

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF SCREENING AND DIAGNOSTIC MAMMOGRAPHY

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

The goal of mammography is the detection, characterization, and evaluation of findings suggestive of breast cancer and other breast diseases. Annual screening mammography of age-appropriate asymptomatic patients results in the greatest breast cancer mortality reduction, diagnosis at an earlier stage, and more treatment options with less treatment-related morbidity [1-9]. Mortality from breast cancer is reduced by more than 40% in screened patients compared to unscreened patients, due to benefits of early detection of smaller, lower stage tumors [10]. Treatment advances are important, but do not replace the benefits of screening mammography [10]. A screening mammogram is an X-ray examination of the breast of an asymptomatic patient. A diagnostic mammogram is an X-ray examination of the breast of a patient with signs or symptoms of breast disease, a possible abnormality detected on screening mammography or other imaging, or prior mammography findings requiring imaging follow-up. Digital breast tomosynthesis (DBT), a mammographic technique that creates thin-section reconstructed images of the breast tissue, may also be used in screening and/or diagnostic settings. DBT decreases the masking effect of superimposed normal tissue, allowing lower recall rates and increased detection of invasive breast cancer compared with 2-D full-field digital mammography alone [11-13]. This document will collectively refer to analog mammography, full-field digital mammography, and DBT as "mammography."

It is essential that all mammography be performed and interpreted with the highest quality possible [14]. All mammography in the United States must be performed in accordance with the Mammography Quality Standards Act (MQSA) legislation and regulations published by the Food and Drug Administration (FDA) [15]. Nothing in this document should be construed to contradict those regulations. In addition, mammography facilities should have policies and procedures in place for imaging patients with disabilities.

II. INDICATIONS AND CONTRAINDICATIONS

A. Screening Mammography in Cisgender Females [3,16-18]

1. Patients undergoing screening mammography should be asymptomatic. If a patient has symptoms or clinical signs of breast disease, diagnostic mammography should be performed instead (see section II.B.).
2. For patients at average risk for breast cancer, annual screening mammography starting at age 40 is [recommended](#) [1-7,19-21].
3. For patients at high risk for breast cancer, annual screening mammography may commence at age 30 (or as specified in the scenarios below). This includes patients [22]:
 - a. With known genetic mutation(s) or syndrome(s) conferring increased breast cancer risk.
 - b. Who have not undergone genetic testing but have a first-degree relative with a BRCA mutation.
 - c. With a 20% or greater lifetime risk for breast cancer based on breast cancer risk model(s).
 - d. With a first-degree relative with breast cancer, who may commence screening 10 years earlier than the age at which the youngest first-degree relative was diagnosed (but not before age 30).
 - e. With a history of chest (mantle) radiation received between the ages of 10 and 30, who should begin screening 8 years after radiation therapy, but not before age 25.
 - f. With biopsy-proven ductal carcinoma in situ, invasive breast cancer, ovarian cancer, or high risk lesion (such as atypical ductal hyperplasia or lobular neoplasia), who should begin screening at the time of diagnosis, regardless of age.
4. Asymptomatic patients previously treated for breast cancer may undergo annual screening or annual diagnostic mammography, as determined by the imaging facility [23,24].
5. Lactating patients may undergo screening mammography, depending on clinical context and underlying risk of breast cancer. Breast feeding and/or pumping immediately prior to the examination may help minimize any effect of lactation on mammographic density [25].
6. Screening should continue without an upper age limit, unless severe comorbidities limit life expectancy or ability to accept treatment [7]. One in five breast cancers occurs in patients 75 years or older [26]. Screening mammography has increasingly favorable metrics among patients age 74–90 years with higher cancer detection rate and fewer false positives compared with younger patients [27]. Screening in patients

age 75 or over reduces treatment-related morbidity from breast cancer [8,9]. Quality-adjusted life-years remain positive for screening up to age 90 [28].

7. A patient may present for a screening mammogram without an advance order from a physician or health care provider.
 - a. A self-referred patient has no health care provider, declines to accept a health care provider chosen by the facility, or has a designated health care provider who declines responsibility.
 - b. A self-requesting patient comes for mammography on their own initiative, but provides the name of their physician or health care provider.
 - i. If the provider declines to accept the mammography report from the facility, the facility should treat the patient as if they were self-referred.
 - c. Direct access to screening mammography is permissible in these instances. However, screening facilities that elect to accept self-referred patients (or self-requesting patients whose providers decline responsibility) must have procedures for appropriate referrals to qualified medical providers if the screening process leads to additional diagnostic imaging, biopsy, or treatment not available at that facility [29].
8. Patients with breast augmentation
 - a. Asymptomatic patients with breast implants may undergo screening mammography.
 - b. Facilities should have procedures in place to inquire whether patients have breast implants before a mammogram is performed.
 - c. If a facility does not provide imaging services for patients with breast implants, it should refer the patient to a facility that does.

