Health Technology Assessment Advice 10 ~ March 2008

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

Recommendations

The Health Technology Assessment was undertaken on the premise that digital mammography will be implemented in the Scottish Breast Screening Programme (SBSP). NHS Quality Improvement Scotland has made the following recommendations to facilitate the implementation of digital mammography in NHSScotland.

Implementation

• Implementation of digital mammography will be complex and careful planning is required to ensure the existing high quality provided by the SBSP is maintained. Input from a wide range of professional groups and from service users will be essential. An implementation group should be formed to agree specific technical requirements, logistical arrangements and timescales.

• Digital technology should be piloted at the earliest opportunity. This should be tested initially on a mobile unit and then extended across one screening centre including the associated mobile units. Full implementation across other centres should follow over a fixed period of time.

Technology

• The decision on whether to recommend computed radiography or direct digital radiography should be taken by an implementation group as the evidence currently available is insufficient to inform a decision.

• A Breast Screening Information System (BSIS) integrated with a Picture Archiving and Communications System (PACS) should be in place to support the implementation of digital mammography. The PACS should be part of the national PACS for Scotland but with features specific to breast screening.

• Digital modalities should be fully compliant with relevant international standards. Comprehensive servicing and repair agreements should be in place, ensuring same-day visits when feasible and necessary to maintain the service.

Minimising implementation and operating costs

• The screening service should optimise the use of digital mammography equipment to 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 within NHSScotland. However, it is acknowledged that there will be local factors influencing the decision to do this.

Prior images

• Film images from the previous screen should be available for reading sessions but the practical approach to utilising prior images may be decided by the individual centre or image reader. It is recommended that prior images are not digitised.

Impact on staff and working practices

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

1.1 This Advice from NHS Quality Improvement Scotland (NHS QIS) is the outcome of a Health Technology Assessment (HTA) determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHS Scotland. All HTAs consider the needs and preferences of patients.

1.2 Breast cancer is the most common cancer affecting women, with approximately 3,600 new cases being diagnosed in Scotland each year. Early detection and treatment reduces mortality; therefore the Scottish Breast Screening Programme (SBSP) offers breast screening using mammography to women aged 50–70 years. Conventional mammography (film-screen mammography [FSM]) involves taking X-rays of the woman’s breast with the image being recorded on a film in a cassette.

1.3 Technological developments have precipitated an increasing use of digital technology throughout NHS Scotland and digital mammography is already being implemented elsewhere in the United Kingdom. This HTA was at the request of The Breast and Cervical Screening National Advisory Group to assist with the proposed introduction of digital mammography into the SBSP. The HTA considered issues associated with implementing digital mammography for breast screening in Scotland, while maintaining the high standards of the existing quality-assured service. The scope was restricted to evaluation of the technology and the practicalities of its implementation. It did not extend to the wider ethical issues associated with screening programmes.

1.4 This Advice is based on critical appraisal and analysis of evidence published in scientific literature and submitted by experts, professional groups, patient interest groups, manufacturers and other interested parties. The assessment process, evidence base, methodology, results and recommendations are described in detail in Health Technology Assessment Report 10: Determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHS Scotland. To help users of this Advice locate additional information provided in the report, relevant sections are referenced in the margins of this document. The words which are in bold are defined in the Glossary.

1.5 The Advice represents the evidence-based views of NHS QIS. Health professionals in NHS Scotland should take account of this NHS QIS Advice and ensure that the recommended actions are implemented to meet clinical need. However, this Advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patient, in consultation with the patient and/or guardian or carer.
2 Summary of clinical and cost effectiveness

Comparing digital mammography with film screen mammography

2.1 The best available evidence from four large prospective studies shows that the clinical effectiveness of digital mammography is comparable with that of FSM. Experience from other European breast screening programmes suggests the same. The outcomes explored included diagnostic accuracy, recall for further assessment and for technical reasons, cancer detection rate and adverse effects.

Comparison of digital mammography systems

2.2 The two main methods of digital mammography are direct digital radiography (DDR) and computed radiography (CR). No published studies comparing the performance of these were found.

Breast screening standards

2.3 Digital mammography meets the national standards for radiation dose and image quality. Evidence also suggests that the rate of repeat examinations and referral for further assessment following digital mammography screening are well within the national target. It is reported from the Norwegian digital mammography screening experience that the number of invasive cancers and ductal carcinomas in situ detected exceeds the minimum detection rate required to meet the national standards. However, no data were identified to evaluate digital mammography against the standards for the number of small (<15mm) invasive cancers or the number of cancers presenting between screening episodes.

Use of prior film images in mammography screening and assessment

2.4 Studies show that the use of prior images in mammography screening significantly increases the specificity of the test and results in a reduction in recall rates. Sensitivity is also increased, but this is not statistically significant. Most studies show that use of prior images for screening does not improve cancer detection rates.

2.5 There is evidence from four studies that the use of prior images in assessment clinics improves diagnostic accuracy.

Cost effectiveness

2.6 Only the cost effectiveness of DDR could be compared with that of FSM, since no evidence pertaining to the cost effectiveness of CR was found. A recent and robust secondary review of the literature comparing digital mammography using DDR with FSM indicated that DDR is more expensive than FSM both in terms of initial capital costs and annual operating costs.

2.7 Limited and observational evidence suggests that DDR and FSM may have similar costs per woman screened if the service adopts a substantial increase in the working hours of the screening programme.
3 Issues for women attending breast screening

3.1 Only one study was identified which included issues for women associated with breast screening using digital mammography specifically. 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.

3.2 The level of comfort experienced by women during digital mammography is no different to that experienced during FSM.

3.3 The literature suggests that innovative service developments such as extended opening hours would be acceptable from the service users’ perspective. The use of mobile vans to increase accessibility to screening is generally welcomed by women, as long as consideration is given to issues such as privacy and location.

