

M Northwestern
Medicine

Incorporating Tomosynthesis
Into Your Practice



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Chicago International Breast Course
The Westin Chicago River North
November 1-3, 2019

Massive marketing muscle pushes 3D mammograms,
despite no evidence they save more lives, investigation
shows

LiX Szabo, Kaiser Health News | Published 8:46 am | Updated 1:34 pm ET Oct 16, 2019

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Here's the biggest news you missed this weekend

House to vote on impeachment inquiry procedures after weeks of GOP attacks

The Washington Post faces backlash for headline calling

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United States Preventive Services
Task Force (USPSTF)

The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of tomosynthesis (3-D mammography) as a screening modality for breast cancer.

Position Statements

A new digital technology, breast tomosynthesis, has shown to have an advantage over digital. To facilitate such large scale outcome data collection, the technology must be widely available. Availability is greatly impacted by reimbursement for the service provided. The To be clear, tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography, positive impact on patient care. ACR presented this evidence during the evaluation process for the new Current Procedural Terminology (CPT) codes 77061, 77062 and 77063 which were developed for CPT 2015.

No technology is used in clinical practice, we anticipate that further studies will clarify its impact on long-term clinical outcomes, including reduced mortality. It will also be important to further evaluate which subgroups of women might benefit most from these exams by age, breast density, frequency of examinations, etc.

To facilitate such large scale outcome data collection, the technology must be widely available. Availability is greatly impacted by reimbursement for the service provided. The Congress requests the decision by the Centers for Medicare and Medicaid Services (CMS) to facilitate access to these exams by covering reimbursement for tomosynthesis and digital breast exams in all 50 states.

To be clear, tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography.

NCCN Guidelines Version 1.2016
Breast Cancer Screening and Diagnosis

SCREENING OR SYMPTOM CATEGORY

Asymptomatic and Negative physical exam

Assess risk

Average risk

- Age 25 to <40 y
- Age 40 y

Increased risk:

- Prior history of breast cancer*
- Greater risk of invasive breast cancer 21.7% in women 25 y (see Table 1)
- Women who have a lifetime risk >20% based on history of LCIS or ADH/ALH
- Women who have a lifetime risk >20% as defined by models that are largely dependent on family history*
- Prior bilateral RT for patients younger than 30 y (eg, meningioma)
- Pathogen suggestive of or known genetic predisposition*†
- † Referred to genetic counseling, if not already done

SCREENING/FOLLOW-UP

- Clinical encounter** every 1-3 y
- Breast awareness**
- Annual clinical encounter**
- Annual screening mammogram (category 1)
- Consider biopsy††††
- Breast awareness**
- Increased Risk Screening Follow-up (See BSCR-2)
- (See NCCN Guidelines for Genetic/Familial High-Risk Assessment)
- Presenting Sign†††† Symptoms (See BSCR-3)

ACR-1

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FDA Accredited Units as of June 1, 2005			FDA Accredited Units as of June 1, 2016			
	Facilities	Units	%	Facilities	Units	%
Total	8,911	13,621	100%	8,740	16,155	100%
Analog		12,747	93.6%	285		1.8%
FFDM		874	6.4%	12,508		77.4%
DBT		0	0%	3,362		20.8%

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Home / Radiation-Emitting Products / Mammography Quality Standards Act and Program / MQSA Insights

MQSA National Statistics

In this section of MQSA Insights, we present the most commonly requested national statistics regarding the MQSA program. These statistics are updated on the first of each month.

