Crisis or Opportunity?

Breast Density Notification, Workflow and the Implementation of Screening Ultrasound

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Breast density notification is becoming a reality in many states across the US by virtue of legislation, as well as growing recognition of the clinical benefit of breast ultrasound when used to supplement screening mammography in women with dense breasts and normal mammograms. With supplementary screening potentially affecting 45% of the women receiving mammograms each year, screening ultrasound is a *disruptive* technology, and its implementation will require a significant shift in the traditional delivery paradigm.

Both mammography and ultrasound have relatively low reimbursement, making the delivery paradigm for screening economically critical. The volume of screening procedures has a leveraging effect on even small revenue or cost numbers, lending further emphasis to efforts to refine and optimize workflow. As we develop in this paper, we expect the reader to conclude that successfully changing the delivery paradigm is not only an imperative economically; it is the only practical way to deliver on the promise of early detection of breast cancer for women.

Before we go into detail regarding workflow in a breast center, it is appropriate to review both the breast center itself, and breast density. A basic understanding of both will allow the reader to more quickly understand how the changes we suggest will improve both patient care and center economics.

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The Breast Center

Twenty years ago it was not unusual for women to receive screening mammograms in general radiology departments and, if there was a problem with the mammogram, to return 3-4 or even more times to receive further mammograms, ultrasound exams and/or other diagnostic procedures to arrive at a diagnosis. If there were lingering uncertainty as to whether the region of interest (ROI) was benign or malignant, an open surgical biopsy would be ordered. With the advent of percutaneous biopsy in the mid 1990s, it became possible for women to receive all of their detection and diagnostic procedures in one location and, with greater sensitivity to the value of patient time, breast centers were developed that catered directly and exclusively to women's breast health needs, providing multiple studies in the same visit.

Most people have some familiarity with breast centers, but there is a less widespread understanding of "who" works in a breast center and "how" they actually function. Understanding these aspects is vital to understanding the care that is delivered and how the "business" of a breast center operates.

Let's look at a typical breast center and then follow patients as they move through the center on a typical visit. Table 1 describes the relationship between patient volumes and procedures in a typical breast center before adding in supplementary screening. Note that we often refer to this relationship as the "breast cascade" as the patient volumes are related to each other.

Table 1: The Breast Cascade

Procedures	From Screening	Other Than From Screening	% of Screening Volume	Total
Screening				
Screening Mammography	10,000		100%	10,000
Diagnostic				
Diagnostic Mammogram (1)	1,000	1,500	25%	2,500
Diagnostic Breast Ultrasound (2)	500	1,000	15%	1,500
Stereotactic Biopsy (3)	75	50	1.5%	125
Ultrasound Biopsy (4)	120	120	2.4%	240
Total Procedures	11,695	2,670	144%	14,365
Breast Cancers Diagnosed (5)	50	50	1%	100

Notes
(1) 10% from native screens/10% clinical referrals/5% SIFU
(2) 5% from native screens/10% from clinical referrals and SIFU
(3) 30% of total biopsies/20% PPV
(4) 70% of total biopsies/30% PPV
(5) Calculated at 1% of mammo screening population but includes clinical referrals

Note that we have included patients who enter the system other than through screening in order to account for women who present with symptoms (e.g., palpable findings, breast pain, nipple discharge, etc.), and those who are returning for a short interval follow-up (SIFU) to allow the physician to relook at a previous low suspicion finding. The number of women in these categories will vary widely between centers, and we have attempted to estimate a "typical" center.

Screening does not require the presence of the physician, and many breast centers designate one day each week (usually Friday) for screening only, and have the physician in attendance four days per week to interpret screening and diagnostic exams, and to perform procedures. If we translate Table 1 into physician daily volumes we will approximate the distribution in Table 2.

