



Real World Experience and Outcomes with Invenia ABUS (Automated Breast Ultrasound) at Fort Jesse's Imaging Center and Gale Keeran Center for Women

Background

Fort Jesse Imaging Center and Gale Keeran Center for Women (GKC) is a spa-like outpatient facility with a focus on women's health. GKC is in central Illinois (IL), which was the first state to pass an insurance law (effective March 27, 2009) mandating comprehensive ultrasound screening coverage of an entire breast or breasts when a routine mammogram reveals heterogenous or dense breast tissue and further screening is determined to be medically necessary by a physician.¹ When adjunct screening is performed by a preferred provider, coverage must be provided at no cost to the insured.¹ An Illinois density inform notification was recently passed and will take effect January 1, 2019. States that have previously passed density inform legislation have required that women be informed of their breast density and the associated risk it poses and referred to their doctors for questions. Illinois' law is the first to direct women to their breast imaging healthcare provider (i.e. radiologist) for information about the notification.²

Given the limitations of mammography in women with dense breast tissue and favorable legislation mandating payment for supplemental screening, GKC installed an Invenia™ ABUS (Automated Breast Ultrasound) from GE Healthcare on October 1, 2016 to enhance their supplemental screening program.

The objective of this study was to document the impact of ABUS in this dually owned, hospital and radiology group practice setting that offers same day service following a routine mammogram.

“Automated Breast Ultrasound (ABUS) represents an important advancement in screening women with heterogeneously dense or extremely dense breasts. Additional breast cancers are detected without the use of ionizing radiation. ABUS allows a more comprehensive evaluation for detecting early breast cancer in women with dense breasts.”

Dr. Ajay Malpani, MD
President Bloomington Radiology

Ft. Jesse
Imaging
Center



GALE KEERAN
*Center for
Women*

2200 Fort Jesse Road | Suites 120 & 130 | Normal, IL 61761

Phone (309) 454-5552

www.ftjesse.com

About Gale Keeran Center for Women

Dedicated to offering superior care, the Gale Keeran Center for Women (GKC) offers high quality care in a spa-like environment with accommodating appointment times for working women and mothers. Their home-like environment, women's waiting room, and warm capes offer patients many conveniences. They also understand patient time is valuable and do their best to ensure minimal wait times.

They offer the latest and greatest technology, including 3D mammography and whole breast ultrasound.



Technologists.



The entire team.

Methodology

The retrospective study analyzed 21 months of data post ABUS implementation (October 2016 to June 2018).

Specifically, the following outcomes were analyzed:

- Mammography utilization trends, by quarter
- ABUS supplemental screening rates, by quarter
- ABUS cancer detection rate with pathology
- Average reimbursement for ultrasound

Prior to study initiation, GKC administrators and clinicians were interviewed to understand best practices and the challenges that had to be overcome to result in a successful ABUS screening program. Those highlights are summarized as well.

