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Digital Breast Tomosynthesis for Screening and Diagnosis of Breast Cancer

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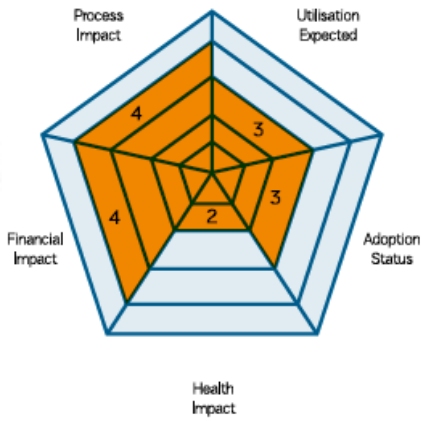
The report (reproduced in part here) is from a recent Health Technology Forecast from ECRI, which evaluated digital breast tomosynthesis (DBT) as part of its Health Technology Assessment Information Services (HTAIS). An expert panel was convened by ECRI Institute to review information on this topic.

Ratings and Rationales of Potential Impact



Note: The following ratings and comments reflect the opinions and consensus of an expert panel convened by ECRI Institute.

Anticipated Utilisation**:** 3 (Expected to be used by 40% to 60% of patients with the anticipated indications)

Digital breast tomosynthesis (DBT) is a 3D breast imaging technique based on full-field digital mammography (FFDM) technology, designed to reduce unnecessary callbacks during mammography screening and to replace other diagnostic tools. If DBT becomes accepted as a screening exam and is reimbursed, based on additional evidence of clinical benefit, it will likely displace conventional mammography screening. However, if DBT is reimbursed for only specific patient subgroups (e.g., those with dense breasts) within the general screening population, it is unlikely to completely replace conventional FFDM. If DBT is used primarily for diagnostic purposes, it will be another option among many follow- up test options after an inconclusive mammogram.

Estimated Adoption Status:

3 (0% to 25% of facilities that would be expected to adopt have adopted)

Since the first DBT system's marketing approval in 2011 (Hologic Selenia), Hologic estimates 600 to 800 of its Selenia systems have been put in use in the United States (since time of writing the latest estimate is around 1100 purchases (Beck 2014). Since 2011, Internazionale Medico Scientifica has entered the European market, Fujifilm has entered the European and U.S. markets, and GE Healthcare and Siemens Healthcare are developing DBT systems. GE Healthcare intends to submit data from a trial expected to be completed in November 2013 to support its premarket approval application in the United States. Siemens Healthcare is awaiting FDA approval for its system. Fujifilm offers the Amulet Innovality (FDA-approved and marketed as Aspire Cristalle in the United States). The significant costs of upgrading current FFDM systems to DBT systems or buying new ones are potentially slowing adoption.

Potential Health Impact:

2 (Expected to make a small improvement to patients' health and/or QOL)

DBT is likely to be used to follow up after an inconclusive mammogram. The technology could serve as an additional tool that could obviate the need for additional tests or unnecessary biopsies, but it is unlikely to find many cancers that would not otherwise be detected by other diagnostic tools. As a screening tool, the technology might increase cancer detection rates and reduce unnecessary recalls, particularly for patients with dense breasts.

Potential Financial Impact:

4 (Expected to have a substantial financial impact)

The expert panel thought that DBT systems will be expensive, with more advanced workstations and significant data archiving costs, compared with available mammography systems. Costs will depend on whether DBT is used as a screening or diagnostic test. As a screening exam, it will require about four gigabytes (uncompressed data) of data storage capacity per patient and could make screening large patient populations cost prohibitive, especially without adequate reimbursement.

Potential Process and Infrastructure Impact:

4 (Expected to have a substantial process impact)

Implementing DBT would significantly increase data storage, digital infrastructure requirements (i.e., bandwidth, archive volume, workstations), and workload for information technology staff, especially if used as a screening exam. As a diagnostic exam, DBT could reduce the number of patient biopsies and follow-ups using other diagnostic modalities. A two-view DBT exam could increase radiologist workload, because of the additional imaging data volume. Significant radiologist training may be required for the appropriate, accurate, and efficient use of DBT, "not only in the appearance of different abnormalities but also in the widely varying appearances of normal tissues leading to negative findings," reported one DBT researcher.

Overview

Screening for breast cancer is typically done using full-field digital mammography (FFDM). About 10% of screened women are called back for follow-up of a suspicious or inconclusive spot on the screening mammogram. Follow-up can include diagnostic mammography, magnetic resonance imaging (MRI), ultrasound, fine-needle aspiration or surgical biopsy. Clinicians diagnos breast cancer in about 10% of patients called back for further testing. Avoiding the number of false-positive screening mammography results and unnecessary follow-up exams is desirable.

