How to Assign Initial Method of Detection in Diagnostic Reports

From the ACR Breast Commission, Screening and Emerging Technology Committee

PROPOSAL: We propose to facilitate the capture of the initial Method of Detection (MOD) in state registries by including a code for MOD in radiology reports that is consistently placed and easily discovered by abstractors. We propose that initial MOD will be defined for each patient as one of the following 3 options: 1. Screening detection with imaging, 2. Patient or Provider detection of signs or symptoms, 3. Neither screening with imaging nor patient or provider detection. We propose to have radiologists prospectively assign the initial MOD at the conclusion of diagnostic imaging evaluations when tissue sampling is recommended, before cancer is diagnosed, to avoid bias. The initial MOD will be included in the diagnostic radiology reports for all patients who do not already have an active diagnosis of breast cancer and receive a final BI-RADS assessment of 4 or 5 and recommendation for tissue sampling. Initial MOD for the subset of patients subsequently diagnosed with breast cancer can then be discovered by abstractors and transferred into regional, state and national registries. Audits of the data should demonstrate that the initial MOD assigned before diagnosis is highly accurate. Initial MOD data, linked to individual patients, will provide an opportunity to understand the direct associations of how breast cancer is detected with treatment and outcomes for patients in the United States.

Assigning Initial MOD:

It is imperative that the initial MOD be accurate to reflect the truth, prospectively assigned to avoid bias, easily discovered by abstractors to minimize added work, and correctly transferred to registries for future scientific investigation. We propose to have radiologists assign a single MOD (S, P or N) to the diagnostic report at the conclusion of the diagnostic imaging evaluation for each patient who is recommended for biopsy. The diagnostic radiologist will need to review recent prior imaging, which is part of the standard clinical process during the work-up, to determine the MOD. The diagnostic radiologist will have the expertise to understand the subtle nuances of the complete imaging, history and clinical information and be uniquely suited to accurately assign the initial MOD at the time of patient evaluation and report creation. We propose to have the diagnostic radiologist add a line at the end of the radiology report that reads:

The MOD for the right/left breast is Sma/Sdbt/Sus/Smri/Scem/Snuc/So/Pat/Pro/Ppp/N.

We believe this approach minimizes the added burden of work to the radiologist. The radiologist signs the report as usual and no additional follow-up is required. In the next step, the abstractor looks for the MOD among the imaging reports for patients diagnosed with breast cancer.

Abstracting Initial MOD to Databases:

Placing a single initial MOD at the bottom of a diagnostic report is designed to facilitate discovery of the MOD by the abstractor. Abstractors currently gather most of the information related to a new cancer diagnosis from clinical reports. Most of the abstracted information comes from the pathology reports. However, other clinical notes are utilized as needed. Rather than ask the abstractor to retrospectively sift through multiple radiology reports and recreate the sequence of events with clinical history to determine the MOD, we prospectively supply it in a single consistent location: after the impression of the diagnostic breast imaging report. This approach maximizes accuracy and minimizes the added burden on the abstractor.

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Definitions for Initial Method of Detection

The initial MOD of breast cancer is defined as the first means by which a breast cancer becomes apparent to any radiologist, provider or patient prior to histologic confirmation of the diagnosis. Initial MOD includes image-based screening, other imaging or laboratory tests, self-examination by a patient, clinical physical examination by a healthcare professional, or physical symptoms experienced by the patient. Screening with mammography, ultrasound, MRI and other tests may provide the initial imaging findings of breast cancer that lead to a diagnosis. Other imaging or laboratory tests, not designed to primarily evaluate the breast, such as chest CT or brain MRI, may provide the initial findings that lead to a diagnosis of breast cancer. Self-examination and clinical breast examination may detect initial physical signs of breast cancer such as lumps, thickening or tenderness that lead to a diagnosis. Patients may experience and seek care for initial symptoms of breast cancer such as nipple discharge, erythema, pain, dimpling or skin ulceration that lead to a diagnosis.

MOD Category S: Detection of Breast Cancer from an Image Based Screening Examination

MOD Category S includes imaging-based screening examinations performed specifically to detect breast cancer in an *asymptomatic* population. Screening involves the binary decision of recommending action before the next routine screening versus recommending no action until the next routine screening. When the initial finding of a possible breast cancer is detected on an image-based screening examination and additional action is recommended (i.e. BI-RADS 0), then the MOD is category S. Subcategories are defined so that the first specific screening modality allowing the radiologist to detect the cancer can be captured and abstracted.