Study Participants

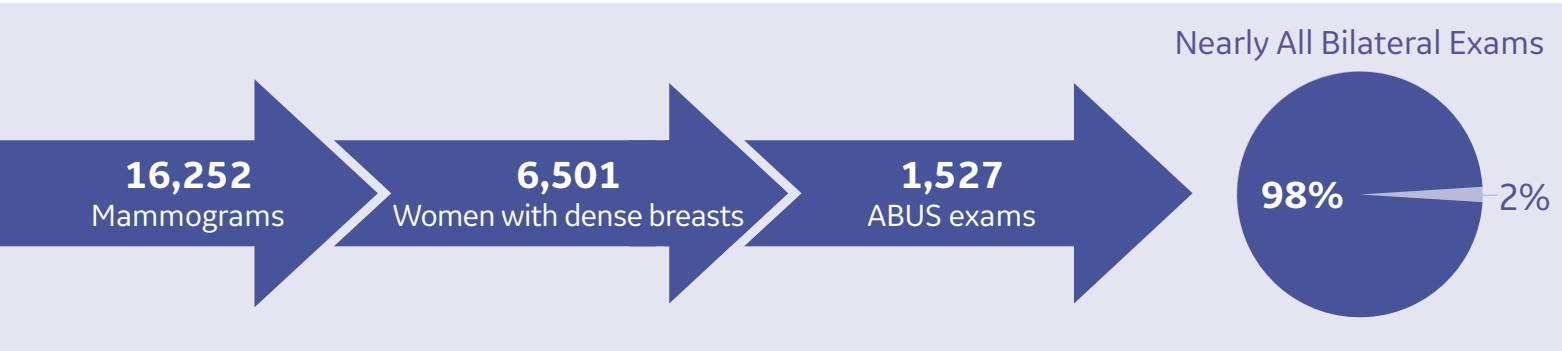
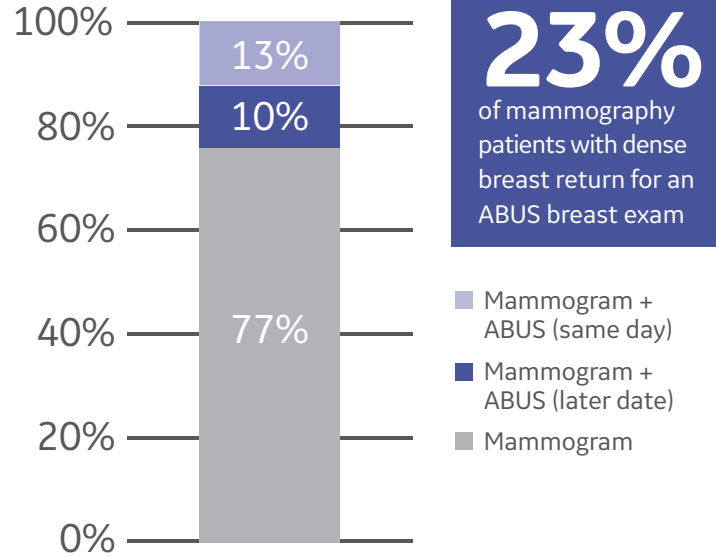
During the 21-month study period, 16,252 women had a mammogram. The majority (88%) of the women received screening exams (n=14,252). A recent study estimated that 43.3% of US women 40 to 74 years of age have heterogeneously or extremely dense breasts.³ Based on this prevalence, 6,501 women were estimated to have dense breasts within the study population.

While density notification was not mandated in Illinois at the time of this study, patients were informed of breast density and offered supplemental screening with Invenia ABUS. Amongst those women offered supplemental screening, 23% (n=1,527) opted to have an ABUS exam (i.e., capture rate). Although ABUS is only used as a screening tool at GKC, 98% of the exams were billed as a bilateral procedure. 2% of the ABUS exams were unilateral procedures performed in women with prior mastectomies.

"In order to provide the best patient care, we felt it was necessary to schedule ABUS on the same day as their screening mammogram to provide them with same day convenience. Our goal at our women's center is to take away any obstacles and provide the most up-to-date imaging services. We know how important the patient's time is and we want to honor that."

Melissa Marx, Administrator

Mammography + ABUS Distribution



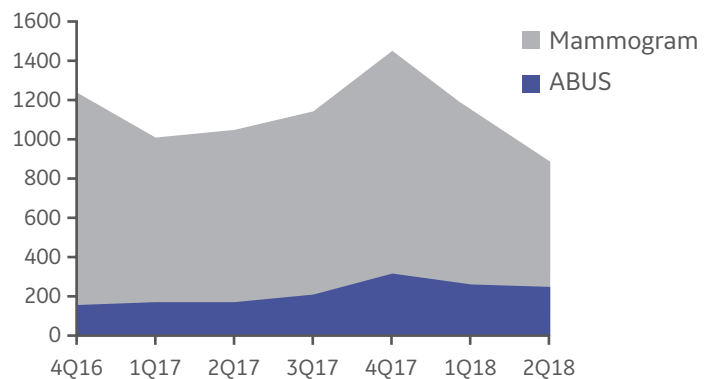
Quarterly screening utilization for mammography and ABUS are displayed at right. Quarterly capture rates vary and range from 15% to 37%. Utilization peaked for both procedures during the fourth quarter of 2017.