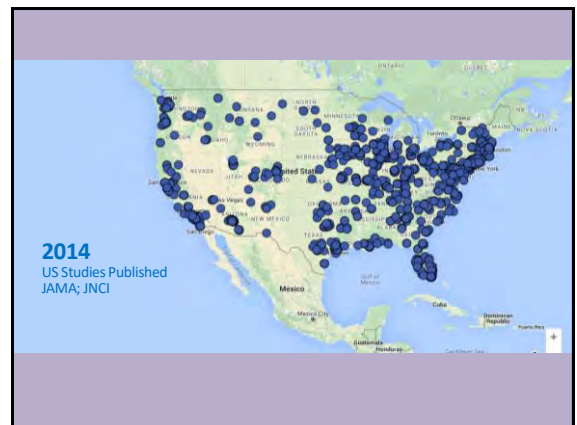
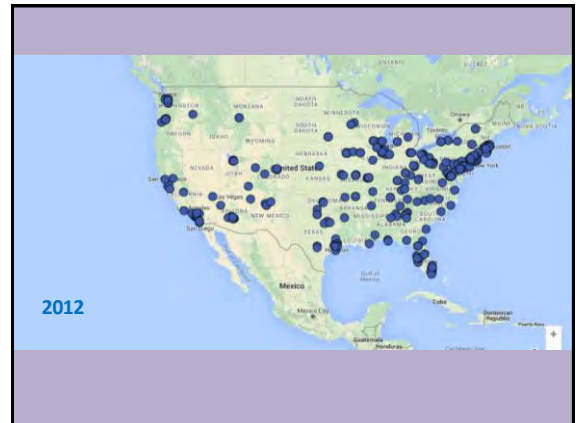
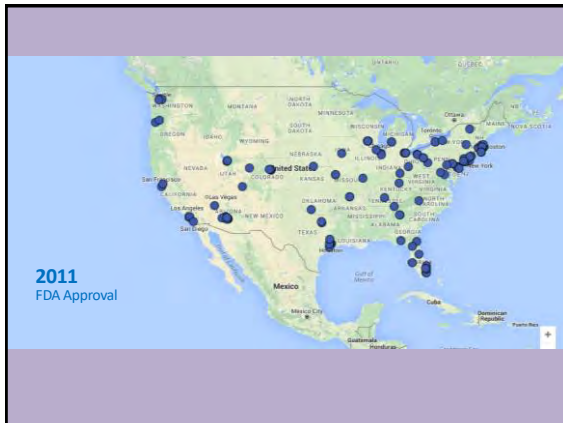
Certification statistics, as March 1, 2019

Total certified facilities / Total accredited units	8,699 / 16,581
Certified facilities with FFDM units / Accredited FFDM units	8,614 / 12,758
Certified facilities with DBT units / Accredited DBT units	4,971 / 2,883

31% of Mammography Units are DBT capable

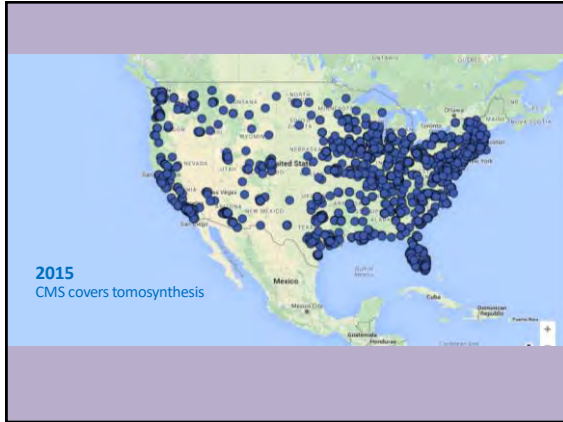
<https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/Ju01113838.htm>

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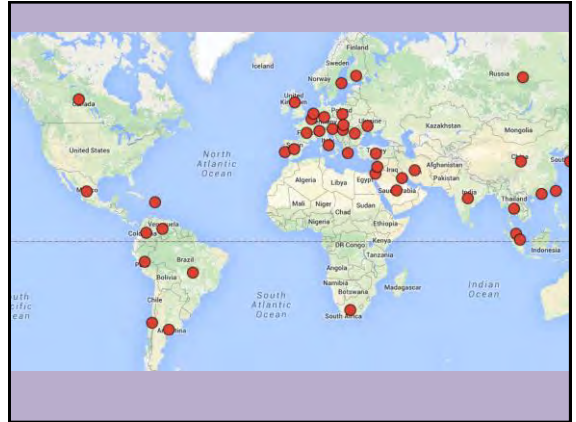





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Coding & Payment

Mammography Coding


Mammography is described using the following codes:

G0202	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed.
G0204	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral.
G0206	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral.

