DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**
Food and Drug Administration
Center for Devices and Radiological Health

Brief Summary of the National Mammography Quality Assurance Advisory Committee Meeting – September 15, 2016

Introduction:

The National Mammography Quality Assurance Advisory Committee met on September 15, 2016.

The following presentations/discussions were given:

1) Recently Approved Alternative Standards: Presentation Only by Timothy J. Haran, Deputy Director, Division of Mammography Quality Standards, Food and Drug Administration (FDA).

2) American College of Radiology Digital Mammography Quality Control Manual: Presentation Only by Eric A. Berns, Ph.D., Diagnostic Medical Physicist, Assistant Professor, Department of Radiology, Denver Health Medical Center.

3) Mammography Quality Standard Act (MQSA) Analyses of Compliance Cases: Presentation followed by Committee Discussion by Rachel T. Evans, Compliance Officer Team Lead, Division of Mammography Quality Standards, Food and Drug Administration.

   This presentation focused on the Mammography Quality Standards Act (MQSA) and sought input from the Committee on any trends seen in the analysis, why the trends may be occurring, and possible actions to be sought. The Committee discussed compliance cases and inspection citations data analysis. The Committee suggested that AMR failures for positioning may not represent an absolute increase, but a relative increase due to significantly less equipment violations with newer technology, and requested the inspection citations and AMR data used in the compliance analysis.

   The Committee thought that FDA should consider the seriousness of any inspection citation in addition to the frequency with which a violation is cited, when considering removing inspection citations from the inspection process. It was suggested that the FDA consider weighing the elimination of inspection questions against what would be in the best interest of the patient.

   The Committee had no comments on the elevation of some MQSA inspection questions to a Level 2 citation and the removal of Level 3 violations from the MQSA inspection program.

4) MQSA: Beginning the Next Quarter Century with a Spotlight on Image Quality: Presentation Followed by Committee Discussion by Helen J. Barr, M.D., Director, Division of Mammography Quality Standards, Food and Drug Administration.

   This presentation described a proposal called “Enhancing Image Quality Using the Inspection Program (EQUIP).” FDA sought the Committee input on anticipated facility questions related to the proposal.

The Committee discussed if the ongoing assessment of the effectiveness of the additional inspection questions under EQUIP should be carried out both in the grace period first year as well as in outlying years. Suggestions were made as to when, during the inspection itself, the most beneficial time would be to discuss the new inspection elements with facility personnel and discussed that outreach to mammography facilities prior to implementation would be needed, especially to radiologic technologists. There were some concerns expressed that patients' access to mammography services could be affected if facilities got inspection violations and had to close. FDA explained the proposed phased in compliance strategy: giving both inspectors and facilities time to become familiar with the inspection questions prior to implementation. The Committee also discussed the need to insure consistency among inspectors in their interpretations and implementation of the additional image quality questions. The Committee provided feedback that some inspectors created somewhat of an adversary environment during the inspection and suggested a feedback mechanism for facilities to rate their experience with their MQSA inspector as well as more outreach to facilities on the availability of the MQSA facility hotline (1-800-838-7715, http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/ucm506118.htm).

5) Breast Tissue Density, Cancer Risk, and State Patient Notification Laws: Presentation followed by Committee Discussion by David L. Lerner, M.D, Medical Officer, Division of Mammography Quality Standards, Food and Drug Administration.

   This presentation included issues related to breast density. The discussion focused on how a requirement to report breast density might be perceived, based on experience from people who work in states with a reporting requirement. This session did not discuss whether there should or should not be a requirement to report breast density.

   The Committee discussed the fact that density and other risk factors for breast cancer are complex and multifactorial, that this information is difficult to condense into a letter to the patient, and that a one-on-one conversation is preferable. One member stated that her facility gives patients a brochure about density, but expressed concern that after several years of receiving this literature, patients may simply ignore and discard it. A member practicing in a State without a density notification law said that she discusses multiple risk factors in a patient's history, not limited to density, and offers genetic counseling, but added that the discussion of risks is a long and important conversation that requires many resources. There was also discussion of the most appropriate person to explain density to patients; it was described as a burden on primary/referring health care providers, who have many other issues they must also discuss with the patient. Some Committee Members felt that the best person to discuss the issue with patients is the interpreting physician (radiologist), but this could increase the time burden on radiologists and lead to decreased access to mammography. A Consumer Representative who also serves as a Patient Representative suggested that the issue of density might be addressed with public service announcements that encourage patients to raise the issue of breast density with their health care providers adding that when patients have knowledge, they can change how they meet with their providers. They also stated that because many States have no notification laws, a Federal law is needed. One Committee member stated that the division between the two middle categories of scattered fibroglandular densities and heterogeneously dense breasts can be difficult and is part of a broader continuum. Thus, the density categories are being used to split patients into dense and non-dense in a way that the categories were not designed for.

6) Enhancements to MQSA Inspector Presentation Only by Preetham Sudhaker, Chief, Program Management Branch, Division of Mammography Quality Standards, Food and Drug Administration-Presentation Only.

7) Committee Discussion: What are the Future Challenges for MQSA? By Helen J. Barr, M.D., Director, Division of Mammography Quality Standards, FDA.

This discussion included future challenges for MQSA, such as the role of synthesized 2D images. FDA sought Committee input on this challenge as well as what future challenges MQSA might encounter.

Most of the Committee Members agreed that 2D images synthesized from digital breast tomography (DBT) images could be used to accredit facilities, given that most accreditation failures are for poor patient positioning which is captured by the synthesized images. Most members agreed that this was preferable to obtain images that patients might not clinically need, solely for accreditation purposes. There was also general agreement that 2D images could probably be used as a surrogate to accredit DBT units, but that using a synthesized 2D phantom image might not be adequate. Issues around the sharing of digital images between facilities were discussed; members shared challenges regarding not being able to open digital images from other facilities. Some members thought that information technology solutions might be possible, as well as more manufacturer outreach on how to properly load images. There was a discussion around the volume of mammograms required to be read by MQSA interpreting physicians, with general agreement that accuracy improves with increased volume of interpretation, but that making any changes such as raising the volume would have to take into account interpreting physicians who practice at lower volume facilities, and that perhaps enhancing the MQSA-required medical audit is needed to assist with the quality of interpretations, no matter what the volume.

Public Speakers

The following Open Public Speakers attended the meeting: 1) Nancy M. Cappello, Ph. D., Director and Founder, Are You Dense Advocacy, Inc. 2) Mr. Julian Marshall, Chief Marketing Officer, Volpara Solutions, Inc. 3) JoAnn Pushkin, Executive Director, DenseBreast-info, Inc. 4) Louise Miller, Radiologic Technologist, Mammography Educators, LLC 5) Joan Lunden, Author, Joan Lunden Productions 6) Wendy Marshall, Radiologic Technologist, Mammography Quality Management and 7) Debra L. Monticciolo, M.D., American College of Radiology and Scott and White Healthcare.

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