II. INDICATIONS AND CONTRAINDICATIONS

B. Screening Mammography in Transgender Patients

1. Recommendations for transgender patients with average risk for breast cancer depend on sex assigned at birth, use and duration of hormones, and surgical history. Annual screening mammography starting at age 40 is recommended for male-to-female (MtF) transgender patients who have used hormones for = 5 years, as well as for female-to-male (FtM) transgender patients who have not had gender-affirming surgery [30].

II. INDICATIONS AND CONTRAINDICATIONS

C. Diagnostic Mammography

1. Diagnostic mammography is used to evaluate clinical breast findings, such as an area of palpable concern, a persistent focal area of pain or tenderness, skin/nipple changes, or suspicious nipple
2. A clinical breast finding may be elicited when a patient presents for a screening. If so, a diagnostic mammogram should be performed instead.
 - a. The facility should have a process for converting a screening mammogram to a diagnostic examination (which may comprise both mammography and targeted ultrasound).
3. Diagnostic mammography is used to evaluate abnormal imaging findings identified on screening
 - a. Occasionally, diagnostic mammography may be requested to characterize breast findings identified on imaging examinations not specific to the breast, such as computed tomography (CT), positron emission tomography/computed tomography (PET/CT), or magnetic resonance (MR)
 - b. Diagnostic mammography may be indicated to further evaluate a finding identified on a breast MR examination.
4. Diagnostic mammography should be performed for follow-up evaluation of a mammographic finding assessed as "probably benign" at a prior diagnostic examination, as defined by the [ACR Breast Imaging Reporting and Data System \(BI-RADS®\)](#) [31].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiologic technologists who work in mammography must meet the requirements in the MQSA final rule published by the FDA [15].

IV. SPECIFICATIONS OF THE EXAMINATION

A. Screening Mammography

1. The screening examination should ideally be limited to technically adequate bilateral craniocaudal (CC) and mediolateral oblique (MLO) views. However, additional views may be required to visualize breast tissue more effectively.
 - a. Evaluation of the augmented breast should include, when possible, standard implant in-field CC and MLO views as well as implant-displaced views in the CC and MLO projections [32].
 - b. DBT may be performed.
 - i. Compared to standard mammography, DBT has been found to increase the number of cancers detected and to decrease the recall rate, with benefits sustained over multiple years of screening [12,33]. These advantages have been found to be especially pronounced in certain populations, including patients under age 50 and patients with dense breast tissue [11,34-36]. However, interpretation time does increase. For further information, see the [ACR Practice Parameter for the Performance of Digital Breast Tomosynthesis \(DBT\)](#) [11].
 - ii. DBT may be used in patients with implants, and is typically only performed on implant-displaced views [11].
2. The interpreting physician does not need to be present at the facility to monitor the examination when the patient is imaged.

IV. SPECIFICATIONS OF THE EXAMINATION

B. Diagnostic Mammography

1. A diagnostic mammogram may include full-field CC, MLO, and/or supplemental views to evaluate an area of clinical or imaging concern.
 - a. Supplemental mammographic views may include spot compression, spot compression with magnification, or other special views [32,37-40].
 - i. When determining which views to perform, the distance from the area of concern to the digital detector (or image receptor) should be minimized if possible [32].
 - b. DBT may be performed.
 - i. Lesion characterization may be improved with DBT, especially for noncalcified lesions, spiculated masses, and asymmetries [11].
2. Diagnostic mammography should be performed under the immediate supervision of the interpreting physician[2].

[2] Immediate supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure. Immediate supervision may also be accomplished via telemammography as long as the interpreting physician is immediately available (see section VII.C).

IV. SPECIFICATIONS OF THE EXAMINATION

C. Request for Diagnostic Mammography

The written or electronic request for a diagnostic mammography examination evaluation should provide sufficient

information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason(s) for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for a diagnostic examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

IV. SPECIFICATIONS OF THE EXAMINATION

D. Image Labeling

1. All mammographic images should be labeled in accordance with FDA MQSA requirements [41] and the ACR BI-RADS Atlas [31]. The FDA allows workstations used for final interpretation the ability to temporarily switch off the image identification information, provided that the standard or default setting shows the image identification information [42].
2. Both hardcopy and softcopy labeling must include specific information in a permanent, legible, and unambiguous manner, placed so as not to obscure anatomic For complete list, see the [MQSA website](#) [15].

IV. SPECIFICATIONS OF THE EXAMINATION

E. Markers

1. Radiopaque markers may be placed on the breast prior to imaging in order to identify areas of clinical concern (such as a palpable lump) or other entities that could affect interpretation (eg, raised skin lesions or postsurgical changes).
2. Facilities should consider consistent use of radiographically distinct markers to indicate palpable areas of concern, skin lesions, and surgical scars. It may also be helpful to record such findings on the patient's intake sheet and/or technologist worksheet.

