

**Advice Statement 005/18**

**April 2018**

**In asymptomatic women attending for breast screening, what is the clinical and cost effectiveness of digital breast tomosynthesis (DBT) in addition to full-field digital mammography or synthetic 2D (FFDM or S2D) images, compared to FFDM alone?**

**Advice for NHSScotland**

For asymptomatic women attending routine breast screening, digital breast tomosynthesis (DBT) plus full-field digital mammography (FFDM) is better at detecting invasive cancer compared with FFDM alone.

However, when DBT is used in addition to FFDM, this results in a double radiation dose. Furthermore, the cost effectiveness of DBT is unclear; the existing evidence does not evaluate the potential impact of DBT on longer-term outcomes such as interval cancer rates and breast cancer mortality, and the impact on false positives and recall rates is not clear.

On balance, DBT should not currently be used in the screening population, although a large UK-based study of clinical and cost effectiveness is currently underway (PROSPECTS) and the results should be published around 2020.

*NHSScotland is required to consider Scottish Health Technologies 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 DBT in routine breast screening.

Evidence note 77 was produced by Healthcare Improvement Scotland in response to this request.

**Background**

- Currently in Scotland, women aged between 50 and 70 are invited to participate in breast screening every 3 years, based on the fundamental principle of informed choice. Women over 70 years are encouraged to arrange an appointment. At a population level, the estimated effect of the UK breast screening programmes is a 20% reduction in breast cancer mortality in women invited for screening. Over the last decade, most screening programmes have changed from 2D analogue mammography to full-field digital mammography (FFDM). This represents the current standard for most mammography programmes.
- This advice relates to the addition of digital breast tomosynthesis (DBT) to FFDM (or synthetic 2D, S2D) in routine breast screening.

- 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.
- The radiation dose from DBT is equivalent to FFDM. When DBT is used as an adjunct to FFDM, this results in a double radiation dose (for more information on radiation dose, see safety section). A possible alternative to prevent a double radiation dose may be the use of an S2D image, generated from the DBT dataset, in place of the FFDM image.
- The use of DBT along with FFDM may be more accurate in detecting cancers than FFDM alone. However, as with any screening programme the population level health benefits need to be balanced against the unavoidable harms at the participant level, and other potential issues.

## **Clinical effectiveness**

### *Cancer detection*

- A good quality systematic review from 2017 pooled the results from 11 studies evaluating the diagnostic value of DBT plus FFDM compared with FFDM alone for routine breast screening. Four were large prospective studies (encompassing 37,085 participants). The remaining seven studies were retrospective and included 75,532 participants who had DBT plus FFDM, and 175,825 participants who had FFDM alone. The authors concluded that DBT plus FFDM was better at detecting invasive cancer (particularly early invasive cancer, stage T1 or N0), compared with FFDM alone (pooled risk ratio 1.33, 95% CI<sup>1</sup> 1.17 to 1.51). The authors also reported that there appeared to be no benefit of DBT in detecting ductal carcinoma in situ (pooled risk ratio 1.20, 95% CI 0.94 to 1.52). A further six systematic reviews published during 2016 or 2017 were identified. All had a slightly different focus, and included some additional studies, but were generally consistent in their conclusions with regards to improved cancer detection with DBT plus FFDM, compared with FFDM alone.

### *False positives and recall rates*

- Several studies included within the reviews reported statistically significant reductions in false positives and recall rates when DBT plus FFDM was compared with FFDM alone. However, the magnitude of difference was greater in some studies than others. These differences may be partly explained by different processes used to decide who to recall, differences in reader experience, and variation in baseline recall rates between units.

### *Women with dense breasts*

- A rapid review from 2016 assessed the evidence on the use of DBT in the screening of women with dense breasts specifically. The authors included four prospective European studies, and four retrospective studies from the USA. Due to differences in breast cancer rates, demographics and screening practices, the authors presented the results for the European and US studies separately. The European studies encompassed 10,188 women with dense breasts, receiving predominantly biennial screening, and pooled results showed significant incremental breast cancer detection in 3.9/1000 screens attributable to DBT ( $p < 0.001$ ). This conclusion was supported by the other systematic reviews that reported on the use of DBT in the screening of women with dense breasts.

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<sup>1</sup> CI = confidence interval

### *Longer-term outcomes*

- The current evidence base does not report on the impact of DBT on longer-term outcomes, such as interval cancer rates and age-specific mortality. For this reason, it is not possible to establish whether the overall benefits of adding DBT to routine breast screening are sufficient to tolerate potential associated harms (for example, over-diagnosis) and issues (see 'Context and organisational aspects').

### *S2D images to replace FFDM*

- An NHS (England) position paper (2016) on the use of tomosynthesis states that at present there is insufficient evidence to support the use of S2D images in place of FFDM. However, subsequently published retrospective studies have supported the proposal that S2D images can be used in place of FFDM images.

### **Safety**

- Possible harms from breast screening programmes are over-diagnosis, radiation exposure, and patient anxiety. This issue was evaluated in the independent Marmot review in 2013, which estimated that for 10,000 UK women invited to screening from age 50 for 20 years, about 681 cancers would be found of which 129 would represent over-diagnosis, and 43 deaths from breast cancer would be prevented. The report concluded that UK breast screening programmes confer significant benefit and should continue.
- One of the systematic reviews states that adverse events associated with mammography are rare, and that none of the included studies described any adverse events associated with DBT or FFDM.
- According to Public Health England, the mean glandular dose (MGD) for a two-view examination with FFDM is 3mGy. The risk of radiation-induced cancer for a woman attending FFDM screening (two views) is between 1 in 49,000 to 1 in 98,000 per visit.
- The radiation dose from DBT is similar to FFDM. Therefore, using DBT as an adjunct to FFDM results in a double radiation dose.

### **Cost effectiveness**

- No cost-effectiveness evidence generalisable to NHSScotland was identified.
- A large UK-based study is currently underway (PROSPECTS), the aim of which is to compare the cost effectiveness of breast cancer screening using DBT plus FFDM or S2D images with screening using FFDM alone by measuring cancer detection rates, interval cancer rates, size and lymph node status of Grade 2 and 3 invasive cancers in intervention (DBT+FFDM or S2D) and FFDM (standard care) groups. This is likely to be an important part of the evidence base for NHSScotland. Final results should be available around 2020.

### **Participant and social aspects**

- The evidence examined for the clinical and cost effectiveness sections of the evidence review did not discuss participant experience of DBT as compared with current practice in breast screening.

### **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.
- There are potential issues regarding adding DBT to FFDM as a screening tool. These include increased: costs, quality assurance requirements, training, data storage requirements and scan and read times. While not definite obstacles to implementation, they would need to be taken into consideration.

#### **Further research**

- Current evidence on the use of DBT in asymptomatic women attending for breast screening appears to be at stage 2b or 3 of the [IDEAL-D](#) framework.
- Further research is needed to evaluate the potential impact of breast screening using DBT on longer-term outcomes, such as interval cancer rates and breast cancer mortality. Some of these gaps should be addressed by the PROSPECTS study, which includes interval cancer rates as an outcome.

#### **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**  
**Scottish Health Technologies Group**



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