Table 2: The Breast Cascade – Daily Interpretation (4-day week)

Procedures	From Screening	Other Than From Screening	% of Screening Volume	Total
Screening				
Screening Mammography	50		100%	50
Diagnostic				
Diagnostic Mammogram (1)	5	8	25%	13
Diagnostic Breast Ultrasound (2)	2	5	15%	7
Stereotactic Biopsy (3)			1.5%	1
Ultrasound Biopsy (4)			3.5%	2
Total Procedures			142%	73
Breast Cancers Diagnosed (5)	.25	.25	1%	0.5

Notes
(1) 10% from native screens/10% clinical referrals/5% SIFU
(2) 5% from native screens/10% from clinical referrals and SIFU
(3) 30% of total biopsies/20% PPV
(4) 70% of total biopsies/30% PPV
(5) Calculated at 1% of screening population but includes clinical referrals

The breast center in Tables 1/2 will have 2 digital mammography rooms, as single ultrasound unit and a stereotactic unit. The professional staffing will be two mammography technologists, a sonography technologist, and possibly a technology assistant. None of the professional staff, including the physician, will be working at capacity. Approximately one third of the space in the typical clinical breast center is devoted to clinical delivery.

As we follow the patient through her interactions with the center we will see the other people and processes that affect the delivery of services. Our patient begins the process by calling the center to schedule an appointment. The scheduler has to go through a number of questions with the patient to determine (1) that the exam is proper-

ly a screening exam; and, (2) that it has been at least a year from her most recent mammogram so that her insurance will cover the expense. Screening and diagnostic mammograms are different in several respects, and schedules are not interchangeable, so it is very important to get the patient scheduled appropriately the first time.

When our patient comes to the center for her appointment she will need to go through a registration process that is intended to (1) update the patient's medical record to reflect any pertinent information that may have changed since her last visit, (2) get signatures on the various consents, and other paperwork requiring signature, (3) verify insurance, and (4) assure that the foregoing all occurs in a secure manner to protect the patient's privacy. Following registration the patient will be directed to a gowned waiting area where she changes into a gown before her exam.

The mammography technologist or an aide will escort the patient from the gowned waiting area to the mammography room. In the room the technologist will ask the patient several questions regarding changes in her breast health over the past year. She will then have her breasts positioned in the mammography unit, be put under compression, and images of two different views per breast acquired. Positioning and compression are critical to good images, and it takes the special skills of a technologist to obtain both while keeping the patient satisfied with her experience.

After dressing in her street clothing, the patient returns to the reception area for check out before leaving the center. There is no copayment or deductible requirement for insured patients, but if the patient has no insurance she will need to either pay for or make arrangements to pay for her services.

After the patient leaves the mammography room her images are sent to the radiologist's workstation and are merged with her medical record. The radiologist reviews the images and reports the encounter, usually with a subspecialized mammography reporting system that facilitates clinical and patient reporting, as well as maintenance of an electronic medical record. Traditionally the radiologist would also dictate a report that would be sent on to the referring physician and, since 1998, a report in lay language will also be sent to the patient. The medical record and the archiving system for images that allow for interpretation and reporting represent very substantial investments that are required to assure the security and privacy of the images and medical record.

If the patient has an abnormal mammogram she will typically receive a call from the breast center, as well as her report, and she will need to go through the entire scheduling and registration process again. The process is complicated somewhat, however, because the law requires that each diagnostic procedure have a referral from the patient's physician; a requirement that typically demands one full time employee.

There are other tasks in the breast center that take place behind the scenes. Mammography equipment is subject to quality control procedures that must be performed and logged at regular daily, weekly, or monthly intervals. Patient navigators assist diagnosed patients with support and scheduling, and there are, of course, routine maintenance functions for all equipment must be performed.

The last, and certainly not the least, task for the breast center is billing. It is not unusual to find breast centers with 40-50 third party payer contracts, each with different terms and conditions. Payment under these contracts is not automatic and, as a general rule, payers use every ruse to avoid or delay payment. Billing and collection are time consuming tasks that must be kept current and involve considerable human and capital resources.