IV. SPECIFICATIONS OF THE EXAMINATION

F. Viewing Issues

1. Images acquired from digital mammographic systems should be viewed in accordance with the [ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Mammography](#) [43].
2. Screen-film images should be viewed in accordance with the 1999 ACR Mammography Quality Control Manual [32].

IV. SPECIFICATIONS OF THE EXAMINATION

G. Double Reading and Computer-Aided Detection

Double reading and computer-aided detection may slightly increase the sensitivity of mammographic interpretation and may be used. However, this increased sensitivity is usually at the expense of decreased specificity and increased recall and/or biopsy rates [44].

IV. SPECIFICATIONS OF THE EXAMINATION

H. Image Retention in Accordance with MQSA Regulations

For information regarding image retention, see the MQSA Final Regulations and Additions to Policy Guidance [45].

IV. SPECIFICATIONS OF THE EXAMINATION

I. Comparison with Prior Breast Imaging Studies

1. Comparison with prior breast imaging studies is an important part of mammography interpretation [37,46,47].
2. If prior breast imaging studies are needed to assess mammographic findings, an attempt should be made to obtain them.
3. Digitized images of previously obtained screen-film mammograms may be used for comparison purposes if the interpreting physician deems them acceptable [48].
4. Facilities must be able to provide images of original high diagnostic quality to other mammography facilities or to referring physicians in accordance with MQSA regulations [15].

IV. SPECIFICATIONS OF THE EXAMINATION

J. Mobile and Telemammography Settings

1. If mammography is performed in a mobile setting, the mammography quality control (QC) technologist must verify satisfactory performance of the mobile unit using a test method that establishes adequate image quality before any mammograms are performed at each location [15,32,49].
2. Screening mammography may take place without an interpreting physician in attendance.
 - i. The mammography services provided must follow all the practice parameters herein.
3. Diagnostic mammography may be performed without the interpreting physician on site ("diagnostic telemammography"). However, because diagnostic evaluation often includes real-time correlation of mammographic, sonographic, and clinical findings, this practice is less optimal
 - i. Diagnostic telemammography may be used only in circumstances of limited patient access, in order to facilitate patient care.
 - ii. If performed, the responsible physician should be immediately available to review images and provide direction throughout the examination.
 - iii. The mammography services offered must follow ACR practice parameters and the MQSA final rule as published by the FDA with strict adherence to documented protocols [15].

V. DOCUMENTATION

A. Documentation: Mammogram Report

1. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [50] and consistent with the MQSA final rule published by the FDA [15].
1. The mammogram report should:
 - a. State whether the mammogram is being performed as a screening or diagnostic examination
 - i. In the diagnostic setting, the clinical and/or imaging concern(s) that prompted the examination should be acknowledged.
 - b. Describe the patient's mammographic breast density, using one of the four BI-RADS breast density categories.
 - c. Describe detected abnormalities and pertinent observations, using BI-RADS terminology whenever

possible.

- d. Establish level of suspicion of malignancy and provide final assessment, using BI-RADS terminology .
 - e. Provide recommendations for patient management.
2. Overall final assessment of findings should be based on all imaging studies performed at that patient visit. In addition, they must be classified according to the FDA-approved final assessment categories [9] and should follow the categories defined in BI-RADS Atlas [31].
- a. BI-RADS Category 0 assessments are assigned to incomplete evaluations, in which additional mammographic views, ultrasound, or previous studies are necessary to assign a final assessment category. When additional imaging is recommended, the facility should:
 - i. have the capacity to perform the recommended examination(s); or,
 - ii. arrange for a cooperating facility to perform the recommended examination(s); or,
 - iii. refer the patient to a facility able to perform the recommended examination(s).
 - b. "BI-RADS®? category 0 should not be used for diagnostic breast imaging findings that warrant further evaluation with MRI. Rather, the radiologist should issue a final assessment for the combined diagnostic mammography and US examinations in a report that is made before the MRI is performed. If further evaluation with MRI is warranted, the radiologist should incorporate this recommendation into the patient management recommendations in the combined mammography/US report" [31]. If the recommended MRI examination is not performed, the combined diagnostic breast imaging report will stand as issued.
 - c. A BI-RADS Category 3, 4, or 5 assessment is strongly discouraged for a screening mammogram, even though in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. Rather, patients with screening abnormalities should be given a BI-RADS category 0 assessment and recalled for further diagnostic studies [31].

