

# The "Laboratory" Effect: A Review of Radiologists' Performance and Variability in Clinical and Laboratory Mammography Interpretations in Saudi Arabia

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## Abstract

Mammography interpretation is a critical component of breast cancer detection, and its accuracy significantly impacts patient outcomes. In Saudi Arabia, the demand for mammography exams has increased substantially, posing challenges for radiologists, especially due to the limited number of trained professionals. This study explores the variability in mammography interpretations between clinical and laboratory settings, focusing on the influence of the laboratory environment on radiologists' performance. The objective was to assess the sensitivity, specificity, predictive values, and overall performance of clinical versus laboratory readings, comparing results across different radiologists. The study highlights the factors contributing to variability, including training, equipment calibration, and institutional protocols. It also underscores the importance of continuous professional development, quality assurance measures, and standardized protocols to reduce discrepancies in interpretation. By examining real-world case studies, the research provides insights into the impact of the laboratory effect and offers recommendations for improving mammography reading consistency. The findings emphasize the need for enhanced training, collaboration, and the integration of advanced technologies like AI-assisted tools to optimize mammography interpretation practices in Saudi Arabia and beyond.

## 1. Introduction

Mammography readings play a critical role in the early detection of breast cancer, empowering women to undertake preventive measures. As such, mammography is a crucial modality for screening and detecting incidental findings in women. Worldwide, the number of mammography wet exams is on the rise. Saudi Arabia is no exception; the volume of mammography exams has increased over 8-fold, from 6,710 exams in 2007 to 56,541 exams in 2017 (Alakhras et al., 2021). This increase necessitates additional clinical mammography interpretation by radiologists. Unfortunately, the supply of mammography-trained radiologists in Saudi Arabia is limited, leading to an exacerbation of the already existing clinical workload challenges.

Reading mammograms is complex, involving subjective judgment and decision-making under uncertainty, with a high degree of variability in radiologists' interpretations. This variability can be detrimental as it can lead to interpretative discrepancies and missed findings, as well as unnecessary workups and procedures. While several studies have focused on radiologists' performance and variability in mammography interpretation in laboratory settings, it remains an open question whether the same trends hold in clinical settings. Furthermore, most existing studies are based on the U.S. healthcare system, which differs greatly from the Saudi context. Notably, Saudi Arabia is a developing country, and the challenges faced by its healthcare system are distinct when compared to developed ones. In Saudi Arabia, there is also great variability in the performance of radiologists/interpretive providers in mammography readings.

Most studies have only examined either clinical or laboratory settings, even though the settings differ greatly in design, mammograms read, workflow, and hence the possible confounding factors. This is especially relevant given that mammography exams usually start with a clinical interpretation, and additional laboratory interpretations are usually made later. Therefore, one aim of this study is to examine the influence of the laboratory effect on radiologists' performance and variability in clinical and laboratory mammography interpretations. To facilitate the interpretation of results pertaining to this aim, it is necessary to provide an overview of studies that have investigated the laboratory effect, as well as studies that fall short of this, focusing outside the laboratory effect or the Saudi context altogether. (Dunn et al.2021)(Statsenko et al.2022)

### 1.1. Background and Rationale

In response to the rapidly increasing incidence and resultant healthcare burden of breast cancer, Saudi Arabia implemented the National Breast Cancer Screening Program in November 2013. A screening mammogram must undergo a clinical interpretation by an NHS-employed radiologist. Following a clinical interpretation, a mammogram, either screen or symptomatic, may also undergo a "laboratory" interpretation. A mammogram interpreted in a laboratory setting was viewed as a secondary reading. Typically, these readings are performed by non-consultant radiologists in training or by consultant radiologists outside routine clinical reading sessions. However, in Saudi Arabia, there is a single training pathway for radiology, and hence all radiologists, upon completion of training, have the same level of qualification. As such, the additional laboratory reading is by design by radiologists who are at the same training level as those who performed the clinical reading (Alakhras et al., 2021). Where laboratory interpretations are used, clinical and laboratory reads are considered either in succession or concurrently on the same mammogram. In this context, comparisons can be made within reading "modes," where both clinical and laboratory reads are by the same observer, and also between reading modes, where a clinical read is by one observer and a laboratory read by another.

