PROTOCOL

AI-Assisted Mammography Screening: A Systematic Review and Meta-Analysis of Cancer Detection, Recall Rates and Workflow Outcomes

Prepared a priori before literature search | 2026

1. Title

AI-Assisted Mammography Screening: A Systematic Review and Meta-Analysis of Cancer Detection, Recall Rates and Workflow Outcomes.

2. Registration

This protocol was prepared a priori and is deposited on the Open Science Framework (https://doi.org/10.17605/OSF.IO/PHZY6).

3. Review question

In women undergoing screening mammography, does AI-assisted reading (concurrent support, triage or reader replacement) improve cancer detection rate, reduce or stabilise recall rate, and reduce radiologist workload compared with standard double reading?

4. Objectives

Primary: Quantify the absolute and relative effects of AI-assisted mammography screening on cancer detection rate (cancers per 1000 screens) and recall rate versus standard double reading.

Secondary: Summarise effects on sensitivity, specificity, positive predictive value of recall, reading time, throughput and workload reduction; explore heterogeneity by AI role, study design and setting.

5. Eligibility criteria (PICOS)

Population: Women attending asymptomatic screening mammography (organised or opportunistic programmes).

Intervention: Any commercial or research AI system used as concurrent decision support, triage/gatekeeper, or replacement of one human reader.

Comparator: Standard single or double human reading without AI.

Outcomes:

- Primary: Cancer detection rate (per 1000 screens); Recall rate (proportion or per 1000).
- Secondary: Sensitivity, specificity, PPV of recall, reading time, throughput, relative workload reduction.

Study designs: Randomised controlled trials, prospective cohorts, large retrospective before-after comparisons, paired non-inferiority designs, implementation studies with empirical outcome data.

Exclusions: Pure diagnostic-accuracy studies without screening context; case series; editorials; conference abstracts without full data; systematic reviews; non-English publications; studies published before 1 January 2021.

6. Information sources and search

PubMed/MEDLINE, Embase, Scopus, and the Cochrane Library were searched from 1 January 2021 to the search date. Complementary hand-searching of reference lists of included studies and recent reviews. Full Boolean search string combining MeSH and free-text terms for artificial intelligence / machine learning / deep learning / CAD, mammography / breast cancer screening, and outcomes (cancer detection, recall rate, sensitivity, specificity, false positive, workflow).

7. Study selection

Title/abstract screening and full-text assessment were performed independently by two reviewers against eligibility criteria. Disagreements were resolved by discussion and, if needed, a third reviewer. A PRISMA 2020 flow diagram will be reported.

8. Data extraction

Pre-piloted form capturing: study identifiers, design, country/setting, sample size, AI system and role, outcome counts (CDR, recall, sensitivity, specificity, PPV), and workload metrics. Key numerical results from the largest studies to be cross-verified against original publications.

9. Risk of bias

RoB 2 for randomised trials; ROBINS-I for non-randomised studies. Domain-level and overall judgements summarised.

10. Data synthesis

Random-effects meta-analysis (DerSimonian-Laird estimator with Hartung-Knapp adjustment) for absolute differences in CDR and recall rate, and for odds ratios of sensitivity/specificity where data allow. Heterogeneity assessed with I^2 and Cochran's Q. Pre-specified subgroups: study design, AI role, geographic region. Leave-one-out and low-risk-of-bias sensitivity analyses. Publication bias examined with funnel plots and Egger test when ≥10 studies. Certainty of evidence rated with GRADE.

11. Software

R (meta, metafor packages) for quantitative synthesis.

12. Ethics

Secondary analysis of published aggregate data only. No new human participants; institutional ethics approval not required.

13. Amendments

Any amendments to this protocol will be documented with date and rationale in the final manuscript.

This protocol was prepared a priori for deposition on the Open Science Framework prior to completion of the literature search and data extraction.