A day in the life of the radiologist at our hypothetical breast center involves the interpretation of about 50 screening mammograms, supervision and interpretation of around 20 diagnostic procedures and performing an average of about 3 biopsies. Most physicians prefer to interpret the screening mammograms in a block, as this adds to efficiency, and many come into the center early in the morning to interpret the exams from the prior day. The diagnostic imaging requires initial direction from the physician as to what area of the breast to work-up, then interactive follow-up with the technologist as the images become available. It is not unusual to find 3-6 images to allow the physician to reach a confidence level to call what he or she is seeing benign or to move the patient on to a biopsy. Biopsies further complicate workflow because of the unavailability of the physician during the procedure, which tends to back up the interactive diagnostic process with the technologists.

During the physician's day he or she must also sign off on reports that have been generated in the system, call the physicians of women he diagnoses with cancers, keep up with current breast literature, and perform the responsibilities mandated of the physician by MQSA. We stated earlier that the volume of Table 1/2 did not represent

the capacity of the center, but it is easy to see that the management of center and physician workflow ultimately affects capacity.

The reader should recognize that there are two different components of an episode of care:

- The non-clinical efforts represented by center administration, scheduling, reception, medical records, transcription/reporting and billing.
- The clinical care represented by the physician, technologists and technology aides.

The most critical factor to remember when considering workflow in breast imaging is that the only imaging that can truly be "engineered" is screening. The main reason that this process can be engineered is that the acquisition of the mammogram can be separated from the interpretation of the mammogram, and each individual facet of the delivery process can thereby be addressed. One of the principals of engineering the screening process is defining technologist tasking in terms of her unique training and skills. For example, the technologist should not spend inordinate amounts of time escorting patients around the facility, and should not be involved in routine recording of patient histories. Since the technologist also controls the mammography unit, reducing technologist time per exam provides a double benefit in terms of workflow.

Screening mammography interpretation can also be much more effective for the physicians, when the screening mammograms can be interpreted in "batches" rather than individually. Allowing physicians to interpret a series of mammograms allows them to get into "screening mode" where they can review and report a mammogram in 45-180 seconds, with an average for very productive interpreting physicians probably falling in the 45-60 second range.

The distinction between screening and diagnostics, for both mammography and ultrasound, is that the physician reviews screening images *expecting normalcy*, but is focused on defining an apparent *abnormality* on a diagnostic study. This may seem like two sides of the same coin, but when the expectation is "normal", the physician is *sensitive* to slight differences and the abnormal seems to "pop" out of the normal background. Because the task is to detect, rather than to diagnose, identifying the abnormal without defining the abnormality is sufficient for screening. Approximately 8-10% of screening mammography patients in the US will be recalled for further diagnostic studies.

By contrast, diagnostic studies are designed to move the physician's impression from an abnormal finding to confidence in a *specific* finding that the abnormality is benign or sufficient suspicious for a malignancy that a biopsy is required. This process often requires several different mammographic views, and frequently ultrasound. In all instances, however, the objective is to move the suspicion of the physician to relative certainty whether the ROI is benign or malignant. Importantly, diagnostic imaging involves *interactive* procedures, requiring the presence and the direction of the supervising physician.

A constant challenge for the center, however, is that screening mammography has traditionally been delivered as a "stand alone" procedure and, as such, the revenue from the one procedure has to bear all of the costs – medical and non-medical – of the visit. Non-medical costs of an outpatient visit have been estimated at $25-75, depending upon the facility (hospital programs are more expensive). Thus, for a screening mammogram that might reimburse as low as $150, the portion that is available to cover the actual medical care is reduced by 17-50%. It is this fact that has driven much of the focus on workflow in progressive centers.

Breast Density

A detailed review of breast density is beyond the scope of this paper, but there are a few important points that bear emphasis. The first of these is that breast density really means *radiographic* density, or the way the breast appears in a mammogram. Breast density cannot be felt or found in any way other than by imaging. On a mammogram fatty tissues are transparent to x-rays, and therefore these tissues appear black on the image. Dense areas absorb x-rays and appear white on the image, but unfortunately cancers also absorb x-rays and therefore dense tissue can be confused with or hide breast cancers on the mammogram. There is also strong evidence that breast density is associated with an increased risk of breast cancer.

