technologies, however there was insufficient evidence to compare the performance of these. DDR does not involve handling cassettes which may save time for mammographers, allowing appointments to be shorter or alternatively providing more time to interact with women. However, CR is at present cheaper than DDR, particularly if no additional screening capacity is required and the existing FSM machine has a long remaining useful life. Where additional screening capacity is required, or where the existing FSM machine is being replaced and large bulk discounts (50% assumed) are available for DDR equipment, the difference in the costs of DDR and CR may be less pronounced.

The literature search identified a robust systematic review which indicated that DDR is more expensive than FSM both in terms of initial capital costs and annual operating costs, although there may be some savings resulting from fewer consumables. Observational evidence suggests that it is possible to provide a DDR service at a similar cost per woman screened as FSM if the screening programme substantially increases its operational hours. The budget impact assessment (Section 9.5) provides estimates of the replacement costs of FSM machines with DDR and CR machines, using purchase costs from the manufacturers of £230,000 for each DDR machine, £70,000 for each CR machine and £50,000 for an FSM machine. Assuming a 30% increase in annual throughput per machine, the current estimated replacement cost with DDR is £8.1 million, falling to £4.5 million if replacement is with CR. The total cost of a DDR programme over 10 years is estimated at £28.4 million, compared with £21.2 million for a CR programme.

No evidence was identified to suggest that the transition to digital mammography will be unacceptable to women attending screening. It is likely that from their perspective, the procedure will be similar to FSM but with a lower dose of radiation with some digital mammography technologies and less chance of recall for technical reasons.

The organisational issues associated with implementing digital mammography throughout NHS Scotland are numerous and complex, and local factors will need to influence decision making. To help ensure that digital mammography provides NHS Scotland with value for money, equipment should be used more intensively to increase the number of screens per machine and reduce...
the fixed cost per screen. There are specific accommodation requirements for digital mammography modalities (which may be temperature sensitive) and for PACS equipment. Further considerations for mobile screening units include, but are not limited to, the ability of equipment to withstand regular movement and the placing of diesel generators and extractor fans. Implementing digital mammography will have a major impact on the workforce, in terms of both working hours and practices, and training requirements, all of which could have a potential impact on recruitment and retention of staff.

During the introduction of digital mammography, previous images will be on film for an interim period of at least 3 years until all women have undergone a subsequent screen or examination using digital technology. Currently, previous films are displayed at the time of reading new films. The literature indicates that this reduces the number of women recalled unnecessarily. Continuing the practice of displaying previous films will either require facilities for displaying both film and digital images, or digitisation of previous films. The latter is costly and there is no clear evidence that this would be cost effective or produce images of a high enough quality.

Careful planning, informed by a wide range of professional groups and service users, is essential during the implementation of digital mammography across NHSScotland to ensure the existing high quality of service is maintained.

Recommendations

The HTA has been carried out based on the premise that digital mammography will be implemented in the SBSP whilst ensuring that the high quality of the programme is maintained. These recommendations therefore relate only to how the implementation should take place.

Technology

• A Breast Screening Information System (BSIS) integrated with a Picture Archive and Communication System (PACS) should be in place to support the implementation of digital mammography in Scotland. These systems should function as a single package of technology from the user's viewpoint. The BSIS should have facilities for administration, call/recall, data entry at reading and the compilation of statistics.
• A national PACS for breast screening is recommended. This should be part of the national PACS for Scotland but with features specific to breast screening.
• The full benefits of digital mammography will be achieved in a paper-lite environment where images and most of a woman's records are stored electronically. It is recommended that direct entry of results is included in the specification for the IM&T system as it is recognised that this has a number of benefits.
• Images taken at assessment clinics such as ultrasound and stereotactic images should also be stored on the PACS. The breast screening PACS should have facilities to share images between the screening and the symptomatic services, but should not automatically extract non-breast images. Additionally mammography images should not be automatically retrieved from the national PACS when women attend hospital for other reasons. A facility to print images should be available at each screening centre.
• Digital modalities should be fully compliant with International Digital Imaging and Communications in Medicine (DICOM). HL7, Integrating the Healthcare Enterprise (IHE) and subsequent standards.
• Digital modalities and mobile units should have comprehensive servicing and repair agreements in place. In particular, the agreement should ensure same-day visits when feasible and necessary to maintain the service.
• Loss-less compression of images is recommended for images taken at the last screen attended. Lossy compression should be considered for images taken at any earlier screens if sufficient quality is achieved.
• The decision on whether to recommend CR or DDR as the preferred digital technology should be taken by an implementation group. The evidence currently available is insufficient to inform a decision at this time.
• The cost and feasibility of a range of technologies for image transfer from mobiles should be considered at the time of implementation, including fixed connections, satellite connections and manual transfer (e.g. using CD, portable hard drive, data pen, connecting a landline).
• Generators on mobile units should be suitably soundproofed and positioned to cause minimum disruption to staff, women and the surrounding residents. Digital modalities have a narrow tolerance for temperature and generators for mobile units may need to run continuously to maintain the temperature within the required range.
• Consideration of computer-aided detection (CAD) is outwith the scope of the HTA and its use is not currently recommended. However, a review of the evidence is recommended at a later date.

Minimising implementation and operating costs

• The screening service should optimise the use of digital mammography equipment in Scotland and thus reduce the number of machines required, while giving due regard to local circumstances and implications for staff and women to be screened.
• Co-location of screening and symptomatic services should be considered if this would help to maximise the use of staff and imaging equipment and reduce the total number of machines needed. However, it is acknowledged that there will be local factors influencing the decision to do this.
• The screening service should seek to minimise implementation and operating costs while taking account of local constraints. This may be achieved by, for example: adopting flexible working patterns, use of spare capacity in digital mammography machines purchased for use in the symptomatic service, and optimal scheduling between assessment clinics and screening sessions.
There should be complete transparency of the assumptions used in each centre to determine the number of machines required. Relevant factors include the number of women who qualify for screening, population projections, attendance rates, appointment length, training time, downtime for breaks, set-up and close-down time, and travel time for mobiles.

**Prior images**

- Prior film images should be available at reading sessions. The practical approach to this may be decided by the individual centre or image reader.
- Currently it is recommended that prior film images are not digitised. At the time of implementation, this should be reconsidered and implemented only if high quality images can be obtained in a cost-effective manner and if a failsafe approach to tagging images is available.

**Impact on staff and working practices**

- The implementation of digital mammography will have a major impact on staff requirements and working practices. It is expected that there will be a change in tasks undertaken by several functions including administration staff, transport officers and radiographer helpers. There will be a significantly greater requirement for IM&T skills including PACS management. Additional time will be required to train staff during the implementation period. The use of flexible working patterns may affect the working hours of many staff groups.
- An IM&T and PACS manager should be identified at each screening centre. In some centres this role may be shared with another job function.
- Training requirements and recruitment policies should take into account anticipated changes to the tasks and roles of staff at an early stage. This should be done in partnership with the staff.

**Implementation**

The SBSP currently provides a very high quality service. The implementation of digital mammography will be a real opportunity for staff to redesign the service to meet the needs of women in Scotland over the coming years. However, it is recognised that implementing digital mammography will be very complex and therefore careful planning is required to ensure this high quality is maintained. This will need input from a wide range of professional groups as well as from users of the service. It is recommended that:

- The SBSP should take into account the requirements for digital mammography detailed within this HTA when planning the implementation of two-view mammography.
- The views of users of the service should be a key factor in planning and implementation.
- Digital technology should be piloted at the earliest opportunity. The machines should first be piloted on a mobile unit to ensure that the technology can withstand the weather conditions and transport requirements (eg ferry crossings) specific to Scotland. A local PACS system should be used at this stage. This should meet DICOM, HL7 and IHE standards so that images may eventually be stored on the national PACS. Digital machines, the PACS and BSIS should then be piloted across one centre including the associated mobile units. Lessons learned from both pilots should be disseminated across the SBSP and full implementation across other centres should follow over a fixed period of time.
- An implementation group with appropriate subgroups, supported by National Services Division (NSD) should be formed to:

1. Agree interim arrangements for the implementation of two-view mammography and for replacing redundant equipment in light of the recommendations of this report.
2. Ensure digital mammography is introduced to an agreed timescale and in a planned way, coordinating with the implementation of digital imaging technology in Scotland on a wider front.
3. Recommend the digital technology (ie CR or DDR) for: new equipment required to support the implementation of two-view mammography; redundant machines requiring replacement prior to full implementation of digital mammography; non-redundant machines to be replaced to achieve full implementation of digital mammography. The decision should take into account the evidence available in this HTA plus any more recent evidence relating to: the technical qualities of each modality, operating patterns, the number of machines required, experiences of users of digital mammography, costs, and the advantages and disadvantages of using different modalities within the service.
4. Draw up a detailed specification for the IM&T requirements for implementation including development of the BSIS, a national PACS for screening, and the IM&T infrastructure needed to support the transfer of large volumes of data. This should be carried out at an early stage by an IM&T subgroup.
5. Consider all options for purchasing the modality, taking into account requirements for servicing and consumables. Leasing options in addition to capital purchase options should be considered, as well as bulk purchase across Scotland in conjunction with the symptomatic service or with the NHSBSP in England and Wales.
6. Ensure the modality has a robust quality assurance and safeguarding process.
7. Ensure that comprehensive servicing and repair agreements are in place so that downtime of equipment is minimised.
8. Liaise with screening centres on the development of working patterns to ensure a high daily, weekly and annual utilisation of the digital screening equipment.

9. Take account of evidence emerging from screening services using digital mammography and other technologies.
2 INTRODUCTION

In 2005, the Scottish Executive Health Department (SEHD) published Delivering for Health which outlined its ‘e-health strategy’ for establishing a common information and communications technology system (Scottish Executive, 2005). This is essential if NHSScotland is to deliver integrated care services, giving the opportunity for faster, safer, more efficient and more patient-centred services. One activity generated by the strategy was the creation of a national Picture Archive and Communications System (PACS) to enable electronic transfer of digital records such as X-rays and scans. National roll out of this system was to be complete by June 2007 and such developments have precipitated an increasing use of digital technology throughout NHSScotland.

The Breast and Cervical Screening National Advisory Group requested that NHS Quality Improvement Scotland (NHS QIS) considers a Health Technology Assessment (HTA) to assist with the proposed introduction of digital mammography into the Scottish Breast Screening Programme (SBSP). NHS QIS agreed to undertake the HTA and published a Project Initiation Document setting out the key questions in December 2006.

In England, a similar project has already been undertaken considering the same evidence and issues as this HTA, and resulted in a recommendation to implement digital mammography immediately.

Digital mammography is already being implemented in some screening centres in the United Kingdom (UK). In England, the NHS Breast Screening Programme (NHSBSP) Digital Imaging Technologies Steering Group reported that frequently mammography is the only area of an imaging department still using film and as such it is becoming increasingly difficult to maintain film-screen mammography (FSM) equipment and good quality film processing chemistry. Advantages of converting from FSM to digital mammography include the potential for reduced radiation dose, environmental benefits, a reduction in repetitive tasks for mammographers with some technologies and immediate access to and assessment of images, thus necessitating fewer technical repeats.

The purpose of the HTA is to explore the most clinically and cost-effective way to implement digital technology for breast screening across Scotland, while maintaining the high standards of the existing quality-assured service. The scope is restricted to evaluation of the technology and the practicalities of its implementation, and does not extend to the wider ethical issues associated with screening programmes.

Section 3 of this document provides information on NHS QIS and on the HTA process. Background on breast screening in Scotland and digital mammography is provided in Section 4. Clinical and cost effectiveness are summarised in Sections 5 and 6, respectively. Issues of importance to women undergoing screening are explored in Section 7 and the considerable organisational issues associated with the transition to digital mammography are presented in Section 8. Section 9 discusses the findings and presents the recommendations along with a preliminary estimate of the financial implications of these.

NHS QIS is committed to equality and diversity. This document, and the research on which it is based, have been assessed for likely impact on the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation. For a summary of the equality and diversity impact assessment, please see www.nhshealthquality.org.

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1 On 3 September 2007, Scottish Ministers formally adopted the title Scottish Government to replace the term Scottish Executive as an expression of corporate identity. The Health Department has been replaced by Health Directorates.
3 BACKGROUND ON NHS QUALITY IMPROVEMENT SCOTLAND

NHS QIS was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland. NHS QIS sets standards, monitors performance and provides NHSScotland with advice, guidance and support on clinically and cost-effective practice and service improvements.

Health Technology Assessment

HTA is an internationally recognised process used by NHS QIS to advise NHSScotland about a specific health intervention, eg medicine, equipment or diagnostic test. HTA evaluates the clinical and cost effectiveness of the various ways in which a particular intervention can be used, comparing alternatives where appropriate. Patient and organisational issues are also considered.

Evidence is identified by systematic literature searching and assimilating expert evidence, the views of patient interest groups and manufacturers. The evidence is then critically appraised and robust analyses are undertaken by expert staff. Surveys may also be undertaken to ascertain current clinical practice and patient preferences.

This assessment was conducted by NHS QIS staff from a variety of disciplines, with input from health professionals expert in the particular area of interest (see Appendix 1). Peer review and wide public consultation ensures that all views are considered.
4 SETTING THE SCENE

4.1 Breast screening in Scotland

Breast cancer is the most common form of cancer among women, both in Scotland and worldwide. Approximately 3,600 cases are diagnosed each year in Scottish women, with 80% of these found in women over 50 years of age (NHS National Services Scotland, 2006).

It is not yet possible to prevent breast cancer, but it has been proven that early detection and treatment reduces mortality by up to 25% in women aged between 50–70 years. In Scotland, breast screening is offered to all women in this age group every 3 years as part of the SBSP. It aims to detect breast cancer in symptom-free women to allow treatment when it is likely to be more effective and less invasive.

The screening process uses mammography; X-rays of each breast are taken while carefully compressing the breast. Mammography can identify small abnormalities that cannot be detected by a physical examination.

There are six fixed breast screening centres in the north (Inverness), north east (Aberdeen), east (Dundee), south east (Edinburgh), south west (Irvine), and west (Glasgow), and these centres are supported by 18 mobile screening units. In 2005–2006, there were 159,847 women screened.

NHS QIS published clinical standards for breast screening in December 2002 (Clinical Standards Board for Scotland, 2002). These incorporate the NHSBSP Standards. Peer review visits to all breast screening services in Scotland were carried out to assess the performance against these standards and a national overview was published in November 2003 (NHS Quality Improvement Scotland, 2003a). NHS QIS is committed to undertaking follow-up reviews of breast screening services at 3-yearly intervals. A status report of the follow-up review of the SBSP was published in December 2006 (NHS Quality Improvement Scotland, 2006).

4.2 The technology

4.2.1 Digital image capturing equipment

Conventional mammography involves taking X-rays of the woman's breast, with the image being recorded on a film in a cassette. This is film-screen mammography (FSM). In digital mammography, X-rays are converted to digital images which can be viewed on a workstation screen (soft copy) and are stored electronically rather than transferred to film. There are two main methods of digital mammography:

- computed radiography (CR) which records the image on a reusable plate housed within a cassette that is scanned using a laser reader to produce the digital image
- direct digital radiography (DDR) which uses solid-state detectors to convert X-rays into electrical signals to produce an image of the breast.

Both DDR and CR are methods of full-field digital mammography (FFDM), a term which distinguishes these from the add-on small-field systems used for localisation and biopsy already in widespread use. The term refers to the size of the imaged field (ie covering the whole breast). Throughout this report, the term ‘digital mammography’ refers to FFDM.

CR is the first generation of digital mammography systems, which uses photostimulable-based technology. Existing FSM mammography machines can be used and are therefore not redundant, meaning that CR incurs lower initial capital costs than DDR. Similar to FSM, CR is an indirect way of acquiring X-ray images and is a two-stage process: in CR, X-ray photons interact with a phosphor screen, known as the image plate, which stores a latent image until processed. The reusable imaging plate is contained in cassettes which are inserted into a bucky (cassette holder) and then into a reader. A laser beam is scanned across the plate, releasing stored energy as light emissions which are read by a photomultiplier. The scanning process generates an electrical signal that is processed into a digital image and viewed on a workstation display (known as a soft copy) or printed out as film analogues (hard copy) on a laser printer (Ho et al., 2002; NHS Cancer Screening Programmes, 2006c). The cassettes used with some machines are lighter than those currently used for FSM.

DDR systems acquire images directly in digital form, as the detector and reader are built into the breast platform of the X-ray unit (NHS Cancer Screening Programmes, 2006c). There are two types of detectors in DDR systems: direct and indirect conversion designs. These methods of image capture represent different generations of technology. Indirect conversion designs employ a two-step process of detecting X-rays and use a phosphor layer as the X-ray converter; the phosphor layer absorbs the X-rays and generates light photons which are detected by an array of photodiodes to generate an electrical signal. There has been considerable development in technology of indirect conversion detectors, and these include charge coupled devices and flat panel phosphor systems (Ho et al., 2002).

Direct conversion detectors use a photoconductor to absorb the X-rays and directly generate a data signal. Photoconductors which are currently available are based on amorphous selenium or silicon wafer. Other systems using gaseous detectors are being developed. Most systems employ a flat-plate detector but slot scanning is also available (eg Sectra Microdose) (Alex Watt, Medical Physicist, Scottish Healthcare Supplies. Personal communication).

4.2.2 The workstation and image processing

The steps of acquiring and displaying an image are separate. It requires two types of workstation: an acquisition workstation (where the mammographer can immediately view the image) and a high specification reporting station (where the images are interpreted).
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An acquisition workstation usually comprises a single monitor for image review, and is located at the plate reader for CR systems and adjacent to the X-ray unit for DDR systems. The workstation enables input and review of patient and examination information and a limited range of image processing facilities. The exact facilities vary by manufacturer. In DDR systems, the workstation provides an operating system for image acquisition.

The reporting workstation usually comprises two high specification and high resolution monitors, matched in performance and mounted side by side in portrait orientation. In addition, there is usually a separate monitor for the Breast Screening Information System (BSIS). In DDR systems, the image is available seconds after exposure. A complete package of image processing tools to enable image manipulation and enhancement should be available. The system can keep a record of the individual user protocols. The image processing tools provided vary according to the manufacturer of the system but can include:

- **invert** which inverts the grey scale (black to white/white to black) which can assist visualisation of certain tissues
- **window width/level** to alter the brightness and contrast to optimise visualisation of data
- **zoom** to magnify the image
- **edge enhancement** to improve the edge differentiation (but may also enhance noise and reduce visibility of low contrast objects)
- **region of interest** to select a specific region of the image
- **measurement** to measure distance in real space
- the ability to annotate an image
- statistics to provide numerical data such as pixel count.

Tools for handling, storage and communication facilities are also available at the reporting workstation (NHS Cancer Screening Programmes, 2006c).

Workstations which handle images are not compatible with all modalities and many are manufacturer dependent. It is desirable that both primary and secondary display systems are calibrated in accordance with the Digital Imaging and Communications in Medicine (DICOM), HL7 and Integrating the Healthcare Enterprise (IHE) standards. These standards enable the integration of devices from different manufacturers, and ensure that the medical image displayed on calibrated imaging devices has a consistent greyscale appearance regardless of the specification of the device.

**4.2.3 Picture Archiving and Communications System (PACS)**

With FSM, women’s films are stored for a minimum of 9 years (Legood & Gray, 2004). Digital mammography may virtually eliminate the requirement to store hard copy films as images can be archived digitally using PACS.

Typically, a PACS comprises data storage devices, image display devices, database management software and links to image and/or image data acquisition devices, connected by computer networks. There are also generally connections to other information systems.

Once transmitted to a PACS, digital data may be stored in an image archive that is:

- centralised, with a single, large disc-based online storage facility that can accept data from anywhere in an institution and similarly distribute the data
- distributed, where image data from the local modality can be stored for subsequent distribution as necessary and a number of archive devices are attached to a PACS network (Turner et al., 2002).

**4.2.4 Breast Screening Information System (BSIS)**

The BSIS supports the national breast screening programme and should fulfil the following functions:

- identification, invitation and recall
- recording attendance for screening
- recording results of screening
- monitoring the screening process.

Call/recall systems must be able to identify all individuals eligible for screening and ensure seamless transition as women move through NHSScotland.

The existing Scottish administration system was designed to enable computerised screening scheduling, result recording, problem follow up and statistical reporting for eligible women. The system is Windows driven and is made up of pull-down menus; it uses an Oracle Database in a Unix/NT Environment. It requests information regarding eligible women from the Community Health Index (CHI). The CHI extracts these data which it passes back to the administration system to then create a record for each woman. Screening centre staff then liaise with the appropriate general practice to allocate appointments to these women. In some circumstances, a woman may also self refer for screening in which case a record will be created for her on the SBSP administrative system.

Attendance and results are recorded on the system, which also produces results letters and labels for women and general practitioners (GPs).

To support digital mammography, the BSIS must be fully integrated with the PACS so that the two systems function as a single package of technology from the user’s perspective. The functions required for the BSIS and PACS are described in more detail in Section 8.3.
5 CLINICAL EFFECTIVENESS

5.1 Literature search

Literature searches to identify secondary evidence such as HTAs, systematic reviews and ongoing research relevant to the HTA questions were undertaken in May 2006. Sources used included, for example, the Cochrane Database of Systematic Reviews and the Database of Reviews of Effects. Additional searches were undertaken in September 2006. These searches were undertaken to identify guidelines and any grey literature or reports of relevance. Sources used included the National Library for Health’s Guidelines Finder, websites of professional associations and the NHSBSP, and general internet searching using Google and the meta-search engine Vivisimo.

The primary literature was searched for two specific questions in January 2007. Both searches were designed to maximise specificity rather than sensitivity:

- the use and storage of prior images
- the use of CR.

The search for prior images was undertaken in the following databases, using the OVID platform:

- MEDLINE
- EMBASE
- CINAHL
- MEDLINE in Process.

No specific indexing terms for the ‘prior images’ concept exist, so free text searching around this phrase using synonyms was used. The search was restricted to English language papers.

The search on use of CR was undertaken in:

- MEDLINE
- EMBASE
- MEDLINE in Process
- CENTRAL.

The results of this search were filtered to retrieve only randomised controlled trials. This was done using the Cochrane Highly Sensitive Search Strategy (Glanville et al., 2006). This search was also restricted to English language papers.

Citation searching to identify additional papers of interest was undertaken using Web of Science in February 2007.

A complete list of sources searched and a copy of the search strategies are included in Appendix 2. All included strategies were those used to search MEDLINE. These strategies were adapted to search the other listed databases. A complete listing of all strategies can be obtained by contacting NHS QIS.

For each of the search strategies, abstracts were read for all relevant titles and full articles were obtained where appropriate. Studies were included which examined the use of prior images with current images in mammography screening and assessment. There is a lack of literature specifically considering digital mammography, so FSM studies have also been considered. All articles that compared the test accuracy against a standard reference, with or without clinical information and studies in which mammograms were read twice by the readers were considered. All articles that measured outcomes such as sensitivity and specificity or that had receiver operated curves, or performance of observers were also included as were those that looked at percentage change and costs. Studies exploring computer-aided detection (CAD) and its performance with current and prior images were excluded. Data extraction was performed by one reviewer, with a second reviewer assisting where there was difficulty in interpretation of articles. Any differences were resolved by discussion.

5.2 Digital versus film-screen mammography

5.2.1 Sources of evidence

In the secondary literature, there are several up-to-date reviews of the clinical performance of digital mammography compared with FSM for breast screening (Blue Cross Blue Shield Association, 2006; Hailey, 2006; ECRI, 2007; Young et al., 2005b). The best available evidence consists of four large prospective studies including more than 75,000 women. The three screening cohorts (Pisano et al., 2005b; Skaane et al., 2005; Lewin et al., 2002) and one randomised trial (Skaane et al., 2007) were conducted in North America and Norway between 1999–2003.

One of the cohort studies (Oslo I) only enrolled women aged 50–69 years (Skaane et al., 2005), whereas the screening populations in the other three studies included women from the age of 40. Two studies conducted subgroup analyses in the age group 50–69 years (Oslo II)(Skaane et al., 2007), and >50 years (Digital Mammographic Image Screening Trial [DMIST]) (Pisano et al., 2005b).

The DMIST study included the five digital mammography machines available at the time, including four DDR and one CR machines. One type of DDR machine was used in the Norwegian studies and its prototype, a technically inferior machine to those sold for clinical use, was used in the earliest study conducted in the United States of America (USA).

The conclusions from the secondary literature sources are consistent and, on the basis of the methods reported, are likely to be reliable. The authors of a literature review conducted on behalf of the NHSBSP Digital Imaging Technologies Steering Group suggested that, of the four major studies, the results from the Oslo studies may be particularly applicable to the UK context given the similarity of the methods to routine screening in the NHSBSP (Young et al., 2005b). Accordingly, they emphasised the importance of good viewing conditions, following a strict reading protocol, and careful training for image readers switching from FSM to digital...
mammography. The conclusions are summarised below and the individual primary studies are summarised in Table 5-1.

5.2.2 Results of literature search

**Diagnostic accuracy**

In the DMIST study, the number false positives was high for both digital mammography and FSM although the difference was not statistically significant. Based on reference standard information at 455 days follow up, for every 185 cancers detected with digital mammography, 42,570 women were screened and 3,470 healthy women underwent additional testing because of false-positive results. The comparable numbers for FSM were 174 cancers detected and 3,505 women undergoing additional testing unnecessarily (calculated from data reported in Pisano et al. (2005b)). The available data on recall rates and cancer detection rates for women aged 50–69 years in the Oslo I and Oslo II studies shown in Table 5-1 indicate that around 80% of women recalled on the basis of a positive result from digital mammography or FSM were found on further assessment not to have breast cancer.

The available evidence suggests that in screening populations overall digital mammography and FSM have similar diagnostic accuracy. Both modalities produce many false positives. Some cancers that would be detected by FSM will not be detected by digital mammography and vice versa.

