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On this episode, I will discuss MQSA and ACR regulations for mammography, including the mammography audit. This is a topic that I think is not well covered in many board review resources yet it is important for the Core Exam and high yield for the Certifying Exam for those test takers that elect mammography to be a part of the Certifying Exam.

**First question, what is the definition of a positive mammography screening examination according to the ACR BIRADS Atlas?**
A positive mammography screening examination typically means a screening exam has been given a BIRADS category 0 assessment. The ACR BIRADS Atlas goes on to state that although use is discouraged, and I emphasize that the BIRADS Atlas discourages you from doing this, if screening exams were given BIRADS 3, 4 or 5 assessments, those would also count as a positive screening examination. Again, the BIRADS Atlas recommends that we only use BIRADS 0 for a positive screening exam, meaning that there is a finding on the exam that needs further work up with diagnostic imaging. For the Core Exam, I would avoid assigning a BIRADS 3, BIRADS 4 or BIRADS 5 assessment on a screening mammogram. If you see a finding that needs further evaluation, it should be given a BIRADS category O. That is the definition of a positive mammography screening examination.

**What is the definition of a positive diagnostic mammography examination?**
A positive diagnostic exam is an exam that was given a BIRADS 4 or BIRADS 5 assessment.

**What is the definition of a negative diagnostic mammography examination?**
A negative diagnostic examination is an exam that was given a BIRADS category 1, 2, or, importantly, a category 3 assessment. Note that BIRADS category 3 is considered a negative assessment. If a BIRADS 3 exam turns out to be cancerous within one year of a BIRADS 3 being assigned, this would count as a false negative examination in your mammography audit. Examples of a false negative assessment are cancer that is diagnosed within one year of a screening exam that was assigned BIRADS 1 or 2, or a diagnostic exam that was assigned a BIRADS category 1, 2, or 3.

**What are the three types of positive predictive values discussed in the ACR BIRADS Atlas?**
I remember the first time I encountered a positive predictive value 3. I was bewildered because I did not understand how there could be more than one type of positive predictive value. Nonetheless, the ACR BIRADS Atlas describes three types. Can you tell me what these are? Let us start with positive predictive value 1, which is often abbreviated PPV1. Positive predictive value one is the percentage of all positive screening examinations that resulted in a diagnosis of cancer within one year of the screening exam. Note that PPV 1 equals the positive predictive value of screening examinations that resulted in diagnosis of cancer within one year of the screening exam.

Positive predictive value 2 is the percentage of all positive diagnostic exams recommended for tissue diagnosis or surgical consultation that resulted in a cancer diagnosis within one year of the diagnostic exam.

Positive predictive value 3 is the percentage of all biopsies performed because of a positive diagnostic examination that resulted in a cancer diagnosis within one year of the biopsy. Per the ACR BIRADS Atlas, positive predictive value 3 is the biopsy yield of malignancy or the positive biopsy rate. I also think that positive predictive value 3 is the positive predictive value most likely to be tested on the examination.

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However, I would be aware that PPV 1 relates to screening examinations, PPV2 relates to diagnostic examinations and PPV 3 relates to biopsies that are performed. There are some exceptions to what I just stated that are discussed in the ACR BIRADS Atlas and if you are interested in learning more, go ahead, and access a copy of the ACR BIRADS Atlas and read about the positive predictive values and how they are defined. Nonetheless, what I have presented keeps it simple and I think will allow you to successfully answer many questions that you could encounter on radiology board exams.

**What is the ACR BIRADS Atlas definition of sensitivity?**
Sensitivity is defined as the probability of interpreting an examination as positive when cancer exists.

**What is the ACR BIRADS Atlas definition of specificity?**
Specificity is the probability of interpreting an examination as negative when cancer does not exist.

**What is the ACR BIRADS Atlas definition of cancer detection rate?**
The ACR considers cancer detection rate as the number of cancers detected per 1000 patients examined. The number 1000 is a key thing to remember. The rate you are describing for cancer detection is the number of cancers detected per 1000 patients examined for screening mammography. The screening cancer detection rate is the number of cancers per 1000 screening examinations.

**What is the ACR BIRADS Atlas definition of the abnormal interpretation rate?**
The abnormal interpretation rate is the percentage of examinations interpreted as positive for screening mammography. The abnormal interpretation rate is the same as your screening recall rate.
Are BIRADS category 3 assessments included for consideration when determining an abnormal interpretation rate for a diagnostic exam?
The answer is no. A positive diagnostic exam is an exam that was given a BIRADS category 4 or 5 assessment. A BIRADS category 3 assessment is considered a negative exam for a diagnostic study and therefore BIRADS category 3 exams do not count towards the abnormal interpretation rate for diagnostic mammography.