With dense breast tissue presenting both the problem of lowering the sensitivity of the screening mammogram by masking cancers, and actually increasing the risk of an individual with dense breasts developing a cancer, it has become evident that we must look beyond the mammogram if we are to improve screening. Mammography is still an excellent technology in women with predominantly fatty breast tissue, but in

women with dense breasts, supplementary imaging with a modality in which dense tissue is transparent is important.

Before discussing supplementary imaging, however, we must discuss how density is determined in clinical practice. Breast density has traditionally been measured by radiologists comparing light and dark parts of a mammogram, breast density is the volume of dense tissue divided by the volume of the breast and then multiplied by 100 to get a percentage. Reported using the BI-RADS™ density categories, this provides a relative picture of density. However, this subjective assessment is operator dependent and entirely qualitative. According to a 2006 study in *Academic Radiology*, agreement between interpreting physicians in estimating density is only about 60 percent in the middle two BI-RADS density categories, in which the differentiating line between low and high tissue density is found.

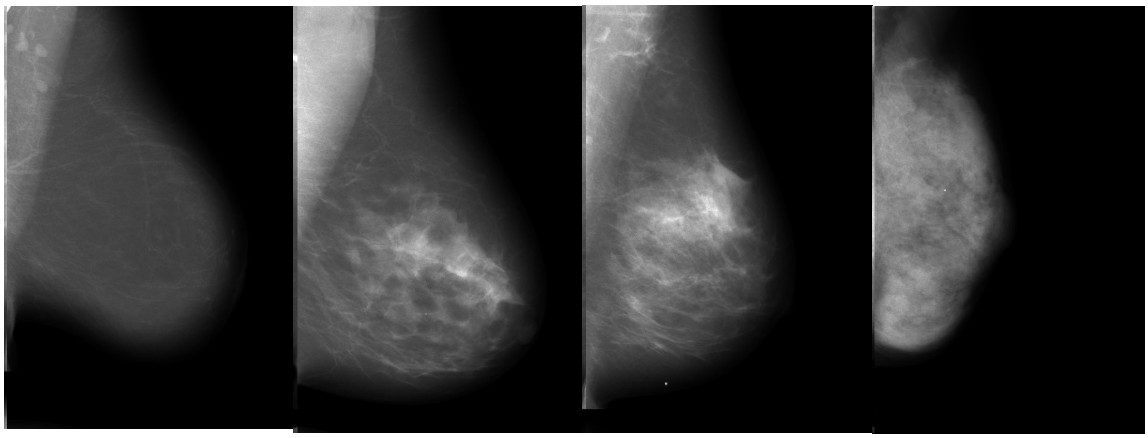

Figure 1: BI-RADS™ Density Categories illustrated.

Figure 1 illustrates the BI-RADS density categories from fatty (Category 1), through scattered densities (Category 2), heterogeneously dense (Category 3), to extremely dense (Category 4). Even a casual observer can easily distinguish between a fatty Category 1 breast and an extremely dense Category 4 breast, but the difference between scattered densities (Category 2) and heterogeneously dense (Category 3) tissue is subtle and it is easy to understand the subjectivity involved in the decision of whether the breast tissue density is Category 2 or Category 3.

Another challenge of the BI-RADS reporting system for tissue density is that it is two-dimensional and the breast is three-dimensional and varies dramatically in shape, size and composition between individuals. An area that appears almost white on a

mammogram could be a single highly dense area or it could be several densities overlying each other. It is impossible to tell from simply viewing the two dimensional images.

To support an increased dependence on supplemental imaging, we must remove the subjectivity of physician assessment of density, and give referring physicians and patients alike a sense of confidence in the density determination process. Volpara® (Matakina International, Ltd., Wellington, NZ), one of two commercially available density software solutions, meets these criteria by providing an objective volumetric assessment of breast tissue density and is cleared for use with all digital mammography units. Using the "for processing" digital images from a mammogram, and a state-of-the-art algorithm developed by some of the world's leading imaging scientists, the software presents interpreting physicians with an assessment of the percentage of dense tissue contained within the breast and a mapping of that percentage to a Volpara Density Grade (VDG). The VDG is a number from 1 to 4 and the mapping has been set so as to optimize the relationship between VDG and BI-RADS breast density category.