The DMIST cohort study, designed to have sufficient statistical power to detect a small difference in diagnostic accuracy, found no statistically significant difference between the two modalities in the screening population overall. Evidence from subgroup analysis in DMIST suggests that digital mammography is more accurate than FSM in women <50 years of age, in those who are pre- or peri-menopausal and in women with dense breasts.
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado-Massachusetts, USA</td>
<td>Prospective, screening cohort, paired design, each woman underwent FFDM &amp; FSM; blinded independent single reading of images using BI-RADS and a percentage probability of malignancy scale; soft-copy reading of FFDM; prior mammograms available during FFDM and FSM interpretation; follow up 1 year.</td>
<td>4,945 asymptomatic women presenting for screening mammography enrolled at 2 sites; 4,489 women underwent 6,736 examinations (some women had 2 or 3 annual mammograms during the study period). Eligible age ≥40 years; enrolled population mean age 55.6 years, SD 9.8. Exclusion criteria: breast implants.</td>
<td>FFDM (prototype machine and display system, predecessor to GE Senographe 2000D). FSM (GE DMR, Kodak Min-R 2000). Two-view mammography (FFDM &amp; FSM) of each breast. Reference standard: cancer status determined by biopsy within 1 year of imaging or follow up (subsequent screening mammogram or clinical detection) or cancer registry data.</td>
<td>Recall rate, cancer detection rate, biopsy rate, PPV, AUC. McNemar 2 test for paired data, p&lt;0.05 statistically significant; ROC curve analysis.</td>
<td>Recall rate FFDM 793/6,736 (11.8%), FSM 1,001/6,736 (14.9%) (p&lt;0.001). Number of cancers detected at imaging FFDM 27/42 (64%), FSM 33/42 (79%) (p&gt;0.1). Number of cancers detected (including 8 negative on imaging that became palpable within 1 year) FFDM 27/50 (54%), FSM 33/50 (66%) (p&gt;0.1). Cancers detected FFDM only 9, FSM only 15, both 18. Biopsy rate FFDM 94/793 recalled (11.8%), FSM 143/1,001 recalled (14.3%) (p&lt;0.001). PPV FFDM 27/793 (3.4%), FSM 33/1,001 (3.3%). AUC FFDM 0.74, FSM 0.8 (p=0.18).</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Participants</td>
<td>Interventions</td>
<td>Outcomes</td>
<td>Results</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>DMIST, USA &amp; Canada Pisano et al. (2005a) Pisano et al. (2005b) Date Oct 2001–Nov 2003</td>
<td>Prospective, screening cohort, sample size calculation, paired design; each woman underwent FFDM &amp; FSM in random order; independent blinded double reading of images using BI-RADS, a bespoke 7-point rating scale and a call-back scale; hard- and/or soft-copy reading of FFDM; follow up 455 days (15 months) and 1 year; analyses adjusted for potential verification bias.</td>
<td>49,528 asymptomatic women presenting for screening mammography enrolled at 33 sites; 42,760 included in the analysis, including 203 who did not receive both tests. Mean age 54.9 years (IQR 47, 62). Exclusion criteria: focal/dominant lump, nipple discharge, breast implants, pregnant, unable to undergo FSM/provide mammograms for review after 1 year, previous lumpectomy for breast cancer.</td>
<td>FFDM (SenoScan, GE Senographe 2000D, Lorad/Trex, Lorad/Hologic Selena, Computed Radiography for Mammography). FSM (various mammographic machines and screen film products). Two-view mammography (FFDM &amp; FSM) of each breast. Reference standard: biopsy within 15 months or follow-up mammogram after at least 10 months.</td>
<td>Primary: AUC in the entire study cohort. Secondary: AUC in prespecified subgroups, sensitivity, specificity, PPV, recall rate. Analysis confined to the fully verified group. ROC curve analysis, p&lt;0.003 statistically significant; McNemar χ² test for paired data.</td>
<td>Difference in AUC 0.03, 95% CI: -0.02, 0.08 (p=0.18). No significant difference in AUC between FFDM and FSM in ≥50 years of age, postmenopausal, less dense breasts subgroups. Using reference standard information at 455 days follow up: Positive mammograms FFDM 3,665/42,570 (8.6%) FSM 3,679/42,745 (8.6%) Number of cancers detected FFDM 185/335 (52%), FSM 174/335 (55%) (p=0.39) Number of cancers detected FFDM only 63, FSM only 52, both 122, neither 98. 1-year follow up, BI-RADS: Sensitivity FFDM 0.70 (95% CI: 0.64, 0.76) FSM 0.66 (95% CI: 0.60, 0.72) (p=0.37) Specificity FFDM 0.92 (95% CI: 0.918, 0.922), FSM 0.92 (95% CI: 0.918, 0.922) (p=0.74) PPV FFDM 0.05 (95% CI: 0.04, 0.06) FSM 0.05 (95% CI: 0.04, 0.06) Recall rate reported as 8.4% for FFDM and FSM.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Participants</td>
<td>Interventions</td>
<td>Outcomes</td>
<td>Results</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Oslo I, Norway</td>
<td>Prospective, screening cohort, paired design, each woman underwent FFDM &amp; FSM; independent double reading of images using a 5-point rating scale (no prior mammograms); soft-copy reading of FFDM; recall by consensus (prior mammograms available); follow up 2.5 years.</td>
<td>3,683 women enrolled from invited attendees of a population-based screening programme (eligible population 9,932, number invited to enrol and criteria for invitation not reported). Age 50–69 years. Exclusion criteria: age 40–49 years.</td>
<td>FFDM (GE Senographe 2000D). FSM (Siemens Mammomat 300, Kodak Min-R 2000). Two-view mammography (FFDM &amp; FSM) of each breast. Reference standard: biopsy within weeks of screening or follow up to subsequent screening round 2 years later, including national cancer registry data.</td>
<td>Recall rate, cancer detection rate, PPV₁ (based on abnormal mammogram), PPV₂ (women who underwent FNA). McNemar $\chi^2$ test for paired data, $p&lt;0.05$ statistically significant.</td>
<td>Initial reading: Recall rate FFDM 168/3,683 (4.6%), FSM 128/3,683 (3.5%) ($p&lt;0.02$) (ECRI, 2007). Cancer detection rate FFDM 23/3,683 (0.62%), FSM 28/3,683 (0.76%). Number of cancers detected by FFDM 23/31 (74%), FSM 28/31 (90%) ($p=0.23$). Number of cancers detected FFDM only 3, FSM only 8, both 20 (65%). PPV₁ FFDM 20/168 recalled (12%), FSM 26/128 recalled (20%). PPV₂ FFDM 20/52 FNA (39%), FSM 26/57 FNA (46%). Sensitivity FFDM 74.2%, FSM 90.3% (NS) (Blue Cross Blue Shield Association, 2006). 2-year follow up: Including 7 true positives at initial reading dismissed at consensus meetings (4 interval cancers and 3 subsequent screening round cancers): Cancer detection rate FFDM 27/3,683 (0.73%), FSM 31/3,683 (0.84%) ($p=0.48$). Number of cancers detected FFDM only 7, FSM only 11, both 20 (53%).</td>
</tr>
</tbody>
</table>
Oslo II, Norway Skaane et al. (2007)
Date Nov 2000–Dec 2001

Prospective, women were randomised to FFDM or FSM (30:70), allocation not concealed, randomisation adjusted for age and area of residence; independent double reading of images using a 5-point rating scale (without prior mammograms); soft-copy reading of FFDM; recall by consensus (prior mammograms available); follow up 18 months in the 45–49 years group and 2 years in the 50–69 years group.

23,929 women who attended a population-based screening programme during the study period.
Age 45–69 years
45–49 years: FFDM n=2,935, FSM n=7,082.
50–69 years: FFDM n=4,009, FSM n=9,903.

FFDM (GE Senographe 2000D).
FSM (as Oslo I).
Two-view mammography (FFDM & FSM) of each breast.
Reference standard: biopsy within weeks of screening or breast cancer registry surveillance data.

Recall rate; cancer detection rate; PPV1 (based on abnormal mammogram), PPV2 (women who underwent FNA).
X2 tests, p<0.05 statistically significant.

Overall:
Recall rate FFDM 4.2%, FSM 2.5% (p<0.01)
Cancer detection rate FFDM 41/6,944 (0.59%), FSM 64/16,985 (0.38%) (p=0.03)
PPV1 FFDM 13.0%, FSM 15.1% (p=0.68)
PPV2 FFDM 42.7%, FSM 39.0% (p=0.56).

Age 50–69 years:
Recall rate: FFDM 173/4,009 (4.3%), FSM 229/9,903 (2.3%)
Cancer detection rate: FFDM 32/4,009 (0.80%), FSM 50/9,903 (0.50%)
PPV1: FFDM 18.5%, FSM 21.8%
PPV2: FFDM 52.5%, FSM 50.5%.

Age 45–49 years:
Recall rate FFDM 121/2,935 (4.1%), FSM 196/7,082 (2.8%)
Cancer detection rate FFDM 9/2,935 (0.31%), FSM 14/7,082 (0.20%)
PPV1 FFDM 7.4%, FSM 7.1%
PPV2 FFDM 25.7%, FSM 21.5%.
5.2.3 CR compared with DDR

The literature search found no published studies comparing the clinical effectiveness of different types of digital mammography machines, which reflects the experience of other reviewers (ECRI, 2007). The DMIST study included a CR machine and four DDR machines (Pisano et al., 2005a). The diagnostic accuracy for digital mammography did not differ significantly according to the type of digital machine used, however, insufficient cancers were detected to support definitive conclusions (Pisano et al., 2005b).

5.2.4 Other studies comparing digital technology with FSM

Two studies comparing digital mammography with FSM in women aged 50–69 years in population-based screening programmes in Norway and Italy have been reported, one in full and one as a symposium abstract (Vigeland et al., 2007; Bonardi et al., 2006). Both programmes implemented independent double reading of mammograms and performed soft-copy reading of digital mammograms. Comparisons were made between units providing digital mammography and those providing FSM. However, the studies did not have a randomised or cohort design and therefore their results carry less weight than those reported in Sections 5.2.2 and 5.2.3. The Norwegian study reported on the prevalent round of screening, while the Italian study considered all rounds but reported no significant difference in prevalent versus incident mammography between the two screening groups. Results for both studies are summarised in Table 5.2. In both reports, the investigators found a significantly lower rate of technical recall with digital mammography. One study (Vigeland et al., 2007) reported a significantly higher cancer detection rate and a higher positive predicted value for digital mammography, while the other (Bonardi et al., 2006) reported a significantly higher overall recall rate for digital mammography.

5.2.5 Reports of digital mammography screening systems evaluated in the UK

Four NHSBSP equipment reports documented evaluations of DDR machines in routine breast screening in England (NHS Cancer Screening Programmes, 2006d; 2006e; 2007g; 2007i). In some of the evaluations, the equipment was installed on mobile units, however these units were in static locations and not moved regularly. The findings on throughput and technical recalls are summarised in Table 5.3.

5.2.6 Breast screening standards outcomes

The NHSBSP has produced a set of national standards for breast screening (NHS Cancer Screening Programmes, 2005). Additionally NHS QIS has produced standards for SBSP in collaboration with service users and providers of breast screening services in Scotland (Clinical Standards Board for Scotland, 2002). NHS QIS regularly assesses the performance of breast screening services across NHSScotland against these standards. The evidence identified in the literature suggests that the clinical standards for breast screening in Scotland for which outcomes data were available can be met by digital mammography.
Table 5-2 Summary of results from other European breast screening programmes

<table>
<thead>
<tr>
<th>Location, date, digital mammography system</th>
<th>Number of women screened</th>
<th>Recall rate</th>
<th>Cancer detection rate</th>
<th>PPV</th>
<th>Technical recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Digital mammography</td>
<td>FSM</td>
<td>Digital mammography</td>
<td>FSM</td>
</tr>
<tr>
<td>挪威</td>
<td>18,239</td>
<td>4.1%</td>
<td>4.2%</td>
<td>0.81%</td>
<td>0.62%</td>
</tr>
<tr>
<td>Vigeland et al. (2007)</td>
<td>Feb 2004–Dec 2005</td>
<td>Lorad Selenia</td>
<td>p=0.645</td>
<td>p=0.029</td>
<td>p=0.014</td>
</tr>
<tr>
<td>意大利</td>
<td>21,313</td>
<td>4.1%</td>
<td>3.6%</td>
<td>0.62%</td>
<td>0.53%</td>
</tr>
<tr>
<td>Bonardi et al. (2006)</td>
<td>Jul 2004–May 2005</td>
<td>GE Senographe 2000D</td>
<td>P&lt;0.001</td>
<td>P=0.27</td>
<td>P-value NR</td>
</tr>
</tbody>
</table>

NR=not reported.
Table 5-3 Summary of NHSBSP evaluations of digital mammography systems in breast screening in England

<table>
<thead>
<tr>
<th>Location, date, digital mammography system</th>
<th>Number of women screened</th>
<th>Throughput (appointment time)</th>
<th>Technical recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>WSCBSS NHS Cancer Screening Programmes (2006d) 4 Apr–4 Nov 2005 Sectra MicroDose Mammography system</td>
<td>Not reported</td>
<td>Digital mammography 5 min FSM 6 min</td>
<td>Digital mammography 3</td>
</tr>
<tr>
<td>Nottingham NHS Cancer Screening Programmes (2006e) 24 Jan–5 May 2005 GE Senographe 2000D</td>
<td>1,269</td>
<td>Appointment times no different to working with FSM</td>
<td>Range of examination times 6.38–8.11 min</td>
</tr>
<tr>
<td>London, NHS Cancer Screening Programmes (2007g), Feb–Sept 2005, Hologic Selenia</td>
<td>2,704</td>
<td>Average 7.3 min (expected to decrease by about 1 min following software improvement)</td>
<td>-</td>
</tr>
<tr>
<td>Cambridge and Huntingdon, NHS Cancer Screening Programmes (2007h), commenced Mar 2006, Siemens Novatron</td>
<td>370</td>
<td>Minimum 7.4 min (expected to decrease by about 1 minute following software improvement)</td>
<td>FSM 6 min</td>
</tr>
</tbody>
</table>

WSCBSS: Warwickshire, Solihull and Coventry Breast Screening Service.
5.2.6.1 Image quality and radiation dose

The methods of measuring the dose standards for digital mammography are the same as those for FSM systems. The NHSBSP requires a value of <2.5 mGy mean glandular dose per film for a standard breast (NHS Cancer Screening Programmes, 2005) and the Clinical Standards Board for Scotland (CSBS) requires a value of <2.0 mGy mean glandular dose per film for a standard breast (Clinical Standards Board for Scotland, 2002).

Radiation doses reported in all seven available evaluations of digital mammography by the NHSBSP were below the NHSBSP target of <2.5 mGy (NHS Cancer Screening Programmes, 2006a; 2006d; 2006e; 2007a; 2007d; 2007e; 2007h). However, the evaluation of one machine (Agfa CR 85-X, NHS Cancer Screening Programmes, 2007e) reported a dose of 2.14 mGy and did not quite meet the more stringent CSBS standard of <2.0 mGy.

The mean glandular doses of radiation required for different digital mammography machines to reach the minimum and achievable threshold gold thickness were presented in NHSBSP equipment report 0707 (NHS Cancer Screening Programmes, 2006e) and are reproduced in Table 5-4 and Table 5-5 respectively.

<table>
<thead>
<tr>
<th>System</th>
<th>Human (M GD) for 0.1 mm</th>
<th>Predicted (M GD) for 0.1 mm</th>
<th>Human (M GD) for 0.25 mm</th>
<th>Predicted (M GD) for 0.25 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fisher Senoscan</td>
<td>0.55</td>
<td>0.42</td>
<td>0.48</td>
<td>0.53</td>
</tr>
<tr>
<td>Sectra MDM</td>
<td>0.60</td>
<td>0.82</td>
<td>0.67</td>
<td>0.46</td>
</tr>
<tr>
<td>Siemens Novation</td>
<td>0.63</td>
<td>0.61</td>
<td>0.52</td>
<td>0.63</td>
</tr>
<tr>
<td>Hologic Selenia</td>
<td>0.85</td>
<td>0.55</td>
<td>0.80</td>
<td>0.53</td>
</tr>
<tr>
<td>GE DS</td>
<td>1.01</td>
<td>0.82</td>
<td>0.87</td>
<td>0.83</td>
</tr>
<tr>
<td>FSM</td>
<td>1.17</td>
<td>1.30</td>
<td>1.07</td>
<td>1.36</td>
</tr>
<tr>
<td>Fuji Profect CR</td>
<td>1.67</td>
<td>1.78</td>
<td>1.45</td>
<td>1.35</td>
</tr>
<tr>
<td>Agfa CR 85-X</td>
<td>2.00</td>
<td>1.94</td>
<td>0.86</td>
<td>1.42</td>
</tr>
<tr>
<td>Kodak CR (EHR-M2)</td>
<td>2.29</td>
<td>2.34</td>
<td>1.45</td>
<td>1.80</td>
</tr>
<tr>
<td>Test CR</td>
<td>4.52</td>
<td>4.17</td>
<td>2.33</td>
<td>2.12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>System</th>
<th>Human (M GD) for 0.1 mm</th>
<th>Predicted (M GD) for 0.1 mm</th>
<th>Human (M GD) for 0.25 mm</th>
<th>Predicted (M GD) for 0.25 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fisher Senoscan</td>
<td>1.16</td>
<td>0.90</td>
<td>0.98</td>
<td>1.09</td>
</tr>
<tr>
<td>Sectra MDM</td>
<td>1.27</td>
<td>1.74</td>
<td>1.37</td>
<td>0.95</td>
</tr>
<tr>
<td>Siemens Novation</td>
<td>1.56</td>
<td>1.21</td>
<td>1.14</td>
<td>1.27</td>
</tr>
<tr>
<td>Hologic Selenia</td>
<td>1.84</td>
<td>1.19</td>
<td>1.68</td>
<td>1.12</td>
</tr>
<tr>
<td>GE DS</td>
<td>2.35</td>
<td>1.57</td>
<td>1.80</td>
<td>1.87</td>
</tr>
<tr>
<td>FSM</td>
<td>2.48</td>
<td>3.03</td>
<td>2.19</td>
<td>2.83</td>
</tr>
<tr>
<td>Fuji Profect CR</td>
<td>4.26</td>
<td>3.29</td>
<td>3.52</td>
<td>2.65</td>
</tr>
<tr>
<td>Agfa CR 85-X</td>
<td>5.03</td>
<td>4.88</td>
<td>2.20</td>
<td>3.15</td>
</tr>
<tr>
<td>Kodak CR (EHR-M2)</td>
<td>5.34</td>
<td>5.45</td>
<td>3.03</td>
<td>3.74</td>
</tr>
<tr>
<td>Test CR</td>
<td>11.5</td>
<td>9.90</td>
<td>5.96</td>
<td>5.63</td>
</tr>
</tbody>
</table>
5.2.6.2 Recall for technical reasons

The available data from the DMIST study, two European population-based screening programmes and four evaluations of DDR in routine breast cancer screening in England indicate recall rates for technical reasons are within the NHSBSP and CSBS standard of <3% of total examinations (Pisano et al., 2005b; Vigeland et al., 2007; Bonardi et al., 2006; NHS Cancer Screening Programmes, 2006d; 2006e; 2006g; 2006d).

5.2.6.3 Referral for further assessment

The NHSBSP and CSBS standards for referral for further assessment are expressed as percentages for prevalent and incident screen (Clinical Standards Board for Scotland, 2002). In the population-based prevalent round screening of women aged 50–69 years in Norway, the recall rate due to digital mammography findings was 4.1% (Vigeland et al., 2007). The corresponding NHSBSP and CSBS targets for prevalent screen are <7% and <10% respectively.

Following third round screening in Oslo II, 4.3% of women aged 50–69 years were referred for further assessment as a result of digital mammography findings (Skaane et al., 2007). The NHSBSP and CSBS targets for the incident screen are <5% and <7% respectively.

5.2.6.4 Number of cancers detected

The NHSBSP and CSBS standards for the number of cancers detected are expressed as prevalent and incident screen (Clinical Standards Board for Scotland, 2002). The population-based prevalent round screening of women aged 50–69 years in Norway, the recall rate due to digital mammography findings was 4.1% (Vigeland et al., 2007). The corresponding NHSBSP and CSBS targets for prevalent screen are <7% and <10% respectively.

The prevalence of ductal carcinoma in situ (DCIS) detection rate of 0.21% (2 in 1,000) in women aged 50–69 years (Vigeland et al., 2007). The prevalent screen detection rate for invasive cancers was 5.6 in 1,000. Data from the 50–69 years subgroup in Oslo II correspond to an incident (third round) digital mammography screen detection rate of 5.7 in 1,000 for invasive cancers and 2.2 in 1,000 for DCIS (Skaane et al., 2007). Oslo II found no statistically significant difference in the interval cancer rate overall (both age groups). No data were identified to evaluate digital mammography against the standards for the number of small (<15mm) invasive cancers detected.

5.3 Use of prior film images in mammography screening and assessment

A subgroup of the HTA topic group raised the issue of whether or not prior film images should be used in reading once digital mammography is available. Prior images are those which are taken at previous breast screening sessions. During the first 3 years following the implementation of digital mammography, prior images will be available on film practical difficulties will need to be overcome in order to view them alongside digital images (see Section ). However, after 3 years of implementation the issue will not arise as prior digital images will be available for most women and can be readily used in image reading. In the current film-based screening environment, image readers use prior images along with current images for reading and interpretation. The European Commission suggests the use of prior images when reading current mammograms since it is thought to increase cancer detection and reduce recall rates for assessment (European Commission, 2001). This section explores the evidence regarding the use of prior film images in screening and in assessment clinics. A later section on organisational issues considers the use of prior film images in the SBSP based on this evidence (Section 8.10.1) and looks at the option of digitising prior film images (Section 8.10.2).

The search strategies identified 590 abstracts. Irrelevant titles and abstracts were excluded and 20 articles that studied the use of prior images in mammography screening and assessment were retrieved and evaluated. Of these, 10 articles met the inclusion criteria and are summarised in Appendix 3. Nine articles were excluded: two studies considered CAD and its performance when used with current and prior images in mammography, and seven articles were comments and letters in response to the three of the original articles included and one article was in relation to prior images with ultrasound. Studies included were retrospective or observer studies where mammography reports are retrospectively reviewed. The results of individual primary studies identified by this review are summarised qualitatively. No attempt was made to pool the data quantitatively due to the heterogeneity of the studies.

Use of prior images in mammography screening

The majority of the studies were conducted in FSM programs. Most of the studies showed that use of prior images does not improve cancer detection rates but does result in an increase in specificity of the screening method and a subsequent reduction in recall rates (Callaway et al., 1997; Thurfell et al., 2000; Burnside et al., 2002; Sumkin et al., 2003; Kleit & Ruiz, 2003). Although sensitivity was increased, the improvement was not statistically significant. However, some of the studies lacked the power to detect a statistically significant difference.

Sumkin et al. (2003) assessed and compared mammograms acquired 1 or 2 years previously during mammographic interpretations. The authors found that use of prior images is important for accurate diagnosis and state that ‘mammograms obtained one year previously where available should be used as a reference or the latest prior image should be used as the optimal reference’.

Roelofs et al. (2007) studied the situations where prior images were always available and when they were only available when requested by readers. Reading was carried out using digital images with prior FSM images digitised.
using a scanner. Reader performance was improved when prior images were always available (p<0.001) and when prior images were available on request (p=0.007) compared with reading without prior images. Furthermore performance when prior images were always available was better than when they were only available on request (p=0.001).

**Use of prior film images in assessment clinics**

Four relevant studies were identified. These were conducted in FSM programs and showed that use of prior images in assessment clinics improves diagnostic accuracy. Results of one study showed that comparing new images with prior images increased true-positive findings (Burnside et al., 2002). Broeders et al. (2003) showed that it is feasible to identify poor features such as architectural distortion and non-spiculated high density masses which are associated with a possible improvement in diagnosis and reduction in breast cancer. Another study where both prior and current images have been digitised and read in a soft-copy environment shows that using prior images led to a statistically significant improvement in precision when classifying masses (Varela et al., 2005). The average reading performance using prior images also increased. The authors suggest the use of prior images for routine diagnostic purposes and classifying masses to improve the decision-making process and recommend the use of prior images whenever an abnormality is suspected, to reduce subsequent examinations and improve diagnostic accuracy. The results of all the studies suggest that prior images should be used in assessment clinics.

**Costs of using prior film images**

Two studies found that obtaining prior images is expensive, time consuming, not always successful in practice and only has a positive impact on clinical management and cancer detection in a limited number of cases (Bassett et al., 1994; Wilson et al., 1996). The overall costs and time involved in obtaining prior images from other facilities are substantially higher than obtaining them from the same facility. Only 1% of the previous readings or interpretations were changed. A number of problems were encountered whilst obtaining previous mammograms. The higher costs outweighed the clinical benefits in these two studies conducted in small private sector screening sites in the USA. However, the studies were of poor quality and not directly relevant and applicable to the UK context.

**5.4 Conclusions**

The evidence shows that the diagnostic accuracy of digital mammography is comparable with that of FSM. Digital mammography meets the national standards for radiation dose and image quality. There was insufficient evidence to compare the performance of DDR with CR.

The available literature regarding the clinical impact of using prior images with current images consistently favours the use of prior images for screening and assessment in mammography. However, higher costs will be involved and there is insufficient evidence to determine whether the use of prior film images is cost effective.
6 COST EFFECTIVENESS

6.1 Introduction

Section 2 explains that the purpose of the HTA is to explore the most clinically and cost-effective way to implement digital technology for breast screening across Scotland. This section provides a review of the evidence on the relative cost effectiveness of DDR compared with FSM. No evidence pertaining to the cost effectiveness of CR compared to DDR or FSM was found.

No economic model has been conducted. This was unnecessary because the clinical evidence shows the technologies have similar diagnostic accuracy (see Section 5.2.2). In such circumstances a cost minimisation analysis is the appropriate form of analysis and this is presented in Section 9.5.

Sections 6.2.1 and 6.2.2 describe the search for evidence. Sections 6.2.3 and 6.2.4 explain the selection criteria and provide an overview of the studies. Section 6.2.5 provides evidence from service providers in England and Section presents the discussion and conclusions.

6.2 Sources of evidence

6.2.1 Literature search

Initial searches were undertaken in May 2006 to identify economic evaluations relevant to the HTA. The following databases were searched: the NHS Economic Evaluation Database (NHS EED) and the Health Economics Evaluation Database (HEED). In addition, the websites of the world’s major health economics research centres were searched for relevant economic evaluations. A report published by the Canadian Agency for Drugs and Technologies in Health (CADTH) in October 2006 (Hailey, 2006) was identified. It was decided that the cost information obtained from this publication, as well as other literature identified in the secondary searches, removed the need to search the primary literature.

6.2.2 Request to manufacturers, service operators and topic group members

In January 2007, NHS QIS wrote to the manufacturers of FSM and digital mammography machines inviting them to submit evidence for the HTA. Specifically they were asked to provide information on the cost to implement and operate their system for fixed and mobile screening sites.

In April 2007, the operator of the digital service in Exeter was invited to describe the important factors when setting up that service, including the relative costs of the systems.