**Name as many of the data points as you can that are specified for the basic, clinically relevant audit.**
According to the ACR BIRADS Atlas, the basic clinically relevant audit, which is the audit I would be most familiar with for radiology board exam purposes, specifies that facilities must obtain many data points that include the dates of the audit period, the total number of exams considered in the audit broken down by number of screening exams and number of diagnostic exams that were interpreted. Separate audits should be performed for screening versus diagnostic imaging. These should not be grouped together. Rather, the audit should also include the number of BIRADS 0 recommendations that were made, the number of BIRADS 3 recommendations that were made, the number of BIRADS 4 and 5 recommendations that were made, and results of tissue diagnosis in terms of being benign versus malignant for BIRADS category 0, 3, 4 and 5 assessments. Note that you must attempt to collect tissue diagnosis results for all exams for which tissue diagnosis was recommended, whether that biopsy was performed at your facility or elsewhere. You must also obtain data regarding cancer staging metrics such as the histologic type of cancer for invasive cancer size, nodal status, and tumor grade. You also need to include analysis of any known false negative mammography examinations. That is a lengthy list, but if you acquire those data points you have acquired the majority of what is required for the basic clinically relevant audit.

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**What about BIRADS category 6 cases? Are BIRADS category 6 cases included in the basic clinically relevant audit?**
As a reminder, BIRADS category 6 cases are assigned to imaging that is performed when breast cancer has already been diagnosed and has not yet been surgically resected from the breast. All BIRADS category 6 cases will be assigned for patients who currently have breast cancer still in their breast as it has not yet been surgically resected. BIRADS category 6 cases are not included in the audit. Reasons why these are not part of the audit include that these examinations are all known to have cancer, so these exams are not performed to evaluate for the presence or absence of malignancy. Also, including these cases would skew the data for diagnostic exams because these all have cancer, so the cancer detection rate for BIRADS category 6 cases would be 100% and would falsely elevate your diagnostic performance metrics. The primary purpose of the audit is to determine the performance of cancer detection in those cases wherein the presence of cancer is unknown. Further pre-surgical breast imaging on category 6 cases is no longer counted in the audit.

**After collecting the data for the basic clinically relevant audit, what calculations need to be determined?**
The calculations that must be determined for the basic clinically relevant audit include true positives, false positives, PPV1, PPV2, PPV3. PPV again is the abbreviation for positive predictive value. The cancer detection rate, the percentage of invasive cancers that are node negative, the percentage of minimal cancers, the percentage of cancers that are stages zero and one, and the abnormal interpretation rate for screening exams, which is also the screening exam recall rate must all be calculated.

**What is the definition of a minimal cancer?**
A minimal cancer is an invasive cancer that is less than or equal to 1 centimeter in size or ductal carcinoma in situ (DCIS) of any size. Minimal cancers are the smallest invasive cancers defined as being less than or equal to 1 centimeter in size or DCIS. Even if DCIS is extensive throughout the breast, it would still be considered a minimal cancer because it is DCIS and is not invasive.

**According to the ACR BIRADS Atlas, what are the three major goals of breast cancer screening?**
According to the ACR BIRADS Atlas, the three major goals of breast cancer screening are as follows.
First, find a high percentage of the cancers that exist in a screening population. In other words, radiologists should have a high cancer detection rate.
Second, find those cancers within acceptable ranges of screening recalls and recommendations for tissue diagnosis. The goal is to maximize the cancer detection rate while minimizing cost and morbidity to the patient. To evaluate your success here, you should look at recall rate and the positive predictive values to help inform whether these goals are being met.
Third, find a high percentage of small node negative early-stage cancers, as these are the cancers more likely to be curable per the ACR BIRADS. Therefore, data such as the percentage of node negative cancers, the number of minimal cancers, and the number of stage zero and stage one cancers are collected.

**After analysis of medical audit data, what are acceptable mammography performance ranges for cancer detection rates and abnormal interpretation rate? In other words, what is an acceptable cancer detection rate and what is an acceptable recall rate per the ACR BIRADS Atlas?**
An acceptable cancer detection rate for the BIRADS atlas is greater than or equal to 2.5 cancers per 1000 examinations. Remember we covered before that cancer detection rate is always the number of cancers

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per 1000 cases, and according to the ACR Atlas, breast imagers should detect at least 2.5 cancers per 1000 examinations.

The abnormal interpretation rate, which, when discussing screening examinations is also your screening recall rate, should be in the range between 5% to 12% of all screening exams. That means that a BIRADS category 0 assessment should be assigned between 5 and 12% of the time when reading screening exams, and that is considered an acceptable recall rate range.

**How frequently must breast imaging audits be performed?**
According to the ACR BIRADS atlas, an audit must be initiated no later than 12 months after the date a new facility becomes certified, and thereafter be completed within an additional 12 months of when the audit was initiated. If you start a new breast imaging center, you must initiate the process of collecting your data for the audit within 12 months after the center has become certified, and then complete the audit within an additional 12 months. The reason for this delay is it does take a while to acquire enough examinations to be audited and then to complete the audit. After that initial audit is completed, the audit is then performed every 12 months thereafter.

I now want to present a few of my own personal thoughts regarding studying for the ABR core exam and ABR certifying exam regarding the breast imaging audit. For the Core Exam, residents should know basic concepts of the audit, many of which I have outlined in this episode. For the Certifying Exam considering those that select breast imaging as an emphasis area, the test taker must know detailed information and must carefully study the BIRADS atlas to understand breast imaging audit details. Please be aware that questions on the breast imaging audit and acceptable performance metrics for screening and diagnostic mammography are fair game on the ABR core exam. For those selecting breast imaging emphasis on the Certifying Exam, the ACR and FDA requirements for breast imaging practices must be studied in some detail.