Mammography screening has become a widely used screening modality due to its ability to reduce breast cancer mortality. Continuous quality assurance of screening programs is, therefore, of utmost importance. Breast cancer is the most frequently diagnosed cancer in women in Saudi Arabia, accounting for 29% of all cancer cases. Saudi Arabia is a rapidly developing nation. Breast cancer screening programs find it challenging to keep pace with this new demand from breast cancer screening mammograms and mammograms submitted for symptomatic clinical work-up. Diagnostic mammograms screening mammograms of women enrolled in the Saudi National Breast Cancer Screening Program often require multiple interpretations. In addition, clinical mammograms, mammograms taken because of a presenting clinical symptom, also require interpretation by a radiologist. Breast cancer is the leading cause of cancer-related death among women in Saudi Arabia. There is a significant disparity in screening mammography interpretation performance between clinical and laboratory mammography reading modes. This wide variability in performance is associated with differences in reporting workload and time taken to interpret mammograms. There is a significant disparity in screening mammography interpretation performance between clinical and laboratory mammography reading modes. The widescale variability in performance is associated with differences in the screening mammography interpretation performance between clinical and laboratory mammography reading modes. (Basudan, 2022)

### 1.2. Research Aim and Objectives

The purpose of this study was to investigate the effect of a "laboratory" on the performance and variability of clinical and laboratory mammography readings among three radiologists in Saudi Arabia. This research is timely and relevant given recent advances in laboratory mammography and the important role of the radiologist in clinical interpretation. The findings of this study could help in planning future laboratory mammography installations, mammography residency education, and tracking mammography reading performance and variability over time. The specific objectives of the study were to: 1) determine the overall sensitivity, specificity, positive predictive value, and negative predictive value of clinical and laboratory readings, and to compare performance across radiologists and between reading types; 2) analyze the distribution of clinical and laboratory reading performance for all five outcome measures, and to compare performance across radiologists and between reading types; and 3) assess the effect of a "laboratory" on clinical and laboratory reading performance and variability, incorporating covariates for comparison across outcomes, radiologists, and reading types.

## 2. Radiologists' Performance in Mammography Interpretations

Interpreting mammograms is the reading of safety reports generated from the lab, which assess the performance of mammography equipment against national standards to comply with regulatory requirements. It is important to note that the mammograms being interpreted in this study are screening mammograms and not diagnostic mammograms, which are

requested by clinicians upon examination of patients with clinical symptoms appearing on prior screening mammograms. Screening mammograms are the primary detection method against breast cancer for women of a certain age and thus require careful interpretation (Alakhras et al., 2021). A mammogram interpretation describes the auditor, usually the head radiologist of the facility, employing a specific clinical procedure for interpreting mammograms taken in the laboratory mammography environment. It summarizes the performance of the laboratory mammography environment and the clinical interpretation audit reports generated from the clinical mammography environment. Although the clinical and laboratory mammography interpretations are similar in languages spoken, environment design, and equipment used, there are considerable differences in the objectives and procedures between the two. Most mammography interpretative studies have focused on one or the other. Therefore, this review seeks to present an overview of radiologists' performance in interpreting mammograms by catering to both environments while highlighting their differences (Taplin et al., 2008). Standard performance metrics such as accuracy, sensitivity, and specificity are first defined, with an explanation of how these metrics are applied for effective diagnosis. A discussion of the care levels and training/experience of the radiologists reading the mammograms follows, emphasizing the direct impact of these factors on interpretation outcomes. Then, findings from various interpreting studies across the world, with a focus on Saudi Arabia, are reviewed. Finally, the methodology of interpretive studies is discussed, along with the procedures for reading mammograms. The review ends by discussing the clinical mammography environment's particulars while noting areas needing further research, such as quality control measures to help enhance performance in mammography readings. Statistics indicate that breast cancer is the most prevalent cancer among women and the leading cause of cancer-related death. Recommendations for mammography screening for women above a certain age, as early detection through screening significantly improves treatment outcomes. In Saudi Arabia, women aged 40 and above are screened for breast cancer through mammography. (AlAbdulKader et al.2023)(Alqahtani et al.2021)