HTA topic group members were also invited to submit relevant evidence.

6.2.3 Selection criteria

Studies were excluded if:

- they were not screening studies
- no data were reported on the costs and outcomes from adopting DDR technologies.

One systematic review (Hailey, 2006), published in October 2006, was included. This updated an HTA published in 2002 (Ho et al., 2002). This review contained all the relevant studies selected from the electronic search. The methodology adopted in the review was robust, giving confidence in its results. One of the main studies that contributed to the review was performed in England for the NHSBSP (Legood & Gray, 2004). The estimated costs and staff savings in that study should generalise to the SBSP. Therefore the results of the literature review can be used as direct evidence to inform decisions in the Scottish setting.

6.2.4 Overview of studies

In October 2006, CADTH updated the findings of a Technology Report first published in 2002 (Ho et al., 2002), comparing the technical, clinical and economic aspects of DDR with FSM.

The update (Hailey, 2006) drew on clinical evidence from four major comparative studies of DDR with FSM published since the original report. These were the two Norwegian based studies, Oslo I (Skanne et al., 2003), and II (Skanne & Skjennald, 2004), and two from the USA, one by Levin et al. (2002) and DMIST (Pisano et al., 2005b). Section 5 of this HTA summarises the accuracy, measured in cancer detection rates, and the recall rates, for each of the four studies.

The update noted that the two studies reported that DDR machines had higher initial purchase costs (between 1.5-4 times) and higher annual service costs, compared with those for FSM (Hailey, 2006).

A third UK study (Legood & Gray, 2004) estimated that the cost of screening 10,000 women could be about £160,000 with DDR (without hard-copy imaging) compared with FSM costs of £115,000. Thus DDR could cost almost 40% more per woman screened.

The base case in this UK study assumed clinical equivalence of DDR and FSM, and the same recall rates and throughput times for each woman screened. The DDR costs included an annualised capital charge. This was calculated from capital cost estimates made by GE Healthcare and Hologic®, two suppliers whose machines were being piloted by the NHSBSP. The costs include an element for a PACS but the report noted these may underestimate the full costs of PACS. No costs for a BSIS to store women’s records were included.

The FSM costs included an annual capital charge based on the equipment required to take, process and read conventional X-ray films. Cost estimates were made for a mobile unit with no on-board processing and for a single site with film processing, handling and reading all conducted at the same site.
Additional costs for each service included annual service contracts, consumables and storage. For the digital mammography service using DDR, the assumed staff savings were:

- 3 minutes of mammographer time per woman screened as a result of not processing films
- 45 seconds of radiographic assistant time for each set of films
- 2 minutes of administration time to retrieve and return a woman’s records.

A sensitivity analysis assumed a 25% increase in the productivity of mammographers following the introduction of digital mammography because they no longer need to process films. The resultant estimated costs of digital mammography fell to around £130,000; 13% higher than the cost of FSM (£115,000).

The study noted further research is required into the full costs of PACS systems, the additional costs and administrative staff savings from a BSIS system, the recall rates and impact on mammographers’ workload of digital mammography and the best options for implementing digital mammography including training requirements and use of film and digital images.

The update concluded that digital mammography machines provide a similar accuracy to FSM machines but at a higher cost (Hailey, 2006).

6.2.5 Review of information from manufacturers, service operators and topic group members

Four manufacturers provided capital and maintenance cost information which was commercial and in confidence and is therefore not presented in this report. Pooling these data suggests that the capital costs for a DDR machine operating in either a fixed or mobile site are about £230,000 compared with £70,000 for a CR machine. Annual maintenance costs are about £21,000 for DDR and £8,000 for CR. A topic group member with experience of purchasing FSM machines advised that these can cost up to £50,000 each depending on the precise specification (Alex Watt, Medical Physicist, Scottish Healthcare Supplies. Personal communication, May 2007).

The service operator of the Exeter fixed and mobile units advised that when it evaluated the cost of operating a digital screening service compared with a film-based system the former was no more expensive and offered additional non-financial benefits. These included:

- an improved working environment which is quieter, cleaner and paper-lite
- no films and chemicals to be handled
- a reduction in repetitive tasks enabling staff to focus on customer care
- the opportunity to trial innovative working patterns such as remote reporting and distributed reporting.

The main financial benefit was obtained by increasing the utilisation of the machines by extending the screening day to 9 hours, thereby spreading the fixed costs over a higher volume of output. Other savings were possible from lower administration costs, reduced storage space and fewer consumables (Sandra Solomon, Clinical Lead Exeter Screening Service, BDM Inhealth Group. Personal communication, May 2007).

The cost to the NHS of the digital service in Exeter is £60 per woman screened. No accurate direct comparisons are possible with the SBSP because of differences in the service delivery, particularly of quality control. However, if one deducts the costs for the central coordination role of National Services Division (NSD) from the published Scottish cost for 2005–2006 of £67 per woman screened (Information and Statistics Division, 2005) then the average Scottish costs were about £57 per women screened (David Steel, Project Manager Screening Programme, National Services Division. Personal communication, June 2007). These figures suggest that moving from FSM to digital mammography may result in similar costs per woman screened if the Scottish service is able to increase machine utilisation to levels similar to those achieved in Exeter.

The Exeter system and thus cost base do not provide a fully integrated screening, PACS and BSIS service; the additional costs of achieving such an integrated system may be reduced by further staff cost savings from, for example, having an efficient BSIS and removing the need to use CDs to store screening images. However, no estimate of the net cost is available.

6.3 Discussion and conclusions

The literature search identified a recent and robust secondary review of the literature comparing the cost effectiveness of digital mammography using DDR and FSM (Hailey, 2006). This review indicated that the overall clinical accuracy of the two screening modes was similar. Under this assumption, a cost minimisation analysis is sufficient to enable conclusions to be drawn on the comparative cost effectiveness of the two screening modes. The evidence all indicated that DDR is more expensive both in terms of initial capital costs and annual operating costs.

However, using more recent data from a service that was able to negotiate discounts on the initial capital costs and achieve a high level of utilisation of machines (9 hours per day with safeguards in place to minimise downtime), the evidence suggests that DDR need be no more expensive per woman screened than the current costs for FSM. In addition, the digital service may have other advantages especially for staff by offering an improved working environment particularly if accompanied by steps to remove many of the administrative tasks associated with client contact from the screening offices to a service provider.

In conclusion, there is limited observational evidence that DDR and FSM may have similar costs per woman screened but this is only possible if the service achieves a substantial increase in the utilisation of the machines. No evidence of the cost effectiveness of CR compared to DDR or FSM is available.
7 ISSUES FOR WOMEN ATTENDING BREAST SCREENING SERVICES

7.1 Introduction

In any large service review, it is important to consider the views of service users; in this HTA, women eligible for breast screening. A useful overview of women's perception of procedure-related pain associated with digital mammography was published by the NHSBSP in 2006. It concludes that factors which are not affected by the type of equipment have the predominant influence on pain and satisfaction in mammography (NHS Cancer Screening Programmes, 2006b).

A non-systematic review of the literature directly relevant to the HTA was undertaken. Only one study included issues for women associated with breast screening using digital mammography specifically (Liang et al., 2003). Of the women who responded to the questions relating to digital mammography in the study, exactly half reported that the procedure was 'more comfortable' than FSM; the other half reported that it was 'less comfortable'. The study is limited by the extremely small number of women responding to the questions on digital mammography. Furthermore, as the authors also note, women's understanding of the test(s) was not clear, since the comfort levels during digital mammography should be the same as during FSM.

However, the literature on breast screening in general gave an insight into the acceptability from the service users' perspective of the service changes that may arise from implementation of digital mammography. Issues explored in this section include:

- extending the hours of the service
- experience of screening on fixed centres and mobile units
- radiation dose
- women's response to repeat examinations.

A more detailed review of the literature on issues for women relating to breast screening in general is provided in Appendix 4.

With any health intervention, staff can positively or adversely influence the service users' experience and good communication is always important. Generic issues such as these and patient information and informed consent are not considered here.

7.2 Methodology

As part of the process to help define the assessment questions, an initial search for HTAs, systematic reviews and other evidence-based reports was undertaken in May 2006 and September 2006. Secondary research, identified by this search, and which discussed issues for women relating to digital mammography, was considered for inclusion in this section.

To identify the primary literature, an initial search was undertaken in February 2007. The following bibliographic databases (all via OVID) were searched:

- MEDLINE
- EMBASE
- MEDLINE in PROCESS
- CINAHL
- PsycINFO.

The search focused on identifying qualitative research and used a methodological filter published by the HEDGES team (McKibbon et al., 2006). This search identified many relevant papers, and the decision was made not to undertake any additional searches of the primary literature.

In addition, the websites DIPEX (www.dipex.org) and Electronic Quality Information for Patients - EQUIP (www.equip.nhs.uk) were also searched. Literature identified by the NHSBSP, in their breast screening literature database (www.nhs.thescienceregistry.com/search.asp?title=1) were also examined. Reference lists and bibliographies of studies were also checked for additional papers of interest.

A list of the sources searched and a copy of the strategy used to search MEDLINE is included in Appendix 2. This strategy was adapted to search all other databases. A complete listing of all strategies can be obtained by contacting NHS QIS.

There is considerable literature on the topic of women's views and experiences of mammography but studies vary extensively making direct comparisons difficult (Brett et al., 2005; NHS Cancer Screening Programmes, 2006b). Attendance at breast screening is partially dependent upon the system of health care. USA research, by the far the most voluminous, was not included when it related to how service funding may affect usage, although other USA research is reviewed. A range of different methodologies were drawn upon and included large-scale analyses using national databases and surveys of particular groups (eg ethnic groups, older women, disabled women) whilst a small number of studies used focus groups and a very few, interviews, to ascertain women's views of the service.

Studies also varied in the ways in which they measured individual behaviour, the scales and scores utilised, the age range of women approached (eg from women in their 20s to women in their 80s and 90s), and whether or not the study was prospective or retrospective. Most studies excluded women who had had breast cancer.

7.3 Results

7.3.1 Service issues

The literature on women's views of the service is extensive. Of particular relevance to this HTA are service issues such as appointment systems and convenience of access. The latest evidence about best practice and performance of
the SBSP demonstrated that it is possible to deliver services, address issues and improve attendance rates (NHS Quality Improvement Scotland, 2006).

**Extended opening hours**

It is clear from the literature that aspects of service delivery are important, although studies vary in terms of how influential are factors such as opening hours, as well as travel time and socioeconomic group on uptake and attendance. Since one of the HTA recommendations is to consider flexible working patterns such as extended hours, it is useful to review the literature relating to such changes. A study in Manchester, UK, funded by NHSBSP, assessed the effect of extended hours (offering Saturday appointments from 9.30am-12.30pm) on women who did not attend the first screening round (Readman & Asbury, 1999). Results of the trial indicate that there was no significant difference in attendance. However, elsewhere extending the hours for appointments has been successful. A Scottish pilot project examining use of extended hours for screening sessions has shown a good uptake of screening and an increase in attendance rates (NHS Quality Improvement Scotland, 2006). A study in Edinburgh found that attendance was good until 7.30 but reduced after 7.30 pm, before 9 am and on Saturday mornings. However, when patients elected to have a Saturday morning appointment attendance was improved. Additionally, anecdotal evidence from other breast screening services using extended hours is described in Section 8.9.

**Accessibility**

Studies from a number of countries and using a range of methods confirmed the overall finding that ease of access to the screening facility is of considerable importance to women (Kee et al., 1993; Sutton et al., 1994; McNoe et al., 1996; Aro et al., 2001). Women in rural areas are less likely to take up the offer of screening (Stark et al., 1997; Gram & Slenker, 1992; Maxwell, 2000). In a Scottish study, Kohli et al examined travel time and women’s attendance at an assessment centre over a 12-month period. The authors found that the costs of attending the centre were on average, high (Kohli et al., 1995). They found that for the attendees, travel time and distance were considerable (average return journey 21.5 miles and 1.73 hours), mean costs were £6.06 (1995 prices) and there was a need for multiple journeys (2–6 journeys). The researchers noted that actual costs to the attendees are often not factored into overall costs of service reorganisation but that health services planners should not forget to take these costs into account when reorganising services.

Some authors conclude that convenience is only one of a number of influential factors. For example, when the service was moved in Bolton, Maxwell studied changes in attendance patterns and concluded that although there was a direct relationship between attendance and distance to the unit, the most significant factor affecting attendance rates was socioeconomic group, with the highest rates among women in the least deprived areas (Maxwell, 2000).

**Screening experience on fixed centres and mobile units**

Overall, women report considerable satisfaction with mobile units, although they do report a different screening experience. Two focus group studies report women’s views of mobile units (Skinner et al., 1995; Hamilton et al., 2003). In the UK study, women had attended either a mobile unit, a hospital-based unit or a temporary site in a health clinic, thus allowing for some comparisons in location (Hamilton et al., 2003). The authors commented that an unexpected finding was that those women who had experienced both the hospital and mobile unit preferred the mobile unit (seen as more cosy, easy to locate and personal) although the women acknowledged that space was limited and there was little privacy to ask questions or discuss sensitive issues. Skinner et al explored the impact of introducing mobile units into their USA programme (Skinner et al., 1995). The mobile units were seen as acceptable if women’s concerns were addressed, notably about privacy and quality. Concerns about privacy were two-fold; some women did not want to be seen entering or exiting the unit, whilst others wanted to be reassured about privacy during changing and being examined. The quality issues were about the equipment and the staff being the same standard as in a fixed centre. Convenience was rated highly but again with a qualifier, that the unit was parked in an appropriate health-related venue.

Engelman et al. (2005) reported that women liked the facility to be pleasant and welcoming and saw the waiting time as an opportunity to be provided with educational materials. Prolonged waiting time was seen as negative, especially waiting whilst undressed.

With DDR, time will not be required for processing films and consequently radiology staff may have more time to interact with women during the appointment.

7.3.2 Dose of radiation

Fear about radiation was reported by women in a number of studies as a concern (Ahmed et al., 2005; Bobo et al., 1999; Zapka & Berkowitz, 1992). It did not necessarily prevent women attending for screening but it is important that women are told of the lower dose of radiation with some digital technologies.

7.3.3 Repeat examinations

As discussed in Section 5, digital mammography enables immediate access to and assessment of images. This means that the image quality can be checked at the screening appointment, reducing the number of women who are recalled for a second mammogram due to technical problems with the first. Literature was identified exploring the effect of recall on women, however it related to recalls due to mammography abnormalities that were subsequently identified as false-positive results.

Brett et al. (2005) systematically reviewed the literature relating to the impact of being recalled for further tests.
where a diagnosis of breast cancer was not reached. They concluded that women recalled as a result of a false positive are reported to experience anxiety although the literature does not contain agreement about the length and degree of anxiety created by being asked back for further investigations. The authors also noted conflicting evidence as to whether undergoing further testing has an impact on future attendance at breast screening. Ong & Austoker (1997) found in their UK study of recalled women that communication was very important; talking to someone just before the tests was valued, especially by those women who reported distress.

The number of false positives with digital mammography does not differ significantly from that with FSM (see Section 5.2.2). Therefore, the impact of recall for further investigation because of a false-positive result from a screening mammogram is of no more or less relevance for digital mammography than for FSM. The effect of technical recalls on women is unknown. However, it is probable that recall for any reason has the potential to cause women inconvenience and anxiety. Additionally, it will lead to additional travel costs for women, particularly for those living in rural locations, who may need to attend at a fixed unit for recall. A reduction in technical recalls as a result of digital mammography is therefore likely to be welcomed.

7.4 Conclusions

The literature suggests that innovative service developments, such as taking the service to those in different areas (both inner city and rural) and offering extended hours for screening would be acceptable from the service users' perspective. Such innovative aspects should be piloted with relevant populations. Mobile units are favourably received but attention should be paid to privacy issues and location of the unit. The reduction in radiation dose with some digital technologies and the reduced likelihood of technical recall will also benefit women.
8 ORGANISATIONAL ISSUES

8.1 Introduction

A subgroup of the HTA topic group (see Appendix 1) was convened to consider the specific organisational issues relating to the introduction of digital technology as a component of the breast screening programme. In addition to the advice provided by the group, evidence was sought from the literature and opportunities to learn from established breast screening programmes elsewhere in the UK were explored.

The equipment required for implementing digital mammography in breast screening consists of the modality (image capturing equipment), a BSIS and a system on which to store and retrieve images (PACS). These are discussed in Sections 8.2, 8.4 and 8.5 respectively. Additionally Section 8.3 describes the overall information management and technology (IM&T) requirements for digital mammography. Image interpretation and reporting are considered in Section 8.6 and accommodation requirements for equipment in Section 8.7. The remaining sections then consider issues raised by the subgroup concerning the implementation of digital mammography: service location (Section 8.8), scheduling machine use (Section 8.9), use and storage of prior images (Section 8.10), workforce issues (Section 8.11) and implementation (Section 8.12).

8.2 Digital image capturing equipment

This section considers digital image capturing equipment required for mammography screening. CR technology is considered in Section 8.2.1, DDR in Section 8.2.2 and the two technologies are compared in Section 8.2.3. The additional equipment required to support digital technology is described in Section 8.2.4 and quality assurance (QA) requirements are considered in Section 8.2.5.

8.2.1 CR technology

CR machines retain some of the advantages and disadvantages of FSM in that they use imaging plates. Advantages involve the cost saving of not needing to purchase X-ray equipment and the similarity in the way that the plates are used during the woman's examination. However, the plates still need to be handled by the equipment operators and mammographers will need to leave the screening room in static centres if CR readers are shared between X-ray machines. Thus using CR may prove more time consuming than using DDR machines, and could lead to a longer appointment time per woman. The reliability of the plates is not yet known and, due to their degradation over time, some manufacturers have already recommended regular replacement. This is costly both financially and in terms of staff time.

Currently, Fuji is the only manufacturer of a CR machine that has been both technically assessed and clinically evaluated (NHS Cancer Screening Programme, 2006a). However, the machine has been evaluated in assessment clinics and not yet for routine screening. Machines manufactured by Kodak and Agfa have proven technically adequate (NHS Cancer Screening Programme, 2007d; 2007e), but have yet to be clinically evaluated.

In Scotland, a Fuji CR machine is being used in the west of Scotland screening service for all women attending assessment clinics, following its successful evaluation (NHS Cancer Screening Programme, 2006a). CR is also being used in the north of Scotland service. In the Derby breast screening service a CR machine has been piloted on a mobile unit (that moves regularly) since May 2007 and staff have found the system reliable and straightforward to use. The machine was developed by Fuji specifically to meet requirements for mobile use. The Derby service is planning to install CR in preference to DDR on all mobile units as it perceives CR to be less sensitive than DDR to movement and changes in temperature (Karpal Hayer, Service Manager, Derby Breast Screening Service. Personal communication). It is understood that CR machines have also been successfully piloted on a mobile unit that moves regularly in the Netherlands. However, the Irish Breast Screening Service (IBSS) ruled out the use of CR in either fixed centres or mobile units on the grounds that it would confer no work advantage compared with DDR.

8.2.2 DDR technology

DDR offers an improved workflow compared with FSM, with the advantage of reducing repetitive activity such as film cassette handling. Current users of digital mammography have found that this can shorten appointment times by about one minute (Matthew Wallis, Director and Sharon Hofmeister, Senior Radiographer, Warwickshire, Solihull and Coventry Breast Screening Service. Personal communication). Some technical evaluations of DDR technology reported a longer appointment time (see Section 5.2.5), however the appointment time reduced for some technologies following software improvements and it is likely that mammographers will take less time once fully familiar with the new equipment. To support two-view mammography Scotland has recommended that appointment times are increased by one minute and this has been borne out in practice by services undertaking two views (Matthew Wallis, Director and Sharon Hofmeister, Senior Radiographer, Warwickshire, Solihull and Coventry Breast Screening Service. Personal communication). If both two-view mammography and DDR are introduced there may be little overall change in the current appointment length. In Exeter appointments using DDR for two-view mammography last 6 minutes and in Coventry 5 minutes. DDR therefore has the potential to increase the throughput of women per clinic. Furthermore, staff in the Coventry service have found that, regardless of the shorter appointment time, more time is available for mammographers to interact with women with DDR since they do not need to leave the room.

DDR equipment is temperature sensitive and may need to be left on overnight to keep the detector at the correct temperature or would otherwise require time to warm up and for calibration when switched on (calibration is required every time the equipment is switched on). Failure
to maintain a suitable temperature can cause significant detector damage with some machines. Some DDR machines may also be more sensitive to motion than FSM machines. In Scotland, around 80% of screenings are carried out on mobiles that are moved regularly and it is important that machines are able to withstand movement and the extremes of Scottish weather.

To date, four DDR machines have been clinically evaluated in routine breast screening: the Sectra microdose full-field X-ray machine with Sectra breast imaging PACS; the GE Senographe 2000DD; the Hologic Selenia; and the Siemens Novation (NHS Cancer Screening Programmes, 2006; 2006c; 2007g; 2007i). Results of these evaluations are summarised in Section 5.2.5.

DDR is not available currently in any Scottish screening units, but is used in a few screening units elsewhere in the UK and Europe. It was chosen as the preferred option by the IBSS and the Exeter screening service. The Exeter service has successfully used a DDR machine for over a year on a mobile unit that moves regularly and found it to provide excellent reliability.

8.2.3 Comparing CR and DDR

The available evidence for CR and DDR compared with FSM is reviewed in Section 5.2 and Section 6. This suggests that both technologies are at least as effective as FSM. Additionally there is evidence to suggest technical recall rates will be reduced with digital technology.

Insufficient evidence was available to compare the clinical effectiveness of DDR with CR. Other advantages of DDR compared with CR include an improved workflow, the potential for a shorter appointment time and a lower radiation dose with some digital machines (NHS Cancer Screening Programme, 2007e). However, the radiation dose will depend on the manufacturer and the process of optimising image quality and dose that each system undergoes. Manufacturers have suggested that making full use of software options may further reduce the radiation dose while preserving image quality. CR currently has the advantage of a cheaper capital cost than DDR (see Section 9.5). It may also be more robust to temperature and movement fluctuations on mobiles, require fewer adaptations for installation on mobile units (see Section 8.7) and it can be used with X-ray units for existing FSM equipment.

The decision between technologies should be made by an implementation group (see Section 8.1.2) and should take into account: the relative technical qualities and ergonomics of each modality; whether the machine is to operate on a fixed or mobile unit; operating patterns; experiences of users of digital mammography (including the symptomatic service); costs; the management of periods during which mixed technologies will be used; and any new evidence becoming available including revised costings. Information on ergonomics of several digital machines is provided in a report published by the NHSBSP (NHS Cancer Screening Programme, 2007f). The Royal College of Surgeons Breast Radiology Big 18 Group has recently recommended that DDR equipment is used to replace FSM equipment in England (Hilary Dobson, Clinical Director, West of Scotland Breast Screening Service. Personal communication).

8.2.4 Additional equipment to support digital technology

Two types of workstation are required for digital mammography: an acquisition workstation where the mammographer can immediately view the image and a high specification reporting station where the images are interpreted (see Section 4.2.2). Although the true potential of digital imaging will only be achieved in a paper-lite environment (eg saving cost of film and reducing storage), hard copies may be required initially to transfer images to symptomatic units. Therefore a high resolution laser printer capable of providing a true representation of the soft-copy image is required at each screening centre.

8.2.5 QA for digital technology

A robust QA system underpins the success of the current breast screening programme. This is no less the case for digital modalities, with the increasing complexity of the equipment. Many of the routine QA tests are analogous to tests on FSM systems, so that once staff are familiar with the equipment, the QA process may not take significantly longer. Operators may experience problems with image display due to the infrastructure for uploading images. Initially staff will require training and, for some systems, changes to technique for positioning before they are able to use digital technology successfully. A significant investment of time will be required initially to set up testing protocols, redesign software to monitor the QA results and develop the medical physics expertise to commission and support the QA system. The Exeter service found that it took staff about 1 month to become trained. Furthermore, based on the experiences in the DMIST trial (Pisano et al., 2005b), alternative QA tests which aim to reduce time and costs have been proposed (Hailey, 2006). The NHSBSP has published a set of routine quality control tests for digital mammography systems (NHS Cancer Screening Programme, 2007b). In addition, evaluation of the performance of all soft-copy display devices against manufacturer’s and DICOM, HL7 and IHE (http://ihe.net/Mammo/) specifications will be required, which will add to the workload, due to the large number of monitors required.

8.3 Overview of information management and technology (IM&T) requirements

This section provides an overview of the IM&T requirements for the implementation of digital mammography. The BSIS will contain facilities for administration, data entry at reading and the compilation of statistics. The PACS will be used to store mammograms and will be physically separate. The BSIS should be fully integrated with the PACS at or soon after implementation and the two systems must then function as a single package of technology from the user’s viewpoint. Both the
BSIS and PACS are expected to take at least 2 years to develop. Therefore work on their specification must be started at the earliest opportunity. It is recommended that an IM&T subgroup of the implementation group (see Section 8.12) is formed to work out specific details of how to meet the requirements. The overall system (BSIS integrated with PACS) is required to perform several complex functions. These include:

- link to the CHI database (measures should be in place to ensure that a woman's unique CHI number is used)
- call/recall of women
- map attendances to available mobile units and fixed centres to optimise use of machines
- integration of BSIS and PACS forming a single electronic breast screening record for women
- provide information about women required for screening on mobile units
- record informed consent for biopsies
- facility to store and recall mammograms so that all mammograms per woman required for reading are recalled within 1 second (eight images on implementation of two views)
- facility to transfer mammogram images between mobiles, fixed centres and hospitals at adequate speed and in a secure manner
- facility to print images
- provision for reporting of image reading results in a manner to suit the image reader workflow/requirements (eg provide for double reading and arbitration, text edits and possibly voice recording)
- inform necessary parties of results, invite referrals and refer women into existing pathways for those with breast cancer symptoms
- provide area and national statistics and performance indicators (eg for the British Association of Surgical Oncology [BASO] and other annual reports)
- provide risk management systems to, for example, ensure all images are read appropriately and arbitration takes place when necessary
- provide a high level of security and robust backup facilities. Anti-virus measures should include the implementation of regularly updated detection and recovery software.
- comply with information governance requirements in terms of access to data and confidentiality. Electronic transmission and storage of digital images incurs a risk of compromising data security and breaching confidentiality. It will be essential to ensure that policies are in place to avoid this.