3.4 A number of studies reported that women may have concerns regarding exposure to radiation during breast screening. Therefore women may be reassured that some digital mammography technologies have the potential to reduce radiation doses.

3.5 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.

4 Summary of organisational issues

4.1 There are potential advantages and disadvantages associated with the two main types of digital image capturing equipment (CR and DDR). CR systems, like FSM systems, use imaging plates; adopting CR would not necessitate the purchase of new X-ray equipment. DDR offers an improved workflow and reduces repetitive activity such as film cassette handling. Some technical assessments indicate that the same image quality may be achieved with a lower radiation dose with DDR compared with CR.

It is expected that technical recall rates will be greatly reduced with both DDR and CR as image quality can be checked immediately by the mammographer and any retakes can be done during the same appointment.

4.2 A Breast Screening Information System (BSIS) is required with facilities for administration, data entry at reading and the compilation of statistics. It may take several years to develop a BSIS suitable for the SBSP, depending on the option chosen from the following: design and develop a new purpose-built BSIS; adapt the current SBSP information system; or purchase and adapt a system already being used by another breast screening service.
4.3 A Picture Archiving and Communications System (PACS) is a necessary component of a digital mammography screening service and is used to store mammograms. The development of a national PACS for SBSP may take up to 2 years. While the specification of the PACS will be complex and is beyond the scope of this HTA, issues for consideration include image storage, format and size of images and methods of transferring and sharing images.

4.4 There are specific accommodation requirements for digital modalities which are 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 inclement weather. Ventilation and power supplies will require consideration. A suitable reading environment is necessary to optimise viewing conditions for soft-copy reporting.

4.5 The HTA considered and rejected the possibility of altering the current complement of six fixed screening centres. Assessment clinics are an important part of the work of the fixed centres and overall there are likely to be no benefits in changing the location of centres when digital mammography is implemented.

4.6 Co-location of assessment clinics with the symptomatic service offers the potential for more sharing of equipment and a reduction in travel time for staff working in both services. This would require careful consideration of the terms of the arrangement, such as administration, maintenance costs, image storage, QA issues and prioritising equipment.

4.7 Digital mammography incurs initial capital costs, however increasing the number of hours during which machines are used will decrease the number of machines required and lead to a corresponding reduction in the cost per woman screened. There is evidence from some services using digital mammography in England that extending the hours for screening appointments is successful.

4.8 When digital mammography is introduced, previous images will be film based for an interim period of at least 3 years until all women have undergone a subsequent screen or examination using digital technology. There is no clear evidence to support digitisation of previous images.

4.9 Implementing digital mammography will have a major impact on the workforce, in terms of both working hours and practices, and training requirements. This could have potential implications for the recruitment and retention of staff.
5 Budget impact

Assuming a 30% annual increase in throughput, the cost to replace FSM machines is currently estimated to be £8.1 million for DDR and £4.5 million for CR.

6 Implications

SBSP, NSD and NHS boards should consider the findings of this report when planning and reviewing their breast screening services.

7 Review

As NHS QIS chooses broad topics for HTAs, it is likely that new evidence will emerge which bears on the specific recommendations on an ongoing basis. Rather than having a fixed review period, NHS QIS will determine the importance of new evidence and produce report addenda in which the evidence is analysed and any alteration to the recommendations is explained. If a major change is required, the Health Technology Assessment Report, Advice and Understanding our Advice will be rewritten.

Further information

- Health Technology Assessment 10: Determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHS Scotland.
- Understanding our Advice: Determining the most clinically and cost-effective way of implementing digital mammography services for breast screening in NHS Scotland.
- All NHS QIS documents are available in a variety of formats on request and from the NHS QIS website, www.nhshealthquality.org
**Glossary**

<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Breast Screening Information System (BSIS)</td>
<td>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.</td>
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<tr>
<td>Computed radiography (CR)</td>
<td>A type of digital mammography which 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.</td>
</tr>
<tr>
<td>Digital mammography</td>
<td>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.</td>
</tr>
<tr>
<td>Direct digital radiography (DDR)</td>
<td>Direct digital radiography acquires digital images directly as the detector plate and reader are built into the platform of the X-ray machine.</td>
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<tr>
<td>Health Technology Assessment (HTA)</td>
<td>A multidisciplinary field of policy analysis, which studies the medical, social, ethical and economic implications of development, diffusion and use of the technology.</td>
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<td>Mammography</td>
<td>X-ray examination of the breast. Using low-energy X-rays, fine details of breast tissue can be visualised, particularly in the presence of calcification, or soft tissue masses, enabling the early diagnosis of breast cancer.</td>
</tr>
<tr>
<td>Picture Archiving and Communications System (PACS)</td>
<td>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.</td>
</tr>
<tr>
<td>Screening</td>
<td>Examination of people with no symptoms, to detect unsuspected disease.</td>
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**Assessment Advice**

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<tr>
<th><strong>Sensitivity</strong></th>
<th>The ability of a test to detect a disease. A test with a sensitivity of 90% will give a positive result in 9 out of 10 people who have the disease.</th>
</tr>
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<tbody>
<tr>
<td><strong>Specificity</strong></td>
<td>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 (i.e., a correct result) in 9 out of 10 people who do not have the disease.</td>
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<tr>
<td><strong>X-rays</strong></td>
<td>An imaging technique that uses beams of penetrating electromagnetic energy.</td>
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NHS Quality Improvement Scotland

NHS QIS was set up to improve the quality of health care in Scotland. Its role is to set standards and monitor performance and provide NHSScotland with advice, guidance and support on effective clinical practice and service improvements.
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- electronic
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