

Judith A. Wagner, R.N.
609E Eastwyn Bay Drive
Mequon, WI 53092

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I spoke before this FDA committee last year and unfortunately am unable to attend the second meeting. I appreciate the opportunity to have my comments read into the record.

I continue my advocacy to inform women about how to make quality breast care decisions and recently even spoke to an Engineering Firm for a Wellness Luncheon at which 6 of the 23 who attended were men. I continue to be asked to speak as one person tells another. Knowledge opens minds to search for quality of care and we must be able to provide it for women.

MQSA Reauthorization is scheduled for 2007. Three studies have been a part of the information that will set this reauthorization apart from any previous MQSA Reauthorization.

- The IOM Study-Improving Breast Imaging Quality Standards
- The National Mammography Quality Assurance Advisory Committee Meeting
- The GAO Study-“Mammography. Current Nationwide Capacity is Adequate, but Access Problems May Exist in Certain Locations”, July 2006

Senator Mikulski’s Committee will be reviewing the gathered information in order to make informed decisions for the Reauthorization of MQSA.

I continue to hear the same responses from those physicians concerned with improving the delivery of breast care for women:

- Poor Reimbursement
- Liability Issues
- Shortages of technologists and qualified "clinical breast radiologists"
- Need for more educational opportunities in breast care
- Need to make breast care a “subspecialty” of radiology
- Need to standardize the breast diagnostic procedures for all physicians performing them
- Need for breast care to be an area of medicine that will create the desire for physicians to enter fellowship programs

On the other hand I hear the following:

- That to mandate more requirements will decrease the number of physicians reading mammography and performing diagnostic breast procedures
- Increasing the standards of care may cause the closure of some breast centers and thus decrease access to breast care for women

Breast care and interventional procedures are evolving at a very rapid pace. Senator Barbara Mikulski introduced MQSA in 1992. I am sure these requirements initially set the medical community in a tailspin. Yet they rose to the challenge and breast cancer detection has improved, i.e. diagnosis of DCIS increased by 25% due to improved screening. But as with anything, as breast care evolves so must the requirements.

I advocate mandating accreditation for all image-guided needle breast biopsies. I realize that until MQSA has had a name change to Breast Imaging Quality Standards Act, the FDA will not be able to include ultrasound or MRI guided breast biopsies, only stereotactic breast biopsies. But with new imaging modalities on the horizon such as tomosynthesis, and the increasing use of digital mammography, standards need to be put in place to ensure that the patient is receiving breast care delivered by those who are most qualified and are performing these procedures with the highest standards possible.

As I listen to commentaries about the evolution of the Beta Max to the VCR tape and now to CDs and beyond, it is evident that if we do not require standards for breast care delivery then it will quickly become an overwhelming task, if it isn't already.

A most recent article in **Diagnostic Imaging**, "Screening Mammography, Practitioners consider Europe in the quest for better quality"(see article) gives a clear picture of the obstacles involved with the US breast care model. In Europe, breast care is preformed by dedicated Clinical Breast Radiologists, who have standards under which they must practice with continual job training and performance testing.

Workflow issues:

- Workflow issues are also of great significance. Digital imaging technology has opened the way for a more streamlined method to send mammograms and other imaging modalities from one place to another, which certainly could influence issues of access and radiology shortages in lower populated areas. See article by Jerry Kolb, "Going Filmless: Lessons from a Swedish Breast Center" We need to look at the European example of efficiency with a more receptive attitude.
- A recent article, January / February 2006, Breast Health Services, "Improving Access and Quality for Breast Health Services" describes a hospital in Staten Island, New York that wanted to develop a "breast center" approach to the provision of breast health services. The hospital had a 3- fold objective, which it did accomplish:
 1. To reduce wait times for the complete spectrum of breast imaging services.
 2. To improve the quality of care.
 3. To improve the patient's overall experience

The hospital had a group of 10 radiologists providing services, each with different levels of training; no radiologist spent more than 50% of his or her time doing breast imaging, which was identified as a key area for improvement. The evolution of this "breast center" and the key role of the Dedicated Breast Radiologist are explained in detail in this article—"An evolution for quality".

In our very global society we need to look toward "Centers of Excellence" that will receive mammography from outlying sources such as mobile units and satellite clinics; one central place, where the best, most up-to-date equipment will be located and the Clinical Breast Radiologist is the "key coordinator".

Lastly regarding electronic workflow--Electronic management takes any paper flow pattern and ascertains the most efficient means of increasing productivity of the organization utilizing

electronics. This would increase productivity and revenue as well as reduce unnecessary work for the breast care team, leaving more productive time to actually perform and interpret mammography. You have to take the "final outcome" and break it down into individual steps on how to get to the desired result.

This methodology needs to be streamlined and refined for ultimate efficiency in the breast center. Data programs to gather statistical information, standards of performance related to outcomes will be extremely important.

Time cannot be recaptured and what is done in this fleeting time will have significance for the future of breast care. Those radiologists who have been the "Pioneers of Breast Care" will need to be replaced by "New Pioneers" who will have the same passion and determination to save lives by diagnosing and treating breast cancer at an early, curable stage. Their challenges will be even greater as the diagnostic equipment reaches far beyond the early methods of Xerography and then Mammography. This is a world of change, where you can email someone in Europe and have a response in minutes. So it is with breast care. Digital mammography has opened the breast care communication network and now we have to put standards in place to ensure women will receive the best care as time quickly slips away.

Thank you,

Judith A. Wagner, R.N.
Breast Cancer Patient Advocate
Breast Cancer Survivor