

Society of Breast Imaging letter to the NMQAAC on Recording Breast Density in Mammography Reports and Patient Lay Summaries

The Society of Breast Imaging (SBI) is a non-profit organization whose members consist of board-certified radiologists, physicists, and mammography technologists. These professionals have a special interest and expertise in imaging the breast. Our core purpose is saving lives through early detection. The SBI has worked to promote mammographic screening for 25 years, based on solid scientific evidence. Annual screening with mammography beginning at age 40 has been scientifically proven to significantly decrease breast cancer mortality. This screening recommendation is also supported by the American Cancer Society, the American Society of Obstetrics and Gynecology, and the American College of Radiology (ACR). We applaud the role that the FDA has played in increasing image quality and improving mammography in the United States.

The SBI believes that accurate and accessible information is extremely important for patients and their doctors. We encourage use of the ACR's BI-RADS lexicon, which facilitates communication by suggesting standardized phrases and terminology for breast imaging reports. The BI-RADS lexicon describes four categories for breast parenchymal density and recommends their use in all reports. Greater breast parenchymal density lowers the sensitivity of mammography. It may also increase the patient's overall breast cancer risk,

although the extent of this effect is controversial. By alerting the clinician to the overall breast parenchymal density, he or she can understand the radiology report in context for his or her particular patient. This data can be used together with other pertinent patient medical information, such as family history of breast cancer, the patient's own cancer history, the patient's past surgical history, etc., to decide if additional overall breast cancer risk assessment and/or supplemental screening are warranted. As such, the SBI supports the routine placement of breast parenchymal density in the mammographic report.

Lay summaries are routinely sent to patients regarding the results of their mammograms. This is a process that the SBI supports. Whether or not the specifics of breast density will be of benefit or lead to confusion or other unintended consequences for the patient is unresolved. Consideration should be given to the wide variability of assessing breast density and the lack of consensus on what risk it represents, in isolation, to the patient. The SBI does not oppose such reporting but remains concerned about the end result. If it leads to better dialog between the patient and her clinician, we would applaud it. If, however, it leads to unnecessary testing, non-scientific approaches to screening, or an increase in the number of benign breast biopsies, it would be viewed less favorably. We strongly support evidence-based medical decision making and hope that additional research will make the best direction on this issue more clear in the near future.

The SBI welcomes comments from the FDA on this or other matters and would be happy to address any additional questions.