Breast tomosynthesis is described using the following add-on codes:

77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206) When breast tomosynthesis is furnished, practitioners should report one of G0202, G0204, G0204 and one of G0279 or 77063.

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/FAQ-Mammography-Services-Coding-Direct-Digital-Imaging.pdf>




Breast Tomosynthesis CPT Codes

Screening breast tomosynthesis

- 77063
- To be billed in conjunction with G0202

Diagnostic breast tomosynthesis (add on codes)


- G0279
- To be billed in conjunction with G0204 or G0206 (bilateral/unilateral)



Reimbursement for Tomosynthesis 2015, 2016, 2017, 2018

G0202 - Screening Mammography, bilateral	\$134.80, \$135.98, \$138.17 (plus CAD)
77063 - Screening Digital Breast Tomosynthesis, Bilateral	\$56.13, \$55.85, \$55.45, \$56.15
TOTAL	\$190.93, \$191.83, \$193.45, \$195.84
G0206 - Diagnostic Mammography, unilateral,	\$129.43, \$129.61, \$134.94 (plus CAD)
G0279 - Diagnostic Digital Breast Tomosynthesis, Uni or Bilateral	\$56.49, \$55.85, \$56.35, \$56.16
TOTAL	\$185.92, \$185.46, \$191.29, \$192.60
G0204 - Diagnostic Mammography, bilateral	\$164.11, \$165.06, \$171.19 (plus CAD)
G0279 - Diagnostic Digital Breast Tomosynthesis, Unilateral or Bilateral	\$56.49, \$55.85, \$56.35
TOTAL	\$220.60, \$220.91, \$227.54, \$228.96

www.acr.org/Advocacy/News/Archive/2014/20141114-Issue/Information-on-Coding-Values-and-Coverage-for-Tomosynthesis
www.cms.gov

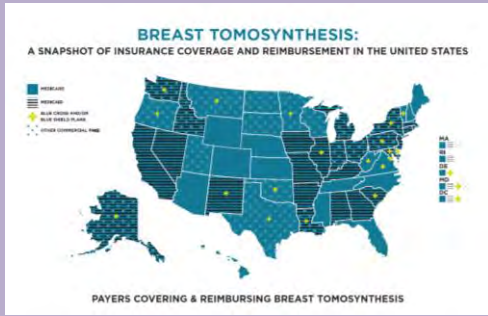




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Tomosynthesis Reimbursement



Breast Tomosynthesis Accreditation

Update April 2018

DBT Accreditation- UPDATE APRIL 2018

- FDA has now required that DBT units be accredited
 - DBT is now considered a separate unit from DM unit
 - Two separate accreditations
- ACR is approved to be accrediting body
- If you are currently in the re-accreditation process, you must accredit your DBT units at this time
- Otherwise, you may continue to use DBT until reapplication process
- Accreditation will expire 3 years post approval
- MQSA Certification Extension Approval Letter from the FDA needs to be submitted as well as the Medical Physicist Equipment Evaluation

Scenario 1. DBT - 2D Synthesized Images Available (whether or not 2D-Syn is used for interpretation)

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	Whatever is primarily used clinically: 2D clinical set (cc and mlo), or 2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set	2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

Scenario 2. DBT - 2D Synthesized Images Not Available on System

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	2D clinical set	2D clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

Important Points

- No reconstructed tomosynthesis images will be accepted
- If your machine is DBT capable but you are not using it clinically you don't have to accredit the DBT portion
- If you are only using DBT and not the DM portion of the machine (synthetic imaging only) you still must accredit the DM portion of the machine

Official Letterhead of Residency Program

[] Date of Letter []
To: Director of the Clinic
Re: [] name [] successfully completed residency in diagnostic radiology on [] date []. During the period of [] months required, program [] evaluate [] name [] name [] obtained the following training and experience specific to mammography:

1. At least 3600 hours, or its equivalent, of didactic instruction in mammography. (Of training on the interpretation of mammograms, including techniques to optimize photon, rotation, effect, and scatter production.)