Digital breast tomosynthesis (DBT) is a 3D breast imaging technique based on FFDM technology. A tomosynthesis system's x-ray tube moves along an arc, in a sweeping or pause-and-shoot manner, around a portion of the breast to acquire 13 to 25 2D projections from slightly different

angles in about 10 to 20 seconds (Anthem Insurance Companies, Inc.). Resulting 2D projections individually have lower resolution than FFDM 2D images; they are digitally manipulated to create tomograms (i.e., slices) in any plane and then combined for 3D reconstruction that reveals depth. The number of tomograms that can be created depends on the number of 2D projections captured during the x-ray sweep. Slices can be displayed individually (resembling conventional mammograms with sharper detail) or in dynamic “movie” mode. According to developers, a 3D reconstruction of the breast reduces the problem of overlying tissue that might be mistaken for lesions or that might obscure small cancers, particularly in dense breasts (McCullough 2011; Anthem Insurance Companies, Inc. 2013; Hologic 2011).

A DBT exam is similar to a conventional mammogram in how a technologist positions the patient's breast. Image acquisition typically takes 10 to 20 seconds (Anthem Insurance Companies, Inc. 2013). Once the images are taken, a radiologist interprets the scans. Several researchers are developing computer-assisted detection (CAD) software to help radiologists identify lesions from the images (Hologic 2011; Sahiner et al. 2012).

DBT can be used on its own or in combination with FFDM. When used on its own, software can translate 3D data into a 2D image similar to FFDM. A 2D image is useful to compare a patient’s most recent exam with past exams that were performed using FFDM or film mammography.

Because DBT and FFDM systems share a common physical platform, some FFDM systems can be upgraded from the same manufacturer to add DBT capability, depending on the configuration. Upgrading an FFDM unit to offer DBT may require a new gantry (i.e., supportive framework), because some FFDM gantries are not designed for the precision movement involved in tomosynthesis (Siemens AG).

Manufacturers include:

• Hologic, Inc. (Bedford, MA, USA)

• Fujifilm Medical Systems (Dusseldorf, Germany; Stamford, CT, USA)

• General Electric (GE) Healthcare (Chalfont St. Giles, UK)

• Siemens Healthcare, Inc. (Erlangen, Germany)

• Internazionale Medico Scientifica (IMS; Bologna, Italy)

Hologic, GE Healthcare, and Siemens also offer commercially available FFDM systems that can serve as the platform for a new DBT system (Siemens AG; GE Healthcare 2013; Hologic 2013). IMS’ Giotto Tomo system is built as a separate device requiring its own platform (I.M.S. Internazionale Medico Scientifica).

Hologic was the first manufacturer to reach the U.S. market, in 2011 with its Selenia Dimensions 3D DBT (Hologic 2013a) The Selenia system is optimised to take two breast views, craniocaudal (CC) and mediolateral oblique (MLO), under two breast compressions similar to FFDM. A CC view is taken from directly above a horizontally compressed breast, and a MLO view is taken at about a 45o angle to the side of a diagonally compressed breast. When used with FFDM, a DBT scan and FFDM scan from one view can be taken under one compression. Hologic has developed C-View 2D, software that creates computer-generated 2D images from DBT 3D images, which purportedly negates the need for concurrent FFDM scans and reduces the total radiation dose (Hologic 2013b). Hologic has also developed the Affirm Breast Biopsy Guidance system, integrative hardware and software that can guide biopsy sampling in real time, for use with its DBT system (U.S. Food and Drug Administration 2013b). Hologic is working to expand its contrast-enhanced FFDM into DBT to visualise vascularity more clearly (Froeling et al. 2013).

GE Healthcare is developing a DBT system called SenoClaire, which creates a 3D image using the MLO view only, purportedly reducing the necessary radiation dose. SenoClaire uses software to optimise views of lesions in dense breasts and microcalcifications in breasts of any density (GE Healthcare 2013). GE Healthcare is also developing software to generate 2D images from 3D data.

Siemens is developing its True 3D Breast Tomosynthesis system. The technology reportedly works by moving in a 50o arc around the breast—a larger angle than other scanners. Wider angle movement purportedly allows all imaging to be taken during a single breast compression instead of two (Siemens AG). Siemens is also developing a contrast-enhanced scan for DBT (Hornig et al. 2012).

