

Original Research

Innovations for pediatric otitis media screening for community pharmacy practice in Thailand: A scoping review and conceptual research and development with preliminary testing

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Abstract

Background: Accurate differentiation of acute otitis media (AOM) and otitis media with effusion (OME) requires direct visualization of the tympanic membrane (TM), yet front-line assessment remains challenging in community settings, contributing to unnecessary antibiotic prescribing. This review synthesized contemporary evidence on patient-operable otoscopic technologies to inform diagnosis-first pediatric ear care and evidence-based device development.

Methods: A PRISMA-ScR-compliant scoping review following the Arksey and O'Malley framework was conducted. MEDLINE, Embase, Web of Science, Scopus, Cochrane CENTRAL, IEEE Xplore, trial registries, Thai databases, and grey literature were searched (2000–present). Eligible studies evaluated patient-operated or patient-operable technologies for pediatric otitis media, including smartphone video otoscopy, artificial intelligence (AI), short-wave infrared (SWIR) otoscopy, optical coherence tomography (OCT), and adjunctive tympanometry. Evidence was narratively synthesized, and methodological limitations were mapped.

Results: Contemporary evidence consistently supports a diagnosis-first strategy requiring confirmation of middle-ear effusion and TM inflammatory signs before antibiotic treatment. Smartphone-based video otoscopy combined with AI represents the most mature front-line technology, demonstrating reported diagnostic accuracy ranging from approximately 85% to 95%, feasibility for tele-otology, and potential to reduce unnecessary antibiotic use. SWIR and OCT provide higher-confidence confirmatory assessment of middle-ear effusion (reported sensitivity/specificity 80–91%) but remain constrained by cost and operational complexity. Evidence synthesis further informed the conceptual design of a child-friendly video otoscopy platform integrating an adjustable-focus micro-camera, standardized image-quality assurance, and tele-otology compatibility.

Conclusions: Smartphone-assisted video otoscopy, supported by AI and standardized imaging protocols, is currently the most practical technology for diagnosis-first pediatric otitis media screening. Evidence-informed device development and integration into community pharmacy and primary care may strengthen antimicrobial stewardship, although prospective multicentre clinical validation remains essential before routine implementation.

Keywords: acute otitis media screening, video otoscopy, tele-otology, antimicrobial stewardship, pediatric diagnostics

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INTRODUCTION

Otitis media in early childhood is a leading driver of primary-care visits and antibiotic prescribing, particularly among children younger than five years whose eustachian tubes are physiologically immature, resulting in suboptimal middle-ear ventilation and mucous clearance compared with adults¹. Robust epidemiologic evidence identifies recurrent viral upper-respiratory infections, atopy, supine bottle-feeding, and exposure to tobacco smoke as risk factors that promote negative middle-ear pressure and effusion, thereby

predisposing to acute otitis media (AOM) and to otitis media with effusion (OME) in the absence of acute inflammation¹⁻³. The clinical and societal consequences are substantial, including school absenteeism, caregiver work loss, and—when effusion persists—adverse effects on auditory function and language development¹⁻³.

However, emerging evidence now supports a “diagnosis-first” approach prior to any antibiotic therapy⁴, in contrast to traditional empiric treatment based largely on estimated infection probability. Specifically, antibiotics for AOM should be reserved for cases in which middle-ear effusion is confirmed together with tympanic-membrane inflammation (e.g., bulging, erythema, reduced mobility) and consistent acute symptoms, following technically sound otoscopy—augmented, when indicated, by pneumatic otoscopy or tympanometry⁴. This strategy improves discrimination of OME—a condition that, in most instances, does not warrant antibiotics—and facilitates structured communication with caregivers (e.g., 48–72-hour watchful waiting with analgesia and planned reassessment), which is central to antimicrobial stewardship in pediatric practice¹⁻³. These developments raise practical challenges for primary-care pharmacists, particularly in Thailand where pharmacists are not permitted to perform invasive physical examination. The operational question is how best to support diagnosis-first care within this scope of practice. Poowaruttanawiwit and colleagues⁵ previously proposed a



pharmacy-appropriate examination framework to improve diagnostic accuracy for AOM (2021), yet the accompanying device has not been produced for clinical use or obtained medical-device registration. Figure 1 illustrates representative tools for middle-ear assessment: (A) devices in routine general practice; (B) advanced technologies under development and evaluated in research settings; and (C) the NU_Oto (NUO) device.