## 2.1. Clinical Mammography

Clinical mammography refers to the imaging of a patient's breasts, typically performed with low-dose X-ray systems, in a clinical setting to assist in the diagnosis of breast abnormalities. Clinical images are either screening or diagnostic images. In regard to screening clinical images, similar to laboratory images, a cohort of patients is screened for the presence of breast abnormalities that may have been previously undetected. Alternatively, a patient may present with one or more specific signs or symptoms of breast abnormality that necessitate the taking of diagnostic clinical images. Regardless, clinical mammography interpretation considers the reading of clinical mammography images by radiologists, typically following a series of events that constitute a clinical workflow.

Initially, a patient meeting certain criteria is screened, and clinical mammography images are acquired with a mammography system. A patient's eligibility for screening is typically determined by patient screening history, age, and the presence of risk factors for breast cancer such as family history and ethnicity. Afterwards, the acquired clinical mammography images are formatted into a digital file and tagged with relevant information such as patient identification, acquisition time, and imaging technique. The clinical images, along with the associated information, are then forwarded to a picture archiving and communication system (PACS) for storage and retrieval. A clinical workstation connected to the PACS is used by radiologists to view the clinical images in conjunction with the associated information and patient history. Finally, the clinical mammography images are interpreted by a radiologist, and a clinical report is generated concerning the findings of the interpretation (Alakhras et al., 2021).

The most common image acquisition method for clinical mammography is the use of dual-energy solid-state digital systems. In mammography, the term "clinical" refers to the use of mammography in a clinical setting, typically hospitals, as opposed to a laboratory setting. Clinical mammography is used to assist in the diagnosis of breast cancer and therefore is read by radiologists who typically undergo more rigorous training compared to those reading laboratory mammography images. Despite the training, there are still many challenges that potentially lead to false negative readings, similar to those faced within a laboratory setting. Clinical mammography interpretation results in variability and inconsistency in the interpretation amongst radiologists, and diagnostic performance metrics typically score below the global average (Taplin et al., 2008).

Having a robust clinical practice is particularly critical in clinical settings involving triaging, as poor clinical practice consistency across practitioners may greatly affect patient outcomes. For instance, a clinical practice that has good average performance but wide variability could potentially lead to consistent poor outcomes for some patients. In general, a clinical setting's clinical practice is scrutinized, audited, and regulated such that it is standardized as much as possible. Nonetheless, clinical practices are still affected by variability in the reliance on clinical judgment, particularly in more subjective aspects

such as mammography interpretation. Given the interpretation is considered a clinical judgment, it is important to discuss interpretation results within the context of clinical interpretation. (Guerra-Farfan et al.2023)

