UCLA leads $16 million PRISM trial testing the use of artificial intelligence to augment breast cancer screening

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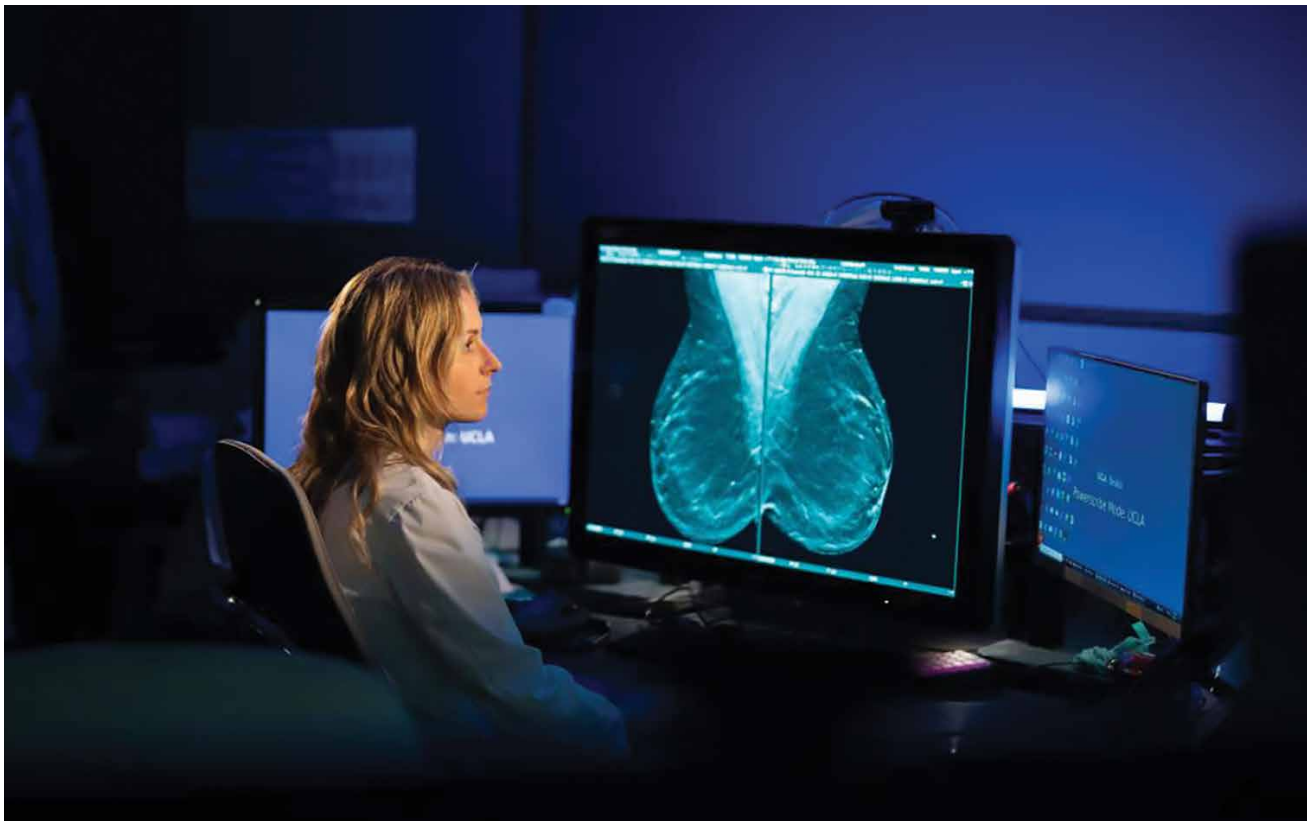
In concert with UC Davis, UCLA is leading a large clinical study across six institutions and multiple clinical sites to validate the effectiveness of using AI assistance when radiologists interpret screening mammograms. The PRISM Trial (Pragmatic Randomized Trial of Artificial Intelligence for Screening Mammography) is a prospective, randomized control trial that will track cancer detection and callback rates as its primary outcomes. The trial is led by Joann Elmore, MD, MPH, professor of medicine in the UCLA Department of Medicine and professor of health policy and management at the UCLA Fielding School of Public Health (dual PI), Diana Miglioretti, PhD, professor and division chief of biostatistics at UC Davis (dual PI), Christoph Lee, MD, MS, MBA, professor of breast imaging at the University of Wisconsin, Madison (co-PI) and Hannah Milch, MD, UCLA associate professor of radiology (co-PI and UCLA site PI).