8.4 The Breast Screening Information System (BSIS)

The administrative functions required by the BSIS (detailed in Section 8.3) are the same as the current Scottish information system (see Section 4.2.4). Much of the information contained within the BSIS is also required by the PACS, for example the PACS will need to know which examinations have been entered on the BSIS so that an appropriate entry can be made in the PACS database. Additionally it is important that historical records made on the current information system may be transferred to the BSIS.

At the time of writing, the English National Breast Screening System (NBSS) was not integrated with a PACS for digital mammography. It is understood that a link with a PACS is being piloted with five suppliers of digital mammography modalities. From this, a specification for a generic link will be drawn up and this would become a requirement for all digital mammography modalities. It is expected that the NBSS integrated with PACS will be available for piloting within the next few months. However, some technicians voiced concerns as to whether integration between PACS and NBSS would be feasible.

The IBSS has built a PACS onto its existing bespoke administrative system (MBSP). Although the process has not been without problems, the digital functionality can now be used on three different machines in Dublin. The IBSS looked for a common environment to allow the interaction between different digital modalities, workstations and the administrative system. The next release of the MBSP (2.18) will supply that common environment and provide the basic functionality throughout the service.

It is understood that a digital service with an information system integrated with PACS is used in Sweden. The information system was developed by Sectra who supplied the digital mammography modalities. In the Netherlands an integrated information and PACS system provided by Fuji ("Synapse") is used with Fuji CR machines.

The SBSP should consider the options of:

- designing and developing a new purpose-built information system specifically to meet the needs of the SBSP
- adapting the current SBSP information system
- purchasing and adapting the system used by another breast screening service already implementing digital mammography.

Developing a BSIS suitable for the SBSP is likely to be complex and expensive and may take several years. Therefore implementation work should be started at the earliest opportunity.

8.5 Picture Archiving and Communications System (PACS)

A PACS is a necessary component of a digital mammography screening service and should be piloted prior to the full implementation of digital mammography. Where possible, FSM machines should not be replaced until the IM&T infrastructure is in place, however in some situations interim arrangements may need to be made to allow limited use of digital technology prior to the availability of the national PACS.

PACS is currently being rolled out throughout Scotland as part of a national initiative, following testing at two hospitals in Glasgow (Southern General Hospital and Victoria Infirmary). Images are stored in a central image archive in Livingston, backed up in Edinburgh. An NHS network is being implemented concurrently with the PACS.
rollout to enable connectivity through Scotland (N3 network).

It is recommended that a PACS is provided at each screening centre with images stored in the central image archive at Livingston. These PACS should be part of the national PACS but with specific characteristics to suit the requirements of the SBSP. Images taken at both screening sessions and assessment clinics should be stored, including ultrasound and stereotactic images. The specification should take account of the need to share images with the symptomatic service. Additionally where the screening and symptomatic services are co-located, the logistics of saving images onto different PACS (i.e. breast screening PACS and national PACS for general radiology) will need to be considered. Alternatively there may be advantages to storing all mammography images (including those from the symptomatic service) on the breast screening PACS, with the option to copy symptomatic images to the PACS for general radiology.

The specification of a national PACS for breast screening will be complex and is beyond the scope of this HTA. It is anticipated that the system may take up to 2 years to develop. It is therefore recommended that its specification is started at the earliest opportunity by an IM&T subgroup of the implementation group. Some requirements for the SBSP PACS are described in the following sections.

**Image storage**

Once transmitted to a PACS, images should be stored in a central data storage unit. Consideration should be given to the length of time that the SBSP need to store images as this would need to be built into the PACS. At present, breast screening images must be stored for at least 9 years. Storage space can be saved by compressing images and various approaches have been developed to do this. It is suggested that for images taken at the latest screen, loss-less compression algorithms (which fully preserve the image of the breast, but not the surrounding area) should be used. After this, previous images are less likely to be required and so lossy algorithms (which do not completely preserve the original image of the breast) may be sufficient. However, further work is required to determine whether the quality of images obtained following lossy compression is sufficient. Images may be deleted after 9 years.

Images are processed once taken and manufacturers often implement this in different ways (see Section 4.2.2). The appearance of images viewed may vary depending on the type of processing and the workstation used to view the image. Additionally it should be borne in mind that CAD software to aid reading requires access to unprocessed images, although the use of this technology is not currently recommended. It is usual to store only processed images and this is likely to be the approach taken initially. However, for the longer term, consideration should be given to methods for standardising image processing or alternatively to storing unprocessed images in addition to processed images if costs are not too great.

**Format for images**

PACS requires image data meet DICOM, HL7 and IHE (http://www.ihe.net/Mammmography/) standards. An NHSBSP evaluation in Coventry found the DICOM standards very comprehensive and not easy to implement. Interface software to perform the DICOM conversion would be a good long-term solution but too complicated and time consuming for an interim solution. HL7 is a much simpler protocol and was used for the interface in Coventry. Full details are given in NHSBSP Equipment Report 0601 (NHS Cancer Screening Programmes, 2006d). The IHE has recently developed standards for integrating various parts of a digital IM&T mammography system.

**Image size**

Owing to the number of images generated and the size of the image files, mammography creates large amounts of image data. Different imaging modalities produce images requiring different amounts of data for their representation. In order to calculate the amount of storage required for a PACS, the data on the typical image sizes for each modality can be used (Turner et al., 2002). The image file sizes produced by a representative range of machines currently available in the UK are summarised in Table 8-1.

Table 8-1 Digital mammography image sizes

<table>
<thead>
<tr>
<th>Pixel pitch (µm)</th>
<th>Max image size 18 x 24cm</th>
<th>24 x 30cm</th>
<th>Average²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fuji CR¹</td>
<td>50</td>
<td>33</td>
<td>55</td>
</tr>
<tr>
<td>GE Senographe DS²</td>
<td>100</td>
<td>9</td>
<td>–</td>
</tr>
<tr>
<td>GE Senographe Essential</td>
<td>–</td>
<td>–</td>
<td>14</td>
</tr>
<tr>
<td>Hologic Selenia²</td>
<td>70</td>
<td>17</td>
<td>27</td>
</tr>
<tr>
<td>Sectra Microdose²</td>
<td>50</td>
<td>–</td>
<td>48</td>
</tr>
<tr>
<td>Siemens Novation²</td>
<td>70</td>
<td>–</td>
<td>27</td>
</tr>
<tr>
<td>Giotto Image MD³</td>
<td>85</td>
<td>11</td>
<td>20</td>
</tr>
<tr>
<td>Planmed Sophie Nuance³</td>
<td>85</td>
<td>11</td>
<td>20</td>
</tr>
</tbody>
</table>

¹Lawinski et al., 2004  ²Lawinski et al., 2005  ³8.7% of images at larger size based on data in Young et al., 2005a
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With the equipment currently available, the size of a single image is in the range of 9 MB for the GE Senographe 2000D or Senographe DS to 55 MB for a 24x30cm 50µm CR image. GE has developed the Senographe Essential to provide a larger field of view and it is probably more realistic to regard its image file size of 14 MB as the likely practical minimum.

The largest file size listed above is that of a 24x30 cm image obtained by 50 µm resolution CR. However, a review of doses in NHSBSP in 2001 and 2002 found that, on machines equipped with both film sizes, only 8.7% of images were obtained using 24x30 cm film. If this percentage is maintained, the average image size from 50 µm CR would be approximately 41 MB and the effective maximum file size from current machines would be 48 MB (Sectra Microdose). With two-view mammography, this equates to a volume of data per woman screened of 56–192 MB for prevalent screen. A decision to employ two views at all screening rounds would result in 56–192 MB per woman at every screening round. Images for larger women are likely to generate a larger volume of data. The number of such women is likely to increase in the future with obesity recognised as an epidemic in Scotland. However, the additional data requirement has not been taken into account in the following calculation. The mammography modalities eventually chosen will have a significant effect on the data volumes produced by the programme.

Calculation of the total data volume that would be produced annually in the SBSP if digital mammography were to be fully implemented requires an estimate of the size of the screened population. In 2005–2006 a total of 159,847 women were screened. An estimate of numbers screened per annum for the years 2007–2010 is shown in Table 8-2 based on population estimates and an assumed uptake of 72% with 8% self-referral.

The PACS should be built to meet the needs of the assessment clinics as well as screening and should make provision to store ultrasound and stereotactic images. Of the total number of women screened, it has been estimated that approximately 6% will be recalled for assessment and that this will involve a further two images on average. Ultrasound images and stereotactic images for some will also require to be archived. Stereotactic images range in size from 1–3.7 MB (or 14.7 MB in high resolution). However, these images are smaller than digital mammograms and the numbers involved are low; the total data volume involved is almost certainly less than the uncertainty in the following estimated totals but could be assessed more precisely if required. The likely range of total data volume per year for the SBSP is shown in Table 8-3. The volume of data required is similar to that for all radiology in Greater Glasgow & Clyde NHS Board which is between 30–35 TB per year.

**Transfer and sharing of images**

Ready access to all images in the SBSP should be provided between the six screening centres and symptomatic services in hospitals (including pathology services and operating theatres). The PACS and BSIS should retrieve only images relating to mammography and not other images that may be stored for women. Similarly breast screening images should not be automatically retrieved from the PACS for general radiology when women attend radiology for other reasons. PACS systems in hospitals will need to take into account the additional requirements for transferring and viewing screening images. This will also need to be built into any business plans to co-locate screening and symptomatic services.

A network for the PACS will transport the images from the servers or modalities to the displays and the data storage unit. The design of the network can greatly affect the speed at which images can be transferred and retrieved.

**Table 8-2 Estimate of women screened per year by the SBSP**

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>168,000</td>
<td>170,000</td>
<td>172,000</td>
<td>175,000</td>
<td>170,000</td>
</tr>
</tbody>
</table>

**Table 8-3 Estimated volume of data produced per year by the SBSP**

<table>
<thead>
<tr>
<th>Description</th>
<th>Number of women per year</th>
<th>Minimum data volume per woman (MB)</th>
<th>Maximum data volume per woman (MB)</th>
<th>Minimum total data volume per year (TB)</th>
<th>Maximum total data volume per year (TB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number screened</td>
<td>170,000</td>
<td>56</td>
<td>192</td>
<td>9.5</td>
<td>32.6</td>
</tr>
<tr>
<td>Multiple images (1%)</td>
<td>1,700</td>
<td>56</td>
<td>192</td>
<td>0.095</td>
<td>0.32</td>
</tr>
<tr>
<td>Assessment (6%)</td>
<td>10,200</td>
<td>56</td>
<td>192</td>
<td>0.57</td>
<td>1.92</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>10.17</strong></td>
<td><strong>34.84</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Specialist hardware is required for networks to function. The bandwidth (the amount of data that can be transferred in a given time) should be sufficient to transport the image data at a satisfactory speed. For film reading it will be necessary to retrieve all images for a woman from the PACS within 1 second (four images per women initially on implementation, and eight images after 3 years when digital mammography images from a previous screen become available). Current images will be available on the local centre PACS but prior images will need to be retrieved from the central image archive. Additionally, when remote reading is undertaken, batches of images from a screening session (with eight images for up to each of 50 women) will need to be transferred between centres or hospitals. However, these batch transfers will not usually need to be carried out at speed and could sometimes occur overnight. The transfer of images from the SBSP to the symptomatic services is expected to represent only a small volume of data. It is expected that availability of prior images on the PACS will lead to a reduction in cost as there will eventually no longer be a need to send film packages between centres or to symptomatic services.

8.6 Image viewing and reading

The image viewing equipment required for screening and image reading has been described in Section 4.2.2. 8.6.1 Image viewing during screening

A monitor should be available to radiographers during screening sessions in fixed centres and mobile units. It has been suggested that these monitors have a resolution of at least 3 megapixels. This will allow the technical quality of images to be assessed before the woman departs, greatly reducing the need for technical recall and hence conferring a major advantage of using digital mammography. A monitor should always be available in the screening room and sometimes it will be beneficial to link to an additional monitor outside the room so images can be viewed whilst other women are screened.

8.6.2 Image reading

Two high resolution monitors are required for image reading. With digital mammography systems, results can be recorded electronically by being entered directly into a BSIS via a computer keyboard, key pad, personal computer screen touch pad or a dedicated input device or bar code reader. The reporting system should incorporate:

- reasons for technical recall
- instructions for administration staff
- the type and area of suspected abnormality
- actions or further investigations at assessment
- annotated comments on features
- facility to mark up the images on screen (eg to indicate areas for review).

Any annotations on images (including prior images) should be saved in the PACS with the image. However, they should not automatically be made visible to subsequent readers. The reading software should allow image readers flexibility in how they look at images but have a fixed protocol/format for data entry so that data are stored in a consistent manner across the SBSP. There should be robust safeguarding procedures for ensuring that results are entered correctly.

The implementation group (see Section 8.12) should establish a detailed specification for image reading and reporting requirements.

8.6.3 Computer-aided detection (CAD)

A full assessment of CAD is beyond the scope of this HTA. However, once digital mammography is implemented, it will be possible to use CAD software. It analyses digital images using pattern recognition programs to identify abnormal areas of mass, density or calcifications that may indicate potential malignancies, and flags up these sites to the reader for further analysis. CAD may be a useful way to obtain a second opinion and thus improve diagnostic accuracy. Furthermore, in the future, the use of a single reader plus CAD may be of sufficient accuracy to reduce the need for double reading. A recently published technology assessment did not recommend CAD as an adjunct to an image reader (Blue Cross Blue Shield Association, 2006). This was also the conclusion reached by a large trial published recently (Fenton et al., 2007). It is not currently recommended that CAD is used but a full assessment of the evidence available should be considered in the future.

8.6.4 Shared image reading

One of the advantages of digital mammography is that the electronic availability of the image enables image reading to be carried out at different centres and in other locations. The Exeter service is planning to pilot home reading, however appropriate access and confidentiality restrictions would need to be in place if this was to be considered for the SBSP. Shared image reading has several benefits, some of which are outlined:

- helps to alleviate peaks and troughs in work resources due to periods of unplanned leave and vacancy
- facilitates sharing of teaching cases
- facilitates seeking third opinions
- facilitates remote QA
- flexibility in the pairing of readers is possible (this may have the potential to reduce recall rates for assessment)
- enables flexible working and makes extended hours feasible
- reduces the problems of insufficient films available at the end of some sessions for certain readers and will eliminate hanging/turnaround times.

8.7 Accommodation

Digital mammography modalities, particularly DDR machines, are sensitive to changes in temperature meaning that room temperature needs to be kept within a strict range. Therefore greater cooling and heating will be
required for digital machines than for FSM machines. The energy needs and planning of the environmental control systems and equipment layout require careful consideration (NHS Cancer Screening Programmes, 2006d).

There are particular requirements for rooms where PACS reporting workstations are sited and for the general areas where the clinical workstations will be. Printers and workstations will all require space, together with power supplies and network connections. PACS servers and image data archives will have special housing requirements regarding temperature, humidity and access control (Turner et al., 2002).

A suitable reading environment must be created to optimise viewing conditions for soft-copy reporting. With soft-copy viewing, brightness of the display is far less than that of the conventional view box for FSM. Ambient light levels should meet current standards and any reflections on monitor screens should be eliminated (Ho et al., 2002). Simultaneous viewing of hard- and soft-copy images will be needed in the short term until prior digital images are available. Some image readers using digital mammography have reported that a small dental screen is sufficient for viewing prior images. These image readers often only considered it necessary to view prior film images when a digital image did not provide a clear-cut result. This is considered further in Section 8.10.

There will be additional accommodation considerations for mobile units. Existing mobile units will need to be stripped of FSM machines and adapted to accommodate digital equipment. Changes to the floor plan may be required to accommodate the equipment and should take into account the weight of new machines and the implications of shorter appointment times (eg more changing and waiting facilities may be required). However, it is expected that fewer changes will be necessary for installing CR compared with DDR. In the Derby Breast Screening Service minimal changes were required to install CR machines on a mobile unit previously equipped with FSM (Karpal Hayer, Service Manager, Derby Breast Screening Service. Personal communication). Greater control of temperature fluctuations will be required, particularly for DDR machines, and digital machines must be able to withstand regular movement. Digital technology requires more power than FSM systems and the power must be on constantly for some modalities, necessitating the use of an extractor fan to expel heat from electrical components and possibly upgrading the power supply. Consideration should be given to the placement and specification of generators and air extractor fans to provide minimum disturbance to those working on the mobile and to residents and businesses in close proximity. The use of overnight generators has caused local complaints in the past.

Mobile units in Scotland are not in general connected to power supplies, landline telephones or computer networks. Images resulting from digital mammography may be transferred to fixed centres using compact discs or portable hard drives and this has proved successful in other services (for example Exeter). A computer connection would enable staff to access information available on the BSIS and PACS. However, there may be security/confidentiality issues to consider if images were transferred by broadband, wireless or satellite connections. Due to the difficulties currently experienced by the SBSP in finding appropriate sites for mobile units it would not be practical at present to consider relocation so that such connections were available. However, it is suggested that the relocation of mobile units is considered in the future.

8.8 Location of services

8.8.1 Screening centres

Currently there are six breast screening centres in Scotland (see Section 4.1) each consisting of a fixed centre and several mobile units. The fixed centres provide facilities for screening, assessment clinics, film reading and administration for the screening unit. However, the north of Scotland screening service provides assessment remotely outside the centre. Women with abnormal mammograms are recalled to attend assessment clinics. These carry out further diagnostic testing on women (biopsy, cytopathology, pathology and further imaging) and recommend further treatment within the symptomatic service (located in hospitals).

The subgroup considered whether the introduction of digital mammography provided reasons to consider altering the current complement of six screening centres. It was concluded that assessment clinics were an important part of the work of the fixed centres and that overall there were likely to be no benefits in changing the location of centres even when digital mammography was implemented. Fewer centres would mean some women attending for assessment would need to travel further and this was unlikely to be acceptable (see Section ). The possibility of combining administrative services into a central unit was also considered but dismissed. Centres would still require administrative staff on site for assessment clinics and centralising other administrative functions could cause a lack of coordination in scheduling screening sessions between clinical and administrative staff, while providing a relatively small cost saving. There may still be benefits in outsourcing letter sending to a central site, however this is unrelated to the implementation of digital mammography and therefore not considered.

8.8.2 Co-location of fixed centres with symptomatic services

There may be advantages in co-locating assessment clinics with the symptomatic service. There is potential for sharing of equipment and a reduction in travel time for staff working in both services. However, an agreed allocation of utilisation between the services would be required based on clinical demand and the targets to be met by each service. Additionally agreements will need to be in place relating to administration, maintenance, breakdowns, QA issues, image storage, etc. The decision
to co-locate will be influenced by practical and local considerations such as capacity requirements, site issues, operational details, funding streams and regional planning requirements.

Co-location is already working effectively in the east of Scotland and north of Scotland centres and three of the remaining centres are developing business plans to co-locate in the future. Some of the advantages and disadvantages experienced by the centres that have co-located are described below.

The east of Scotland SBSP report 2006 noted significant benefits from combining screening and symptomatic services. It covers north east NHS Fife and NHS Tayside. It is based in Ninewells Hospital in Dundee and integrated with Tayside symptomatic mammography service (NHS Quality Improvement Scotland, 2006). The service has been integrated with the symptomatic breast imaging service since 1999. Staff and equipment are shared between both the services. The main benefit of integrating the services is that the standard of the symptomatic mammography service has been raised. All staff have been trained to the SBSP standards and QA testing for equipment also meets these standards. Staff also have improved access to the increased variety of clinics and patient types. There has been much better communication between the services and also easy access to information, eg to find out when symptomatic patients last had a screening mammogram.

The main disadvantage of combining the services is the reduction in flexibility. As many different types of clinic (such as screening, assessment, new patient symptomatic, return patient symptomatic, family history) and procedure (such as core biopsy and localisations prior to surgery) take place, it can be difficult to respond to the needs of one service, for example arranging additional screening, due to room requirements of the other service. The financial implications of integrated services are not known as the budgets for both the services are separate (Debbie Archibald, Service Manager, East of Scotland Breast Screening Service. Personal communication).

The north of Scotland SBSP report 2006 also noted important benefits associated with the combined delivery of both the screening and symptomatic services (NHS Quality Improvement Scotland, 2006). In April 2004, the North of Scotland Breast Screening Service moved to a new centre based in Raigmore Hospital, Inverness. The new Highland Breast Centre accommodates both the symptomatic service and the breast screening service. Administratively, the services are run separately, but all other disciplines are run jointly. A potential benefit to women participating in screening in the Inverness area is that they are screened in the fixed centre as opposed to the mobile unit parked in the hospital grounds, although some women may prefer mobile units (see Section 7.3.1). In both centres, systematic peer review and regular multidisciplinary team meetings were found to be the most effective ways of improving practice and quality of services (Judith Rodgers, Administrator, North of Scotland Breast Screening Service. Personal communication).

To date co-location has only been considered for the current screening centres. There may also be advantages in symptomatic centres in other locations undertaking screening work, particularly where digital technology is available. However, it would be important to ensure facilities met the high standards required for screening.

8.9 Optimising the use of digital machines

A service using digital technology will have higher initial capital costs than the current service using FSM technology, particularly if DDR is implemented. However, if machines are used for more hours (per day/week/year), the number of screening machines required by the service will be reduced and lead to a corresponding reduction in cost per woman screened. Greater hours of use may lead to extra costs for mammographers working a shift system and for the additional wear and tear on equipment, however these costs are unlikely to outweigh the savings made in machine costs. The extent of savings made by using machines for more hours should be considered in the light of updated technology costs at the time of implementation. This section describes approaches that may be considered for optimising the use of machines.

8.9.1 Flexible working patterns

Extending the hours for appointments offers the potential to reduce the number of machines required by the service. This is already being used successfully by some services using digital mammography in England (eg Coventry, Exeter and Somerset) and the Netherlands and evidence available in the literature and anecdotally suggests that attendance is unaffected or possibly improved when extended hours are used for screening sessions (see Section 7.3.1). Furthermore, women below retirement age may find it most convenient to attend outside working hours.

The digital service in Exeter uses a shift system to achieve extended hours and also holds evening (5.30pm–8.30pm) and Saturday screening sessions when required. They have not found that attendance rates are affected. A shift system is successfully used in the Somerset screening service on mobile units to provide the extra capacity required to implement two-view mammography. This has proved acceptable to mammographers and popular with women (Willson & Middleton, 2006). In Coventry a shift system is used during the summer months only. In the Netherlands a split shift system is used with two mammographers working 8am–4pm and 9am–5pm on mobile units so there is no break in screening over lunchtime.

The majority of the SBSP are not using extended hours at present and in some situations machines may be used for shorter days, for example in remote locations where mammographers have long distances to travel. There would be advantages in exploring the potential for using extended working hours locally prior to the implementation of digital mammography both for fixed and mobile units. However, there are particular issues for mobile units in some locations that need to be taken into...
account: remoteness, weather, darkness during winter months, the availability of public transport. There may also be implications for recruitment and retention if mammographers are required to work longer hours or to work a shift system, and transport officers are required at different times of day. Surveys of women's views may also help to establish whether attendance would be affected by the introduction of extended hours in Scotland. The east of Scotland service plans to survey the views of women on the use of extended hours relating to both fixed and mobile units.

8.9.2 Machine use in fixed centres

In fixed centres machines are often used for screening sessions and assessment clinics. It is understood that often longer appointments for screening are scheduled compared with mobile units. The feasibility of running some screening sessions in a manner similar to sessions on mobile units should be considered. Additionally any other alterations to schedules for screening sessions and assessment clinics that would increase machine use should be considered.

8.9.3 Sharing with the symptomatic service

Co-location of screening services with the symptomatic service has been considered in Section 8.8.2. There may be potential to optimise shared machine use between the services and to use extended hours for screening sessions. However, this would require careful planning between the two services as considered in Section 8.8.2.

8.10 Use and storage of prior film images

In the current film-based screening environment, prior films are displayed along with current films for reading. In introducing digital technology, previous images will be film based for an interim period of at least 3 years until all women have undergone a repeat screen using digital technology. If prior films are used during reading, either both film and digital technologies will be required, or previous films will need to be digitised. Both options pose practical difficulties. The difficulty with the first is that the two technologies have different lighting requirements and there is a greater risk of neck strain. This has been reported by some image readers who are reading using digital images and prior film images. However, digitising films is expensive and the approach to tagging images so they correspond to the correct women on the digital system needs to be failsafe. This section considers whether the use of previous film images in screening is important and whether prior film images should be digitised.

8.10.1 Use of prior images during reading

The evidence for using prior images during reading has been considered in Section 5.5. It indicates that the use of prior images during reading did not lead to a clear improvement in sensitivity but led to a reduction in recall rates. Evidence also shows that use of prior images in reading images taken at assessment clinics improves diagnostic accuracy. However, the studies available all used single technologies (ie all images either FSM or digital) and did not compare reading using digital images with and without prior films taken using FSM.

There are two alternatives for making prior film images available for reading: all films hung on a viewer; or batches of films made available only when there is doubt about diagnosis from the current digital image. However, with the second option it is important that images are in the same order in the batch as on the digital system. Although there is some evidence to suggest the first approach will lead to improved performance, this was based on reading digitised prior images and it is unclear whether similar results would be obtained when reading involved both digital and FSM technologies (see Section 5.3). The first approach also has some disadvantages - it will be more costly as staff will be required to hang the films, there will be greater space/room requirements, and there may be an increased risk of neck strain for image viewers.

Some users of digital technology (Exeter and Dublin screening services) have suggested that the higher quality of digital images compared with FSM images makes the use of prior images less necessary. However, in Coventry all prior films are hung on a roller viewer in the order that current digital images appear on the workstation. After 2 years none of the eight image readers had developed neck strain from this arrangement, although one experienced reader only considered it necessary to hang prior film images when there was doubt about a diagnosis. Hanging the prior images required additional space and the combined heat from the roller viewer and workstation made the reading environment uncomfortably hot.

In conclusion it is recommended that prior film images are made available for viewing during film reading as it is important that satisfactory recall rates are maintained in the SBSP. It is unclear whether hanging prior film images for all women will lead to an increase in performance that is justified by the extra inconvenience and cost involved. Therefore individual centres should decide on the practical approach, weighing up the potential for improved accuracy from hanging all prior film images against the extra costs and practical difficulties.

8.10.2 Digitisation of prior film images

A study carried out in Norway demonstrated the successful digitisation of prior film images in the Norwegian Breast Cancer Screening Program (NBCSP) with minor problems (Pedersen et al., 2004; Roelofs et al., 2007). The NBCSP in Troms and Finnmark undertook a gradual transition from FSM to digital mammography. Prior images for all women who attended at first and second rounds of screening were digitised and stored in the PACS. The biggest issues identified were scanning time, error messages, manual entry of data and discrepancies and difficulties in identifying these images. However, these digitised images have so far not been used in routine screening and hence any practical experience of using them as prior images in reading has not yet been evaluated. Another potential disadvantage of digitising
prior images is that their quality may be poorer than that of the original film images (Karen Duncan, Consultant Radiologist, North East of Scotland Breast Screening Service. Personal communication).