Improving Cancer Detection — Supplementary Ultrasound

The imaging technologies that are transparent to breast density and fit the screening model essentially include only MRI and ultrasound. Molecular breast imaging would be included as well, except for the radiation dose that it imposes on organs other than the breast. MRI is considered to be too expensive to utilize generally, being reserved for women with very high risk. Ultrasound does not use ionizing radiation, and it is an economic modality for use in breast screening. It is labor intensive and operator dependent, however, and sonography technologists are both rare and expensive. From a human resource perspective alone it would be impossible to deliver supplementary ultrasound to all women who qualify for the exam by virtue of dense breast tissue, using hand held ultrasound delivered by either physicians or sonography technologists.

Another issue with supplementary ultrasound is that the number of false positive findings – patients who have to go on to further diagnostic studies but who do not have cancer. Much of this problem can be traced to the fact that the technologist (or physician) who is performing the "screening" breast ultrasound stops screening and reviews specific regions of interest in the course of the exam. These ROIs are typically captured on one or a series of single frame images for review by the physician, and often lead to unnecessary recalls of patients for additional imaging.

Automated breast ultrasound (ABU) systems have been developed to meet the challenges of operator dependence, labor supply, and excessive false positive results. The ABU technologies all acquire ultrasound images of the entire breast automatically. A mammography technologist often guides the acquisition process, but the tasks are simple and a trained tech assistant can accomplish the acquisition. Automation removes operator dependence, but of perhaps more importance, the separation of the acquisition of ultrasound images from the review by the physician allows the physician to review image sequences rather than single frames, thus providing more information and permitting the physician to satisfy him or herself with respect to the character of the ROI. Most ROIs will be benign and ABU will thereby reduce false positive results and the need to recall the patient for further diagnostic studies.

Workflow — Adding Screening Ultrasound

Now let's add to the breast center the burden of providing an additional screening exam for up to 45% of the women who now receive screening mammograms. The exam is predicated on a finding that the patient has dense breasts. The current consensus evidence is that if a woman is found to have BI-RADS density 3-4 she will qualify for supplementary breast ultrasound, but if not, then the screening mammogram will be clinically sufficient.

The principle problem with breast density in a workflow context is that it has traditionally involved a subjective quantitative determination by the physician, made at the time of the screening interpretation. In a center that uses block reading of screening mammograms, patients would need to be recalled for any adjuvant screening imaging if subjective evaluation of density is used. With 40-50% of women fitting in the highly dense category, the magnitude of the problem is readily apparent.

In the "callback" scenario the supplementary screening ultrasound exam creates two very difficult problems. The first of these is that the supplementary imaging is another "stand alone" procedure which, if ultrasound, carries relatively low reimbursement. The second challenge, however, is an even greater impediment.

We know from experience that the problem of recommending patients to return to the center on a later date for a supplementary exam is primarily a compliance issue even when payment for the exam is assured. In Connecticut, where the law mandates payment by insurance, only 16% of those who were asked to return for ultrasound did

so. In California, where neither notification nor payment were mandated, a practice that provided notification experienced a very low rate of patient compliance with the recommendation of supplementary ultrasound (in this case AUS), *until* they made the procedure available immediately following the mammogram. In fact, the effect on compliance of offering immediate supplemental ultrasound to women with high density was an *8-fold increase* over the method of traditional patient recall.

Through interviews with patients the California center determined that the barrier to compliance was *not* the fact that patients had to personally pay for the procedure, but rather it was convenience. As one woman explained: "I am a very busy woman. I only have one day a year to give to my breasts!" She felt, quiet appropriately, that screening should not take two days. The additional visit would require more time off of work, and her screening mammograms had never caused her any reason for concern in the past, so why, she reasoned, come back for another test?

Medicine has, all too unfortunately, seldom considered the convenience of patients. The screening mammogram is already the most inconvenient aspect of women's preventative care, as it is not delivered along with other wellness elements in their routine annual visit to the primary care physician. Adding yet another visit for screening is inconvenient, expensive, and compliance may even be impossible for some women.