2. (DBT) In residency program director: This may include this paragraph if the resident has passed the American Board of Radiology (ABR) or the American Board of Medical Specialties (ABMS) certification examination and received a diplomate of the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), or the Board of Certification in Radiology of the College of Physicians and Surgeons of Ontario (CPSO) in addition to the residency []

3. At least 60 hours of specific instruction concerning medical education in mammography.

(DBT) In residency program director: These 60 hours may be included in the three months of training described in #1. If they are not included in an additional 60 hours of training. This paragraph may be deleted if the three months of training is already documented in #1 []

4. At least eight hours each of training in digital, the mammography, microfilm, screen film mammography, full field digital mammography, and/or a digital breast tomosynthesis (DBT) system. If a DBT system, you must describe the manufacturer and version of image storage before the resident was trained []

(DBT) In residency program director: These eight hours may be completed in the three months of training described in #1 or the 60 hours described in #2. A trainee may train for an additional 8 hours of training. If trainee is not included in the letter as a mammography resident, as specified, it will not be counted toward the required minimum eight hours of training in full field digital mammography (FFDM) []

5. Head of department: During the three months of an interpreting program, the mammographers from the questionnaire of at least 200 letters within the last 6-month period of the resident's program [] give (date of 3-month period) []

or []

If the resident (in his/her contract) the certifying board's examination in diagnostic radiology, at the first certificate date, the 6-month period could have been any time within the last 3 years of the resident's program [] give (date of 6-month period) []

or []

If the resident (in his/her contract) the residency training in June 2014 or later, the 6-month period could have been any time within the last 3 years of the resident's program [] give (date of 6-month period) []

(DBT) The "or" above does not mean the resident was not a resident physician in regard to the first certifying examination []

(Return to an official of the Residency Program)



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Value analysis of digital breast tomosynthesis for breast cancer screening in a commercially-insured US population

Boniface MM, Kalra VB, Miller JD, Fajardo LL ClinicoOutcomes Res. 2015;Jan 12:7-53-63

Costs			
Screening costs per patient (including CAD line)			
FFDM	\$192.26	Trojan Health Analytics ¹ Bonafide et al ¹¹	
FFDM + DBT	\$248.28		Assumptions: FFDM cost plus 33%
Follow-up services costs in year following diagnosis (per patient)	\$1,205.29	Trojan Health Analytics ¹	
One-year post-diagnosis breast cancer costs by stage		Trojan Health Analytics ¹ / Morrison et al ¹²	
Stage 0 (DCIS/LCIS)	\$75,462	Turgeon et al ¹³ / Lindfors et al ¹⁴	
Stage 1	\$43,536		
Stage 2	\$66,472		
Stage 3	\$103,800		
Stage 4	\$273,368		

Abbreviations: CAD, computer-aided detection; DBT, digital breast tomosynthesis; DCIS, ductal carcinoma in situ; FFDM, full-field digital mammography; LCIS, lobular carcinoma in situ.

- Stage 4 costs +281.4% more than mean overall costs



Value analysis of digital breast tomosynthesis for breast cancer screening in a commercially-insured US population

Table 2 Cost estimation for follow-up services

Diagnostic service	Mean, per patient unit costs	Utilization by patients with follow-up (%)	Cost (weighted for utilization)
Diagnostic mammography	\$167	80.45%	\$136.47
Ultrasound	\$233	65.77%	\$152.96
Outpatient office visit with breast-related diagnosis	\$270	23.54%	\$63.50
Computer-aided detection (including extra screening day)	\$30	29.95%	\$11.87
Guided biopsy (including pathology and image guidance costs)	\$7,413	14.85%	\$575.28
Open biopsy (including pathology and anesthesia costs)	\$4,522	4.55%	\$205.74
Magnetic resonance imaging	\$1,108	2.96%	\$122.83
Fine needle aspiration	\$649	1.96%	\$121.33
Diactogram	\$194	<0.1%	\$0.09
Total			\$1,205.29

Note: All data derived from the Trojan Health Analytics MarketScan[®] Research Database.¹¹



Value analysis of digital breast tomosynthesis for breast cancer screening in a commercially-insured US population