The NHSBSBP equipment report 0601 (NHS Cancer Screening Programmes, 2006d) indicates that, based on manufacturers’ experience from different countries, digitisation of prior images is not practical. Digitisation of previous images was included in the Coventry evaluation to see whether this might be an appropriate choice for the UK context. The opinion of those involved in this evaluation was not to recommend digitisation at present. This was also the view of staff at the west of Scotland centre who were loaned a digitiser but found it very labour intensive to use. The digital service in Exeter also decided not to digitise prior films. Further work in this area is being carried out by a PhD student supervised by Alistair Gale at Loughborough University and, when complete, may help to determine whether there are benefits of digitisation.

In conclusion there is no clear evidence to recommend the digitisation of prior images and given the costs involved, it is suggested that it is not undertaken. However, digitisation should be reconsidered if further evidence to support its use becomes available.

8.11 Workforce issues

Section 8.11.1 describes the current administration and staffing situation in the SBSP. The following sections then consider the changes that will occur following the implementation of digital mammography.

8.11.1 Current administration and staffing

A breast screening programme employs a multidisciplinary team of clinical and non-clinical staff. The NHSBSBP document on organising a screening programme recommends that accountability for the service should be defined in terms of clinical and programme management (Briggs et al., 2002). Clinical management refers to management of clinical aspects of screening and assessment. The clinical team comprises consultant radiologists, breast clinicians, breast care nurses, clinical specialists, consultant surgeons, pathologists, radiographers, assistant practitioners and radiographer helpers. Programme management oversees the day-to-day administration and non-clinical management of the service. It is undertaken by administrative staff and their managers. The SBSP also employs transport officers for mobile units. Appendix 5 gives a breakdown of the staff currently employed in the SBSP.

8.11.2 Changes to working practice and environment

Digital mammography will lead to changes in working practice and responsibilities for many groups of staff.

Mammographers

Mammographers will no longer need to handle cassettes or process films with DDR machines, however they will still need to handle cassettes with CR machines. It is likely that a shorter appointment time can be achieved with DDR. In Coventry staff have found that DDR has also allowed more time to interact with women despite a shorter appointment time. Additionally the working environment will be cleaner and quieter without film processors.

If extended hours for screening are introduced, mammographers may need to work a shift system to cover longer hours of screening sessions per day.

Image readers

The BSIS developed for digital mammography will allow image readers (often radiologists) to undertake direct entry of results when reading images. A study to evaluate the costs of digital mammography compared with FSM in a clinical setting reported that reading time almost doubled (Ciatto et al., 2006). However, radiologists in services using digital mammography in Dublin and Exeter have suggested that reading is slightly faster than with FSM. Thus it is not known what impact digital mammography will have on the time required for image reading in the SBSP.

Digital mammography will also allow reading sessions to take place remotely. For example, readers in another centre can read images and facilities may be provided to allow reading to take place in non-screening NHS sites (eg radiology departments).

In the short term, there will be a need to view digital images on a monitor along with prior film images on a light box. It is difficult to provide lighting to support both technologies and image readers may have an increased risk of developing neck strain from continually turning to view the two types of image. However, this would be less likely if prior films were only viewed when the digital image does not provide a clear-cut result. Additionally consideration should be given to restricting the length of time image readers spend looking at monitors to avoid eyestrain. The Exeter service have found that reading sessions involving approximately 180 examinations can be completed in 3–3.5 hours including regular breaks.

Radiographer helpers

When digital mammography is implemented, radiographer helpers will no longer be required to spend time processing films and loading and unloading them onto viewers. However, for a 3-year period there will still be a need to extract prior films, although these may not need to be loaded onto viewers.

Administrative staff

The introduction of the BSIS for digital mammography will affect the tasks undertaken by administrative staff. These
8.11.4 Physics support

The skills mix of staff will be altered by digital mammography. A large IM&T resource is essential for setting up and running the BSIS and PACS systems required for digital mammography. More staff with IM&T skills will be required. Additionally, a manager of the BSIS and PACS system at each screening centre is required to ensure issues are dealt with on a daily basis, however it is anticipated that this role could sometimes be combined with another job function. For example, in Coventry the BSIS and PACS are managed by a clinician and in Dublin by a medical physicist.

Eventually, staff will no longer be required to hang film images for reading sessions.

Digital images may be transported on CDs or hard drives from mobile units by mammographers. Transport officers will not need to transport carrying magazines but may still be required to transport the CDs or hard drives if this is not done by mammographers.

When digital mammography is implemented, data entry for screening will not be required and eventually there will only be a need to retrieve previous physical records for women returning for assessment. Thus the need for administrative tasks will be reduced. The outsourcing of letter sending, if undertaken, would also affect requirements for administrative tasks, although this is unrelated to implementing digital mammography.

Recruitment policies should take account of anticipated changes to skills mix at an early stage.

8.11.5 Training

Staff will require training in the use of digital mammography during the implementation period. This will apply to radiographers, radiologists, image readers, assistant practitioners, imaging department assistants (radiographer helpers), breast clinicians, administrative staff and medical physicists. Additional time should be factored in during implementation to provide this. It has been suggested that more training time may be needed for image readers than for mammographers as they will not use the equipment full time. Staff working in the digital service in Coventry have suggested that the skills required to use digital technology can be quickly acquired and staff are usually competent within a few weeks. The Exeter service allowed 6 weeks for staff to become familiar with digital equipment (while still using FSM technology for screening) then one week of downtime was allowed for the changeover to digital mammography.

There will be a greater requirement for IM&T skills for the majority of staff and there may be advantages in providing training in this area prior to implementation of digital mammography.

8.12 Implementation plans

Implementing digital mammography will be very complex and therefore careful planning is required to ensure a high quality service is maintained. This will need input from a wide range of professional groups as well as from users of the service. It is recommended that an implementation group, with appropriate subgroups, supported by NSD is formed to lead the transition to digital mammography and address the aspects below.

8.12.1 Specification of IM&T requirements

The BSIS and PACS may each take 2 years or more to develop (see Sections 8.3–8.5). An IM&T subgroup of the implementation group should be convened at an early stage to draw up a detailed specification of the IM&T requirements for implementation. This will include the BSIS, a national PACS for screening, and the IM&T infrastructure needed to support the transfer of large volumes of data. Advice from the Quality Assurance Reference Committee should be sought on the medico-legal implications of storing images using lossy compression on the PACS.

8.12.2 Pilots

The subgroup of the HTA topic group agreed that digital mammography should be piloted as soon as possible. The machines should first be piloted on a mobile unit to ensure that the technology can withstand the weather and transport conditions specific to Scotland (e.g. dampness, cold winters, narrow roads, ferry crossings), without significant periods of downtime. It is unlikely that the PACS integrated with the BSIS will be available in time for the pilot, however the images generated should be DICOM, HL7 and IHE compliant so that in the future they can be placed on the national breast screening PACS. The implementation group should specify a plan for the pilot detailing the aspects to be addressed, e.g. assess the reliability of the modalities, compare CR and DDR, assess appointment length, determine the practical approach to using prior film images for reading, determine the time required for reading, and assess risks. The NHSBSP reports relating to the evaluation of digital mammography equipment (NHS Cancer Screening Programme, 2006c; 2007c) should be considered.
Once the PACS and BSIS have been developed, digital mammography should be piloted on all machines in one centre including fixed and mobile units. Lessons learned from the pilot should be disseminated to the SBSP. Full implementation across other centres should then follow to a timescale determined by the implementation group.

8.12.3 Purchase of equipment and roll out

Digital mammography should be introduced to an agreed timescale and in a planned way, coordinating with the implementation of digital imaging technology in Scotland on a wider front. This will include agreeing interim arrangements for the implementation of two-view mammography and for replacing redundant equipment in light of the recommendations of this report.

The group will recommend which technology (ie CR or DDR) should be used for each situation when a new machine is required:

- to support the implementation of two-view mammography
- to replace redundant FSM machines prior to full implementation of digital mammography
- to replace non-redundant FSM machines during full implementation.

For example, the use of CR with existing X-ray machines during their remaining lifespan may be an attractive low-cost option. The decision between technologies should take into account: the relative technical qualities and ergonomics of each modality; whether the machine is to operate on a fixed or mobile unit; operating patterns; experiences of users of digital mammography (including the symptomatic service); costs; the management of periods during which mixed technologies will be used; and any new evidence becoming available including revised costings.

Any new technology considered for use should be evaluated in a screening setting from both a technical and clinical perspective. Evidence from the UK NSHSP has been evaluated should be considered when purchasing digital mammography equipment for SBSP. These evaluations are summarised in Section 5.2.5.

Servicing models with suppliers (including maintenance agreements and contingency planning) should be explored when planning implementation and should take into account that contracts may be bound by NHS policy procedures. Leasing and capital purchase options should be considered, as well as bulk purchase across Scotland or with the NHSBSP in England and Wales. There may also be potential to bulk purchase with the symptomatic service where procurement for digital mammography is currently being considered, although this would need careful planning at an early stage (Peter McConnell, Procurement Office Acute Sector, National Procurement Division. Personal communication). Any bulk purchases should not jeopardise an agreed timescale for implementing digital mammography in the SBSP. Comprehensive servicing and repair agreements should be agreed so that downtime of equipment is minimised. The Exeter service has recommended a repair agreement ensuring same day visits when faults arise and that servicing is carried out at weekends to avoid time lost for screening. All modalities should also have a robust quality assurance and safeguarding process.

8.12.4 Workforce

The implementation group should develop and seek agreement with staff on working patterns to ensure a high daily, weekly and annual utilisation of the digital screening equipment.

8.12.5 New evidence

The implementation group should take account of evidence emerging from screening services using digital mammography and other technologies.
9 PRINCIPAL FINDINGS, LIMITATIONS AND RECOMMENDATIONS

This section considers the principal findings, further research required, limitations and uncertainties, and makes recommendations concerning the implementation of digital mammography in the SBSP. A preliminary estimate of the costs to implement these recommendations is also provided.

9.1 Principal findings

9.1.1 Scope of the HTA

The HTA focuses on establishing the most effective approach to implementing digital mammography in the SBSP, having assumed that the technology will be implemented and is fit for purpose. It has primarily considered the organisational issues relating to implementation. The clinical and cost effectiveness evidence from the secondary literature has been summarised and issues relating to women undergoing screening considered.

9.1.2 Summary of findings

Clinical evidence showed that digital mammography is at least as effective as FSM. The evidence suggested no overall difference between the technologies in terms of diagnostic accuracy and recall rates for assessment. There was insufficient evidence to compare the performance of CR with DDR. The available evidence indicated that digital mammography met national standards for radiation dose, referral for assessment and numbers of cancers detected.

Little evidence is available to assess the cost effectiveness of DDR compared with FSM. Limited observational evidence suggests similar costs per woman screened for DDR and FSM may only be achieved if the SBSP increases the utilisation of imaging machines. No evidence pertaining to the cost effectiveness of CR was found.

The evidence on the use of prior images during reading suggested their availability had no effect on cancer detection rates but that recall rates were lower. There was no clear evidence available to support the digitisation of prior images.

There was little published evidence to inform many of the organisational issues identified. Informal reports and anecdotal evidence from current users of digital mammography have largely informed the HTA on these issues.

Using digital machines for longer hours will reduce the number of digital machines and mobile units required and hence reduce cost. This could be achieved by screening women outside usual working hours (ie before 9am, after 5pm or at the weekend), and by considering alternative scheduling for machines use within fixed centres. The available evidence indicated that scheduling appointments outside the 9am–5pm period was likely to be acceptable to staff and would not affect attendance rates. The co-location of screening and symptomatic services may also lead to a saving in the number of machines required to be reduced.

A BSIS integrated with a PACS should ideally be available at the time of implementation or as soon as possible afterwards. Each of these systems may take 2 years or more to develop.

There were few issues for women in implementing digital mammography. From their point of view, the procedure would differ little from FSM and although there may be a similar length of time for appointments, the mammographer would need less time for processing film if DDR was used and may have more time to interact with the women. The likelihood of being recalled for technical reasons is likely to be reduced with digital mammography causing less anxiety to women. As previously stated, women may be required to attend for screening appointments outside the hours of 9am–5pm, however the evidence available suggests that this would be acceptable. Radiation dose is less with some digital equipment.

In conclusion, digital mammography is clinically effective and may be cost effective if an increase in the utilisation of machines can be achieved. The conclusions reached by the topic group on other issues are detailed in the recommendations.

9.2 Further research

The paucity of evidence comparing the clinical and cost effectiveness of CR and DDR meant that it has not been possible to recommend a digital modality to use across the SBSP. More research involving a direct comparison in a screening setting is required to assess the relative merits of the two modalities.

There was insufficient evidence available to recommend the digitisation of prior film images. An assessment of any new evidence at the time of implementation is recommended.

It is possible to store images using lossy compression (which does not completely preserve the original image of the breast) and this may be acceptable for images taken before the previous screen. However, further work is required to determine whether the quality of such images is sufficient. Further work is also required to consider the feasibility of standardising methods for image processing or, alternatively, of storing both processed and unprocessed images.

Although an assessment of CAD did not form a part of the HTA, this technology may yield benefits and reduce the need for double reading. A more detailed review of the evidence for CAD is recommended once digital mammography is implemented.

Mobile units in Scotland are not usually connected to power supplies, landline telephones or computer networks. A computer connection would enable staff to
access information available on the BSIS and PACS. Although making such connections may not be practical at present, in the longer term the feasibility of doing this should be considered.

Digital mammography is a new technology and as yet there is limited experience in the screening environment. The SBSP should take account of evidence emerging from screening services using digital mammography and other technologies and, following implementation contribute to this research.

9.3 Limitations and uncertainties

The decision to adopt CR or DDR is not straightforward. No study has compared the two technologies directly, although there is weak evidence from one study to suggest they have similar diagnostic accuracy. The costs of DDR are significantly higher at present. However, it is anticipated that these costs will fall as more machines are produced yielding economies of scale for the manufacturers.

There are also organisational considerations which are relevant to the decision. DDR offers an improved workflow that has the advantage of reducing the number of repetitive routines such as handling of film cassettes and offers the potential to increase the throughput of women per clinic because of a faster screening time for each woman.

NHSBSP equipment evaluations show that, while CR accredited systems are within tolerance for the commissioning tests, DDR accredited systems use a lower dose of radiation to produce the same image quality as CR systems. Image quality on both systems may improve further with each upgrade. The NHSBSP equipment evaluations suggest the CR and DDR machines evaluated are similar in terms of pixel size, technical recall rates and connectivity. No report on the evaluation of a CR system for operation on a mobile is available yet.

The cost effectiveness of digital mammography is dependant on the current costs of the modalities, the PACS and the IM&T infrastructure required to operate these. These costs are expected to change over coming years and therefore the likely cost effectiveness at implementation is difficult to assess. An increase in the working hours of the screening programme is likely to make the technology cost effective but this is based on the simple assumption that fewer machines will then be required and not on published evidence.

The main remit of the HTA was to consider the most effective way of implementing digital mammography. However, there is very little published evidence available to answer many of the questions identified and much of the evidence is based on experience. Therefore a pilot of digital mammography is crucial so that lessons may be learned.

The recommendation on the use of prior images is largely based on evidence relating to FSM technology. As digital images are of better quality than film images, these may perform well without prior images. However, evidence for this is unlikely to be available before the implementation of digital mammography in the SBSP.

There was limited evidence to assess whether an immediate or phased roll out would be preferable, either from the viewpoint of the functioning of the service or from a cost perspective. The decision will be made by the implementation group (see Section 9.4) after considering the practicalities and costs of the two alternatives.

9.4 Recommendations

The HTA has been carried out based on the premise that digital mammography will be implemented in the SBSP whilst ensuring that the high quality of the programme is maintained. These recommendations therefore relate only to how the implementation should take place.

Technology

- A Breast Screening Information System (BSIS) integrated with a Picture Archive and Communication System (PACS) should be in place to support the implementation of digital mammography in Scotland. These systems should function as a single package of technology from the user’s viewpoint. The BSIS should have facilities for administration, call/recall, data entry at reading and the compilation of statistics.
- A national PACS for breast screening is recommended. This should be part of the national PACS for Scotland but with features specific to breast screening.
- The full benefits of digital mammography will be achieved in a paper-lite environment where images and most of a woman’s records are stored electronically. It is recommended that direct entry of results is included in the specification for the IM&T system as it is recognised that this has a number of benefits.
- Images taken at assessment clinics such as ultrasound and stereotactic images should also be stored on the PACS. The breast screening PACS should have facilities to share images between the screening and the symptomatic services, but should not automatically extract non-breast images. Additionally mammography images should not be automatically retrieved from the national PACS when women attend hospital for other reasons. A facility to print images should be available at each screening centre.
- Digital modalities should be fully compliant with International Digital Imaging and Communications in Medicine (DICOM), HL7, Integrating the Healthcare Enterprise (IHE) and subsequent standards.
- Digital modalities and mobile units should have comprehensive servicing and repair agreements in place. In particular, the agreement should ensure same-day visits when feasible and necessary to maintain the service.
- Loss-less compression of images is recommended for images taken at the last screen attended. Lossy compression should be considered for images taken at any earlier screens if sufficient quality is achieved.
• The decision on whether to recommend CR or DDR as the preferred digital technology should be taken by an implementation group. The evidence currently available is insufficient to inform a decision at this time.

• The cost and feasibility of a range of technologies for image transfer from mobiles should be considered at the time of implementation, including fixed connections, satellite connections and manual transfer (eg using CD, portable hard drive, data pen, connecting a landline).

• Generators on mobile units should be suitably soundproofed and positioned to cause minimum disruption to staff, women and the surrounding residents. Digital modalities have a narrow tolerance for temperature and generators for mobile units may need to run continuously to maintain the temperature within the required range.

• Consideration of computer-aided detection (CAD) is outside the scope of the HTA and its use is not currently recommended. However, a review of the evidence is recommended at a later date.

Minimising implementation and operating costs

• The screening service should optimise the use of digital mammography equipment in Scotland and thus reduce the number of machines required, while giving due regard to local circumstances and implications for staff and women to be screened.

• Co-location of screening and symptomatic services should be considered if this would help to maximise the use of staff and imaging equipment and reduce the total number of machines needed. However, it is acknowledged that there will be local factors influencing the decision to do this.

• The screening service should seek to minimise implementation and operating costs while taking account of local constraints. This may be achieved by, for example: adopting flexible working patterns, use of spare capacity in digital mammography machines purchased for use in the symptomatic service, and optimal scheduling between assessment clinics and screening sessions.

• There should be complete transparency of the assumptions used in each centre to determine the number of machines required. Relevant factors include the number of women who qualify for screening, population projections, attendance rates, appointment length, training time, downtime for breaks, set-up and close-down time, and travel time for mobiles.

Prior images

• Prior film images should be available at reading sessions. The practical approach to this may be decided by the individual centre or image reader.

• Currently it is recommended that prior film images are not digitised. At the time of implementation, this should be reconsidered and implemented only if high quality images can be obtained in a cost-effective manner and if a failsafe approach to tagging images is available.

Impact on staff and working practices

• The implementation of digital mammography will have a major impact on staff requirements and working practices. It is expected that there will be a change in tasks undertaken by several functions including administration staff, transport officers and radiographer helpers. There will be a significantly greater requirement for IM&T skills including PACS management. Additional time will be required to train staff during the implementation period. The use of flexible working patterns may affect the working hours of many staff groups.

• An IM&T and PACS manager should be identified at each screening centre. In some centres this role may be shared with another job function.

• Training requirements and recruitment policies should take into account anticipated changes to the tasks and roles of staff at an early stage. This should be done in partnership with the staff.

Implementation

The SBSP currently provides a very high quality service. The implementation of digital mammography will be a real opportunity for staff to redesign the service to meet the needs of women in Scotland over the coming years. However, it is recognised that implementing digital mammography will be very complex and therefore careful planning is required to ensure this high quality is maintained. This will need input from a wide range of professional groups as well as from users of the service. It is recommended that:

• The SBSP should take into account the requirements for digital mammography detailed within this HTA when planning the implementation of two-view mammography.

• The views of users of the service should be a key factor in planning and implementation.

• Digital technology should be piloted at the earliest opportunity. The machines should first be piloted on a mobile unit to ensure that the technology can withstand the weather conditions and transport requirements (eg ferry crossings) specific to Scotland. A local PACS system should be used at this stage. This should meet DICOM, HL7 and IHE standards so that images may eventually be stored on the national PACS. Digital machines, the PACS and BSIS should then be piloted across one centre including the associated mobile units. Lessons learned from both pilots should be disseminated across the SBSP and full implementation across other centres should follow over a fixed period of time.

• An implementation group with appropriate subgroups, supported by National Services Division (NSD) should be formed to:

1. Agree interim arrangements for the implementation of two-view mammography and for replacing redundant equipment in light of the recommendations of this report.
2. Ensure digital mammography is introduced to an agreed timescale and in a planned way, coordinating with the implementation of digital imaging technology in Scotland on a wider front.

3. Recommend the digital technology (ie CR or DDR) for: new equipment required to support the implementation of two-view mammography; redundant machines requiring replacement prior to full implementation of digital mammography; non-redundant machines to be replaced to achieve full implementation of digital mammography. The decision should take into account the evidence available in this HTA plus any more recent evidence relating to: the technical qualities of each modality, operating patterns, the number of machines required, experiences of users of digital mammography, costs, and the advantages and disadvantages of using different modalities within the service.

4. Draw up a detailed specification for the IM&T requirements for implementation including development of the BSIS, a national PACS for screening, and the IM&T infrastructure needed to support the transfer of large volumes of data. This should be carried out at an early stage by an IM&T subgroup.

5. Consider all options for purchasing the modality, taking into account requirements for servicing and consumables. Leasing options in addition to capital purchase options should be considered, as well as bulk purchase across Scotland in conjunction with the symptomatic service or with the NHSSBSP in England and Wales.

6. Ensure the modality has a robust quality assurance and safeguarding process.

7. Ensure that comprehensive servicing and repair agreements are in place so that downtime of equipment is minimised.

8. Liaise with screening centres on the development of working patterns to ensure a high daily, weekly and annual utilisation of the digital screening equipment.

9. Take account of evidence emerging from screening services using digital mammography and other technologies.

9.5 Preliminary estimate of the financial implications of implementing the recommendations

Preliminary estimates of the financial impact of implementing the key recommendations are presented in this section. The capital costs figures have a wide range of uncertainty around them because:

- the number of replacement machines required is uncertain and will be a function of several factors including the potential to reduce appointment times with digital technologies and improving the utilisation of the screening equipment in the centres and mobile units
- the prices of the technologies are reducing as production volumes rise; moreover substantial discounts may be available for bulk purchases
- accurate costings to integrate the SBSP into the national PACS programme will not be possible until the volumes of data associated with the digital images are better established, together with policies on local and national storage, use of prior images and extent of sharing of images across centres. As the national PACS programme itself is implemented, the incremental costs of augmenting that programme for breast imaging may change. For example, as NHS boards operate PACS, actual data volumes may differ substantially from the forecast volumes, changing the forecast capacity available for growth and new services.
- accurate costings for a BSIS will require confirmation of national minimum datasets, QA and clinical audit requirements and development of protocols that can inform the user specification for each of the required tasks and interfaces.

Uncertainties may reduce following feedback from the pilots but these are unlikely to address the key issues identified above. In view of the uncertainty on the cost of technologies, a national procurement exercise should be undertaken to inform a fully developed business case before making any purchasing decisions.

9.5.1 Methodology and assumptions

The methodology adopted is set out in Mauskopf et al. (2007). Specifically, the budget impact assessment:

- adopts the perspective of NHSScotland
- uses data that reflect the size and characteristics of the population and the efficacy and safety of the new and current technologies
- presents the analyses as a series of scenarios
- uses the ‘simplest design that will generate credible and transparent estimates’.

Key assumptions include:

- the three technologies—DDR, CR and FSM—have similar clinical outcomes and safety profiles
- the SBSP will retain its current six screening centres and central support through a medical physics service, a nationally managed mobile fleet, radiographic training, national coordination and commissioning and a national IM&T system
- the mean time for each woman for a mammography screening visit will be the same for CR and DDR
- the mean time for each operator to read the image will be the same for CR and DDR
- the number of retakes, unreported and unavailable images and images lost from patient files will be the same for CR and DDR
- digital mammography will be introduced after the adoption of two-view mammography in the SBSP for women aged 50–70 years.
9.5.2 Results

Preliminary estimates of the budget impact are presented for the capital and operating costs of the following functions: digital mammography machines and associated building costs; BSIS; PACS; project management; training; networking; maintenance; staff; consumables and accommodation.

9.5.2.1 Digital mammography machines and associated building costs

Currently there are 17 fixed mammography machines in the six centres and 18 in mobile units, 35 in total. Adopting two-view mammography (ie an additional cranio-caudal view at the incident round) is estimated to require an additional four fixed and three mobile units (Breast and Cervical National Advisory Group, 2007), giving a total replacement asset schedule of 42 FSM machines.

Four manufacturers (GE and Siemens for DDR and Kodak and Fuji for CR systems) have provided quotes for their respective mammography machines. Informed by these quotes, the budget impact assumes the cost for a DDR machine is £230,000 and £70,000 for a CR machine, excluding the cost of cassettes. These are included as consumables.

Bulk discounts are anticipated to be available particularly for DDR where very substantial bulk discounts have been reported from knowledgeable buyers in the marketplace. A sensitivity analysis assumes a 50% bulk purchase discount is available for DDR and 20% for CR.

The CR option assumes the existing FSM machines are retained and replaced when they reach a 10-year life. With DDR the existing FSM machines will be replaced on implementation.

The cost of replacing the existing FSM machines are included in the cash flow forecasts but not in the direct comparison of DDR and CR.

The analysis assumes that DDR is introduced in 2010, reflecting the lead time required to build a BSIS system and customise the national PACS. This analysis assumes that 13 (30%) of the FSM machines are replaced that year, with replacements for the remaining phased-in as the machines reach a 10-year life. The replacement schedule for the existing 35 machines is provided in Appendix 6.

The cost of an FSM machine is assumed to be £50,000 (Alex Watt, Medical Physicist, Scottish Healthcare Supplies. Personal communication, April 2007). The base case assumes a CR reader is purchased for each mammography machine. Savings may be achieved if one reader is shared between two units in centres.

