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NHS

NHS Breast Screening Programme: current position on use of tomosynthesis

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Public Health England leads the NHS Screening Programmes

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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Contents

Introduction

Until now, digital breast tomosynthesis (DBT) systems should not have been used in the NHS Breast Screening Programme (NHSBSP) except as part of clinical trials or officially organised NHSBSP practical evaluations. However, a number of systems are commercially available and some clinical trials have been published, with data showing their potential for breast screening and assessment.

This paper updates the current position of the NHSBSP on tomosynthesis and the steps that are being taken to establish the role tomosynthesis systems may play in the future.

Evidence for use in assessment

An expert group was established in autumn 2012 to review the evidence for the use of tomosynthesis in assessment. The group found that most publications on the use of tomosynthesis investigated the use of specific machines from single suppliers. At that time, most of available evidence was based on the Hologic Dimensions System. Since then, studies have been published on the use of other manufacturers' tomosynthesis systems as well.

Peer-reviewed literature relating to the Hologic system found that tomosynthesis is at least as good as spot compression views for the assessment of possible soft tissue abnormalities. This conclusion is largely based on trials conducted at Kings College Hospital, London.[1, 2] These studies found no difference between spot compression views and tomosynthesis in the detection of calcifications.
A trial of the GE Healthcare tomosynthesis system[3], carried out in Nottingham and Derby, showed equivalence of tomosynthesis and spot compression views in the assessment of soft-tissue abnormalities.

There is sufficient evidence to justify the use of the Hologic Dimensions tomosynthesis system and the GE Healthcare Essential (SenoClaire) tomosynthesis system in assessment in the NHSBSP.

The use in assessment of some other manufacturers' systems is currently being evaluated and once they have undergone stringent technical and clinical evaluation which will be subsequently published on the GOV.UK website, they will have formal approval for use in breast screening assessment.

Technical and practical evaluations

As with all new equipment to be used in the NHSBSP, when tomosynthesis systems become available, they must undergo rigorous technical and practical evaluation. Technical and practical evaluations of both Hologic Dimensions and GE Healthcare Essential tomosynthesis systems have been completed.[4-7]

The practical evaluations of both Hologic and GE Healthcare tomosynthesis systems[5,7] found that the diagnostic value of tomosynthesis was equal to or better than 2-D imaging. Both evaluations demonstrated that visualisation of calcifications in tomosynthesis is adequate, or comparable to 2-D imaging. It was suggested in one evaluation report[5] that the use of slabs improved the visualisation of calcifications, although further peer-reviewed published evidence is needed to support this.

The practical evaluations of the Hologic Dimensions and GE Healthcare Essential tomosynthesis systems[5,7] show that doses are slightly higher than for 2-D imaging. However, there is as yet no agreed image quality standard for tomosynthesis.

A technical evaluation of the Siemens Inspiration tomosynthesis system[8] has been completed and the practical evaluation is awaited. Other evaluation reports for different manufacturers will be published in due course.

Current clinical and technical issues

The following issues need consideration:

- the files associated with tomosynthesis are much larger than those acquired using 2-D imaging - this has implications for local and archival storage
- the images from currently available tomosynthesis systems are in standard DICOM format known as BTO, or in CT format - most PACS manufacturers have workstations capable of displaying these images
- until further evidence is available, two-view tomosynthesis is advised
- using tomosynthesis does not mean that ultrasound can be omitted - even if the tomosynthesis images appear normal, ultrasound imaging must be used
- at present, there is insufficient evidence to support the use of the synthetic 2-D image that is sometimes produced from a tomosynthesis acquisition as a replacement for a standard digital mammogram
- the radiation dose associated with a one-view tomosynthesis acquisition for 50 to 60 mm thick breasts is typically 2.3mGy for the Hologic Dimensions and 1.5mGy for the GE Healthcare Essential tomosynthesis systems[5,7] - this is slightly more than for the corresponding one-view 2-D acquisitions, 1.6 and 1.3mGy respectively[9], but well below the current national diagnostic reference level (DRL) of 3.5mGy for one-view mammography

Quality control protocols

Guidance on quality control procedures for tomosynthesis systems (for radiographers and physicists) has been published.[10, 11]

Some special phantoms have been developed for use in testing tomosynthesis systems, but there is as yet none proven to be ideally suited for measuring image quality.

Training

The expert group who reviewed the evidence for the use of tomosynthesis in assessment made recommendations on training in the use of tomosynthesis and concluded that this could be provided through any NHSBSP training centre. Minimum requirements for radiologists and radiographers are as follows:

Radiologist training	Radiographer training
Radiologists are required to attend an NHSBSP-recognised training course on the use of tomosynthesis before embarking on clinical use. This should include: • review of a minimum of 60 cases (40 of which must be assessed by the individual working independently) • lectures on the technology, clinical application, and the evidence base • PACS retrieval, information sharing • artefacts • the provision of information about the technology to women • PACS retrieval	This should include: • vendor-specific training • advice on "how to use" • practical and theoretical grounding in the technology from an NHSBSP training centre • routine QC and tolerances, use of phantoms • artefacts • the provision of information about the technology to women • PACS retrieval

Suppliers of tomosynthesis systems should provide specific training and applications training to radiographers and radiologists.

Training for physicists in the quality control of tomosynthesis is provided as part of the basic and update courses organised by the NHSBSP Quality Assurance (QA) Coordinating Group for Physics in conjunction with the Institute for Physics and

Engineering in Medicine. The QA Group also agreed that training may be provided by buddy visits to regions with experience of tomosynthesis systems.

Trials of tomosynthesis in screening

A number of peer-reviewed publications have reported studies which have used tomosynthesis for population-based breast screening, in several different countries. Any researchers wishing to conduct trials using tomosynthesis in screening prospectively will have to apply through appropriate channels (for example, Research and Development Committee) for approval.

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