## 2.2. Laboratory Mammography

Laboratory mammography examines mammograms for abnormalities and possible malignancies in a controlled interpretation environment, either at a dedicated off-site location or on fixed equipment in a mobile unit. Each facility must have a quality assurance program designed to limit the probability of processing errors, equipment malfunctions, and other interpretive deficiencies that may adversely affect women's health care. Some quality control and quality assurance protocols performed at laboratory mammography facilities are not usually practiced in routine clinical settings. For example, daily, weekly, monthly, and yearly calibration of mammographic equipment is mandated in laboratory protocols to ensure mammograms are acquired within acceptable limits for sensitivity and precision. In most clinical practices in Saudi Arabia, calibration is either not routinely performed or results are not documented. Laboratory mammograms are interpreted by a registered radiologist using diagnostic technologies that differ from those employed for clinical interpretations. A review of scientific articles on mammography screening, laboratory clinical trials, and breast cancer outcomes revealed that research initiatives were conducted in clinical settings, while only a few were executed in laboratory environments (Taplin et al., 2008). Hence, it is vital to comprehend the unique factors that govern the performance and variability of mammography interpretations in a laboratory environment and disclose the outputs from the Saudi Arabian laboratory settings. Overall effectiveness in laboratory mammography is assessed with fixed metrics in terms of turnaround time (TAT) between mammograms acquisition and readings, precision in number of possible malignancy grades (C) in each reading, and knowledge base size (K) used to interpret each mammogram. Radiologists have a progressive interpretive reading system, where an acquired mammogram is read by a selected sequence of the same radiologist or multiple other radiologists to limit the probability of missed high-grade malignancies. The readings are either “positive” or “no findings” for mammogram abnormalities. A reading is considered positive for an abnormality if the radiologist assigned a possible malignancy grade  $\geq 1$ . The interpretive outcome for each mammogram is either a miss, when the lowest assigned grade for a reading is  $< 1$ , or detected, when the mammogram is found abnormal after at least one high-grade reading ( $C \geq 1$ ). Laboratory mammography studies reveal variability in overall performance due to differences in mammographic equipment, post-processing technologies, and other methodological discrepancies among the facilities; fixed performance averages range from 70.2 to 98.5% for detected high-grade malignancies and from 44.6 to 94.5% for detected mediolateral oblique views. Variability in net interpretive accuracy is observed mainly due to differences in training and experience levels of the interpreting radiologists, where performance ranges from 70.2 to 88.8% for detected high-grade malignancies. One laboratory study performed same-day acquisitions and interpretations, while in another study reading delay was up to one month. Even slight reading delays of 1-7 days yielded poorer net interpretive accuracy compared to same-day interpretations. Essentially all laboratory studies reported significant variability in performance as a function of differences in mammographic equipment, which affect the certainty and precision of detected abnormalities across laboratory facilities; fixed accuracy averages range from 70.2 to 98.5% for detected high-grade malignancies. In general, routine clinical mammography settings encompassing diverse technologies do not replicate anatomic pathologist's reading panels for fixed-acquisition screening histopathology examinations, wherein fixed performance averages exceed 90% for detected high-grade malignancies. Varied technological setups and acquisition/post-processing methodologies in clinical mammography give rise to significant variability in performance, with net interpretive accuracy typically exceeding the best mammography laboratory sensitivities. Clinical settings should strive to replicate as closely as possible the factors accounting for superior laboratory performance. As with clinical mammography, a foremost concern in mammography laboratory settings is the probability and consequence of missed high-grade malignancies. Of the laboratory studies reviewed, some sensed and reported missed cases; however, in some studies it remains unclear whether high-grade malignancies were missed due to their subtlety or as a consequence of progressively engineered reading systems differing from the clinical paradigm. Even with rigid quality control, facilitation of mammography laboratory readings involves challenges. All Saudi Arabian mammography facilities are accredited by the Central Board for Accreditation of Healthcare Institutions, which mandates quarterly review of equipment calibration and quality assurance tests. Nonetheless, there are difficulties related to efficient equipment upkeep and calibration. Travelling to mammography acquisition locations is costly and time-consuming, but fixed equipment in mobile units may necessitate transfer to central locations for minimum 3-day equipment checks and calibration. (Chen et al.2023)(Yoon et al.2023)

### 3. Variability in Mammography Interpretations

The pivotal function of mammography in the early detection and diagnosis of breast cancer solidifies its standing as the preferred image modality. Despite advancements in technologies and techniques, the reliability of mammography interpretation rests heavily on the expertise of radiologists, making them instrumental in the success of the screening program. However, the diagnostic performance of radiologists is susceptible to various influences, with variability in interpretations significantly impacting performance (Taplin et al., 2008). Variability is an inherent trait of mammography interpretations, with an "interpretation" defined as a mammogram read or opinion drafted by a radiologist. In essence, variations can stem from differences in the same reading by different radiologists or even the same radiologist at different times. With the growing reliance on mammography screening, understanding these variabilities is crucial for the interpretation of performance assessments and for developing strategies to standardize interpretations.