This was attributed to two factors:

1. September – GKC implemented use of a super order with prior authorization provided by the referring physician to perform an ABUS exam, if deemed medically necessary by the radiologist.
2. October – National Breast Cancer Awareness month.

The capture rate growth of ABUS for 1Q18 (vs. 1Q17) and 2Q18 (vs. 2Q17) was 9% and 19%, respectively.

Dense Breast Screening Utilization Trends, by Quarter

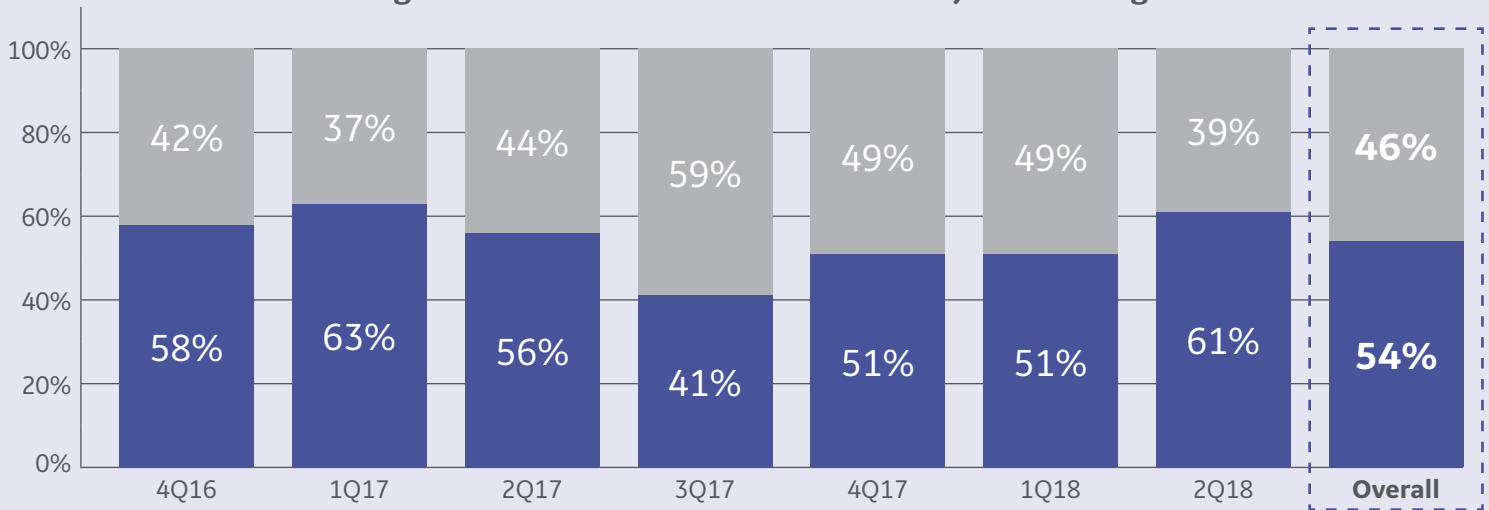


Amongst those who chose to have an ABUS exam, 54% received the exam on the same day as their mammogram. The quarterly range was 41% to 63%.

"We understand that the patients' time is valuable, so we do our best to offer same day scheduling and minimal wait time."