It should be possible, and it is, in fact, financially far more effective to deliver the supplementary screening immediately following the mammogram for those women who have dense breasts. Doing so, however, requires that the density be determined in advance of the supplemental imaging. While a woman's density *could* be determined by reviewing her prior year's report for the radiologist's finding (if one was made), this is cumbersome, does not account for new patients, and has not, to our knowledge, been successfully utilized in actual clinical practice.

Volpara® and the New Workflow Paradigm

The California practice had been using Volpara® (Matakina International, Ltd., Wellington, NZ) for several months to automatically and objectively assess breast density from the screening mammogram as it was acquired. The center physicians developed a protocol to offer AUS to patients whose Volpara Density Grade (corresponding to the BI-RADS density categories) was 3-4, signifying high breast tissue density. Initially patients were informed of their density at the end of the mammogram by the tech-

nologist, who had the information within less than a minute of acquiring the final image, and they were offered the opportunity to schedule a return appointment for the AUS exam before leaving the center, but it soon became evident from patient comments that the preference would be to have same day AUS.

In the actual practice of "moving" patients to AUS following mammography, technologists use the Volpara® finding and posters in the mammography rooms to educate their patients about their personal density. The Volpara® assessment appears on the technologist workstation (see Figure 2, below) within about 2 minutes of the last image, allowing appropriate patients to be moved on to AUS without delay. Volpara® has the additional advantage of being robust and, as an objective assessment tool it removes operator variability from the assessment process.

Offering AUS "to follow" screening mammography does not allow the normal scheduling/order requisition process to be followed, and requires that some flexibility be created in routine processes to allow scheduling to flex according to demand. While this uncertainty can be culturally uncomfortable for a short period of time, as AUS becomes better understood by both patients and referring physicians we can predict the extent of the potential utilization of AUS, and we also know from experience that not all women who are initially offered the additional imaging will comply with the recommendation. The implementation of a program of immediate AUS becomes much more manageable under these circumstances.

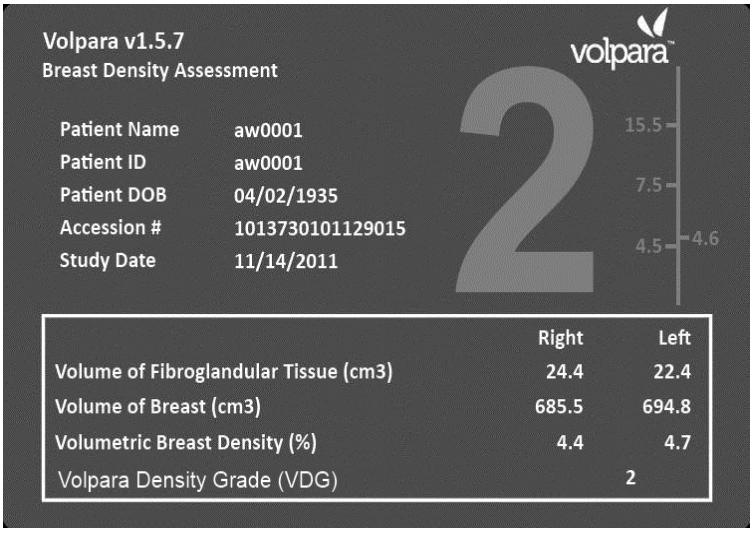

Figure 2: Volpara® secondary capture image as it appears on the acquisition workstation.

While manageable, the operational dynamics of offering another screening service to 45% of screening patients are complex and should not be minimized. This is a large addressable market for any practice, and demands care in the planning and exe-

cution of an adjuvant-screening program. In the following paragraphs we will outline some of the important specifics involved in such an implementation.

Preparation

For the vast majority of women, and even for their primary care physicians, breast density is a new concept. The biggest problem with legislatively mandated density notification in Connecticut turned out to be confusion on the part of these two constituencies over the importance of density, and the lesson of that experience is that ***education*** is of primary importance. Patients should receive advance notice of the proactive efforts of the center to improve the prospects of early detection through supplementary imaging, and referring physicians need a more comprehensive understanding of the nature of breast density, its measurement, and the implications of dense tissue on the care their patients will receive.