Table 3 DBT case analysis results

	Base case analysis		Range analysis	
	Follow-up services rate for FFDM +15.35% and FFDM + DBT +10.88%	Follow-up services rate for FFDM +10.88% and FFDM + DBT +0.35%	Follow-up services rate for FFDM +15.35% and FFDM + DBT +8.89%	Follow-up services rate for FFDM +15.35% and FFDM + DBT +11.89%
Patients adding follow-up services	13,978	13,978	12,878	13,978
Current cancers with FFDM	84,832	4,784	7,891	9,289
Additional cancers with FFDM + DBT	4,321	9,214	5,387	5,478
Total costs				
– current cancers with FFDM	\$54,629,480	\$54,629,480	\$54,629,480	\$54,629,480
– additional cancers with FFDM + DBT	\$52,712,985	\$51,729,278	\$51,738,353	\$52,126,432
– Difference (total cancer costs due to use of DBT)	\$2,916,495	\$4,458,444	\$3,411,476	\$1,793,247
– Extrapolation to 1 million patients	\$1,122,466	\$1,843,768	\$1,405,394	\$722,744
– Extrapolation to 1 million patients	\$1,451,944	\$2,495,121	\$1,871,581	\$4,452,760
– Extrapolation to 1 million patients	\$1,487,793	\$1,187,789	\$1,987,793	\$1,187,793
of breast cancer				
– Per patient, per breast exam	\$4.10	\$4.10	\$4.10	\$4.10
– Current cancers with FFDM	\$4.10	\$4.10	\$4.10	\$4.10
– Additional cancers with FFDM + DBT	\$0.33	\$0.37	\$0.29	\$0.15

Abbreviations: DBT, digital breast tomosynthesis; FFDM, full-field digital mammography; PPV1, per million per breast.



Results

	DM	DM+Tomo	Absolute Difference	Relative change	P-Value
Recall Rate	10.7%	9.1%	16/1000	-15%	P<.001
Cancer Detection Rate	4.2/1000	5.4/1000	1.2/1000	+29%	P<.001
Invasive Cancer Detection Rate	2.9/1000	4.1/1000	1.2/1000	+41%	P<.001
PPV1	4.3%	6.4%	2.1%	+49%	P<.001
PPV3	24.2%	29.2%	5.0%	+21%	P<.001



Friedewald et al JAMA. 2014 Jun 25;311(24):2489-507

Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography Outcomes Analysis From 3 Years of Breast Cancer Screening

JAMA Oncology Published online February 18, 2016 McDonald ES et. al

- **Population level:** Recall rates rose slightly for years 1 to 3 of DBT (88, 90, and 92 per 1000 screened, respectively)
 - DM0 = 104 per 1000 screened (10.4%)
- **Patient level:** Decreasing recall rates (P < .001)
 - DBT1 130/1000 women screened (13.0%)
 - DBT2 78/1000 women screened (7.8%)
 - DBT3 59/1000 women screened (5.9%)



Conclusion


- \$2.4 million/year for hypothetical 1 million member health plan
- \$28.53 per screened patient
 - Based on claims database of >30 million patients/year
 - Clinical data published on DBT
- 4,500 women avoid unnecessary examinations
 - Not including costs to patients
 - **doesn't include possibility of no diagnostic mammogram
- Extrapolation when using DBT
 - Cost for US
 - * Net cost savings of \$28.53 per patient if DBT costs \$50 more per patient
 - * \$550 million annual savings (based on 39 million mammograms per year)





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Provider Challenges


Advocate Lutheran General Hospital

Caldwell Breast Center

- Large community hospital in suburban Chicago
- Part of a larger healthcare system with 12 hospitals
- Comprehensive breast center with 2.5 rads reading breast a day
- 40,000 examinations a year
- 20,000 screening examinations
- 3 screening units
- 3 diagnostic units




Caldwell Breast Center, Advocate Lutheran General Hospital



Advocate Lutheran General Hospital

Acquired one tomosynthesis unit in 2011


- What patients to you image?
- Do you charge patients?
- Do you ask the patients if they want tomosynthesis?
- Who makes the decision?



