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INPLASY

Artificial Intelligence Applications for the Diagnosis of Otitis Media: A Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Faculty of Data Science, City University of Macau.

Review Stage at time of this submission - The review has not yet started.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 August 2026 and was last updated on 21 November 2026.

INTRODUCTION

Review question / Objective To evaluate the diagnostic accuracy of artificial intelligence applications, covering machine learning, deep learning and related computational models, for otitis media of any type in patients of any age, against an adequate reference standard. The question is framed in PIRD format: participants are patients with suspected or confirmed otitis media of any subtype; the index test is any artificial intelligence model applied to clinical, otoscopic, tympanometric, audiometric or imaging data; the reference standard is otoscopy, tympanometry, myringotomy, surgery or expert adjudication; the target condition is otitis media, reported overall and by subtype and age band.

Rationale The registered protocol was restricted to children aged 18 years or younger with secretory otitis media. The searches used the exploded MeSH term Otitis Media, which retrieves every subtype and every age group; no age or subtype limit was applied at the search stage, deliberately, so that sensitivity was not lost before eligibility could be judged.

Of the 70 studies that met the eligibility criteria, 24 addressed the originally registered population and condition. The remaining 46 addressed adults, other subtypes, or mixed populations, and reported diagnostic accuracy against an acceptable reference standard in the same form. Restricting the review to the registered population would have discarded two thirds of the eligible evidence and left a synthesis too small to inform practice.

The scope was therefore broadened to otitis media of all types in all age groups. The decision was taken on 12 August 2026, after the searches and before any study result had been extracted. Analyses and outcomes are otherwise unchanged, and the originally registered population is retained as a pre-specified subgroup, so the paediatric secretory otitis media estimate remains separately reportable.

Condition being studied Otitis media of any type, namely acute otitis media, otitis media with effusion (secretory otitis media), chronic suppurative otitis media and recurrent otitis media, in patients of any age. This replaces the published wording "secretory otitis media in children aged 18 years or younger".

METHODS

Search strategy Three concepts were combined: disease, artificial intelligence methods, and diagnostic application. The disease concept covered all otitis media subtypes and related middle ear and tympanic membrane conditions, using the exploded MeSH term Otitis Media together with free-text terms for the individual subtypes. No age term and no subtype restriction was applied, so the strategy was sensitive to every age group from the outset. The artificial intelligence concept combined generic terms with named algorithms. No methodological filter for diagnostic accuracy studies was applied; quality was assessed at the risk-of-bias stage instead. Limits were Chinese and English language, and inception to the search date. The full strategy for each of the twelve databases is available with the record.

Participant or population Patients of any age with suspected or confirmed otitis media of any subtype, in any clinical setting. No restriction on age, sex, ethnicity or country. Studies enrolling both children and adults were eligible where a combined estimate or extractable subgroup data were reported. This replaces the published population of children aged 18 years or younger with suspected secretory otitis media.

Intervention Artificial intelligence / machine learning / deep learning–based diagnostic models for OME. Eligible algorithms include, but are not limited to: convolutional neural networks (CNN), ResNet, VGG, support vector machines (SVM), random forests, k-nearest neighbors, transfer learning, ensemble methods, and hybrid deep-learning architectures. Input modalities may include otoscopic images, tympanometric curves, pure-tone audiometry data, acoustic reflex data, or multimodal combinations. Threshold- or rule-based methods without a machine-learning component, simple logistic regression without feature engineering, and qualitative expert diagnosis will be excluded.

Comparator Clinical reference standard: pneumatic otoscopy or specialist otoscopy by an ENT/pediatric otolaryngologist; tympanometry (Jerger type B or C); audiological assessment; or myringotomy/tympanocentesis with fluid confirmation. Single reference standards or combinations of these (e.g., tympanometry + otoscopy) are both accepted. Studies without an explicit reference standard will be excluded.

Study designs to be included Diagnostic accuracy studies: cross-sectional studies, case-control studies (nested or traditional), and cohort studies (retrospective or prospective). Both single-gate and two-gate designs are acceptable. Animal studies, conference abstracts, narrative reviews, editorials, case reports, and studies without extractable 2×2 contingency data will be excluded.

Eligibility criteria The exclusion of studies restricted to adult populations without extractable paediatric subgroup data is withdrawn, because it conflicts with the revised population. All other inclusion and exclusion criteria are unchanged: diagnostic accuracy studies of an artificial intelligence model against an acceptable reference standard, reporting data sufficient to reconstruct a 2x2 table, published in Chinese or English.