In addition, it is assumed that building work costing £40,000 for each DR and CR machine in a centre and £10,000 for each DR and CR machine respectively on a mobile unit will be required. In the centres, such monies could be used to facilitate changing the lighting and layout of the reading areas and reconfiguring the areas currently used to develop film. In mobile units, some work will be required to soundproof the generators and reduce temperature and humidity fluctuations. The lower cost for CR on mobiles reflects the experience in Derby (Bob Brown, Director X-ray Systems, FUJIFILM UK Ltd. Personal communication, November 2007).

The cost-effectiveness section (Section 6.3) concluded that DDR need be no more expensive in terms of cost per woman screened if a higher level of utilisation of machines each day is achieved. Improving the utilisation of each machine will reduce the number of replacement machines required. The budget impact has assumed two scenarios: no improvement in utilisation and a 30% improvement in utilisation per machine (ie replace 29 of the 42 machines which are planned to be in use following the adoption of two views at every round). It is anticipated that improvements may be achieved by a shorter appointment time for women and by initiatives to enable the machines to be used more intensively within the existing working day and through longer opening hours if necessary.

The feasibility of operating with 28 machines plus one spare has been validated against national forecasts of the number of screening appointments, assuming a 6-minute appointment per woman screened. However the implications for individual centres have not been reviewed.

For all utilisation scenarios, building costs are assumed to remain at the estimated absolute cost level within the centres, indicating that removing machines is likely to require significant reconfiguration of current services. However, the building costs associated with the mobile units are assumed to fall in line with the reduction in the number of machines.

The resulting costs are shown in Table 9-1. If all machines are replaced using DDR the equipment cost is £9.7 million, with a further £1.7 million required for building modifications, giving a total cost of £11.3 million. The total cost drops to £8.1 million, of which £6.7 million is for the machines, if productivity improvements are achieved such that only 70% of the machines are replaced with DDR.

Replacement with CR machines reduces the costs for like-for-like replacement to £4.0 million. A further £2.1 million is required to replace the existing FSM machines giving a total cost of £6.1 million. Replacing the FSM machines would be necessary under the current FSM programme and is thus not incremental to that programme.

If a 30% productivity improvement is achieved the cost falls to £4.5 million (£3.0 million excluding the FSM machines).

If discounts of 50% for DDR and 20% for CR are achieved from bulk buying then the costs of the respective systems, including building costs are £6.5 million and £5.5 million respectively.
The estimated costs for DDR assuming 29 machines and 50% price discounts fall to £4.8 million, some £0.7 million higher than the cost of introducing 29 CR machines, assuming a 20% bulk discount on the indicative price. This estimate includes replacing the existing FSM machines; excluding that element, the marginal cost of adopting CR compared with FSM is estimated at £2.6 million assuming 29 machines and a cost per machine of £56,000.

9.5.2.2 Breast Screening Information System (BSIS)

The BSIS system for the SBSP is required to perform several complex functions which are described in Sections 8.3 and 8.4. The costs for the call-recall element of three recently implemented screening programmes are: diabetic retinopathy screening £1.5 million; cervical screening £5.5 million; and bowel screening £1.5 million (Peter Croan, Head of Finance & Operations, National Services Division. Personal communication, June 2007). The costs for the cervical cancer system are advised to be atypical. This suggests a 'standard' BSIS could be £1.5 million. However, the SBSP system has several bespoke elements for scheduling the machines and recording results from the PACS imaging software and complex interface requirements. It will also require to be networked across six sites. These factors will add to the costs; in the absence of better information, a central case cost of £3 million and high and low values of £5 million and £1.5 million respectively have been assumed.

9.5.2.3 Picture Archive and Communications System

Section 8.5 discusses the SBSP user requirements for a PACS and Table 8-3 provides an estimate of the volume of data that could be produced each year—a volume comparable to the data volume for the Greater Glasgow and Clyde NHS Board. This information has been shared with Mr A Fleming, Programme Manager, Scottish PACS Programme, NHS National Services Scotland. Further research is necessary to understand how images will be displayed, read and stored, at workstations and on PACS. In the meantime, Mr Fleming has agreed with estimates of £3 million for the central case, and high and low values of £5 million and £1.5 million respectively.

Table 9-1 Digital mammography machines and associated building costs

<table>
<thead>
<tr>
<th>Number of machines with two-view mammography</th>
<th>Fixed centres</th>
<th>Mobile units</th>
<th>Total units</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>21</td>
<td>21</td>
<td>42</td>
</tr>
<tr>
<td>Cost of DDR machine</td>
<td>£230,000</td>
<td>£230,000</td>
<td>£230,000</td>
</tr>
<tr>
<td>Cost of CR machine assuming re-use existing FSM machines</td>
<td>£70,000</td>
<td>£70,000</td>
<td>£70,000</td>
</tr>
<tr>
<td>Cost of CR machine to replace existing FSM machine</td>
<td>£50,000</td>
<td>£50,000</td>
<td>£50,000</td>
</tr>
<tr>
<td>Building costs per machine</td>
<td>£40,000</td>
<td>£10,000 CR</td>
<td>£40,000 DDR</td>
</tr>
</tbody>
</table>

Replacement costs if all machines replaced

<table>
<thead>
<tr>
<th></th>
<th>Fixed centres</th>
<th>Mobile units</th>
<th>Total units</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDR</td>
<td>£4,830,000</td>
<td>£4,830,000</td>
<td>£9,660,000</td>
</tr>
<tr>
<td>Plus building costs</td>
<td>£840,000</td>
<td>£840,000</td>
<td>£1,680,000</td>
</tr>
<tr>
<td>Total costs DDR</td>
<td>£5,670,000</td>
<td>£5,670,000</td>
<td>£11,340,000</td>
</tr>
<tr>
<td>Machines: CR</td>
<td>£1,470,000</td>
<td>£1,470,000</td>
<td>£2,940,000</td>
</tr>
<tr>
<td>Existing FSM machines</td>
<td>£1,050,000</td>
<td>£1,050,000</td>
<td>£2,100,000</td>
</tr>
<tr>
<td>Building costs</td>
<td>£840,000</td>
<td>£210,000</td>
<td>£1,050,000</td>
</tr>
<tr>
<td>Total costs CR</td>
<td>£3,360,000</td>
<td>£2,730,000</td>
<td>£6,090,000</td>
</tr>
<tr>
<td>Total costs excluding FSM</td>
<td>£2,310,000</td>
<td>£1,680,000</td>
<td>£3,990,000</td>
</tr>
</tbody>
</table>

Sensitivity analyses

<table>
<thead>
<tr>
<th>Total costs where:</th>
<th>Fixed centres</th>
<th>Mobile units</th>
<th>Total units</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDR machine price reduced by 50%</td>
<td>£3,255,000</td>
<td>£3,255,000</td>
<td>£6,510,000</td>
</tr>
<tr>
<td>CR machine price reduced by 20%</td>
<td>£3,066,000</td>
<td>£2,436,000</td>
<td>£5,502,000</td>
</tr>
<tr>
<td>Total costs CR including FSM machines</td>
<td>£3,066,000</td>
<td>£2,436,000</td>
<td>£5,502,000</td>
</tr>
<tr>
<td>30% improvement in throughput per machine</td>
<td>14</td>
<td>15</td>
<td>29</td>
</tr>
<tr>
<td>Total cost: DDR</td>
<td>£4,060,000</td>
<td>£4,050,000</td>
<td>£8,110,000</td>
</tr>
<tr>
<td>CR including FSM machines</td>
<td>£2,520,000</td>
<td>£1,950,000</td>
<td>£4,470,000</td>
</tr>
<tr>
<td>30% improvement in throughput per machine and 50% and 20% bulk discounts for DDR and CR respectively</td>
<td>14</td>
<td>15</td>
<td>29</td>
</tr>
<tr>
<td>Total cost DDR</td>
<td>£2,450,000</td>
<td>£2,325,000</td>
<td>£4,775,000</td>
</tr>
<tr>
<td>Total cost CR including FSM machines</td>
<td>£2,324,000</td>
<td>£1,740,000</td>
<td>£4,064,000</td>
</tr>
</tbody>
</table>
9.5.2.4 Project management costs

It is assumed that this project will require significant resources to manage it, requiring a multidisciplinary team representing each key skill and each centre. A 15% on-cost for this function has been added to the total capital cost of the digital mammography machines and associated building costs, the BSIS and PACS costs. Estimates are provided assuming central, high and low costs options for BSIS and PACS; the central and high options assume purchasing 42 additional machines, while the low option also assumes only 29 machines are required.

The resultant costs are shown in Table 9-2.

9.5.2.5 Training costs

The manufacturer of the digital machines will provide training within the initial price. It is assumed that those trained will cascade the knowledge to the necessary staff, with onsite support from the manufacturer. No additional cash costs to NHSScotland are estimated.

9.5.2.6 Additional annual network costs

A sum of £0.3 million each year has been included for additional network costs. Breast Test Wales included £0.1 million within their business case to adopt digital mammography within their service, which has four centres. However that business case does not mention the extent of links to other parts of the NHS. Given the complexity of the Scottish programme and the greater number of centres, a higher estimate has been used for the Scottish project.

9.5.2.7 Annual maintenance costs and replacement of VDUs

The maintenance costs of the digital mammography machines, including tubes, are estimated at 10% of the capital element for digital mammography in line with the estimates from the manufacturers and a 4% annual maintenance cost has been applied to the building costs. A 15% annual cost has also been applied to the BSIS and PACS for software licence and upgrades. The total maintenance costs for the central case and sensitivity analyses are shown in Table 9-3.

In comparison with the cost of FSM, annual savings on existing maintenance contracts for FSM machines, equivalent to 10% of their purchase price (£5,000 per machine), will accrue on the DDR option only; the CR costs include the cost of maintaining the FSM machines. With 42 machines, the annual savings are £0.21 million.

In the cash flow projections, all systems are assumed to require the monitors replaced in year 6 at a cost of £1,000 per monitor.

9.5.2.8 Staff costs

Predicting changes in staff costs in advance of information from the pilots is difficult. There is no evidence to support estimating changes for the majority of functions. For example, an increase in costs could arise as a result of adopting more flexible screening hours for the mobile units and centres but reducing the number of machines from 42 to 29 should release resources. At this stage it is assumed that these two factors have equal and opposite effects. This could be refined once the results from the pilot are known.

It is assumed that the current number of administrative staff grade 2/3 of 56.2 will reduce by 1 in 10 as a consequence of adopting digital technology. This equates to almost six staff across the SBSP. Currently the number of staff handling films exceeds six but some staff redeployment to new functions is assumed to take place. Assuming a staff cost of £14,400 and overheads of 30%, these savings are about £0.1 million per year.

### Table 9-2 Project management costs

<table>
<thead>
<tr>
<th>Scenarios</th>
<th>Total project management costs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Central case</strong></td>
<td></td>
</tr>
<tr>
<td>BSIS, PACS and digital mammography machines and building costs like-for-like replacement:</td>
<td></td>
</tr>
<tr>
<td>DDR</td>
<td>£2,601,000</td>
</tr>
<tr>
<td>CR (including replacing FSM machines)</td>
<td>£1,813,500</td>
</tr>
<tr>
<td><strong>High cost</strong></td>
<td></td>
</tr>
<tr>
<td>BSIS, PACS and digital mammography machines and building costs like-for-like replacement:</td>
<td></td>
</tr>
<tr>
<td>DDR</td>
<td>£3,201,000</td>
</tr>
<tr>
<td>CR (including replacing FSM machines)</td>
<td>£2,413,500</td>
</tr>
<tr>
<td><strong>Low cost</strong></td>
<td></td>
</tr>
<tr>
<td>BSIS, PACS and digital mammography machines and building costs 30% improved utilisation:</td>
<td></td>
</tr>
<tr>
<td>DDR</td>
<td>£1,666,500</td>
</tr>
<tr>
<td>CR (including replacing FSM machines)</td>
<td>£1,059,600</td>
</tr>
</tbody>
</table>
Additional IM&T and PACS staff will be required to manage the new systems. Assuming six staff in total are required across the system at grade 6 (mid point £26,465) plus 30% overheads, the total cost would be £0.2 million.

The adoption of PACS should improve work flows across the screening and symptomatic service and may reduce clinician time in the symptomatic service if, for example, there is a lower incidence of unavailable images or poor quality images. However, no savings have been estimated for these potential benefits.

9.5.2.9 Consumables

Adopting digital mammography will reduce the consumables required for mammography film and X-ray related consumables. The Breast and Cervical National Advisory Group (2007) estimated the extra consumables required for the additional images associated with introducing two-view mammography in the SBSP. Assuming the consumable costs varied only with the additional number of images taken then moving to digital technology could save such costs equivalent to £1.3 million per year.

Operating CR would require purchasing CR cassettes. Based on typical usage patterns and offer prices advised by the manufacturer, and assuming a 2-year life, the additional annual costs of these consumables are estimated at £0.16 million.

Adopting PACS and BSIS may increase running costs, particularly electricity: storing breast images on the central PACS will also increase storage costs but no attempt has been made to quantify these.

9.5.2.10 Accommodation costs

Adopting integrated PACS and BSIS, together with digital mammography machines, may reduce the space requirements in each centre as new images are not stored in bulky film records. However, the existing film and paper records require to be stored for a minimum of 9 years. Off-site storage should reduce costs incurred for rents but will increase handling costs. Given the uncertainty around key drivers such as whether each woman will still have a paper record or if paper files might only be required for those referred for assessment, and that the change in cost is not likely to be material in this context, no further work will be done on this aspect.

9.5.2.11 Summary of additional capital and operating costs

Table 9-4 presents the preliminary estimate of the additional capital and operating costs associated with implementing the recommendations in this HTA. The CR costs are provided inclusive and exclusive of the cost of replacing the existing FSM machines.

The estimated costs for a DDR screening programme are almost £20 million; some 55% of these costs are for the machines and associated work. The BSIS and PACS software represent a further 15% each and the remainder is project management. In comparison the cost of a CR programme to include replacing all FSM machines at the end of their 10-year life is almost £14 million, with the machines representing almost 45% of the costs, the BSIS and PACS systems some 22% each and the balance for project management.

### Table 9-3 Annual maintenance costs

<table>
<thead>
<tr>
<th>Systems</th>
<th>Annual maintenance costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDR and building costs</td>
<td>£1,033,200</td>
</tr>
<tr>
<td>CR, FSM machines and building costs</td>
<td>£546,000</td>
</tr>
<tr>
<td>DDR and building costs: 30% improved use and discounted prices</td>
<td>£391,100</td>
</tr>
<tr>
<td>CR, FSM machines and building costs: 30% improved use and discounted prices</td>
<td>£347,000</td>
</tr>
<tr>
<td>BSIS central estimate</td>
<td>£450,000</td>
</tr>
<tr>
<td>PACS central estimate</td>
<td>£450,000</td>
</tr>
<tr>
<td>Total if like-for-like replacement:</td>
<td></td>
</tr>
<tr>
<td>DDR</td>
<td>£1,933,200</td>
</tr>
<tr>
<td>CR</td>
<td>£1,446,000</td>
</tr>
<tr>
<td>Total like-for-like replacement of machines and for BSIS and PACS:</td>
<td></td>
</tr>
<tr>
<td>DDR</td>
<td>£2,533,200</td>
</tr>
<tr>
<td>CR</td>
<td>£2,046,000</td>
</tr>
<tr>
<td>Total if 30% improved utilisation, discounted prices and low cost options for BSIS and PACS:</td>
<td></td>
</tr>
<tr>
<td>DDR</td>
<td>£841,100</td>
</tr>
<tr>
<td>CR</td>
<td>£797,000</td>
</tr>
</tbody>
</table>
The costs of replacing the FSM machines are not additional costs compared with FSM but do require funding as part of the programme and thus both estimates are relevant to decision makers. The marginal cost of the CR programme compared to the existing programme is £11.5 million.

The forecast additional annual operating costs are about £1 million. The major costs are additional software licences and equipment maintenance and networking costs, with some savings on consumables.

9.5.2.12 Sensitivity analysis

Tables 9-5 and 9-6 provide estimates of the possible range of costs.

The low forecast assumes 29 machines are replaced at the discounted machine price and the low forecasts for the BSIS and PACS software. The operating costs assume a £50,000 saving in network costs, lower maintenance costs in line with the lower capital spend, no additional staff costs and 30% greater savings in consumables compared with the central case.

Under these assumptions the capital costs range from £12.8 million for the DDR option, falling to £8.1 million for CR including FSM machines. In this scenario there are operating cost savings, with the lower consumable costs offsetting higher maintenance and network costs.

The high costs assume 42 machines are replaced and adopt the high forecast for BSIS and PACS. The operating costs assume an additional £150,000 spend on network costs, higher maintenance costs in line with the higher capital spend, no administrative staff savings and 30% fewer savings in consumables compared with the central case.

Under these assumptions the capital costs range from £24.5 million for the DDR option, falling to £18.5 million for CR including FSM machines. In this scenario the increase in annual operating cost is almost £2 million for the DDR option, and £1.8 million for CR savings.

9.5.2.13 Exclusions

No costs are included in the estimate of budget impact for the following items:

- additional electricity, fuel and any space requirements for new equipment
- additional QA costs, particularly capital costs
- any decision by the SBSP to outsource communications to women
- the annual cost of storing images on the PACS
- different modes for image transfer from mobiles
- co-location of screening and symptomatic services
- transition costs when staff may be reading both digital and film images with associated costs of each system.

9.5.2.14 Comparison with forecast costs of the SBSP

To provide a comparison of these forecast costs with current costs, Table 9-7 presents the 2005–2006 actual costs for the breast screening programme, updated for the cost of introducing two-view mammography in the SBSP. These annual costs, including capital charges are estimated at £12.6 million.

### Table 9-4 Total capital and operating costs: central case scenario (42 machines)

<table>
<thead>
<tr>
<th>Capital costs</th>
<th>DDR</th>
<th>CR including FSM machines</th>
<th>CR excluding FSM machines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of machines</strong></td>
<td>42</td>
<td>42</td>
<td>42</td>
</tr>
<tr>
<td>Mammography imaging machines</td>
<td>£9,660,000</td>
<td>£5,040,000</td>
<td>£2,940,000</td>
</tr>
<tr>
<td>Building costs</td>
<td>£1,680,000</td>
<td>£1,050,000</td>
<td>£1,050,000</td>
</tr>
<tr>
<td>Sub total</td>
<td>£11,340,000</td>
<td>£6,090,000</td>
<td>£3,990,000</td>
</tr>
<tr>
<td>BSIS</td>
<td>£3,000,000</td>
<td>£3,000,000</td>
<td>£3,000,000</td>
</tr>
<tr>
<td>PACS</td>
<td>£3,000,000</td>
<td>£3,000,000</td>
<td>£3,000,000</td>
</tr>
<tr>
<td>Project management</td>
<td>£2,601,000</td>
<td>£1,813,500</td>
<td>£1,498,500</td>
</tr>
<tr>
<td><strong>Total additional capital costs</strong></td>
<td>£19,941,000</td>
<td>£13,903,500</td>
<td>£11,488,500</td>
</tr>
<tr>
<td><strong>Annual operating costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Network costs</td>
<td>£300,000</td>
<td>£300,000</td>
<td>£300,000</td>
</tr>
<tr>
<td>Maintenance costs</td>
<td>£1,723,200</td>
<td>£1,446,000</td>
<td>£101,150</td>
</tr>
<tr>
<td>Staff costs</td>
<td>£1,236,000</td>
<td>£101,150</td>
<td>£101,150</td>
</tr>
<tr>
<td>Savings on consumables</td>
<td>(£1,276,850)</td>
<td>(£1,118,930)</td>
<td>(£1,118,930)</td>
</tr>
<tr>
<td><strong>Increase in annual operating costs</strong></td>
<td>£847,500</td>
<td>£728,220</td>
<td>£518,220</td>
</tr>
</tbody>
</table>

Note () indicates savings.
9.5.2.15 Forecast annual cash flow

Appendix 7 shows the forecast annual cash flows for 10 years from 2010 for the two purchase options of DDR machines and CR to include replacing FSM machines. Key messages include:

- the majority of the development costs of BSIS and PACS should be incurred before 2010
- the total cost of a DDR programme over 10 years is estimated at £28.4 million, compared with £21.2 million for a CR programme.

### Table 9-5 Total capital and operating costs: low case scenario

<table>
<thead>
<tr>
<th>Capital costs</th>
<th>DDR</th>
<th>CR including FSM machines</th>
<th>CR excluding FSM machines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of machines</td>
<td>29</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>Mammography machines</td>
<td>£6,670,000</td>
<td>£3,074,000</td>
<td>£1,624,000</td>
</tr>
<tr>
<td>Building costs</td>
<td>£1,440,000</td>
<td>£990,000</td>
<td>£990,000</td>
</tr>
<tr>
<td>Sub total</td>
<td>£8,110,000</td>
<td>£4,064,000</td>
<td>£2,614,000</td>
</tr>
<tr>
<td>BSIS</td>
<td>£1,500,000</td>
<td>£1,500,000</td>
<td>£1,500,000</td>
</tr>
<tr>
<td>PACS</td>
<td>£1,500,000</td>
<td>£1,500,000</td>
<td>£1,500,000</td>
</tr>
<tr>
<td>Project management</td>
<td>£1,666,500</td>
<td>£1,059,600</td>
<td>£842,100</td>
</tr>
<tr>
<td>Total additional capital costs</td>
<td>£12,776,500</td>
<td>£8,123,600</td>
<td>£6,456,100</td>
</tr>
<tr>
<td>Annual operating costs</td>
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<tr>
<td>Network costs</td>
<td>£250,000</td>
<td>£250,000</td>
<td>£250,000</td>
</tr>
<tr>
<td>Maintenance costs</td>
<td>£631,100</td>
<td>£797,000</td>
<td>£652,000</td>
</tr>
<tr>
<td>Staff costs</td>
<td>£1,659,900</td>
<td>(£1,454,600)</td>
<td>(£1,454,600)</td>
</tr>
<tr>
<td>Savings on consumables</td>
<td>(£778,800)</td>
<td>(£407,600)</td>
<td>(£552,600)</td>
</tr>
</tbody>
</table>

Note () indicates savings.

### Table 9-6 Total capital and operating costs: high case scenario

<table>
<thead>
<tr>
<th>Capital costs</th>
<th>DDR</th>
<th>CR including FSM machines</th>
<th>CR excluding FSM machines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of machines</td>
<td>42</td>
<td>42</td>
<td>42</td>
</tr>
<tr>
<td>Mammography machines</td>
<td>£9,660,000</td>
<td>£5,040,000</td>
<td>£2,940,000</td>
</tr>
<tr>
<td>Building costs</td>
<td>£1,680,000</td>
<td>£1,050,000</td>
<td>£1,050,000</td>
</tr>
<tr>
<td>Sub total</td>
<td>£11,340,000</td>
<td>£6,090,000</td>
<td>£3,990,000</td>
</tr>
<tr>
<td>BSIS</td>
<td>£5,000,000</td>
<td>£5,000,000</td>
<td>£5,000,000</td>
</tr>
<tr>
<td>PACS</td>
<td>£5,000,000</td>
<td>£5,000,000</td>
<td>£5,000,000</td>
</tr>
<tr>
<td>Project management</td>
<td>£3,201,000</td>
<td>£2,413,500</td>
<td>£2,098,500</td>
</tr>
<tr>
<td>Total additional capital costs</td>
<td>£24,541,000</td>
<td>£18,503,500</td>
<td>£16,088,500</td>
</tr>
<tr>
<td>Annual operating costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Network costs</td>
<td>£450,000</td>
<td>£450,000</td>
<td>£450,000</td>
</tr>
<tr>
<td>Maintenance costs</td>
<td>£2,323,200</td>
<td>£2,046,000</td>
<td>£1,836,000</td>
</tr>
<tr>
<td>Staff costs</td>
<td>£206,430</td>
<td>£206,430</td>
<td>£206,430</td>
</tr>
<tr>
<td>Savings on consumables</td>
<td>(£982,190)</td>
<td>(£860,710)</td>
<td>(£860,710)</td>
</tr>
<tr>
<td>Increase in annual operating costs</td>
<td>£1,997,440</td>
<td>£1,841,720</td>
<td>£1,631,720</td>
</tr>
</tbody>
</table>

Note () indicates savings increase in annual operating costs.
# Table 9-7 Forecast costs for SBSP

<table>
<thead>
<tr>
<th>Expenditure (£)</th>
<th>Total cost 2005/6</th>
<th>With two-view mammography</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical staff</td>
<td>£2,507,321</td>
<td>£860,000</td>
<td>£3,367,321</td>
</tr>
<tr>
<td>Other staff</td>
<td>£4,365,455</td>
<td>£90,000</td>
<td>£4,455,455</td>
</tr>
<tr>
<td>Medical supplies</td>
<td>£890,667</td>
<td>£520,000</td>
<td>£1,410,667</td>
</tr>
<tr>
<td>Training</td>
<td>£87,065</td>
<td>-</td>
<td>£87,065</td>
</tr>
<tr>
<td>IM&amp;T</td>
<td>£57,640</td>
<td>-</td>
<td>£57,640</td>
</tr>
<tr>
<td>Accommodation costs</td>
<td>£595,683</td>
<td>-</td>
<td>£595,683</td>
</tr>
<tr>
<td>Mobile unit movement costs</td>
<td>£29,249</td>
<td>-</td>
<td>£29,249</td>
</tr>
<tr>
<td>Mobile unit maintenance cost</td>
<td>£102,857</td>
<td>-</td>
<td>£102,857</td>
</tr>
<tr>
<td>Other supplies¹</td>
<td>£2,026,745</td>
<td>£479,000</td>
<td>£2,505,745</td>
</tr>
<tr>
<td>Total expenditure</td>
<td>£10,662,682</td>
<td>£1,949,000</td>
<td>£12,611,682</td>
</tr>
</tbody>
</table>

**Statistics**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Women screened²</td>
<td>159,847</td>
<td>-</td>
<td>170,000</td>
</tr>
<tr>
<td>Cost per woman screened (£)</td>
<td>£66.70</td>
<td>-</td>
<td>£74.20</td>
</tr>
</tbody>
</table>

¹ Includes capital charges for equipment and accommodation
² Estimate of women to be screened in 2008
10 ACKNOWLEDGEMENTS

NHS QIS is grateful to all members of the topic group who have given generously of their time to contribute constructively to the appraisal of the evidence and the writing of this report. We would also like to thank the following individuals for their time and expertise: Sandra Solomon (Exeter Breast Screening Service), Matthew Wallis and Sharon Hofmeister (Warwickshire, Solihull and Coventry Breast Screening Service), Niall Phelan and Fidelma Flanagan (‘Breastcheck’, Eccles Unit, Dublin), Ken Young (Royal Surrey County Hospital, Guildford) and Karpal Hayer (Derby Breast screening Service).