Dr. Hannah Milch, Co-Principal Investigator and Site PI, and Associate Professor of Radiology at UCLA, reviews a mammogram for signs of breast cancer.

Dr. Milch explains, “not only do we want to increase the diagnosis of clinically meaningful cancers that can impact morbidity and mortality, but we also want to minimize how often women are called back into the health system when they’re healthy, but something seen on the mammogram triggers additional tests and sometimes a biopsy — sometimes even surgery — when there’s no cancer. We want to see if AI helps with both.”

While other, smaller studies in more limited experimental settings produced results that have led to FDA approval of some AI products and encouraged their early adoption, history has shown that such experimental use does not always translate into real-world practice. Dr. Milch points to the rapid adoption of an earlier, non-AI technology known as computer-aided detection (CAD), which quickly became popular in the early 2000s as a tool for helping radiologists detect breast cancer. By 2016,

over 90% of imaging centers in the U.S. were using CAD, when some large studies demonstrated that it in fact increased recall rates and adversely affected diagnostic accuracy. "The promise in the experiments that led to FDA clearance and insurance coverage did not translate to real-world practice," states Dr. Milch. "So this time, we want to do a better job by diligently testing AI in real-world practice and trying to make sure that we have the highest level of evidence proving that it works before it is universally adopted, before insurance potentially covers it, and before we tell patients it really helps."

The PRISM Trial aims to include approximately 400,000 mammograms over a period of two years, including patients at six medical centers in five states across the U.S. The study sites include UCLA, Boston Medical Center, UC San Diego, University of Miami, University of Washington and University of Wisconsin, Madison. The vast majority of mammogram images will be digital breast tomosynthesis or 3D mammography as that is the standard at the participating centers, and the growing standard in the U.S. Each center will continue to use its customary workflow, with the only difference being that each mammogram will be automatically randomized to either the AI group or the non-AI group. When the images are interpreted, those in the AI group will have the additional information added by the AI tool. All mammograms will receive standard-of-care full interpretation by a radiologist; when viewing images in the AI group, radiologists will be able to use the AI to gain additional insight, but final decisions are all made by radiologists.

While screening mammography false positives can be detected in the first few months as patients are called back for further workup, determining false negatives generally takes longer. The patients enrolled in the PRISM Trial will be followed via cancer registries to assess cancer outcomes. While callback rates and cancer detection are the primary outcomes of the study, some of the secondary outcomes — which can take longer to uncover — are arguably even more critical. "Interval cancer rate is one of the most important metrics we'll be collecting, because that's one of the best surrogates we have for screening effectiveness," explains Dr. Milch. "You're trying to catch cancers before women present with symptoms, and interval cancers refers to cancers diagnosed after a negative screening mammogram."

Another important secondary outcome involves looking at detection by breast cancer type. If AI is found to assist radiologists in the early detection of breast cancer, for which breast cancer types is it most effective? "We want to be detecting the most clinically meaningful breast cancers," explains Dr. Milch, "the ones that are most likely to be aggressive and affect prognosis, mortality and morbidity."

In addition to tracking clinical outcomes, an important component of the study will be to collect information from both patients and radiologists on attitudes toward the use of AI in screening mammography. Patient focus group sessions will focus on understanding patient perspectives on the use of AI in screening mammography, and could have implications for things like how best to communicate with patients about the use of AI. What is learned in these focus groups could have implications in other areas of health care that are beginning to incorporate the use of artificial intelligence. The study will also include surveys of radiologists to understand their perspective on the use of AI in screening mammography. It will look at variations in radiologists' trust in AI, how they use it and whether they may over- or under rely on it.

The trial is funded through a $16 million award from the Patient-Centered Outcomes Research Institute (PCORI). The AI tool used in the PRISM Trial will be Transpara, which is FDA cleared for 2D and 3D mammography.

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