INTRODUCTION: The American College of Radiology (ACR), U.S. Preventive Services Task Force (USPSTF) and American Cancer Society (ACS) agree that annual screening mammography beginning at age 40 will save the most lives. However, the same organizations disagree over the balance of risks and benefits of screening mammography and recommend different frequencies and ages to initiate early detection of breast cancer in the U.S. The results of randomized controlled trials (RCTs), conducted between 1963 and 1990 from multiple international sources, provide strong evidence that screening mammography significantly reduces deaths from breast cancer. The results of the RCTs have been reinforced and supported by modeling studies inside the U.S. and observational research from national databases outside the U.S. Shortly after the data from RCTs confirmed the benefits of early detection, many developed nations instituted population-wide breast cancer screening programs. The U.S. did not. Administrators of many national health programs outside the U.S. had the foresight to track the initial method of detection (MOD), such as mammography screening or clinical examination, for every patient with a new diagnosis of breast cancer for decades. In examination of data from a large subset of Swedish screening-eligible women, for example, researchers reported that women attending screening had a statistically significant 41% reduction in their risk of dying of breast cancer within 10 years of diagnosis and a 25% reduction in the rate of advanced breast cancers compared to non-attenders. Other nations tracking MOD outside the U.S., such as Australia and Canada, have reported reductions in breast cancer specific mortality exceeding 40%.

KNOWLEDGE GAPS: Many national, state, and local databases in the U.S. such as the National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) program, the Centers for Disease Control’s National Program of Cancer Registries the American College of Surgeons’ National Cancer Database (NCDB) and the ACR’s National Mammography Database (NMD) collect specific data for every patient with a new diagnosis of breast cancer, but MOD has never been included. The North American Association of Central Cancer Registries (NAACCR) does not require registries to MOD. Thus, among developed nations with high rates of breast cancer, the U.S. critically lacks the fundamental ability to directly link breast cancer outcomes to MOD and address the ongoing debate over screening. Without patient specific data on initial MOD, national organizations, such as the USPSTF, ACS, and American College of Physicians (ACP), when examining the impact of screening, still turn to models based on historic data and variable assumptions that are subject to bias. The lack of contemporary, patient specific information
has permitted ongoing speculation and fostered disagreement about the risks and benefits of screening in the U.S. leading to conflicting recommendations, that confuse patients and providers and missed opportunities to save lives. 11,12

DEFINING AND DETERMINING MOD: The initial MOD of breast cancer is defined as the first test or clinical event to trigger the work-up leading to the histologic diagnosis of breast cancer. When national service-screening programs and registries were built in the 1980s and 1990s, the choices for initial MOD were limited. Screen-film mammography was the only image-based screening test. Today, initial MOD can include multiple other image-based screening modalities. Screening with FFDM, digital breast tomosynthesis (DBT), ultrasound, MRI and other tests can now provide the earliest evidence of breast cancer. Self-examination and clinical breast examination (CBE), which detect lumps, thickening or tenderness, can also be the initial MOD leading to a diagnosis. Patients may also trigger detection of breast cancer when they seek care for nipple discharge, erythema, pain, dimpling or skin ulceration. In addition, other imaging or laboratory tests not designed to evaluate the breast, such as abdominal CT or brain MRI, may also offer the initial findings of metastases that lead to a diagnosis of breast cancer.

BENEFITS OF COLLECTING MOD: If MOD can be assigned and collected accurately and without bias for each patient, we could have new primary data, rather than models based on historic data that may no longer accurately represent the diversity of our screening-eligible population or advances in screening technologies. Concrete, patient-specific data could bring the ACR, USPSTF and ACS to consensus recommendations for screening. We could employ the MOD-inclusive data to answer numerous national population-based questions about how screening relates to efficacy, equity, treatment, and breast cancer, such as:

1. What are the relative contributions of screening and treatment to reducing mortality from breast cancer?
2. Should the treatment of stage 1 cancers detected by screening be the same as stage 1 cancers detected clinically?
3. Do patients with screen-detected cancers have different treatment or mortality outcomes compared to patients whose cancers are detected clinically?
4. Do tumors that are screen-detected have different molecular signatures compared to tumors that are detected clinically?
5. Are there racial disparities in screening that impact outcomes?
6. What percentage of breast cancers are not initially detected on screening, and how does this vary by personal risk, breast density, age, or other factors?
7. Are there differences in initial staging for breast cancers initially detected with image-based screening vs clinical or self-examination?
8. Do MOD and outcomes vary with geographic location, and can we use that information to improve access to screening at the local level?
9. Are supplemental screening options (MRI, ultrasound, etc.) improving treatment, morbidity, or mortality from breast cancer?
BARRIERS TO NATIONAL COLLECTION OF MOD: National service health care systems outside the U.S. are less than perfect, but they provide a uniform system for delivering care and collecting data. The U.S. health care system provides cutting edge care with comparatively brief wait times and less regard to cost, but data collection is a patchwork of public and private entities funded by numerous private and public payors competing at the local and regional levels stitched together with different electronic medical records of heterogeneous patient populations. Nearly every state has a tumor registry responsible for tracking valuable information such as incidence, stage, race, and mortality for every case of cancer diagnosed. Currently, patient data from some state registries are de-identified and then sent to SEER. However, 33 states, including Texas, Florida, Illinois, Michigan, Ohio, and Pennsylvania, are excluded from the SEER cancer incidence database (https://seer.cancer.gov/about/factsheets/SEER_Overview.pdf).

ASSIGNING MOD ACCURATELY: Abstractors employed by state, local and hospital registries currently gather information related to a new cancer diagnosis from clinical reports. Most of the information regarding cancer type, size, grade, and receptor status is quickly abstracted from succinct and standardized pathology reports. However, abstractors may turn to the tedious and time-consuming strategy of sifting through other clinical notes. We cannot expect abstractors to retrospectively read multiple radiology and pathology reports to recreate the clinical history to determine the MOD. In addition, if abstractors already know the patient has breast cancer, will they be able to avoid unconscious bias when assigning MOD? It is imperative that assignment of initial MOD be accurate, unbiased, easily discoverable by abstractors, and correctly transferred to registries for future scientific investigation.

ADDITIONAL METHODS OF DEMONSTRATION: It is essential to distinguish initial MOD from additional methods of demonstration (AMOD). AMOD are defined as any additional method, following initial detection, which further characterizes or redemonstrates a cancer. A cancer may be additionally demonstrated by any of the same classifications found in the MOD listed above. Initial MOD must be distinguished from subsequent AMOD. For example, a cancer initially may be detected on screening mammography and then further characterized on ultrasound and MRI. Ultrasound and MRI would be considered AMOD.

SUMMARY: The Screening and Emerging Technology Committee (SETCOM) within the ACR Commission on Breast Imaging is actively exploring how to help U.S. registries accurately collect initial MOD specific to every woman with breast cancer. The SETCOM is dedicated to helping providers and patients understand the current impact of breast cancer screening and early detection in the U.S. Breast radiologists are the experts on breast cancer screening and the SETCOM wants your ideas, input, and help. Please post your ideas and comments on the SBI Engage forum or send email to:

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