We hope this HTA has also achieved an important goal of sharing knowledge and best practice across Scotland.
11 REFERENCES


Broeders MJ, Onland-Moret NC, Rijken HJ, Hendriks JH, Verbeek AL and Holland R. 2003. Use of previous screening mammograms to identify features indicating cases that would have a possible gain in prognosis following earlier detection. Eur J Cancer, 39(12), 1770-1775.


Readman LP and Asbury DL. 1999. Breast screening uptake rates: does access to Saturday sessions lead to improvements? Breast, 8(6), 343-344.


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APPENDICES
## APPENDICES

### APPENDIX 1 MEMBERS OF THE TOPIC GROUP

<table>
<thead>
<tr>
<th>Name</th>
<th>Job title</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debbie Archibald</td>
<td>Service Manager</td>
<td>East of Scotland Breast Screening Service</td>
</tr>
<tr>
<td>Brenda Bellando</td>
<td>Business Manager</td>
<td>West of Scotland Breast Screening Service</td>
</tr>
<tr>
<td>Carol Colquhoun</td>
<td>National Screening Coordinator</td>
<td>National Services Division</td>
</tr>
<tr>
<td>Emilia Crighton</td>
<td>Chair of Organisational Issues sub-group &amp; Consultant in Public Health Medicine</td>
<td>Greater Glasgow and Clyde NHS Board</td>
</tr>
<tr>
<td>Peter Croan</td>
<td>Head of Finance and Operations</td>
<td>National Services Division</td>
</tr>
<tr>
<td>Hilary Dobson</td>
<td>Clinical Director</td>
<td>West of Scotland Breast Screening Service</td>
</tr>
<tr>
<td>Karen Duncan</td>
<td>Consultant Radiologist</td>
<td>North East of Scotland Breast Screening Service</td>
</tr>
<tr>
<td>Fiona Gilbert</td>
<td>Professor of Radiology</td>
<td>University of Aberdeen</td>
</tr>
<tr>
<td>John Harper</td>
<td>Imaging Specialist</td>
<td>Scottish Healthcare Supplies</td>
</tr>
<tr>
<td>Mark Hartswood</td>
<td>Senior Research Fellow</td>
<td>University of Edinburgh</td>
</tr>
<tr>
<td>Margaret Kenicer</td>
<td>Chair of HTA Topic Group &amp; Consultant in Public Health Medicine</td>
<td>Kings Cross Hospital</td>
</tr>
<tr>
<td>Marian King</td>
<td>Clinical Specialist/Regional QA Radiographer</td>
<td>West of Scotland Breast Screening Service</td>
</tr>
<tr>
<td>Sharon Lloyd</td>
<td>eDiamond Project Manager</td>
<td>Oxford University Computing Laboratory</td>
</tr>
<tr>
<td>Ann Mumbly</td>
<td>Superintendent Radiographer/Clinical Lead</td>
<td>West of Scotland Breast Screening Service</td>
</tr>
<tr>
<td>Tracy McKen</td>
<td>Screening, Physical Activity &amp; Obesity Branch</td>
<td>Scottish Government Health Directorate</td>
</tr>
<tr>
<td>Margaret Reid</td>
<td>Professor of Women's Health</td>
<td>University of Glasgow</td>
</tr>
<tr>
<td>Lesley Smart</td>
<td>Consultant Radiologist</td>
<td>Breast Screening Clinic, Edinburgh</td>
</tr>
<tr>
<td>David Steel</td>
<td>Project Manager Screening Programme</td>
<td>National Services Division</td>
</tr>
<tr>
<td>Alex Watt</td>
<td>Medical Physicist</td>
<td>Scottish Healthcare Supplies</td>
</tr>
</tbody>
</table>
APPENDIX 2 STRATEGY FOR LITERATURE SEARCHES

Clinical effectiveness: secondary literature

An initial search was undertaken in May 2006 to identify HTAs, systematic reviews and other evidence-based reports using the following sources:

- National Institute for Health and Clinical Excellence (NICE) www.nice.org.uk
- National Coordinating Centre for Health Technology Assessment (NCCHTA) www.ncchta.org
- Health Technology Assessment Database (HTA) via the Cochrane Library (Internet)
- Cochrane Database of Systematic Reviews (CDSR) via the Cochrane Library (Internet)
- Database of Abstracts of Reviews of Effects (DARE) via the Cochrane Library (Internet)
- Centre for Reviews and Dissemination (CRD), University of York. www.york.ac.uk/inst/crd
- West Midlands Health Technology Assessment Collaboration, Department of Public Health & Epidemiology, University of Birmingham. www.publichealth.bham.ac.uk/wmhtag
- SchARR, University of Sheffield. www.shef.ac.uk/scharr
- South and West R & D Directorate, DEC Reports www.hta.nhsweb.nhs.uk/rapidhta
- ECRI www.ecri.org (subscription)
- Scottish Intercollegiate Guidelines Network (SIGN) www.sign.ac.uk
- Health Services Research Unit www.abdn.ac.uk/hsru
- Aggressive Research Intelligence Facility (ARIF) www.bham.ac.uk/arf
- Health Evidence Bulletins Wales www.hebw.uwcm.ac.uk
- Clinical Evidence (BMJ) www.clinicalevidence.com
- Prodigy www.prodigy.nhs.uk
- Translating Research into Practice (TriP) www.tripdatabase.com
- Bandolier www.jr2.ox.ac.uk/bandolier
- Ongoing Reviews Database http://www.update-software.com/National
- Medical Research Council fundedresearch.cos.com/MRC

Extended searching to identify additional material was undertaken in September 2006. This included the following sources:

- NLH (SEEK) Guidelines Finder
- US National Guideline Clearing House
- New Zealand Guidelines Group
- NHS Breast Cancer Screening Programme - publications
- Royal College of Radiologists
- Society of Radiographers
- International Society of Radiology
- American College of Radiology
- Royal Australia and New Zealand College of Radiologists
- Google
- Vivisimo

Clinical effectiveness: primary literature

The following sources were searched in January 2007:

- MEDLINE (OVID)
- EMBASE (OVID)
- CINAHL (OVID)
- MEDLINE in PROCESS (OVID)
- CENTRAL (OVID)
- Web of Science (ISI) – citation searches

Search 1 – Use and storage of prior images

Database: MEDLINE

Coverage: 1950 to January Week 3 2007

Platform: OVID

Date: 25th January 2007

1. exp breast neoplasms/
2. (breast$ adj3 (neoplasm $ or cancer$ or tumor$)).tw.
3. 1 or 2
4. mass screening/
5. (screening or screened or screens).tw.
6. or/4-5
7. 3 and 6
8. mammography/
9. mammogra$ .tw.
10. or/7-9
11. ((previous$ or prior$ or earlier or past or old$) adj2 (film$ or scan$ or image$ or mammogra$)).tw.
12. ((compare or comparison) adj2 (mammogra$ or film$ or scan$)).tw.
13. or/11-12
14. 10 and 13
**Search 2 – Use of computed radiography**

Database: MEDLINE

Coverage: 1950 to January Week 3 2007

Platform: OVID

Date: 25th January 2007

1. exp breast neoplasms/
2. (breast$ adj3 (neoplasm $ or cancer$ or tumor$)).tw.
3. 1 or 2
4. mass screening/
5. (screening or screened or screens).tw.
6. or/4-5
7. 3 and 6
8. mammography/
9. mammogram$.tw.
10. or/7-9
11. radiographic image enhancement/
12. radiographic image interpretation, computer assisted/
13. image processing, computer assisted/
14. image interpretation, computer assisted/
15. image enhancement/
17. 16 or 11-15
18. “Clinical Trial [Publication Type]” /
19. randomized.ab.
20. placebo.ab.
21. clinical trials/
22. randomly.ab.
23. trial.ti.
24. or/19-24
25. animals/
26. humans/
28. 26 not (26 and 27)
29. 25 not 28
30. 18 and 29

**Economic evaluation: secondary literature**

The following sources were searched in May 2006:

- Health Economics Group, East Anglia  
  [www.med.uea.ac.uk/research/research_econ/HEG_Intro.htm](http://www.med.uea.ac.uk/research/research_econ/HEG_Intro.htm)
- Institute of Health Economics IHE, Alberta, Canada  
  [www.ihe.ab.ca](http://www.ihe.ab.ca)
- LSE London School of Economics and Political Science  
  [www.lse.ac.uk](http://www.lse.ac.uk)
- Southampton University Economics Department  
  [www.economics.soton.ac.uk](http://www.economics.soton.ac.uk)
- Centre for Health Economics Research and Development CHERE, University of Sydney and Central Sydney Area Health Service  
  [www.chere.uts.edu.au](http://www.chere.uts.edu.au)
- International Health Economics Association iHEA  
  [www.healtheconomics.org](http://www.healtheconomics.org)
- Centre for Health Economics and Policy Analysis (CHEPA), McMaster University, Canada  
  [www.chepa.org](http://www.chepa.org)
- Centre for Health Economics (CHPE), University of Melbourne and Monash University, Australia  
- NetEc  
  [www.netec.mcc.ac.uk/NetEc.html](http://www.netec.mcc.ac.uk/NetEc.html)
- IDEAS Internet Documents in Economics Access Service  
  [http://ideas.repec.org](http://ideas.repec.org)

**Patient issues: primary literature**

The following sources were searched in February 2007:

- MEDLINE
- EMBASE
- CINAHL
- PSYCInfo
- MEDLINE in PROCESS
- DIPEx
- EQUIP
- Breast Screening Literature Database – NHS Breast Screening Programme

**Search – patient issues**

Database: MEDLINE

Coverage: 1950 to January Week 4 2007

Platform: OVID

Date: 7th February 2007

1. exp breast neoplasms/
2. (breast$ adj3 (neoplasm$ or cancer$ or tumor$)).tw.
3. 1 or 2
4. mass screening/
5. (screening or screened or screens).tw.
6. 4 or 5
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7. 3 and 6
8. mammography/
9. mammogra$.tw.
10. or/7-9
11. interview.mp.
12. experience$.mp.
13. qualitative.tw.
14. or/11-13
15. 10 and 14

31. (extend$ or extension or long$ or length$) adj3 (hour$ or service$)).tw.
32. or/29-31
33. 10 and 32
34. og.fs.
35. ((share$ or sharing) adj3 (service$ or facil$)).tw.
36. 34 or 35
37. 10 and 36
38. 18 or 28 or 33 or 37

Organisational issues: primary literature

The following sources were searched in February 2007:

- MEDLINE
- EMBASE
- CINAHL
- MEDLINE in Process

Search – organisational issues

Database: MEDLINE

Coverage: 1950 to February Week 3 2007

Platform: OVID

Date: 28th February 2007

1. exp breast neoplasms/
2. (breast$ adj3 (neoplasm$ or cancer$ or tumor$)).tw.
3. 1 or 2
4. mass screening/
5. (screening or screened or screens).tw.
6. or/4-5
7. 3 and 6
8. mammography/
9. mammogra$.tw.
10. or/7-9
11. patient acceptance of health care/
12. patient compliance/
13. patient participation/
14. treatment refusal/
15. health behavior/
16. (attend$ or attendance or uptake).tw.
17. or/11-16
18. 10 and 17
19. health services accessibility/
20. mobile health units/
21. travel/
22. rural population/
23. urban population/
24. urban health/
25. rural health/
26. (access$ or location$ or locate$ or proximity or distance$ or travel$)).tw.
27. or/19-26
28. 10 and 27
29. “appointments and schedules”/
30. reminder systems/
## APPENDIX 3 PRIMARY RESEARCH STUDIES COMPARING THE USE OF PREVIOUS IMAGES WITH CURRENT IMAGES IN BREAST SCREENING

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study design</th>
<th>Interventions</th>
<th>Reference standard</th>
<th>Outcomes</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bassett et al. (1994) USA</td>
<td>Retrospective.</td>
<td>Usefulness and costs of comparing previous mammograms done at the same or another facility. Cases-1,432 Previous mammograms for 1,093 were found.</td>
<td>Reading current mammograms only. Reading current mammograms with prior mammograms.</td>
<td>Clinical management. Biopsy avoided/needed-benign/malignant. Additional imaging. Labour and postage costs.</td>
<td>Clinical management-7 extra biopsies performed. 2 malignant identified. 16 biopsy saved. Average labour and postage costs for prior image received-$12.52. Average labour cost if prior image not received $5.33. Comparing with prior images demonstrated a very small but limited benefit in clinical management and cancer detection. The overall costs and time involved are substantial.</td>
</tr>
<tr>
<td>Broeders et al. (2003)</td>
<td>Reviewed.</td>
<td>Use of previous images to identify the false negatives where earlier detection could have had an impact on diagnosis. Cases-234 Screen detected-142 Interval cancers-92 Lesion visible-117 Readers-2.</td>
<td>Diagnostic mammograms versus previous screening mammograms.</td>
<td>Descriptive analysis. Chi square test. Fisher's exact test.</td>
<td>51 of 117 cancers had poor diagnosis characteristics. Architectural distortion-29 versus 10%; p=0.01. High density mass-25 versus 13%; p=0.06. Architectural distortion and non-spiculated high density masses on previous images are associated with possible gain in diagnosis.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study design</td>
<td>Interventions</td>
<td>Reference standard</td>
<td>Outcomes</td>
<td>Findings</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Burnside et al. (2002)</td>
<td>Retrospective study.</td>
<td>Comparing detection rates in screening and diagnostic mammography between cases that were read with and cases that were read without previous mammograms. 31,713 screening examinations compared with prior images. 8,328 diagnostic examinations compared with prior images.</td>
<td>Screening Reading current mammograms only. Reading current mammograms with prior mammograms. Diagnostic Reading current mammograms only. Reading current mammograms with prior mammograms.</td>
<td>Recall rate. Student t test. Chi square test. Fisher’s exact test.</td>
<td>Recall rate decreased from 4.9% to 3.8% (p&lt;0.0001) without a significant difference in the detection rate (5.5–5.2/1,000, p=0.87) and biopsy yield (40–44%, p=0.56) when prior images used. Diagnostic Rate of abnormal findings/biopsy recommended rate increased significantly from 4.3% to 9.4% (p&lt;0.0001); biopsy yield from 38%–51% (p=0.12); cancer detection rate from 11/1,000 to 39/1,000 (p&lt;0.0001) when prior images were used. No significant difference in mean tumour size. Significant decrease in frequency of auxiliary node metastasis and cancer stage for screening, but not for diagnostic.</td>
</tr>
<tr>
<td>Callaway et al. (1997)</td>
<td>Retrospective study.</td>
<td>Performance of radiologists in comparison and reviewing the effect of previous images in improving diagnostic accuracy. Readers-8 Hard copy Cases-100 12 abnormal (both benign and malignant).</td>
<td>Reading current mammograms only. Reading current mammograms with prior mammograms.</td>
<td>ROC curves/overall performance. Student t test.</td>
<td>Sensitivity nil and recall down. Comparing use of previous films showed no difference in diagnostic accuracy, but led to a significant reduction in subsequent additional and ultrasound examinations. The ROC curve for the group performance remained unchanged when compared with use of previous images. Individual performance analysis showed an increase in their true-positive pick up when prior images were used. The study included only 9 cancer cases (low power).</td>
</tr>
<tr>
<td>Citation</td>
<td>Study design</td>
<td>Interventions</td>
<td>Reference standard</td>
<td>Outcomes</td>
<td>Findings</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Kleit &amp; Ruiz, (2003)</td>
<td>Retrospective.</td>
<td>Analysed the results of women whose mammograms were false positive and investigated the causes. Secondary data from EMR.</td>
<td>Interpretation of data.</td>
<td>Accuracy of readers. Number of false positives-screening test. Diagnostic tests. DCE-detection controlled estimation.</td>
<td>Access to previous mammogram reduced the incidence of false-positive readings by at least half. Mondays and Wednesdays seem to be more prone to false positives than other days in the week.</td>
</tr>
<tr>
<td>Roelofs et al. (2007)</td>
<td>Netherlands</td>
<td>Comparing current and prior mammograms in breast cancer screening. Readers-12 Soft-copy +CAD Digitised old films Cases-160 80 benign/normal 80 malignant. Potential abnormalities located and likelihood of malignancy estimated, indicated whether prior images were considered necessary.</td>
<td>Reading current mammograms only. Reading current mammograms with prior mammograms. Reading prior mammograms on request (only when readers deem it necessary).</td>
<td>LROC performance. Lesion localised fraction LROC analysis. Paired two-tailed student t test.</td>
<td>Sensitivity—nil. Recall rate decreased. Without prior images significantly more observations were made. When only positive cases were considered, no difference was observed. At fixed lesion localised fraction, non lesion localised fraction was reduced by 44% (p&lt;0.001) on average when prior images were read. Reading performance was significantly better when prior images were available. Performance was also increased for combined reading mode (on request only) however this increase was smaller than when prior images were available. Prior images were requested in 24–33% of the cases and more often in positive cases.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study design</td>
<td>Interventions</td>
<td>Reference standard</td>
<td>Outcomes</td>
<td>Findings</td>
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<td>-------------------------------------------------------------------------------</td>
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<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sumkin et al. (2003)</td>
<td>Observer study.</td>
<td>Comparison of present mammograms with mammograms obtained 1 and 2 years prior. Readers 11+1 Cases-128.</td>
<td>Screening Reading current mammograms only. Reading current mammograms with prior mammograms acquired 1 year prior. Reading current mammograms with mammograms acquired 2 years prior.</td>
<td>Performance of observers. Accuracy. Sensitivity. Specificity. Logistic regression.</td>
<td>Radiologists were significantly more precise (p&lt;0.001 when compared with prior mammograms (1 or 2 years prior). Sensitivity using 1 and 2 years prior images did not have an effect (p&gt;0.10) but specificity using 1 year prior images was improved (p=0.03). Comparing mammograms is significant for precise judgements and using the latest prior images appears to be the most favourable for increasing the specificity.</td>
</tr>
<tr>
<td>Thurfjell et al. (2000)</td>
<td>Retrospective study.</td>
<td>Readers-3 Hard copy Cases-150 Screen detected cancer-35 Interval-12 Re-screen-14 89 normal.</td>
<td>Screening Reading current mammograms only. Reading current mammograms with prior mammograms.</td>
<td>Sensitivity. Specificity. Localised lesion fraction. McNemar test with binomial distribution.</td>
<td>Without prior images-40.3 cancers (range 37–42). Specificity 87% (85–88%). With prior images-37.7 cancers (range 34–42). Specificity 96% (94–99%). Increase in specificity was significant for each reader (p=0.0002–0.03). Overall specificity increased. Sensitivity decreased but not significant, so unclear. False-positive recall rate decreased. Lesion localised fraction appear to decrease when prior images are available.</td>
</tr>
<tr>
<td>Citation</td>
<td>Study design</td>
<td>Interventions</td>
<td>Reference standard</td>
<td>Outcomes</td>
<td>Findings</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Varela et al. (2005)</td>
<td>Observer study</td>
<td>Use of prior mammograms for classification of benign and malignant masses. Readers 5+1 Soft copy Cases-198 (mixed) 99 benign 99 malignant.</td>
<td>Reading current mammograms only. Reading current mammograms with prior mammograms.</td>
<td>Observers performance. ROC analysis. Difference in performance. Analysis of variance.</td>
<td>The use of prior mammograms increased the performance of readers in the classification of masses. The average reading performance using prior images increased from 0.763–0.796 Az and the classification precision was statistically significant (p=0.008).</td>
</tr>
<tr>
<td>Wilson et al. (1996)</td>
<td>Retrospective</td>
<td>Usefulness and costs of acquiring and comparing prior images obtained from a different facility. Cases-1,297 756 normal; of these 559 were compared with prior images. 541 abnormal.</td>
<td>Reading current mammograms only. Reading current mammograms with prior mammograms.</td>
<td>Clinical management. Costs.</td>
<td>98% (551) of mammograms had no change when compared. 1% (8) of the previous readings were changed. Labour and postage costs-$21.49.</td>
</tr>
</tbody>
</table>

ROC – Receiver operating characteristic (ROC) curves
LROC – Localised receiver operating characteristic
DCE – Detection controlled estimation
APPENDIX 4 GENERAL REVIEW OF ISSUES FOR WOMEN ATTENDING BREAST SCREENING SERVICES

Introduction

In Section 7 the issues relating to digital mammography for women attending breast screening services were considered. This appendix provides a more detailed review of general issues for women attending including those unrelated to digital mammography.

A non-systematic review of the literature directly relevant to the HTA was undertaken. Only one study explored digital technology in relation to breast screening and therefore this review is of women’s views and experiences of FSM. Its relevance is two-fold.

Firstly, in any large service review it is important to consider the views of service users. In this HTA, service users are women eligible for breast screening and it is important to ascertain their views on the following:

- their experience of undergoing mammography
- reasons for attending screening
- level of understanding
- experience of being screened.

This review highlights the main issues emerging from the literature.

Secondly, there may be ways in which digital mammography could change how mammography is experienced once the technology is established. These are also discussed.

Methodology

As part of the process to help define the assessment questions, an initial search for HTAs, systematic reviews and other evidence-based reports was undertaken in May 2006 and September 2006. Secondary research, identified by this search, and which discussed issues for women relating to digital mammography, was considered for inclusion.

To identify the primary literature, an initial search was undertaken in February 2007. The following bibliographic databases (all via OVID) were searched:

- MEDLINE
- EMBASE
- MEDLINE in PROCESS
- CINAHL
- PsycINFO.

The search focused on identifying qualitative research and used a methodological filter published by the HEDGES team (McKibbon et al., 2006). This search identified many relevant papers, and the decision was made not to undertake any additional searches of the primary literature.

In addition, the websites DIPEX (www.dipex.org) and Electronic Quality Information for Patients - EQUIP (www.equip.nhs.uk) were also searched. Literature identified by the NHS Breast Screening Programme, in their breast screening literature database (www.nhs.thescienceregistry.com/search.asp?title=1) were also examined. Reference lists and bibliographies of studies were also checked for additional papers of interest.

A list of the sources searched and a copy of the strategy used to search MEDLINE is included in Appendix 2. This strategy was adapted to search all other databases. A complete listing of all strategies can be obtained by contacting NHS QIS.

There is considerable literature on the topic of women’s views and experiences of mammography but studies vary extensively making direct comparisons difficult (Brett et al., 2005; NHS Cancer Screening Programmes, 2006a). Attendance at breast screening is partially dependent upon the system of health care. USA research, by far the most voluminous, was not included when it related to how service funding may affect usage, although other USA research is reviewed. A range of different methodologies were drawn upon and included large-scale analyses using national databases and surveys of particular groups (eg ethnic groups, older women, disabled women) whilst a small number of studies used focus groups and a very few, interviews, to ascertain women’s views of the service.

Studies also varied in the ways in which they measured individual behaviour, the scales and scores utilised, the age range of women approached (eg from women in their 20s to women in their 80s and 90s), and whether or not the study was prospective or retrospective. Most studies excluded women who had had breast cancer. Despite the variability, the literature is sufficiently robust to report on three areas, although some studies cut across this simple divide:

- users’ views about the service
- the experience of mammography
- responses to false positives.

Results

The literature on women’s views of the service is extensive. Three themes emerge:

- service issues such as appointment systems and convenience of access
- psychological, behavioural factors influencing uptake
- knowledge and cultural views of breast screening.

Each is discussed in turn.

Service issues

It is clear from the literature that service aspects are important, although studies vary in terms of how influential are factors such as opening hours, as well as travel time and socioeconomic group on uptake and attendance. Since one of the HTA recommendations
includes extending opening hours of the service it is useful to review the literature relating to such changes in the service. A study in Manchester, UK, funded by NHS BSP, assessed the effect of extended hours (offering Saturday appointments from 9.30am to 12.30pm) to women who did not attend the first screening round (Readman & Asbury, 1999). Results of the trial indicate that there was no significant difference in attendance. However, elsewhere extending appointment times has been successful. A Scottish pilot project examining use of extended hours for screening sessions has shown a good uptake of screening and an increase in attendance rates (NHS Quality Improvement Scotland, 2006).

Other approaches like special programs for the homeless, liaison health visitor, and liaising with long-stay hospitals have also proved successful. In the north of Scotland assessments clinics which were usually held on Mondays were extended to other weekdays if attendance rates were high.

Thus innovative service developments, such as taking the service (through the use of mobile units) to those in different areas (both inner city, and rural areas), and out-of-hours clinics have proved successful. The latest evidence about best practice and performance of the SBSP demonstrated that it is possible to deliver services, and address issues and improve attendance rates (NHS Quality Improvement Scotland, 2003b; NHS Quality Improvement Scotland, 2006). The effect of extended hours on staff, extra costs, and other aspects are not reported.

Studies from a number of countries and using a range of methods confirmed the overall finding that ease of access to the screening facility is of considerable importance to women (Kee et al., 1993; Sutton et al., 1994; McNoe et al., 1996; Aro et al., 2001). Women in rural areas are less likely to take up the offer of screening (Stark et al., 1997; Gram & Slenker, 1992; Maxwell, 2000). In a Scottish study, Kohil et al. (1995) examined travel time and women's attendance at an assessment centre over a 12-month period. The authors found that the costs of attending the centre were on average, high. They found that for the attendees, travel time and distance were considerable (average return journey 21.5 miles and 1.73 hours), mean costs were £6.06 (1995 prices) and there was a need for multiple journeys (2-6 journeys). The researchers noted that actual costs to the attendees are often not factored into overall costs of service reorganisation but that health services planners should not forget to take these costs into account when reorganising services.

Some authors conclude that convenience is only one of a number of influential factors. For example, when the service was moved in Bolton, Maxwell studied changes in attendance patterns and concluded that although there was a direct relationship between attendance and distance to the unit, the most significant factor of attendance rates was socioeconomic group, with the highest rates from women in the least deprived areas (Maxwell, 2000) whilst others note that women who report lack of convenience may also be less likely to take up other preventive services (eg Gram & Slenker (1992)).