An integral part of the education process is patient and referring physician assurance of an automatic and objective density assessment, removing the subjectivity of physician assessment of density, and giving referring physicians and patients alike a sense of confidence in the density determination process. Volpara® meets these criteria, works with all digital mammography units, and allows comparison of density year-to-year even if the woman is imaged on different mammography units. Use of Volpara® eliminates variability between physicians and removes concerns of both patients and primary care physicians about subjectivity. We also anticipate the likelihood that third party payors will increasingly demand objective density findings as a prerequisite to payment for the supplementary ultrasound and, Volpara®, with experience over hundreds of thousands of mammograms, will fit this requirement.

Education should ***not*** be limited to patients and their primary care physicians. Early detection is a part of the vision and mission of every breast center, and an aggressive program of supplementary screening will differentiate a center from others in the community. Experience has taught us that it is very important to involve the entire breast center staff in education about breast density and the benefits of supplementary screening to the mission of the center and the health of the women it serves. The message is very strong, and it begins with each individual staff member.

We titled this subsection Preparation, and these efforts, including the implementation of Volpara®, should be commenced prior to the implementation of supplementary

screening. Ideally a 90-day period will accommodate the need to educate, but will not be so long as to delay services that are perceived as valuable, but it should be possible to compress the education period into 45-60 days. Education is a continuing obligation, but we recommend against extending the preparation phase beyond 90-days because extension may communicate reluctance or a lack of high-level commitment to implementation of supplementary screening.

Engineering Workflow

In engineering workflow for the new paradigm it is important to first analyze the screening volume to determine the addressable population of women who might be predicted to be eligible for supplementary screening. Generally speaking, this will be approximately 45% of the screening population, but practices vary in age distribution and if the center's patients tend to be younger then the percentage of that patient group with dense breasts will be higher, while one could expect a lower percentage of women with dense breasts in an older or high-percentage Medicare population.

Not all women with dense breasts will immediately become patients for supplementary screening. The number will depend on many factors:

- Is the study reimbursed?
- Has the patient met her deductible?
- Is the patient "comfortable" with her mammogram?
- How sensitive is the patient to risk?
- How well informed is the patient with respect to the implications of breast density?
- What advice the patient's referring physician is providing her about density and risk?

From Connecticut and other experience, however, we can project with some certainty that if the exam is offered on the same day, and insurance covers the cost (subject to deductibles and copayments); we should see initial compliance approaching, if not greater than 25%. Table 3 illustrates the expected numbers at various volumes and compliance levels.

Table 3: Projected Supplementary Screening Ultrasound Volumes				
	Annual Screening Mammography Volume			
	5,000	**8,000**	**12,000**	**20,000**
Daily Volume	20	32	48	80
Qualifying Dense Patients	**9**	**14**	**22**	**36**
25% Compliance	2	3	5	9
50% Compliance	4	7	11	18
75% Compliance	7	11	17	27

Each of the three available automated breast ultrasound technologies, SonoCiné (SonoCiné, Inc., Reno, NV), Somo•V (U-Systems, Inc., Mountain View, CA), and the Acuson S2000 RBVS (Siemens Healthcare, Malvern, PA), can deliver an examination in 20-minutes. A single unit could therefore provide AUS at volumes up through the 50% compliance level, and through the full compliance level for all but the highest volume center that we have included in Table 1. If we assume that the distribution of density will be relatively normal across a screening population, then it is reasonable to expect that the AUS exam could be furnished on the same day to each patient who requires the exam with, at most, a small wait while another patient is in the AUS room.

Staffing is another issue — or it would be if AUS required a sonography tech to perform the exam. Each of the AUS technologies is, however, basically a robotic device where the probe may be guided by the operator, but is controlled by the device. The operator's role is primarily to ensure that the patient is positioned properly on the table for the exam, that the ultrasound gel is applied, and that the entire breast is scanned in the course of the exam. Many AUS sites use mammography techs, but there are several that have trained technology assistants to perform the AUS procedure.