GKC

Percentage of ABUS Exams Performed Same Day as Mammogram



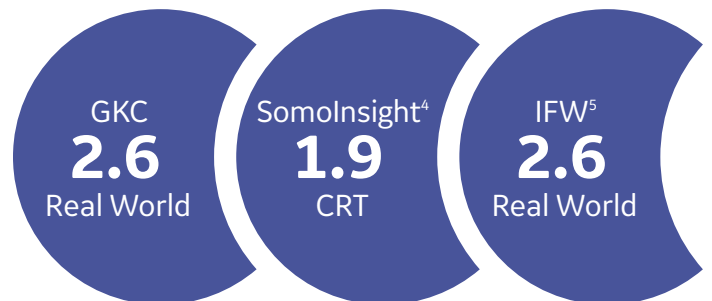
Clinical Outcomes

Supplemental screening with ABUS resulted in greater cancer detection. At GKC, the incremental cancer detection rate with ABUS was 2.6 per 1,000 screened women (4 of 1,527). All cancers were mammographically occult and found in women with heterogeneously dense breast tissue (e.g., BI-RADS® density rating C). In addition, the majority (75%) of the cancers were node negative with lesions ranging in size from 0.6 to 1.8 cm. The majority of the cancers (75%) were detected early at stage two.

The supplemental cancer detection rate of this study was the same as another provider site (IFW) and consistent with the SomolInsight clinical reader trial using Invenia ABUS.^{4,5}

Average time from screening to cancer diagnosis was 10 days.

Cancer Yield from Supplemental Screening with Invenia ABUS (Rate Per 1,000)



Legend: CRT – clinical reader trial; IFW – Imaging for Women (provider site located in Kansas City, MO).

GKC Invenia ABUS Findings

Patient	Age	BI-RADS Breast Density	Risk Factors	Lesion Size (cm)	Pathologic Findings	Cancer Stage	Lymph Node Status
1	63	C	Family Hx	0.6	Invasive Ductal	Grade 1	Negative
2	53	C	Family Hx	1.3	Invasive Ductal	Grade 2	Positive
3	41	C	Family Hx	1.8	Infiltrating mammary carcinoma, ductal type, moderately differentiated with focal minor ductal carcinoma in situ component	Grade 2	Negative
4	79	C	Hx of bilateral biopsy	1.4	Invasive well moderately differentiated carcinoma with squamous differentiation... mammary carcinoma with metaplastic squamous differentiation	Grade 2	Negative

Economic Outcomes

Due to the insurance coverage mandate in Illinois, ABUS reimbursement during the study period was favorable with a 0% rejection rate. Based on the law, coverage for supplemental screening with ultrasound is provided at no cost (i.e., copays or deductibles) to the insured. The average plan payment for all breast ultrasound (unilateral and bilateral) was \$164; at GKC, handheld ultrasound and ABUS are priced parity. Average patient out-of-pocket was \$0, consistent with requirements of the law and suggested that all patients were covered by non-grandfather benefit plans. Compared to ABUS-specific reimbursement rates from another provider site (Imaging for Women in Missouri) and a retrospective claims analysis of 20 regional payers, ultrasound reimbursement rates at GKC are lower than expected.

Best Practices

Success of GKC's supplemental screening program was largely attributable to favorable state-level reimbursement policies. Other factors contributing to their success were provider and patient education, operational efficiencies and traditional marketing outlets.

Education is an ongoing effort and is paramount to the success of any supplemental screening program. Despite no legislation mandating density notification during the time of the study, GKC informed patients of their density at the time of their exam and offered same day supplemental screening. Other patient-centered educational activities included community fairs and Race for the Cure. Referring physician-centered education activities included site visits to provide information on proper ordering and target patients that would benefit most from supplemental screening. These initiatives drove the need for operational efficiencies.

Operational efficiencies that facilitated patient capture are noted below:

- Increase staffing efficiency by cross-training training technologists to perform mammogram and ABUS screening exams
- Use of super order to facilitate same day scheduling
- Density documentation within EMR to facilitate same day scheduling

Traditional marketing outlets to increase demand included print flyers, radio advertisements, and social media (e.g., Facebook).

Challenges

1. **Referring physician education.** Patients typically refer to physicians for their healthcare needs. Due to this, GKC wanted to make sure the physician understood the ABUS process as well as the importance it provided to their patients. To achieve this, they went into referring physician offices and provided training on the proper ordering of ABUS as well as the patients it could benefit.
2. **Consumer education.** With any new technology, patients question the purpose/need of additional imaging. The GKC team took on this challenge to educate patients on breast density and the difference between ABUS and diagnostic breast ultrasounds.