Overall, women report considerable satisfaction with mobile units, although they do report a different screening experience. Two focus group studies report women's views of mobile units (Skinner et al., 1995; Hamilton et al., 2003). In the UK study, women had attended either a mobile unit, a hospital-based unit or a temporary site in a health clinic, thus allowing for some comparisons in location (Hamilton et al., 2003). The authors commented that an unexpected finding was that those women who had experienced both the hospital and mobile unit preferred the mobile unit (seen as more cosy, easy to locate and personal) although the women acknowledged that space was limited and there was little privacy to ask questions or discuss sensitive issues. Skinner et al. (1995) explored the impact of introducing mobile units into their USA programme. The units were seen as acceptable if women's concerns were addressed, notably about privacy and quality. Concerns about privacy were two-fold; some women did not want to be seen entering or exiting the unit, whilst others wanted to be reassured about privacy during changing and being examined. The quality issues were about the equipment and the staff being the same standard as in a fixed unit. Convenience was rated highly but again with a qualifier, that the unit was parked in an appropriate health-related venue.

Psychological, behavioural factors

Research shows that attendance rates of the breast screening service are not evenly spread across any population but are influenced by a range of factors, some of which can be described as psychological, behavioural factors. Thus attendees are more likely also to carry out other health-related preventive behaviours, such as to attend cervical screening and dental check ups; some studies also suggest that engaging in other health behaviours such as exercise, diet, smoking are also predictive of attendance at breast screening (Sutton et al., 1994; Maxwell, 2000).

Anxiety about cancer affects people differently. A recent meta-analysis of studies (Hay et al., 2006) examined the relationship between worry about breast cancer and screening attendance; they found, on reviewing 12 prospective studies, that worry has a small but definite association with attendance at screening. Brett et al. (2005) carried out a systematic review of 54 papers from 13 countries to explore the psychological impact of mammography (where anxiety or worry is specifically measured). They report that the procedure does not create anxiety in women who are given a clear result although on invitation they may experience some anxiety.

Silverman et al. (2001) found that women's concerns about cancers were divided into two sets of risk factors, one being factors over which they had more control, eg smoking, exercise, work environment, no breastfeeding, medications, and one over which they had less control, eg family history, genetics, large breasts. Many women reported that they acted on those factors over which they had some control, and that early detection was better, a belief which women in other studies also firmly held (Orton et al., 1991).
Some studies have concluded that when screening is perceived as positive, women are more likely to repeat the experience. Although many women knew someone who had died of breast cancer or had a family history of the disease, attending screening was perceived to provide reassurance (Bowie et al., 2003; Nehlyudov et al., 2003; Ahmed et al., 2005). Embarrassment was mentioned as an emotion triggered by the experience, but did not always lead to non-attendance (Bobo et al., 1999; Consedine et al., 2004). The message here is that the benefits are seen by many women to outweigh the risks. Fear about radiation was also reported by women in a number of studies as a concern (Ahmed et al., 2005; Bobo et al., 1999; Zapka & Berkowitz, 1992). It did not necessarily stop women attending for screening, but it is important that women are told of the lower dose of radiation with some digital technologies.

By contrast, other studies have shown that some groups of women are fatalistic about cancer and this fatalism is an important barrier to attendance. Fatalism was sometimes linked to their own experience, for example, women in the USA study conducted by Bailey et al. (2000) reported that very few African American women knew others who had survived breast cancer. Some thought that the disease was always fatal and therefore early diagnosis was pointless; that there was a stigma associated with contracting cancer, whilst others reported being so frightened by the thought of finding they had cancer that they did not attend, findings also noted elsewhere (Aro et al., 2001; Phillips et al., 1999; Russell et al., 2006; Fernandez et al., 2005). Bailey et al. (2000) point to the important lessons from these beliefs, namely that speaking out publicly about the disease helps counteract the stigma, that one’s health is one’s own responsibility and that it is important to have ‘visible’ survivors to show that the disease is not necessarily fatal.

Knowledge and cultural factors

A number of studies suggest that the majority of women undergoing breast screening do not understand that mammography does not detect all cancers (Barratt et al., 1999; Silverman et al., 2001; Domenighetti et al., 2003; Davey & Butow, 2006). For example, Silverman et al. (2001) found that nearly half of the sample thought that mammography was either 100% accurate or very accurate and 85% thought that the screening test seldom missed cancers. Domenighetti et al. (2003) reported in a telephone interview study of 4,140 women in four countries that 68% thought that regular screening ‘prevents’ or ‘reduces’ the risk of contracting the disease, and reduces breast cancer deaths in women aged 50 and over by at least a half. Nearly two thirds (60%) also considerably over-estimated the number of deaths prevented by regular screening, thinking it could prevent 40 or more deaths per 1,000 women.

Knowledge (or lack of knowledge) of the aetiology of breast cancer was picked up in a number of studies. On the whole, women understood breast cancer as a uniformly progressive disease, curable if detected early but not so if later (Silverman et al., 2001; Pfeffer, 2004). Women reported that the invitation to attend every 3 years suggested slow progress of the disease whereas other wording in the literature (for example, about seeing a doctor immediately if lumps were found) suggested greater urgency, which they found confusing. There was no sense of the complexity of the biological understanding of the disease.

A repeated finding was that many women did not understand the link between age and incidence of the disease, with studies from different countries reporting that older women were less likely to take up the offer of screening (Fine et al., 1993; Bonelli et al., 1996; Burack et al., 2000; Harris et al., 2002; Maxwell, 2000). Education was a key variable with more educated women being more likely to know that incidence increased with age. Pfeffer (2004) found that the literature provided to UK women gave what they saw as conflicting (and confusing) messages, more geared to younger women. For example, they were told that breast cancer increased with age, yet in the national breast screening programme women older than 70 had to ask for screening. Pictures in the leaflets were of younger, not ageing bodies, and leaflets mentioned screening being carried out after a menstrual period but nothing about when it should be carried out in the years after menopause. Elsewhere women expressed concerns about the value of mammography, with some reporting the low priority they accorded screening by the time they reached an older age.

Research suggests that culture (in its broadest senses, to include religious faith) can have an effect on how women think about their health, whether they take part in preventive health care behaviours and how they understand cancer. Many USA and Canadian studies have shown that ethnicity is often (although not always) associated with negative beliefs about breast screening which inhibit use of the services (eg Adams et al., 2001; Consedine et al., 2004; Maxwell, 2000). In the UK, ethnicity has not been explored in any detail. However, Pfeffer carried out a study with 20 focus groups in London with members of ethnic minority women and white women to explore why women do or do not take up the offer of free breast screening. Women from a range of ethnic minorities reported believing that certain practices (some associated with their faith) protected them against cancer (for example, breast feeding their children, having one partner, eating certain foods) and therefore they were at lower risk.

The literature suggests that some women viewed screening as a valuable option to be taken up whilst others drew on their own faith to support this decision. However, the gender of the doctor was a concern (and potentially a barrier) to the women (a female was preferred). In a very small study of Canadian Muslim women, respondents reported that the Qu’ran provided conflicting beliefs, the first that one accepted what fate offered, and the other, the belief that one should look after one’s health (Underwood et al., 1999). Thus both Underwood et al. (1999) and Pfeffer (2004), reporting results from different countries, concluded that faith issues presented a potentially serious barrier to the uptake of breast screening.
The experience of being screened

Studies have explored what women felt about the process of being screened. Factors that stood out as important included women's views of the general ambience of the unit (already mentioned in terms of mobile units), staff attitudes, and pain associated with the handling of their breasts. Engelman et al. (2005) reported that women liked the facility to be pleasant and welcoming and saw the waiting time as an opportunity to be provided with educational materials. Procedures are important with prolonged waiting time being seen as negative, especially waiting whilst undressed.

It may be that in future the mammographer has more time to interact with women during the appointment and the attitude of the mammographer becomes even more crucial. Currently, research suggests that some are seen as helpful and supportive, with others less so. Interactions with staff were more commonly positive if the staff had a friendly manner and provided an explanation of the test (Ahmed et al., 2001; Orton et al., 1991; Thomson et al., 1996). Researchers found a series of factors which diminished re-attendance, including staff being seen as unhelpful, rude, unsympathetic, rough handling of breasts, unresponsive to complaints, use of technical jargon, as well as inadequate privacy when being asked for personal information (Ahmed et al., 2001; Thomson et al., 1996).

There is a small body of literature from the USA and Europe on the use screening among women with disabilities (usually physical), carried out with the recognition that these women with disabilities may have reduced access to routine screening services (Iezzoni et al., 2001; Mele et al., 2005; Robbins-Cherry & Radford, 2006; Verger et al., 2005). Mele et al. carried out interviews with a sample of USA women with either sensory or physical disabilities. Women reported believing in the value of mammography, but noted the difficulties that their disability created for them physically to go through the procedure. Previous negative encounters with members of the medical profession where staff were unhelpful or ill-at-ease left women with a feeling of lack of respect. In the UK physical access to the unit should be compliant with the Disability Discrimination Act 1995, but elsewhere structural barriers in terms of physical access to the facility were identified as more of a problem for disabled women than for many others. The French study (Verger et al., 2005) of GPs confirms the staff unease and lack of experience in dealing with women with disabilities.

Pain emerges repeatedly as a reason for non-attendance or non-rescreening for breast screening. The topic has been well reviewed in the NHSBSP report (NHS Cancer Screening Programmes, 2006a) which concludes that a number of factors influence women's perceptions of pain, including socioeconomic status and education, prior experience of pain from mammography, and perceptions of the staff and standards of care. In relation to the last factor, communication skills were identified as important in 'promoting positive perceptions of the staff and of the standard of care'. There was also evidence that good communication prior to the mammography reduced the expectation of pain. In their review, they note further factors (although there is less evidence that these factors are associated with pain) including lower age of women, higher density of breasts, presence of symptoms, fear of breast cancer, nervousness prior to mammogram, less ability to use coping strategies and ratio of compression to breast thickness (NHS Cancer Screening Programmes, 2006a). Crucially they note that there is no evidence that the experience of pain influences acceptability of the procedure.

Responses to false positives

The literature on women's responses when recalled for further investigation because of a false-positive result from a screening mammogram is consistent. The one USA study which explicitly reports on digital mammography falls into this category and relates to the acceptability of three new non-invasive breast cancer diagnostic tests prior to biopsy (Liang et al., 2003). The 82 women in the study had undergone FSM examinations and were returning for further diagnostic tests, including magnetic resonance imaging (MRI), digital and sestamibi scanning (nuclear medicine) as the three tests. Relating to the response to digital mammography, exactly half reported that the procedure was 'more comfortable' than FSM, and half, less comfortable. The study is not strong, numbers of those responding to the questions on digital mammography are extremely small, and as the authors also note, women's understanding of the test(s) is not clear, since the comfort levels of the test should be the same as with FSM.

Brett et al. (2005) systematically reviewed the literature relating to the impact of being recalled for further tests where a diagnosis of breast cancer was not reached. They concluded that recalled (false positive) women are reported to experience anxiety although the literature does not contain agreement about the length and degree of anxiety created by being asked back for further investigations. The authors also noted conflicting evidence as to whether undergoing further testing has an impact on future attendance at breast screening. Ong & Austoker (1997) found in their UK study of recalled women that communication was very important; talking to someone just before the tests was valued, especially by those women who reported distress.

Digital mammography allows the quality of the mammogram images to be checked at the time of the visit, thus reducing the number of technical recalls. At least some of the research on false positives excludes technical recalls in their exploration of the effect of recall on women, whilst others do not identify this type of recall as a separate category. Thus the effect of technical recalls on women, and how these are managed within the service, is unknown.

Conclusions

It is noted here as elsewhere that while there is considerable literature on women's responses to breast
screening, it is difficult to carry out close comparisons owing to the wide range of measures and approaches, and types of study and sample. Bearing this in mind, the following conclusions can be drawn:

- mobile units are favourably received but attention should be paid to privacy issues and location of the unit
- innovative aspects of the service should be tried out with particular populations
- good communication is important at every stage of the process
- it is important, for women to give true consent, that they have good understanding of the benefits and risks associated with screening, including the benefits of screening for older women
- information should be tailored to the age group, and ethnicity of the women
- services should be culturally sensitive
- staff can influence women's experience of mammography either way; good communication at the time of the procedure is important.
## APPENDIX 5 STAFFING LEVELS IN THE SBSP 2007

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Grade</th>
<th>North</th>
<th>North east</th>
<th>East</th>
<th>South east</th>
<th>West</th>
<th>South west</th>
<th>Total</th>
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<td>1.4</td>
<td>1.3</td>
<td>2.5</td>
<td>5.75</td>
<td>1.5</td>
<td>13.45</td>
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<tr>
<td></td>
<td>Breast surgeon (sessions/week)</td>
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<td>3</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td></td>
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<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
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</tr>
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<td></td>
<td>Pathologist sessions/week</td>
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<td>5</td>
<td>5</td>
<td>12</td>
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<td>36</td>
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<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>Clinical specialist</td>
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<td>6.3</td>
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<td>22</td>
<td>6.1</td>
<td>56.24</td>
</tr>
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<td>1.2</td>
<td>4</td>
<td>7</td>
<td>2</td>
<td>15.8</td>
</tr>
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### APPENDIX 6 INVENTORY OF MAMMOGRAPHY EQUIPMENT

<table>
<thead>
<tr>
<th>Machine (Mammomat 3000)</th>
<th>Siemens</th>
<th>Mammomat 3000</th>
<th>Serial number/system number</th>
<th>Digital stereo</th>
<th>Put into service</th>
<th>Age (years)</th>
<th>Replacement due with life 8 / 10 years</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Siemens</td>
<td>Mammomat 3000</td>
<td>ARH1946</td>
<td>OPDIMA</td>
<td>23/10/97</td>
<td>9.0</td>
<td>overdue 2007</td>
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<td>Mammomat 3000 Nova</td>
<td>SPS0002287</td>
<td>OPDIMA</td>
<td>25/10/00</td>
<td>6.0</td>
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<td>Mammomat 3000</td>
<td>SPS0000156</td>
<td>OPDIMA</td>
<td>09/07/99</td>
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</tr>
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<td>DMR</td>
<td>00197MAS03</td>
<td>OPDIMA</td>
<td>28/10/96</td>
<td>10.0</td>
<td>overdue overdue</td>
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<td>Mammomat 3000 Nova</td>
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<td>OPDIMA</td>
<td>15/04/04</td>
<td>2.5</td>
<td>2012 2014</td>
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<td>Lorad</td>
<td>M-IV</td>
<td>195 04023132</td>
<td>DSM</td>
<td>08/11/99</td>
<td>6.9</td>
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<td>Instrumentarium</td>
<td>Diamond</td>
<td>20115</td>
<td>Delta 32</td>
<td>15/03/02</td>
<td>4.6</td>
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<td>195 10091762</td>
<td></td>
<td>21/05/02</td>
<td>4.4</td>
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| Machine | Manufacturer | Model | Serial number/system number | Digital stereo | Put into service | Age (years) | Replacement due with life
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### Ultrasound units currently in service in the SBSP

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<td>HDI 5000</td>
<td>01QY2D</td>
<td>03/04/01</td>
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<td>ATL L12.5 50mm</td>
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<td>ATL</td>
<td>HDI 5000</td>
<td>01YMGF</td>
<td>02/07/02</td>
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<td>ATL L12.5 50mm</td>
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<td>Antares</td>
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<td>VFX13.5</td>
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<td>AUS</td>
<td>001371</td>
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<td>002436</td>
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<td>Technos MP</td>
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## APPENDIX 7 FORECAST ANNUAL CASH FLOW


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<th>2012</th>
<th>2013</th>
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### Capital costs

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<th>2012</th>
<th>2013</th>
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</thead>
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### Operating costs

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<td><strong>£847,500</strong></td>
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<td><strong>£847,500</strong></td>
<td><strong>£847,500</strong></td>
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**TOTAL COSTS** | **£1,150,000** | **£4,600,000** | **£8,518,000** | **£847,500** | **£847,500** | **£847,500** |
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<td><strong>Operating costs</strong></td>
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</tr>
<tr>
<td>Network costs</td>
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</tr>
<tr>
<td>Maintenance costs</td>
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</tr>
<tr>
<td>Staff costs</td>
<td></td>
<td></td>
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<tr>
<td>Savings in consumables</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
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</tr>
<tr>
<td>Total operating costs</td>
<td>£728,220</td>
<td>£728,220</td>
<td>£728,220</td>
<td>£728,220</td>
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<tr>
<td>TOTAL COSTS</td>
<td>£1,150,000</td>
<td>£4,600,000</td>
<td>£6,380,470</td>
<td>£1,073,220</td>
<td>£1,245,720</td>
<td>£1,159,400</td>
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## Existing FSM machines replacement schedule (10-year life)

<table>
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<tr>
<th>Year</th>
<th>FSM machines</th>
<th>CR</th>
<th>FSM machine</th>
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<td>2014</td>
<td>3 machines</td>
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<tr>
<td>2015</td>
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<tr>
<td>2016</td>
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<td>2017</td>
<td>7 machines</td>
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<td>2018</td>
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<tr>
<td>2019</td>
<td>42 machines</td>
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## Capital costs

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<td>CR</td>
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<td>£50,000</td>
<td>£150,000</td>
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<td>PACS</td>
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## Operating costs

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<tbody>
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<tr>
<td>Maintenance costs</td>
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<td>£101,150</td>
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</tr>
<tr>
<td>Staff costs</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Savings in consumables</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
<td>£(1,118,930)</td>
</tr>
<tr>
<td>Total operating costs</td>
<td>£728,220</td>
<td>£728,220</td>
<td>£728,220</td>
<td>£728,220</td>
<td>£728,220</td>
<td>£728,220</td>
</tr>
<tr>
<td>TOTAL COSTS</td>
<td>£986,970</td>
<td>£856,470</td>
<td>£986,970</td>
<td>£728,220</td>
<td>£1,331,970</td>
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</tbody>
</table>

## Total costs

<table>
<thead>
<tr>
<th>Year</th>
<th>Total costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>£986,970</td>
</tr>
<tr>
<td>2015</td>
<td>£856,470</td>
</tr>
<tr>
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<td>£728,220</td>
</tr>
<tr>
<td>2018</td>
<td>£1,331,970</td>
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<tr>
<td>2019</td>
<td>£728,220</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Total costs</th>
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</thead>
<tbody>
<tr>
<td>2008-2019</td>
<td>£21,227,700</td>
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</table>
GLOSSARY

A&C
Administrative and clerical

Abnormality
A finding requiring further investigation and/or treatment.

Assessment
The process a women undergoes following an abnormal mammogram in order to obtain a definitive diagnosis.

AUC
Area under (ROC) curve

BASO
British Association of Surgical Oncology

Benign
Non-cancerous.

Biopsy
The removal of a small piece of tissue from an organ or part of the body for laboratory examination. It is an important means of confirming or excluding a diagnosis of cancer from analysis of a fragment of a tissue sample.

BI-RADS
Breast Imaging Reporting and Data System

Breast cancer
A malignant tumour of the breast.

Breast Screening Information System (BSIS)
An information system which contains facilities for administration, data entry at reading and compilation of statistics. BSIS should be fully integrated with PACS, and function as a single package of technology.

CADTH
Canadian Agency for Drugs and Technologies in Health

Call-recall
The process used to invite people for a screening test.

CD
Compact disc

Clinical effectiveness
The evaluation of the balance between benefits and risks in a standard clinical setting using outcomes of importance to the patient.

Community Health Index (CHI)
The CHI number is a unique patient identifier that is allocated to every patient registered with a GP in Scotland. It is entered onto a database that underpins a wide range of patient-care processes in Scotland. There are strict controls on access to patient identifiable details.

Computed radiography (CR)
Computed radiography is a type of digital mammography and acquires digital images through a two-stage process. It stores the X-ray image on a reusable plate and the plate is run through the computer scanner to read and digitise the image. CR allows facilities to continue using their existing FSM machines but replace the cassettes with an imaging plate that acts as a digital adapter.

Computer-aided detection (CAD)
This software enables digital images to be analysed using pattern recognition programs to identify abnormal areas for further assessment.

Confidence interval (CI)
The interval likely to contain the true value of an unknown quantity (eg the true sensitivity of a test). For a 95% CI, if the experiment were repeated many times, 95% of the intervals would contain the value of the unknown quantity that is being estimated.

Cost effectiveness
Used in its broadest form, this term encompasses all forms of economic analysis.

CSBS
Clinical Standards Board for Scotland

DCE
Detection controlled estimation

DCIS
Ductal carcinoma in situ

Diagnosis
Identification of an illness or health problem by means of its signs and symptoms. This involves ruling out other illnesses and possible causes for the symptoms.

DICOM
Digital Imaging and Communications in Medicine is a standard for handling, storing, printing and transmitting information in medical imaging.

Digital image
A representation of a two-dimensional image as a finite set of digital values called pixels.

Digital mammography
Digital mammography, also known as full-field digital mammography, can be acquired by two different methods: computed radiography and direct digital radiography. X-rays are converted to digital images which can be viewed on a computer screen. These images can be stored electronically and manipulated.

Digitisation
The conversion of analogue forms into a digitised form suitable for electronic viewing, manipulation and storage.
Direct digital radiography (DDR)
Direct digital radiography acquires digital images directly as the detector plate and reader are built into the platform of the X-ray machine.

DMIST
Digital Mammographic Image Screening Trial

Eligible women
All women who are to be invited for breast screening. This currently includes all women aged 50–70 years who are registered with a GP, and those women not registered with a GP but who the screening programme is made aware of, eg women in long-stay institutions.

EMR
Electronic medical record

EQUIP
Electronic Quality Information for Patients

False positive
A false-positive test result is one where the test indicates that the person may have the disease of interest, when in fact they do not.

Film-screen mammography (FSM)
Film-screen mammography involves the X-ray of the woman's breast with the image recorded on a film in a cassette.

FNA
Fine-needle aspiration

Full-field digital mammography (FFDM)
A system in which the X-ray film is replaced by solid-state detectors that convert X-rays into electrical signals to produce an image of the breast. Both direct digital radiography (DDR) and computed radiography (CR) are methods of FFDM. The term 'full field' refers to the size of the imaged field (ie covering the whole breast).

GP
General practitioner

Hard copy
An image printed out on a laser printer.

Health technology assessment (HTA)
A multidisciplinary field of policy analysis, which studies the medical, social, ethical and economic implications of development, diffusion and use of the technology.

HEED
Health Economics Evaluation Database

IBSS
Irish Breast Screening Service

IDA
Imaging department assistant

IHE
Integrating the Healthcare Enterprise
(http://www.ihe.net/Mammo/)

IM&T
Information management and technology

Image reader
A healthcare professional trained to interpret screening mammography films.

Incident screen
Any mammographic screen a women has after her first screen. It can identify disease that has arisen since the previous screen.

IQR
Interquartile range

LROC
Localised receiver operating characteristic

Malignant
Cancerous. Such tumours can invade and destroy surrounding tissue and have the capacity to spread. A tumour which is the result of such spread is known as 'secondary' or 'metastatic'.

Mammogram
An X-ray film of the breast.

Mammographer
A person who is trained in the technique of taking X-ray images of breast tissue, usually a radiographer or assistant practitioner.

Mammography
X-ray examination of the breast. Using low-energy X-rays, fine details of breast tissue can be visualised, particularly the presence of calcification, or soft tissue masses, enabling the early diagnosis of breast cancer.

MBSP
The bespoke administrative system for the Irish Breast Screening Service.

Mean glandular dose
The average radiation dose received by the glandular tissues in the breast during a mammogram.

MLS0
Medical laboratory scientific officer

MRI
Magnetic resonance imaging

Modality
Image capturing equipment.

National Health Service Breast Screening Programme (NHSBSP)
The UK-wide programme of free population-based screening for breast cancer.
NBSS  
National Breast Screening System

NHS EED  
NHS Economic Evaluation Database

NHS Quality Improvement Scotland (NHS QIS)  
NHS QIS has been established to lead in improving the quality of care and treatment delivered by NHSScotland. To do this, it sets standards and monitors performance, and provides NHSScotland with advice, guidance and support on effective clinical practice and service improvements.

NSD  
National Services Division

Outcome  
The end result of care and treatment and/or rehabilitation.

Picture Archiving and Communications System (PACS)  
A system on which digital images are stored and retrieved. The system usually comprises data storage devices, image display devices, database management software and links to image acquisition devices. There should be connections to other information systems, such as the BSIS.

PMMA  
Polymethyl methacrylate

Population-based screening  
An investigation available to all eligible apparently healthy people. The aim is to identify a disease or abnormality which may be treated, cured or prevented before symptoms appear.

Positive predictive value (PPV)  
A measure of the reliability of a diagnosis usually expressed as a percentage. A positive predictive value of 10% means that 10 individuals are expected to have the disease for every 100 with a positive test result.

Prevalent screen  
A woman’s first mammographic screen.

Quality assurance (QA)  
The process of ensuring that performance is meeting targets and standards through planned and systematic activities including documentation, training and review.

Radiographer  
A person who is trained in the technique of taking X-ray images of parts of the body.

Radiologist  
A qualified medical practitioner trained in the technique of diagnosing disease by means of X-rays and other imaging methods.

Recall  
The part of the screening system whereby a person is recalled for a repeat screen or an assessment appointment. This includes routine recall and early recall.

ROC  
Receiver operating characteristic

Scottish Breast Screening Programme (SBSP)  
The programme of free population-based screening for breast cancer in Scotland. The SBSP is commissioned by the National Services Division, and is provided through six regional screening centres and 18 mobile screening units across Scotland.

Scottish Executive  
Formerly the name of the Scottish Government. See Scottish Government.

Scottish Government  
The devolved government for Scotland, with responsibilities including health policy and the administration of NHSScotland. Until September 2007, the devolved government was named the Scottish Executive.

SEHD  
Scottish Executive Health Department. The former name of the Scottish Government Health Directorates. See Scottish Government.

Screening  
Examination of people with no symptoms to detect unsuspected disease.

Sensitivity  
The ability of a test to detect disease. A test with a sensitivity of 90% will give a positive result in 9 out of 10 people who have the disease.

Shared imaging reading  
The electronic availability of imaging allows image ‘reading’ to be carried out at different centres and locations by different healthcare professionals.

Soft copy  
A digital image viewed on a computer screen.

Specificity  
The ability of a test to exclude people who do not have disease. A test with a specificity of 90% will give a negative result (ie a correct result) in 9 out of 10 people who do not have the disease.

Technical recall  
Recall for another mammographic screen within the same screening episode due to a technically unsatisfactory mammogram. There are a number of reasons why this can occur, such as equipment fault/failure, operator error or movement of the breast during X-ray.
Two-view mammography
Two mammograms taken from medio-lateral oblique and cranio-caudal views (at present SBSP takes both views at prevalent screens and only a medio-lateral oblique view at incident screens).

UK
United Kingdom

USA
United States of America

VDU
Visual display unit

X-ray
An imaging technique that uses beams of penetrating electromagnetic energy.