Numerous factors contribute to the variability of mammography interpretations, shaping how mammograms are read. Chief among these are the training, experience, and individual biases of the interpreters. Even with casual exposure to mammography, differences in how a mammogram is interpreted can arise. Generally, individual interpreters conceptualize and approach interpretations differently, leading to variabilities in results. Beyond individual differences, a multitude of additional factors can influence interpretation. The advancements in technology and tools, the designs and setups of interpreting environments, institutional policies, and even medicolegal contexts can all affect how mammograms are interpreted. These variabilities, intrinsic to the interpretation process, can produce different outcomes for the same reading and consequence discrepancies in diagnosis and, consequently, patient management strategies. Empirical evidence from mammography interpretation studies will be examined to illustrate these variabilities in clinical and laboratory settings, providing a foundational understanding of efforts undertaken to lessen variabilities. By examining variability in mammography interpretations, a backdrop is formed for the evaluation of performance metrics in the following sections.

#### 3.1. Factors Influencing Variability

Variability in mammography interpretations has been well-documented and is influenced by individual, contextual and systemic factors. Individual factors include cognitive biases, fatigue, differences in training and experience in interpretation, professional discipline and additional qualifications (Taplin et al., 2008), while contextual influences comprise the quality of the imaging equipment, viewer display, reading format, work pressure, backlog control, environmental conditions, reading room design and noise levels. Systemic influences include the institution's protocols, peer review processes, work culture, and degree of openness and honesty in discussing differences in interpretation. These factors can be grouped under the three broad categories of individual, contextual and systemic influences on radiologists. It should be noted that these influences do not act in isolation but are inter-linked and can have a cumulative effect on the outcomes of the interpretations. Though variability in interpretation has been acknowledged as a problem for mammography screening, it remains difficult to address and most solutions only tackle some aspects of variability. Training, continuous professional development, and awareness of the existence and nature of variability are likely to mitigate some variability. However, variability is complex and nuanced; it is likely that many solutions may alter outcomes but will not fully eradicate variability. Nonetheless, understanding how these characteristics influence performance could provide facilities with actionable steps to tackle the challenges posed by variability.

### 4. Case Studies and Research Findings

Case studies provide an opportunity to explore real-world examples that illustrate the research findings in the field of clinical mammography interpretations and the laboratory effects observed in mammogram screenings. A case study approach, consisting of three specific cases, is employed to achieve this objective. Each case study elaborates on the methods used and the outcomes observed, enhancing the understanding of variations in interpretations. Furthermore, the specific challenges faced by radiologists in each case context are highlighted, demonstrating that the issues relating to the laboratory effect are not confined to one particular place or practice. By presenting findings from these case studies, a validation of the research objectives outlined in the introduction is conducted. It is also possible to compare the results among different practice settings, such as hospitals versus clinics. On a broader level, this section serves as a platform to discuss practical implications based on empirical evidence. Finally, it invites further reflection on how the lessons learned from these case studies can inform future practices. (Yapp et al., 2022)(Wong, 2023)

Each case study highlights one or more important facets of the research findings that mammogram screenings at a clinical facility setup differently from hospital practice can have a laboratory effect on the performance of radiologists. The first case

considered has mammogram acquisitions from clinical screenings interpreted in a hospital setting. Unlike the hospital pathology, where a laboratory effect is not observable and clinical readings show lower performance, hospital interpretive readings of clinical examinations render opposite outcomes. It is demonstrated that double reading in clinical setups is essential for acceptable sensitivity levels and that radiologist performance is more sensitive to the variability in the reader pool in clinical setups. A focus on reading workflow sheds light on the time constraints imposed on the interpreters in clinical practice. These findings highlight the need for a different approach to quality assurance in clinical mammography interpretations (Alakhras et al., 2021).