Reimbursement Comparison*

\$164 GKC

\$203 IFW⁵

\$229 Magellan⁶

*Reimbursement = plan paid + patient out-of-pocket.

Sample Super Order

<p>To schedule call: Gale Keeran Center for Women Phone: (309) 452-9001 Fax: (309) 452-9299</p>	<p>Breast Health Services Provider Super Order</p>	<p>FL JESSE Imaging Center</p> <p>GALE KEERAN Center for Women</p>
<p>Patient's Name: _____ D.O.B. _____ Diagnosis: _____ Phone: _____</p>		
<p><input type="checkbox"/> Screening Mammogram</p> <p><input type="checkbox"/> Baseline <input type="checkbox"/> Bilateral <input type="checkbox"/> Implants <input type="checkbox"/> Unilateral RIGHT or LEFT</p> <p>Perform screening Automated Breast Ultrasound if clinically indicated (ABUS) YES NO Perform diagnostic mammo if imaging or clinically indicated? YES NO Perform ultrasound if imaging or clinically indicated? YES NO Perform biopsy or aspiration if imaging or clinically indicated? YES NO</p> <p>Includes: • Provider notified of results • Letter to patient with results • Call back to patients if additional imaging is indicated • Scheduling of call back exams if "YES" is indicated above</p>		
<p><input type="checkbox"/> Diagnostic Mammogram</p> <p><input type="checkbox"/> Baseline <input type="checkbox"/> Bilateral <input type="checkbox"/> Implants <input type="checkbox"/> Unilateral RIGHT or LEFT</p> <p>Perform ultrasound if imaging or clinically indicated? YES NO Perform biopsy or aspiration if imaging or clinically indicated? YES NO</p> <p>Includes: • Provider notified of results • Letter to patient with results • Scheduling of call back exams if "YES" is indicated above</p>		
<p>Patient Instructions:</p> <ul style="list-style-type: none"> • No deodorant, powder, or talc day of exam • If patient has had a mammogram at another facility, please contact that facility to have films sent 		
<p>Appointment: _____ @ _____ at _____ (date) (time) (location)</p> <p>Provider Signature: _____ Date: _____</p> <p>Provider Printed Name: _____</p>		

3. **Insurance/Billing.** It is important to explain to consumers and referring offices that although this is a screening tool, it is not necessarily covered under preventative maintenance. They provide all patients during the scheduling process the CPT code which allows them to call their insurance provider prior to their appointment to see if they will have any out of pocket cost.

"Obstacles in life and work are always an opportunity to grow, learn, be better and do better. Implementing ABUS at GKC continues to push and challenge us – we face pressure in the industry, we face concern and doubt from patients and referring physicians. Yet, we believe in it and that alone pushes us forward."

Melissa Marx, Administrator

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About Invenia ABUS

Invenia ABUS (Automated Breast Ultrasound) is the only ultrasound system approved by the FDA for breast screening. It is a comfortable, non-ionizing alternative to other supplemental screening options for women with dense breast tissue. When used in addition to mammography, Invenia ABUS can improve invasive breast cancer detection by a 37.5% relative increase over mammography alone.⁴

1. Illinois Senate Bill 2442. Accessed at: <http://insurance.illinois.gov/HealthInsurance/women.pdf>.
2. Imaging Technology News. Accessed at: <https://www.itnonline.com/content/illinois-governor-approves-state-breast-density-reporting-bill-law>.
3. Sprague BL, Gangnon RE, Burt V, et al. J Natl Cancer Inst. 2014 Oct; 106(10): dju255.
4. FDA PMA P110006 summary of safety and effectiveness.
5. IFW Case Study. Data on File. GE Healthcare.
6. Magellan National Payer Study. Data on File. GE Healthcare.

Imagination at work

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