Positioning Responsible For Most Clinical Image Deficiencies, Failures

Mammography combines "the science of imaging and the art of positioning" [1]. Although there have been many significant and exciting changes to the technology of mammography since the passage of MQSA in 1999, including the introduction of full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT), one aspect of mammography that remains unchanged and critically important is proper patient positioning.

Positioning is so important because only those portions of the breast which are included on the mammographic image can be evaluated for signs of cancer. Any portion of the breast which is not imaged cannot be evaluated, and cancers in those portions of the breast can be missed. In a 2002 study, the "[s]ensitivity [of mammography] dropped from 84.4% among cases with passing positioning to 66.3% among cases with failed positioning" [2].

Poor positioning has been found to be the cause of most clinical image deficiencies and most failures of accreditation. In 2015, the American College of Radiology (ACR), the largest FDA-approved accreditation body (AB), found that of all clinical images which were deficient on the first attempt at accreditation, 92% were deficient in positioning. Also, in ACR-accredited facilities, 79% of all unit accreditation failures in 2015 were due to positioning. Similar results were noted by the Iowa and Texas state ABs: in 2015, positioning was a cause of 91% of clinical image failures in Iowa and 100% of clinical image failures in Texas.

MQSA requires that the "[c]linical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body" [3]. Positioning failures of clinical images often lead to an Additional Mammography Review (AMR). If the AMR also reveals failing results, the FDA will determine whether the facility’s practice of mammography represents a serious risk to health, and may order a facility to cease performing mammography and to notify all affected patients and their referring health care providers about the facility’s image quality problems. Thus, the consequences of poor positioning can be very significant not just for individual patients, but for mammography facilities as well.

Although the technologist performs the mammogram, the responsibility for correct positioning is shared by the technologist and the interpreting physician. This shared responsibility is reflected in MQSA. The Preamble to the MQSA Final Rule emphasizes that all interpreting physicians are "the final arbiters of the quality of mammography images," and adds, "It is important that they communicate their satisfaction or dissatisfaction with the quality of the images they are provided to interpret to the technologists who produced them. Such communication is the crucial first step in the identification of problems and the initiation of corrective actions" [4].

Thus, to achieve and maintain proper positioning, both training and communication are essential. Technologists should be trained in proper positioning, and should seek feedback from fellow technologists and interpreting physicians. Interpreting physicians, in turn, should review the elements of proper patient positioning, and give constructive feedback to technologists on the positioning of the mammograms that are presented to them for interpretation.

References

3. 21 CFR § 900.12(i).

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http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm495378.html