V. DOCUMENTATION

B. Communication of Mammography Results to Health Care Providers[3]

1. A facility must provide the interpreting physician's written report from the mammogram examination, including the name of the patient and an additional patient identifier, to the patient's health care provider as soon as possible, but no later than 30 days from the date of the mammography examination [15].
2. However, if the final assessment is a BI-RADS category 4 or 5, the facility should make a reasonable attempt to communicate directly with the health care provider as soon as This should occur within 3 working days from the date of interpretation, via either verbal communication or a written report.
 - a. If the health care provider is unavailable, the report should be given to that provider's responsible designee.
 - b. Direct verbal communication with the health care provider should be documented permanently in the medical record, preferably in the mammography report.
 - c. In all cases, the patient's health care provider must receive a written report, even if the results were verbally communicated [15].

[3] If the patient is self-referred, or their named health care provider declines responsibility, see section V.C.3.

V. DOCUMENTATION

C. Communication of Mammography Results to Patients

1. A facility must directly give or send each patient a written summary of their examination results, in lay

terms, no later than 30 days from the date of the mammographic examination [15].

2. However, if the final assessment is a BI-RADS category 4 or 5, the facility should make a reasonable attempt to communicate directly with the patient as soon as This should occur within 5 working days from the date of interpretation.
 - a. Direct verbal communication with the patient should be documented permanently in the medical record, preferably in the mammography If unsuccessful, the communication attempt may be documented.
 - b. In all cases, the facility must provide the patient with a written summary of their examination results, even if the results were verbally communicated [15].
3. For self-referred patients, the facility must directly give or send the patient both the physician's mammographic report and a written summary of their results in lay terms, no later than 30 days from the date of the mammographic examination.
 - a. Reports with an assessment of BI-RADS category 0, 3, 4, or 5 should be communicated as soon as possible to the self-referred patient; this should occur within 5 working days from the date of interpretation. The actual or attempted communication should be documented.
 - i. Facilities must have procedures for referring such patients to a health care provider, with documentation that this has occurred. The radiologist may act as a referring physician if they are willing to accept responsibility for the patient's medical care, and the patient agrees.

VI. EQUIPMENT SPECIFICATIONS

Mammography equipment (digital and screen-film) must meet the MQSA regulations published by the FDA [9]. Equipment used for diagnostic mammography must have magnification and spot-compression capability. The [ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Mammography](#) provides additional guidance for digital mammography acquisition and display equipment [43].

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals in accordance with ALARA principles. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by applicable state, local, or other relevant regulatory agencies and accrediting bodies, as appropriate. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol, using body habitus or other customized method when such guidance is available.

Nationally developed guidelines, such as the [ACR's Appropriateness Criteria](#)[®], should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently[®] for children (www.imagegently.org) and Image Wisely[®] for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with

the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

A. General

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

B. Quality Control

1. A documented QC program with procedure manuals and logs must be maintained and comply with the MQSA regulations published by the FDA [15].
 - a. Accreditation by the ACR Mammography Accreditation Program documents compliance with the requirements in this
2. Quality assurance for full-field digital mammography
 - a. The FDA requires that the facility's quality assurance program be substantially the same as the quality assurance program recommended by the image receptor (ie, digital detector) Mammography facilities should refer to their manufacturer's QC manual for a list of the required equipment tests (including tests of peripheral devices, such as monitors and laser film printers).
 - b. The FDA approved an ACR alternative standard request [51] to allow mammography facilities to use the 2018 ACR Digital Mammography Quality Control Manual [49] and Digital Mammography Quality Control Phantom for routine QC of digital equipment instead of their manufacturer's QC manual.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

C. Radiation Dose

The average glandular dose delivered by a single craniocaudal view of a 4.2-cm thick, compressed breast consisting of 50% glandular and 50% adipose tissue must not exceed 0.3 rad (3.0 mGy), although it is generally much lower [52]. DBT, when acquired in addition to standard full-field 2-D digital images for a screening examination, increases radiation dose; use of a reconstructed ("synthetic") 2-D image as a substitute for standard mammographic images may be employed to reduce radiation dose [11,53].

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

D. Medical Outcomes Audit

1. MQSA regulations require that each facility establishes and maintains a mammography medical outcomes audit program, designed to ensure reliability, clarity, and accuracy in the interpretation of mammograms [15,31,54,55].
2. An audit program allows each facility to follow up BI-RADS categories 4 and 5 assessments, and correlate pathology results with the interpreting physician's findings. In addition, the ACR also strongly recommends follow-up of BI-RADS category 0 assessments [15,31,56].
 - a. Each facility must have a documented policy for collecting outcomes data on biopsied cases

interpreted by its physicians, both individually and collectively, at least
b. It is understood that in most practice situations it will not be possible to obtain follow-up information on all positive

3. The ACR National Mammography Database provides benchmarks for outcomes data including recall rates, cancer detection rates and positive predictive values [57-59].

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