

Advice Statement 004/18**April 2018****In women who have been recalled from breast screening, what is the clinical and cost effectiveness of digital breast tomosynthesis (DBT) compared with coned views?****Advice for NHSScotland**

Digital breast tomosynthesis (DBT) can be used to aid diagnosis for women who have been recalled from initial breast screening for further assessment. Eight studies have compared DBT with supplementary mammographic views (SMVs, which is the current standard of care). In six studies the diagnostic accuracy was comparable, and in two the diagnostic accuracy of DBT was superior.

DBT takes an image of the whole breast. Coned mammographic views require careful positioning of the patient to avoid potential errors resulting from lesions being placed outside the field of compression. DBT would normally replace SMVs, and therefore would not result in an additional dose of radiation. It is not possible to comment on the cost effectiveness of DBT compared to SMV because no economic studies were identified.

DBT is already available but disabled on most of the mammography machines in screening centres within NHS Scotland.

On balance, the Scottish Breast Screening Programme (SBSP) should consider enabling the DBT capability on the machines in screening centres in NHSScotland, for use in women who have been recalled from breast screening for further assessment.

NHSScotland is required to consider Scottish Health Technology Group (SHTG) advice.

Why is SHTG looking at this topic?

This work was requested by Dr Gerald Lip on behalf of the SBSP (Scottish Breast Screening Programme) Clinical Directors Group. The purpose was to establish the evidence base for the use of digital breast tomosynthesis (DBT), in place of coned views, in women recalled from breast screening for further assessment.

The comparator in the question is 'coned views', however in the evidence review, studies were included if they stated that they were comparing DBT to, for example, 'supplementary mammographic views' (SMVs), 'additional mammographic views' or 'diagnostic mammography'. Despite the different terminology used, these seemed to involve mostly coned or magnification mammographic views. The term SMVs has been used to refer broadly to the additional diagnostic mammographic views (mostly coned or magnification views) that women recalled from breast screening may receive.

Evidence note 76 was produced by Healthcare Improvement Scotland in response to this request.

Background

- When abnormalities are observed on breast screening mammograms, women are recalled for further assessment. This normally involves a clinical examination, and additional imaging with supplementary mammographic views (SMVs) and ultrasound. Along with the original mammograms, these additional tests are used to inform a decision on whether or not to perform a biopsy, or to discharge the patient.
- SMVs (generally coned and/or magnified mammographic views) allow improved visualisation of the area of the breast where the abnormality was observed on the original screening mammogram. Unlike standard mammograms that compress the whole breast, coned views involve applying compression only to a specific area of the breast.
- This advice relates to replacing SMVs with digital breast tomosynthesis (DBT).
- DBT is an advanced form of breast imaging. In DBT, the X-ray tube moves in an arc over the compressed breast capturing multiple images, which can be synthesised into a set of 3D images by a computer. As DBT takes an image of the whole breast, it avoids one of the limitations of coned views: the potential displacement of lesions out of the imaging field (which can result in the need for repeat imaging). It may also highlight additional lesions not seen on the original screening mammograms.

Clinical effectiveness

- Eight studies reported outcomes relating to diagnostic accuracy (six retrospective, and two with a prospective and retrospective reading element). The number of lesions (cases) included in the studies ranged from 52 and 354.
- Six studies concluded that for soft-tissue abnormalities, DBT demonstrated comparable diagnostic accuracy when used in place of SMVs. In a further two studies (both retrospective), the results suggested that DBT was superior to SMVs in terms of diagnostic accuracy. The area under the curve figures reported in the studies ranged from 0.87 to 1 for DBT plus full-field digital mammography (FFDM), and from 0.83 to 0.96 for SMVs plus FFDM.
- Despite the retrospective nature of most studies, the authors appear to have taken efforts to minimise bias with regards to the selection of cases, blinding of readers to true diagnosis, and reader recall.
- It is not clear whether the comparable/improved accuracy for DBT applies for the assessment of microcalcifications (the studies either excluded women with calcifications, or the numbers with calcifications were too small to draw any conclusions).
- The studies did not report any sub-analysis by lesion type, grade, or breast density.

Safety

- Studies reported that the radiation dose from SMVs is similar to DBT, though few provided figures. However, repeat views with standard supplementary diagnostic views are not uncommon (for example, due to incorrect positioning of the breast). Therefore, in some instances, DBT may result in a lower dose of overall radiation.

Cost effectiveness

- No cost effectiveness evidence was identified.

Patient and social aspects

- The evidence examined for the clinical and cost effectiveness sections of the evidence note did not discuss patient experience of DBT.

Context and organisational aspects

- DBT is already available but disabled on most of the mammography machines in screening centres in Scotland. DBT is already being used in the symptomatic setting in some centres in NHSScotland. All of the six screening centres in Scotland use the Hologic [Selenia] Dimensions system, and one (Dundee) also uses the Siemens Mammomat Inspiration system.
- Enabling DBT capability on the Hologic [Selenia] Dimensions system requires a software upgrade and purchase of a license (£50,000 per unit, with discounts for multi-license purchases). The Siemens Mammomat Inspiration system in Dundee already has DBT capability, and does not require any upgrading.
- The use of DBT in women who have been recalled from breast screening for further assessment would require some additional resource, including upgrading of existing mammography systems, and an initial period of training and time to allow radiologists to develop expertise in the interpretation of DBT images.
- Based on the evidence also reported in this review, guidance from Public Health England (2016) lists DBT as an option in women who have been recalled for assessment.

Further research

- Current evidence on the use of DBT in women who have been recalled from breast screening for further assessment appears to be at stage 2b or 3 of the [IDEAL-D](#) framework
- There is a need to establish the cost effectiveness and resource implications of replacing additional coned views with DBT in women who have been recalled from breast screening.
- There is a need to establish the influence of breast density and type/stage of cancer on DBT performance.
- Studies should report the difference in radiation dose between coned views and DBT.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. SHTG Advice Statements are intended to inform a decision at a particular point in time. They will however be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the advice given. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Chair
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