Advocate Lutheran General Hospital

Purchase 1 tomosynthesis machine out of 6 June 2011


- Started with diagnostic patients
- Allows the technologists to get used to the new technology, breathing technique
- Allows the radiologists to get comfortable with interpretation
 - US confirmation
 - Higher likelihood of malignancy
- Were not maximizing the technology
- Not as many patients benefited from technology
- Could not advertise, had to select patients
- Had no one to ask for help (5th in country to install, 1st in Midwest)



Advocate Lutheran General Hospital

Purchased 2nd machine December 2011



- Switched to screening after hours (only two machines screening)
- Started to advertise the technology
- Encouraged patients to come after hours
- All patients will get tomosynthesis
- No decisions for the technologists
- Maximized the benefit of tomosynthesis



Northwestern Memorial Hospital

Lynn Sage Comprehensive Breast Center

- Tertiary academic medical center in Chicago
- 40,000 patients screened each year
- 85,000 total procedures each year
- 16 mammogram units
 - 6 used for screening
- 7 ultrasound units




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Northwestern Memorial Hospital
Purchased one tomosynthesis unit 2014

- Used for diagnostic patients
- Some patients requested screening
- Underutilized
- Only one workstation for interpretation
- 15 radiologists needed to train
 - Not enough experience for each




Northwestern Memorial Hospital
Second unit purchased February 2015

- January 1, 2015: CPT code available for Tomosynthesis
- Two machines available at main center out of 4 screening rooms
 - Patients randomized to tomosynthesis rooms
- Patients complained because they were getting charged for what they thought was a covered examination



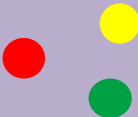

Northwestern Memorial Hospital
Second unit purchased February 2015

- Switched to informing patients at the front desk that there may be a charge associated with the examination
- Front desk not capable of answering questions about tomosynthesis
 - Benefits, risks, dose, cost
- Technologists have 15 min slots and can't wait for patients to call insurance company and/or explain the benefits
- Backlog of patients choosing to have tomosynthesis
- Patients leaving because of the wait




Northwestern Memorial Hospital
Second unit purchased February 2015

- Developed a sticker system
 - Message left on reminder call to investigate
 - Information was in waiting area about the benefits of the technology
 - Front desk asked if they wanted tomosynthesis
 - Yes- green dot sticker
 - Uncertain- yellow dot sticker
 - No- red dot sticker

Northwestern Memorial Hospital
All screening tomosynthesis, no diagnostic tomosynthesis

- Purchased 4 more machines in 2016
- 6/6 screening units were tomosynthesis capable
- July 2016- Illinois legislation requiring insurance companies to pay for DBT
- Maximize the screening capability of tomosynthesis
- Opportunity to advertise the technology
- All patients will get tomosynthesis
- No decision for the technologists
- No time restrictions with imaging



Northwestern Memorial Hospital- Current State
All DBT, but different versions of synthetic imaging

- Now we have almost all DBT machines in screening and diagnostics, but different versions of synthetic imaging
- Still imaging both DM + DBT to avoid the synthetic variables
- Plan on dropping DM when we are 100% same synthetic high resolution imaging at screening



