

Make a difference, not a diagnosis

ABUS Use Case: State of Franklin Comprehensive Breast Centers

The State of Franklin Healthcare Associates Comprehensive Breast Centers perform nearly 20,000 screening mammograms a year and strive to provide supplemental imaging to women with dense breasts, such as automated breast ultrasound (ABUS) and hand-held ultrasound (HHUS), in a single visit whenever possible.

According to Dr. Raymond Kohne, Chief of Imaging at State of Franklin, "Our goal is to make a difference, focusing on catching cancers early, when they are most treatable, and women have the best survival rate."

Dr. Kohne notes that when a patient comes in with either palpable lymph nodes or a palpable mass, he's just making a diagnosis – not making a difference.



Dr. Raymond KohneChief of Imaging at State of Franklin



The site

The State of Franklin Healthcare Associates Comprehensive Breast Centers in Johnson City and Kingsport, Tennessee, are dedicated to the prevention and early detection of breast diseases. The Breast Centers provide state of the art diagnostic imaging and breast health care to patients in the Tri-Cities area of Northeast Tennessee and Southwest Virginia.

Breast density reduces mammography sensitivity

Breast cancer is the most common cancer in women in the United States, except for skin cancers, and represents about 30 percent of all new female cancers each year.¹ The American College of Radiology (ACR) recommends annual mammograms starting at age 40 for women of average risk. The latest ACR guidelines also call for all women to have risk assessment by age 25 to determine if screening earlier than 40 is needed. The American Cancer Society (ACS) recommends that all women between the ages of 45 and 54 get a mammogram each year and that women between 40 and 44 have the option to start screening mammograms every year as well.²,³ Mammography is the gold standard for screening; however, it does not work equally well for all women, particularly those who have dense breast tissue. In fact, studies show that mammography misses one-third of cancers in patients with dense breasts.⁴

"You really have to be passionate, compassionate and empathetic when you work in women's imaging. To me, it's even more than that – it's personal," said Dr. Kohne. "In 2000, my mother-in-law came for Thanksgiving dinner and told me she had lumps under her arm. I immediately left the dinner table and dragged her to the hospital and found that she had Stage 3 C breast cancer. Sadly, the mass had been missed on her mammogram and since it wasn't standard practice at the time, she did not have an ultrasound even though she had dense tissue. She fought for 17 years before passing away.

"Watching my wife experience her mother's fight with cancer was not a pleasant experience. If I can stop other families from having to go through that, then that's my goal. I look at all my patients as family and that's how I take care of them. This is not a job, it's a mission – and we can do better. When people die from breast cancer, there's something missing in the equation," added Dr. Kohne.

Improve cancer detection with ABUS

The State of Franklin Breast Center initiated an ABUS program in 2020, growing from six ABUS exams in the first month to a monthly average of more than 130 ABUS exams. Risk assessment is performed for all patients, using the Tyrer-Cuzick model to personalize screening for women based on their risk factors, including dense breasts. The clinic performs digital mammography, ABUS, HHUS and breast MRI.

"The limitations of mammography in women with dense breasts are well known," said Dr. Kohne. "As a result, supplemental screening is routinely offered in conjunction with mammography. Our techs are trained to recognize obvious heterogenous or extremely dense tissue and discuss ABUS with patients as an option to optimize their screening."

Designed especially for screening, the sensitivity of the GE HealthCare Invenia™ ABUS 2.0 is not affected by dense tissue, allowing the detection of non-calcified carcinomas that are obscured in mammography. Major advantages include providing a volumetric global visualization of the whole breast. Standard exams are reproducible, enabling priors comparison.⁵

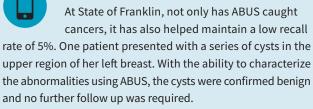
Patient case - Find it early

Shortly after State of Franklin started the ABUS program, a 43-year old woman came in for her mammogram with two young kids – ages 3 and 7. When her mammogram showed that she had extremely dense breasts, supplemental screening with ultrasound or

ABUS was recommended.

"She resisted the ABUS, not because she didn't want the exam, but because she felt she couldn't afford it – which happens a lot in our patient population. I was finally able to convince her that she had to have an ABUS exam – to protect her kids. Those kids still have a mommy today due to the use of ABUS, which found a 9 mm cancer that was missed on the mammogram. Finding it as an early stage cancer saved her life. In my opinion, having the ABUS exam was the best decision she ever made for herself and her kids," said Dr. Kohne.