Category S: initial asymptomatic image-based screening detection

- Category Sma: screening full field 2D film or digital mammography (no synthetic views or DBT)
- Category Sdbt: screening with DBT with full field 2D or synthetic 2D
- Category Sus: screening ultrasound
- Category Smri: screening MRI
- Category Scem: screening contrast enhanced mammography
- Category Snuc: screening PEM or MBI
- Category So: other screening modality (CT, etc)

MOD Category P: Patient or Provider Detected

MOD Category P includes all types of clinical presentations. When a patient discovers and seeks care for a lump or other breast concern or a provider detects the initial finding of a possible breast cancer on physical examination prompting orders for diagnostic imaging evaluation, then the appropriate MOD is category P.

Category P: initial clinical presentation/detection

- Category Pat: patient reported self-examination finding and/or symptom
- Category Pro: provider detected finding on physical examination of asymptomatic patient
- Category Ppp: if it is impossible to determine if the patient or the provider detected it first

MOD Category N: All other means by which a diagnosis of breast cancer is first detected.

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MOD Category N includes other pathways by which the diagnosis of breast cancer initially comes to clinical attention.

Category N: Not detected with image-based screening; not detected by provider or patient.

- Category N: other/incidental finding on non-breast imaging test (chest CT PET/CT thoracic MRI)
- Category N: other/incidental finding on prophylactic mastectomy or reduction surgery
- Category N: search for unknown primary cancer site

MOD Category Guidance

MOD is assigned at the level of the patient. MOD is not specific to a breast or a targeted finding.

MOD Category S Guidance:

Category S includes several additional and important scenarios:

1. Two screening examinations are performed on the same day (e.g. screening mammogram and screening ultrasound) and *reported separately* and only one exam is coded as BI-RADS 0, prompting a recall and recommendation for biopsy, then the MOD would specify the modality prompting the recall. Example: if a screening DBT mammogram and US are performed on the same day and a finding on the screening mammogram is given a BI-RADS 0 assessment and the US is given a BI-RADS 1 or 2 assessment, and biopsy is recommended at the subsequent work up, then the MOD in the diagnostic BI-RADS 4/5 report is Sma.

2. Two screening examinations (e.g. screening mammogram and screening ultrasound) are performed on the same day and the finding is equally and independently identified on both examinations and both examinations are classified as BI-RADS 0 in *separate reports*. A biopsy is recommended at subsequent work-up. In this case, the primary screening examination should be recorded as the MOD. Because screening mammography is the primary screening exam and ultrasound is considered supplemental, the mammogram would be the MOD. Example: A 2D mammogram and MRI are performed on the same day and a BI-RADS 0 is assigned to a finding seen equally on both modalities. The subsequent work-up with ultrasound and mammography confirms a suspicious finding. The MOD in the diagnostic BI-RADS 4/5 report should be Category Sma rather than Smri.

3. Two screening examinations are performed on the same day and *reported together*. The primary screening examination should be recorded as the MOD. Because screening mammography is the primary screening exam and ultrasound is considered supplemental, the mammogram would be the MOD. Example: A suspicious mass is seen on screening US first and seen in retrospect on the DBT screening mammogram. A single report recommending additional imaging is issued. Subsequent work-up confirms a suspicious mass. The MOD in the diagnostic BI-RADS 4/5 report is Category Sdbt.

4. If two screening examinations are performed on separate days, the MOD is assigned for the modality on which the cancer was *initially* identified chronologically, regardless of whether the finding is identified on both exams or how it is seen at the time of diagnostic work-up.

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5. Other types of special screening examinations, such as those described as "diagnostic" but performed on *asymptomatic* women following a clinical history of breast cancer or benign breast biopsy or breast augmentation, are included in the screening group for audit purposes. This is consistent with the audit guidelines in the BI-RADS atlas. Findings detected initially on these examinations in asymptomatic women should also be categorized as screening for the purposes of MOD. Example: A suspicious finding is initially detected on a yearly mammogram in an *asymptomatic* woman with an indication of prior history of breast cancer treated 3 years ago. The subsequent work-up confirms a suspicious finding. The MOD in the diagnostic BI-RADS 4/5 report is Category Sma.

6. BI-RADS 3: If a BI-RADS 3 finding is stable and benign and never progresses to BI-RADS 4/5 assessment, and tissue sampling is never recommended, the MOD will never be assigned. But if a BI-RADS 3 is reassessed as BI-RADS 4/5 on diagnostic surveillance imaging, then the radiologist would code the MOD on that BI-RADS 4/5 diagnostic report. MOD is based on complete review of imaging history back to initial screening or diagnostic examination that detected the finding and triggered the follow-up. Example: If the initial examination related to this finding was a BI-RADS 3 when the patient presented with a palpable lump, then it is coded Pat. If the initial examination was a BI-RADS 0 on screening for non-palpable screen detected calcifications, followed by BI-RADS 3 on the immediate recall diagnostic examination, and then BI-RADS 4 at the 6-month short interval follow-up, then initial MOD is coded Sma for the first examination that triggered the workup and follow-up.

