Digital Breast Tomosynthesis (DBT)

August 26, 2015
Agenda

• eviCore healthcare Introduction
• DBT Technology
• Why DBT
• Evidence Limitations
eviCore healthcare Introduction

- eviCore healthcare (eviCore) is a medical benefits management company with more than 20 years of experience.
- Our evidence-based healthcare solutions that improve the quality of care include Radiology, Cardiology, Medical Oncology, Radiation Therapy, Musculoskeletal, Molecular and Lab, Sleep, and Post-Acute Care and Bundled Payments.

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DBT Technology

**Step 1**
The x-ray source is rotated over a limited arc angle while the breast is compressed.

**Step 2**
A series of low-dose exposures are acquired, creating a series of digital images.

**Step 3**
These projection-view (PV) images are reconstructed into thin slices.

- The reconstructed DBT slices may reduce the camouflaging effects of overlying fibroglandular tissues.
- Manufacturers have applied different methods to develop and perform tomosynthesis:
  - The arc of movement may vary (typically 11-60 degrees).
  - The number of individual exposures may vary (typically 9-25).
FDA Approved DBT Devices

Hologic’s Selenia Dimensions 3D System
Provides 3D breast tomosynthesis images

GE Healthcare’s SenoClaire
Uses a combination of 2D mammogram images and 3D breast tomosynthesis images

Siemens’ MAMMOMAT Inspiration with Tomosynthesis Option
Events Fueling Increased Interest in DBT

May 2013

• FDA approved Hologic’s C-View 2D imaging software for mammography.
• Images are generated using 3D tomosynthesis data which results in less radiation exposure.

November 2014

• CMS-assigned billing codes and reimbursement values to screening DBT.
• ACR released a position statement declaring that tomosynthesis is no longer investigational.

January 2015

• AMA approved three new CPT® codes specific to DBT (77061, 77062, and 77063).
• Modeling study suggested possible net cost saving with DBT by avoiding the use of follow-up services.
# CMS 2015 Tomosynthesis Reimbursement

<table>
<thead>
<tr>
<th>Exam Type</th>
<th>Film</th>
<th>Digital</th>
<th>Digital with DBT</th>
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</thead>
<tbody>
<tr>
<td>Screening Mammogram</td>
<td>$82.70</td>
<td>$134.97</td>
<td>$191.54</td>
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<tr>
<td>Unilateral Diagnostic Mammogram</td>
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<td>Bilateral Diagnostic Exam</td>
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Professional Associations’ Stance on DBT

**USPSTF 2015**
- Draft recommendation for DBT to remain E&I.
- Final recommendation forthcoming.

**ACR 2014**
- Considers DBT to be no longer investigational.
- Encourages more studies to clarify its clinical role and its long-term outcomes.

**SBI 2014**
- Survey concluded: “DBT is becoming more common but remains a limited resource. Clinical guidelines would assist practices in deciding whether to adopt DBT and in standardizing which patients should receive DBT”.

**ACOG 2015**
- Current evidence insufficient to assess benefits and harms as a breast cancer screening modality.
Literature Review

Studies have reported improvements in sensitivity, reductions in recall rates and improved cancer detection rates with DBT.

- Rafferty et al Radiology (2013)
- Ciatto et al Lancet Oncology (2013)
- Haas et al Radiology (2013)
- Skaane et al Radiology (2013)
- Skaane et al Radiology (2014)
- Houssami et al European Journal of Cancer (2014)
- Friedwald et al JAMA (2014)
- Greenberg et al AJR (2014)

While promising, these studies have limitations.
Noted Shortcomings and Cautions

Responding to the Friedewald et al DBT study (JAMA June 2014), breast imaging authorities noted that:

- The nonrandomized design precludes drawing causal inferences about the results.
- The lack of long-term follow-up information limits the ability to provide definitive estimates of false-negative result rates, diagnostic accuracy, interval cancer rates, or over diagnosis.
- The continuing controversy surrounding the most effective strategy for deploying the various available technologies continues unabated.
- Clear consensus is lacking on when to screen, how often, and with what tools, or even which screen-detected cancers could be managed more conservatively.
- Only a multi-site clinical trial can answer the remaining questions definitively.
Dr. Friedewald and other authors acknowledged:

**Learning Curve**
There will be a steeper learning curve for tomosynthesis interpreters.

**More Research**
More research is needed to further delineate how to best use this technology.
Evidentiary Gaps

- Subgroups of women which would benefit from this technology
- Appropriate role (screening vs. diagnostic), optimal frequency
- Long-term impact on clinical outcomes
Conclusion

• DBT is being lauded for its potential benefits with improved screening and diagnostic sensitivity, recall rates, lesion detection, and characterization.
• Although these performance metrics are promising, there are limitations in these studies.
• There is a lack of evidence demonstrating DBT’s impact on long-term outcomes.
• Questions remain regarding the appropriate clinical role(s) of DBT.
• It is unclear regarding which subgroup(s) of women might benefit.
• We are unable to recommend routine coverage of DBT at this time.
State Regulatory Issues

- Twenty-one states have laws requiring that women be notified if they have dense breasts and that they be advised to discuss supplemental imaging with their provider.¹
- According to our research the only state mandating DBT for patients with dense breast tissue is New Jersey (Chapter 196). In addition to DBT, the New Jersey law also mandates coverage for ultrasound and MRIs.
- Connecticut, Indiana, and Illinois also have similar laws on the books mandating coverage such as MRI and US, but not specifically DBT.
- A bill in Illinois (SB 54) mandating coverage for DBT was signed by Governor Rauner on 8/19/2015 and will become effective on 7/1/2016. However, the bill contains a clause that the mandate will not go into effect unless specific conditions are met.
- Connecticut also had pending legislation this session requiring coverage of DBT. This bill ultimately did not pass and failed upon adjournment. Connecticut had a DBT mandate on the books for its Medicaid population, but it was rescinded on February 4, 2015 due to the lack of conclusive evidence for improved clinical outcomes in breast cancer screening and diagnosis with its use.

In early 2014, The NJ General Assembly enacted into law (SB 792) which “Requires insurers to cover breast evaluations and other additional medically necessary testing under certain circumstances and requires certain mammogram reports to contain information on breast density.” This legislation appears to mandate coverage for:

An ultrasound evaluation, an MRI, DBT (aka 3-D mammography), or other additional testing of an entire breast or breasts, after a baseline mammogram examination, if the mammogram demonstrates extremely dense breast tissue, if the mammogram is abnormal within any degree of breast density, or if patient has additional risk factors for breast cancer including but not limited to family history of breast cancer, prior personal history of breast cancer, positive genetic testing, extremely dense breast tissue, or other indications as determined by the patient’s health care provider.

**Note:** The coverage required under this paragraph may be subject to utilization review, including periodic review, by the medical service corporation of the medical necessity of the additional screening and diagnostic testing.
Recommendations for NJ DBT Issues

- DBT may eventually be used in the majority of screening mammograms. However, its use should be purposeful and not unnecessarily repetitive.
- DBT should usually be limited to one procedure per episode of care. DBT will probably not be medically necessary in the majority of diagnostic mammograms if it was performed in conjunction with the screening 2D mammogram. If it was not used in the screening examination, DBT may be used in the diagnostic mammography setting as a problem solving tool.
- With this legislation, it should be acceptable to require a logical progression of diagnostic procedures. For example, if DBT is performed, those results should be obtained before an ultrasound or MRI is obtained.
Questions
Thank You