The second case focuses on the opposite setup, where clinical mammogram screenings are interpreted in a portable unit outside the hospital setting. While findings similar to the first case are observed, this case also highlights that the laboratory effect is not entirely negated in this arrangement. Furthermore, it also shows that without a rigorous reading procedure in place, double reading readings alone may not be sufficient to maintain good sensitivity levels, as evident from the deterioration in interpretive performance in a continuously operated unit. In this context, certain recommendations are made on strategies that could mitigate the effects of interpreted reading variability. (Quilty et al.2023)

## 5. Implications for Practice and Policy

The research findings underscore a critical need for standardization in mammography interpretation processes to enhance diagnostic accuracy. In Saudi Arabia, where inconsistencies in mammography interpretation among radiologists have been observed, mammography readings often resemble a “laboratory” process rather than a unified clinical examination despite standardization efforts in the interpretation procedure (Alakhras et al., 2021). Therefore, training programs specifically designed to address the factors influencing variability are recommended. These programs should explore the potential of pairing less experienced readers with highly experienced ones to optimize training benefits. Regular re-evaluation of training programs is essential to ensure their relevance and efficacy. In addition to training programs, the development of institutional guidelines and protocols is advised to unify practices among radiologists. Although the Saudi guidelines establish a foundation for uniform mammography interpretation, the diversity of practices among individual radiologists suggests a need for supplementary institutional guidelines. Furthermore, the integration of advanced technology, such as Computer Aided Detection systems, is encouraged, alongside the implementation of quality assurance measures to provide feedback on individual performance. Sensitivity audits should be mandatory, tracking the recall rates of detected breast cancers to identify underperforming readers. (Albeshan et al.2022)

Addressing both individual and systemic factors contributing to variability is crucial, as it aligns closely with the research objectives stated earlier. Individual factors encompass the influence of reader experience and training, ranging from a minimum of 5 years to over 30 years of experience interpreting mammograms. Variability in clinical outcomes can be mitigated through appropriate training and experience. Systemic factors consider how the interpretation framework is structured, including aspects such as the reading environment, availability of prior examinations, and the interpretation modality. An improved understanding of how these factors impact variability can aid in designing interventions to enhance performance in laboratory settings. Despite this, it is acknowledged that not all variability should be eliminated, as some environmental variability can benefit performance. Overall, this discussion highlights the need for enhanced training and systematic approaches to tackle consistency issues, with the goal of improving patient care and overall health outcomes. Ultimately, this section serves as a catalyst for change, clearly outlining the necessary actions required to translate research findings into improved clinical outcomes. (Grailey et al., 2021)(Altun et al.2022)(Hua & Wang, 2023)

### 5.1. Recommendations for Improving Interpretation Consistency

To ensure better consistency in the results of mammography interpretations, several recommendations for change are proposed based on the findings of this study. First and foremost, there should be a strengthened focus on educational and training programs that aid in the development of the skills required to conduct the interpretations. In particular, ongoing education efforts and the promotion of additional training opportunities would work toward enhancing the performance of individual radiologists in conducting a particular reading task (Alakhras et al., 2021). Second, the implementation of a set of standardized protocols that guide the reading and interpretation processes could help minimize between-reader differences in interpretation. The establishment of a culture that encourages reading protocol adherence would also benefit consistency in interpretations.

Additionally, the establishment of peer review systems in which a proportion of interpretations are randomly selected for screening by a second radiologist would help identify inconsistent interpretations. Joint reading sessions could also help foster

collaborative practices among radiologists, thereby creating a culture of continuous improvement (Taplin et al., 2008). Technological advancements such as AI-assisted interpretation tools might prove beneficial, as they could expose radiologists to more consistent training samples, allowing them to achieve more consistent results. Likewise, the establishment of regulatory bodies that oversee the mammography interpretation practices at clinics and hospitals would help ensure a minimum level of performance by setting minimum standards for the number of continuing education hours or the requirement of multiple readings.

Finally, ongoing research efforts that follow the same interpretation task over time would be beneficial in analyses of the effectiveness of the recommended measures, as some of them may take time before the effects on consistency become apparent. It is hoped that research efforts like this one, that pinpoint areas in need of improvement and suggest actionable steps toward implementing those improvements, will be undertaken at other institutions where similar analyses could expose other needs for change.

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