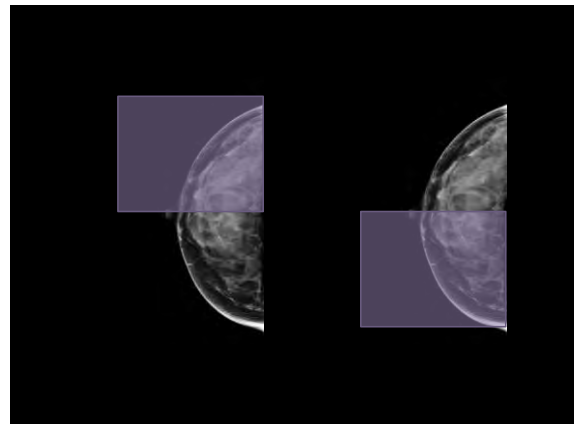
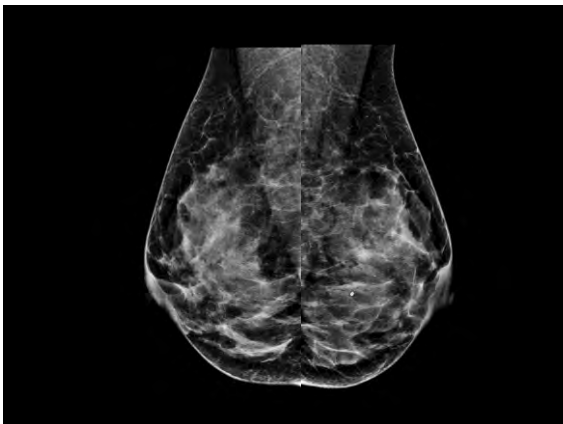
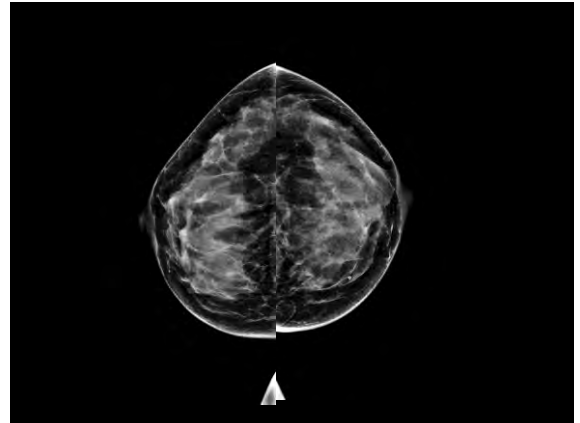
Interpretation

How to Handle all of the Images!

- Different work flows for each radiologist
- Doesn't matter how you approach it as long as it is the same way each time
- Depends on the PACS display

Reviewing tomosynthesis slices

- Have a standardized/systematic approach to reviewing images
- Do it the same way every time!
- Don't fall into the trap of "satisfaction of search"
- Use additional tools if your vendor has them to aid in your approach



Diagnostic Imaging with Tomosynthesis

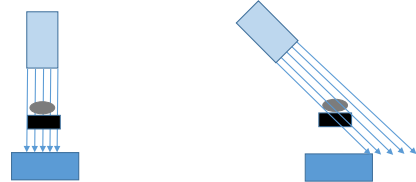
Diagnostic Setting

- Improves ultrasound scan time
- Increases or decreases pre-test probability of lesions being benign or malignant
- Spot compression views can help with areas typically susceptible to motion

Diagnostic Imaging

- Combination mode: DM + DBT
 - Digital Mammogram (DM)
 - Digital Breast Tomosynthesis (DBT)
- Synthesized images only
 - Spot compression views
 - No spot magnification views

No Magnification Views in Tomosynthesis



Diagnostic Protocols

Protocols for Diagnostic Imaging When Not Using Synthesized Imaging

- Call backs:
 - Calcifications: associated mass or just calcs?
 - If just for calcs then no tomo
 - Asymmetry: combo or tomo only?
 - One view asymmetry- combo
 - Two view asymmetry- tomo only
 - Mass: margins well characterized?
 - Fatty breast and/or margins well characterized- no diagnostic mammogram
 - Dense breast and/or margins not seen- tomo only
 - Architectural distortion:
 - Combo



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Protocols for Diagnostic Imaging When Not Using Synthesized Imaging

- Technical Recalls:
 - If motion is on DM, repeat DM
 - If motion is on DBT, repeat DBT
 - Sometimes its hard to determine DBT so sometimes I make a game time decision....
- Follow ups:
 - Calcifications: no DBT
 - Asymmetry with neg US: combo
 - Architectural distortion with neg US: combo
 - Mass: depends on situation



Protocols for Diagnostic Imaging When Not Using Synthesized Imaging

- Spot compression or not?
 - Same protocols as DM
 - Very helpful to fully characterize the abnormality because of decreased motion



Future Directions

- Further patient characteristics: i.e. age and risk
- Interval cancers
- Second and third round screening with tomosynthesis
- Supplemental screening with MRI and US



Thank You

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