IMS is developing the Giotto Tomo system, which is capable of varying the angle of its 13 projections and the dose, specifically for each patient. The Giotto is also compatible with IMS’

stereotactic biopsy system (I.M.S. Internazionale Medico Scientifica).

Company	System	FDA approved	CE marked
Hologic	C-View 2D imaging system	Yes	
	Selenia Dimensions	Yes	Yes
GE Healthcare	SenoClaire	Pending	Yes
Siemens	Mammomat Inspiration System	Pending for DBT use	Yes as upgrade for FFDM system to perform DBT
IMS	Giotto Tomo	N/A	Yes
Fujifilm	Aspire Cristalle	Yes	N/A
	Amulet Innovality	N/A	Yes

Note: Compiled and updated by HealthManagement, July 2014

Regulatory Status

Regulation in the United States of mammography facilities is the Mammography Quality Standards Act. The regulations permit only reversible image compression, not irreversible (i.e., lossy) compression of DBT images (Clunie 2013). As of 2012, the American College of Radiology had no official position on whether compressed DBT images are acceptable (American College of Radiology 2012). DBT images are supported by some picture archiving and communication systems (PACS) providers using Digital Imaging and Communications in Medicine standards (Sectra 2011).

Cost Issues

According to ECRI Institute's PricePaid database (as of October 17, 2013), the Selenia Dimensions 3D system had an average list price of about $786,000 [€586,654] and an average quoted price of about $398,000 [€297,059] (PricePaid a). FFDM systems had an average list price of about $546,000 [€407,523] and an average quoted price of about $278,000

[€207,493] (PricePaid b,c,d). DBT capability may be available by modifying some existing FFDM systems, which vary in cost depending on configuration and features. Upgrading an FFDM system to offer breast tomosynthesis may cost $100,000 [€74,638] or more (McCullough 2011). PACS-supported DBT imaging removes the need to purchase workstations solely for DBT-scan reading by radiologists (Sectra 2011).

DBT developers believe that the technology's greatest potential could be in screening, although pricing for DBT exams is not yet established. Some doctors are charging patients directly for DBT, generally less than $100 (Bassett 2013). Costs associated with upgrading digital infrastructure to accommodate the new workstations, networking requirements, and data archiving demands would likely be extremely high if the technology is used for screening. Hospitals or imaging centres using DBT in a diagnostic setting would likely require fewer costly upgrades to accommodate networking requirements and data archiving, because fewer patients undergo diagnostic scans than have screening scans. Widespread DBT screening might increase revenue for providers if they can recruit new patients, call back fewer patients for false positives, and improve workflow, as reported by KLAS (Bassett 2013).

Reimbursement Issues

As of October 2013, the U.S. Centers for Medicare & Medicaid Services had no national coverage policy for DBT, leaving coverage to the discretion of local Medicare contractors. Ultimately, reimbursement depends on how effective DBT is compared with standard technologies for screening or diagnosis. DBT's viability will likely depend on its ability to reduce the number of patient callbacks after initial breast imaging exams, an outcome that third-party payers are expected to be particularly interested in evaluating when making coverage decisions. Nine representative, major, third-party payers consider DBT to be investigational and deny coverage (Anthem Insurance Companies, Inc. 2013; Aetna, Inc, 2013; CIGNA Corporation 2013; Blue Cross Blue Shield of Alabama 2013; Blue Cross and Blue Shield of Massachusetts; United HealthCare Services, Inc. 2013; Medica 2012; Wellmark, Inc. 2013; Humana, Inc. 2013). Third-party payers are likely to require evidence of significant additional benefit from DBT before they are willing to reimburse tomosynthesis exams at a higher rate than conventional breast imaging modalities, especially for a breast cancer screening indication.

Some centres are working with third-party payers to develop reimbursement policies. Of 44 surveyed imaging centres in the United States using Hologic's Selenia Dimensions 3D system, 25% reported they were receiving reimbursement above the rate for standard mammography. Another 37% stated they were charging patients directly for DBT, generally less than $100 (Bassett 2013). Current procedural terminology (CPT) and Healthcare Common Procedure Coding System codes have not been established for DBT. Physicians performing DBT in conjunction with FFDM procedures have been advised by the American College of Radiology to report the CPT code that represents an unlisted diagnostic procedure code to describe FFDM. If CAD is also performed, the College recommends reporting it separately using a CAD mammography code.

DBT exams are likely to cost less than MRI exams, based on the amount patients are being charged out of pocket for DBT (i.e., $100 or less) (Bassett 2013). As a diagnostic follow-up to conventional mammography, payers may favour DBT over MRI if evidence shows that they are similarly effective.

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