7. Initial MOD should be assigned to *screening* MRI or targeted ultrasounds after screening MRI. If a finding on screening MRI is assessed as BI-RADS 4 or 5 and tissue sampling and targeted ultrasound are recommended, an MOD of Smri should be assigned on the MRI. If the targeted ultrasound is negative (BI-RADS 1) and MR-guided breast biopsy is recommended because the MRI finding is suspicious, the MOD will already have been assigned on the MRI (MOD could be carried over to the ultrasound as Smri but it is not required). If a finding on screening MRI is assessed as BI-RADS 0 because it could be benign or suspicious on targeted ultrasound, MOD is *not* assigned to the MRI. If the final assessment from the targeted ultrasound is BI-RADS 4 or 5 and tissue sampling is recommended, then MOD should be assigned as per usual guidelines which would be Smri.

8. MOD should not be assigned to examinations after tissue sampling has established the diagnosis of cancer. Any mammogram, ultrasound, MRI or other imaging modality employed to further evaluate the extent of disease does not require an MOD. The diagnosis of cancer has already been established and MOD is no longer prospective.

9. MOD should not be assigned to an MRI performed to evaluate the extent of disease. The diagnosis of cancer has already been established and the assignment of MOD is no longer prospective. In the vast majority of cases, MOD will have been assigned on prior diagnostic examinations when tissue sampling was recommended.

10. To remain consistent, MOD should not be assigned to targeted ultrasound examinations recommended after MRI for extent of disease. The diagnosis of cancer has already been established and the assignment of MOD is no longer prospective. In the vast majority of cases,

MOD will have been assigned on prior diagnostic examinations when tissue sampling was recommended.

MOD Category P Guidance:

Detection of Breast Cancer from a Clinical Presentation

1. If a patient presents with clinical signs and symptoms of breast cancer and the imaging test shows a suspicious finding that is subsequently proven to be a cancer, then the MOD in the diagnostic BI-RADS 4/5 report is Clinical Presentation, Category Pat.

2. If a patient presents with signs and symptoms of breast cancer and the imaging test shows an *incidental* finding that is completely distinct from the symptom (i.e. contralateral breast or clearly different location in the ipsilateral breast) and it is suspicious, then the MOD would still be Category Pat because the objective of tracking MOD is to understand the impact of screening mammography. The examination in this scenario is not a screening examination. Example: A woman presents with a palpable mass in the right breast which turns out to be a cyst. Diagnostic mammography shows a suspicious finding in the asymptomatic left (contralateral) breast, then the MOD in the BI-RADS 4/5 report for the left breast is category Pat.

3. If a provider performing a clinical examination detects a sign (lump, retraction, ridge) in an asymptomatic patient, that prompts diagnostic work-up and tissue sampling is recommended, then MOD is Pro.

4. If a patient or provider detects signs or symptoms of breast cancer and the patient proceeds directly to a surgeon or other non-radiologist provider for evaluation, without any imaging, and tissue sampling (needle biopsy or excisional biopsy) by a non-radiologist confirms cancer, then the MOD, when the patient undergoes subsequent diagnostic imaging, for staging is P. If imaging is never performed, then MOD will never be assigned to these cases.

MOD Category N Guidance:

If, after careful review of imaging and clinical data, MOD is Neither S nor P, then N should be assigned. Based on existing practice patterns, N should be assigned a very small fraction of cases.

Additional Methods of Demonstration:

It is essential to distinguish initial MOD from additional methods of demonstration (AMOD). AMOD is defined as any additional method, *following initial detection*, which further characterizes a known cancer. A cancer may be additionally demonstrated by any of the same classifications found in the MOD as listed above. Initial MOD must be distinguished from subsequent AMOD. For example, a cancer initially may be detected on screening mammography (Sma) and then further characterized on ultrasound and MRI. Ultrasound and MRI would be considered AMOD. For the current purposes of data collection and mammography reporting, AMOD will not be collected at this time. However, if the process of collecting MOD can be accurately and widely adopted, and there is a scientific need for collecting AMOD, it could be added as a separate field in the future.

ALL FEEDBACK REGARDING THIS PROTOCOL IS WELCOME AND ENCOURAGED.

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