Patient case – Reducing anxiety



"I didn't have to call her back and she didn't have to worry. This is a tremendous advantage, particularly in breast imaging, where being called in for additional testing creates so much anxiety. If we can reduce this anxiety, we're more likely to get the patients to come in for regular screening, where we can catch things early," noted Dr. Kohne.

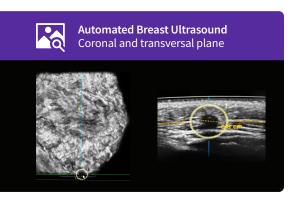
The State of Franklin ABUS program is making a difference, catching six invasive cancers that were not visible on the women's mammograms. "That's making a difference. Ultimately, it's about catching cancers," said Dr. Kohne. "My goal is to catch a cancer at 7-11 mm where we can use less invasive, less expensive treatments that have about a 98 percent survival rate. If I can find this thing at the size of a marble, like with the 43 year old mom, then I'm making a difference."

Improved efficiency with ABUS

ABUS exam time is approximately 20 minutes and the average reading time for physicians for a complete ABUS study is 2-3 minutes. The Invenia ABUS Viewer, now featuring AI Assistant, enables enhanced review of 3D ABUS datasets to assist in detecting breast lesions, helping decrease reading time with a great degree of confidence.

"If you can read breast ultrasound, you can read ABUS. Now, with the AI Assistant, powered by QVCAD,™ my read time is down about 30 percent to about a minute and a half."

"I honestly take longer going and talking to my patients than it takes for me to read the ABUS exam. ABUS is efficient, it's cost-effective and it does a really good job screening women with dense breasts."



State of Franklin ABUS performance

Monthly ABUS exams: 130 average

Cancer detection: 6 invasive mammography

occult cancers

ABUS acquisition: 20 minutes
ABUS read time: 90 seconds

Recall rate: 5 percent



ABUS education and density inform advocacy

Every State of Franklin patient with dense breast tissue (BI-RADS® category C or D) receives a phone call from a nurse navigator or ABUS lead and is personally invited to have supplemental screening. Patients with a lifetime risk greater than 20 percent will have a discussion about Breast MRI.

"These calls have not only helped grow our ABUS volume, but significantly help reduce patient anxiety. When patients with dense breasts come in, we use a video and a presentation to explain what density is and what it means to their breast health. It's all about education," added Dr. Kohne.

In addition to his dedication to educating patients, Dr. Kohne actively advocates for improving the quality of care and reducing patient costs. Working with state Representative Rebecca Alexander, Dr. Kohne testified in support of breast density inform legislation and worked to refine the language for the legislation, as well as the actual notification language for the women of Tennessee. In 2013, Tennessee became the eighth state with Breast Density Inform legislation.

In a major milestone for improving breast cancer screening, the U.S. Food and Drug Administration (FDA) recently announced in March 2023 that all mammography sites will be required to notify patients of their breast density in every state effective September 2024. A key part of the FDA's new guidelines requires mammography providers to educate, inform, and make it compulsory to communicate with patients their breast density.

In May 2023, Tennessee passed legislation which requires health plans to cover diagnostic imaging and supplemental breast screening without cost to the patient. Tennessee is now one of 13 states with such legislation that removes the costs of this imaging, and with it a barrier to early breast cancer detection.

"In Tennessee, we have a very robust safety net that covers cancer treatment, it's just getting patients through the screening process that can be difficult. If you don't diagnose that cancer, then you can't get to that safety net to have the treatment that's required. This is why we really do need to push hard for the "Catch it Early" Act so that women will be screened consistently," said Rep. Rebecca Alexander.

"The biggest challenge right now is getting the federal insurance bill passed so that we can screen – if we can find them, we can make that difference. We've done it in Tennessee, but we really need to push hard on the federal level," concluded Dr. Kohne.



State of Franklin Comprehensive Breast Centers – ABUS decision tree



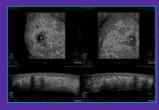
Risk assessment

Risk assessment using Tyrer-Cuzick model.



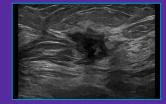
Mammography

Mammography screening for all women.



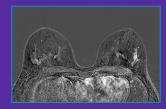
ABUS

ABUS for first line supplemental exam for all asymptomatic women with dense breasts (BI-RADS C and D).



HHUS

HHUS used for symptomatic women and those referred for diagnostic ultrasound exam.



Breast MRI

Breast MRI screening is offered to high risk women in addition to mammography, regardless of breast density.*

* Alternate DBT + MRI and 2D/DBT + ABUS annually in some patients, depending on risk and breast density



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