To review this section, there are no real barriers to implementing AUS as an add-on procedure for qualifying screening mammography patients. Centers that educate and promote AUS with their patients and referring physicians, add Volpara™ to objectively assess density, and provide a pathway for same day service, will see rapid acceptance of the new screening study. Effective implementation of the new paradigm will also add significant revenues for a center, while detecting new and smaller cancers.

Before leaving this section, let's look at the first two tables of this paper; recasting them to include the additional procedures as well as downstream procedures that can be expected to result from the additional screening process. Table 4 recasts the

breast cascade including AUS, and Table 5 brings a micro view of this information, presenting it as daily procedure volumes.

Table 4: The Breast Cascade with AUS					
Procedures		**From Screening**	**Other Than From Screening**	**% of Screening Volume**	**Total**
Screening					
	Screening Mammography	10,000		100%	10,000
	Screening Ultrasound (AUS) (1)	4,500		45%	4,500
Diagnostic					
	Diagnostic Mammogram (2)	1,000	1,500	25%	2,500
	Diagnostic Breast Ultrasound (3)	950	1,000	20%	1,950
	Stereotactic Biopsy (4)	75	50	1.5%	125
	Ultrasound Biopsy (5)	225	150	3.7%	375
	Total Procedures	16,750	2,500	192.5%	19,250
	Breast Cancers Diagnosed	67	50	1.17%	117
Notes	(1) Assume 45% are high density (2) 10% from native screens/10% clinical referrals/5% SIFU (3) 5% from native mammo screens/10% from AUS/10% from clinical referrals and SIFU (4) 20% of total biopsies/20% PPV (5) 80% of total biopsies/30% PPV				

Table 5: The Breast Cascade – Daily Interpretation (4-day week)					
Procedures		**From Screening**	**Other Than From Screening**	**% of Screening Volume**	**Total**
Screening					
	Screening Mammography	50		100%	50
	Screening Ultrasound (AUS) (1)	11		45%	11
Diagnostic					
	Diagnostic Mammogram (2)	5	8	25%	13
	Diagnostic Breast Ultrasound (3)	5	5	15%	10
	Stereotactic Biopsy (4)			1.5%	.5
	Ultrasound Biopsy (5)			3.7%	2
	Total Procedures			192.5%	87
	Breast Cancers Diagnosed	.33	.25	1.17%	0.6
Notes	(1) Assume 45% are high density (2) 10% from native screens/10% clinical referrals/5% SIFU (3) 5% from native mammo screens/10% from AUS/10% from clinical referrals and SIFU (4) 30% of total biopsies/20% PPV (5) 70% of total biopsies/30% PPV				

Note in Tables 4/5 that the numbers are still within the capability of a single radiologist, and that a single technology aide will constitute the increase in direct staffing. Revenues will be increased substantially, however, especially when one takes into consideration the additional 17 otherwise occult cancers that ultrasound can detect, and the treatment revenues that can be realized from those cancers.

It is important to note, however, that Tables 4-5 are predicated on compliance by all screening patients with dense breasts, and this level of compliance can only be achieved if these patients can receive their AUS exams immediately following their screening mammograms. For these women screening will simply include an additional study. It is unlikely that compliance greater than 25% can be achieved if it is necessary to recall screening patients for supplementary screening. The two studies in Connecticut that followed mandatory notification of patients of their breast density registered compliance under 25%, and in each instance patients were required to return for supplemental ultrasound screening.

Summary

The addition of AUS as a supplement for screening mammography is a clinical imperative and a business opportunity, but only when Volpara® is integrated with screening mammography to provide the means and method to vector patients with dense breasts directly on to AUS. Those who embrace the new delivery paradigm will differentiate their centers and lead their communities. Yes, there is a challenge for all who seek to affect change in the established process, but the rewards are substantial. Detecting cancers early reduces both the mortality from breast cancer, and the cost of treatment, but the greatest reward of all will be knowing that you have changed cancer from a brick wall that changes every element of a woman's life, to a speed bump that she will soon pass. That is the true impact of early detection.

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