Information sources Twelve electronic databases were searched from inception to August 2026, with the searches executed on 11 and 12 August 2026: PubMed, Embase, Cochrane CENTRAL, Web of Science Core Collection, Scopus, IEEE Xplore, CINAHL, ProQuest Dissertations and Theses, CNKI, Wanfang Data, VIP (CQVIP) and SinoMed (CBM). Backward and forward citation tracking through Web of Science and Scopus identified 25 additional records. Grey literature and trial registries were checked as registered. No language restriction was applied at the search stage; language was applied at eligibility. The literature search was limited to publications up to August 2026.

Main outcome(s) Diagnostic accuracy of artificial intelligence applications for otitis media, expressed as pooled sensitivity and specificity with 95 per cent confidence intervals and as the area under the summary receiver operating characteristic curve. The target condition is otitis media of any type, replacing the published wording "paediatric

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secretory otitis media". Estimates are reported overall and separately for children with otitis media with effusion, which is the population named in the original registration.

Quality assessment / Risk of bias analysis Methodological quality and applicability concerns of each included study will be independently assessed by two reviewers using the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) tool. QUADAS-2 evaluates four domains: (1) patient selection, (2) index test(s), (3) reference standard, and (4) flow and timing. Each domain is rated for risk of bias, and the first three domains are additionally rated for applicability concerns. Disagreements will be resolved by consensus or by consulting a third reviewer. Risk-of-bias judgments will be summarized in graphical displays (traffic-light plot and summary bar chart) generated in RevMan 5.4 (The Cochrane Collaboration).

Strategy of data synthesis Synthesis follows the registered plan without deviation. Reference management and duplicate removal were performed in Zotero; screening and data extraction were performed in a purpose-built Excel workbook, with two independent reviewers and third-reviewer arbitration. The published record did not name a reference manager or screening platform, so no registered item is contradicted. Summary risk-of-bias figures were produced in RevMan 5.4. The bivariate random-effects model, the hierarchical summary receiver operating characteristic curve and the Deeks test were estimated in Stata 17 using the metandi and midas commands, which is the package named in the registered protocol.

Subgroup analysis The age subgrouping is changed. The registered strata of infants below 2 years, preschoolers aged 2 to 6, school-age children aged 7 to 12 and adolescents aged 13 to 18 presupposed a paediatric population. The pre-specified subgroups are now: children below 18 years versus adults aged 18 years and older, with finer strata where data permit; otitis media subtype; imaging versus non-imaging input; and study design. The paediatric secretory otitis media subgroup reproduces the population of the original registration.

Sensitivity analysis The robustness of the pooled estimates will be tested through the following sensitivity analyses:
1. Excluding studies rated as high risk of bias in any QUADAS-2 domain.
2. Excluding studies with fewer than 30 participants or events in either group (small-study effects).
3. Restricting to studies using a single, well-defined reference standard (otoscopy alone or tympanometry alone).
4. Restricting to prospective studies only.
5. Excluding studies without external validation of the AI model.
6. Excluding studies that contributed disproportionately to heterogeneity (leave-one-out sensitivity analysis).
7. Re-analysis using a univariate random-effects model for sensitivity and specificity separately, to compare with the bivariate results.
8. Re-analysis using a fixed-effect (Mantel–Haenszel) model as a sanity check.

Findings of the sensitivity analyses will be reported alongside the primary pooled estimates, and any substantial changes in the direction or magnitude of the effect will be discussed.

Country(ies) involved Macao, China (first affiliation: City University of Macau) and Hangzhou, China (second affiliation: Hangzhou Medical College).

Keywords artificial intelligence; machine learning; deep learning; diagnostic accuracy; otitis media; sensitivity and specificity; systematic review; meta-analysis.

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Notes NATURE AND TIMING. This amendment broadens the scope of protocol INPLASY202680038, published on 9 August 2026. The registration preceded the searches, which were executed on 11 and 12 August 2026. The scope was revised on 12 August 2026, after the searches and before data extraction. No study result had been extracted at that date, so no result was known when the

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decision was taken. No separate registration has been created for this project.

DEVIATIONS DISCLOSED. (a) The scope was broadened as set out in the Rationale field. (b) This amendment is submitted after the revised methods had been implemented; the deviation will be reported in the publication. (c) The cutoff date for literature search in the published record has now been supplemented and clarified. (d) The author list is expanded from three to five and the corresponding e-mail address is changed.

ANTICIPATED EFFECT ON ANALYSIS AND INTERPRETATION. Broader eligibility raises clinical and methodological heterogeneity. This is handled by reporting the primary analysis separately for the originally registered population of children with otitis media with effusion, by pre-specified subgroup analyses by age band and subtype, and by wording the conclusions for otitis media as a whole rather than for any single subtype. Subtype-specific pooled estimates are reported only where the subgroup analysis supports them.

REVIEW PROGRESS. The review is complete: 10,502 records were identified, 8,385 remained after deduplication, 246 full texts were assessed, 70 studies were included and 29 entered quantitative synthesis. The review status is updated through the status form.

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