In this context, community pharmacists are positioned as *front-line screeners and triagers*, rather than diagnosticians, operating within clearly defined professional and regulatory boundaries. The proposed device and workflow are intentionally designed to support early identification, structured referral, and antimicrobial stewardship, facilitating timely escalation to physicians or otolaryngologists when indicated, rather than enabling independent diagnosis or treatment decisions. This role delineation aligns the use of patient-operable otoscopic technologies with safe pharmacy practice while strengthening diagnosis-first care pathways and reducing inappropriate antibiotic use.

A review of medical literature and practice guidelines highlights the centrality of direct tympanic membrane assessment for accurate differentiation of middle-ear disease. In a retrospective study from Italy, Folino et al.⁶ showed that correct diagnosis of AOM requires visualization of tympanic membrane pathology with confirmation of middle-ear effusion (MEE) plus acute inflammatory signs, rather than reliance on nonspecific symptoms alone. Among children with recurrent AOM (2015–2021), diagnostic concordance between primary-care/emergency pediatricians and otolaryngologists was 72.4%, revealing a meaningful accuracy gap in routine practice. The most frequent pitfall was labeling “red TM without bulging” as AOM (32/37 discordant cases), followed by opaque TM without bulging—both patterns more consistent with OME than with AOM, and not sufficient for AOM confirmation. By analogy, community pharmacists in Thailand—who typically do not visualize the tympanic membrane prior to triage—are likely at even greater risk of diagnostic misclassification. Importantly, TM bulging emerged as the clinical sign most strongly associated with bacterial middle-ear infection and should be used to distinguish AOM from OME; in the absence of bulging, clinicians should defer definitive AOM labeling to reduce unnecessary antibiotic use⁶. These observations align with international practice guidelines published since 2013 and increasingly emphasized after 2020^{2,7-9}. Nevertheless, Thailand presently lacks an updated community-pharmacy algorithm for AOM differentiation that reflects this contemporary evidence base¹⁰.

This article aims to synthesize and appraise contemporary medical evidence on patient-operated tools and methods for differentiating otitis conditions, with the practical goal of informing community pharmacists and health-policy decision-makers. The review distills diagnostic performance, feasibility,

and implementation considerations to guide community pharmacy practice in alignment with current evidence and to prepare for anticipated shifts in diagnostic paradigms. Ultimately, the intended outcome is to support judicious, evidence-based antibiotic decision-making by clarifying when antimicrobial therapy is indicated and when watchful waiting or adjunctive evaluations are more appropriate.

METHODS

Design, protocol, and reporting

A scoping review was conducted to map the breadth and characteristics of evidence on patient-operated or patient-operable tools and methods for differentiating pediatric otitis entities (AOM vs OME), including detection of MEE, and their implementation in primary care, community pharmacy, and tele-otology. Methods were based on Arksey and O'Malley's framework¹¹, as advanced for evidence synthesis, and were reported in accordance with PRISMA-ScR¹². A protocol specifying objectives, eligibility, outcomes, and analysis plans was finalized before screening, time-stamped and archived, with all deviations documented in an audit trail.

Eligibility criteria (PCC framework)

Population (P): Children and adolescents (0–18 y). Studies including mixed ages were eligible if pediatric data were extractable or the technology was intended for pediatric use.

Concept (C): Tools/methods enabling patient-operated or patient-operable “in-ear digital **visualization**” and allied diagnostics for AOM/OME/MEE (e.g., smartphone video otoscopy ± AI/image analysis; advanced optics such as SWIR otoscopy and OCT otoscope); supportive physiologic tests when explicitly paired for care pathways (e.g., tympanometry).

Context (C): Primary care, emergency triage, community pharmacy, tele-otology, or peri-operative/tertiary settings when informing front-line use (e.g., accuracy studies using intra-operative reference standards).

Study designs: Diagnostic accuracy studies, prospective/retrospective cohorts, method development/validation for AI, feasibility/implementation studies, and guideline/consensus statements with original methods. Case reports/series <10 patients and purely opinion pieces were excluded.

Outcomes (a priori): Diagnostic performance (Se/Sp/Accuracy/PPV/NPV/AUC), agreement (κ/ICC), imageability/quality pass rate, feasibility/usability, operator/setting requirements, costs, and implications for antimicrobial stewardship.

Language/time window: no limit; 2000 to present.

Information sources and search

The following sources were searched: MEDLINE (PubMed),





Figure 1. Tools for middle-ear assessment

Note. NUO (Figure 1C) is an evidence-informed, pharmacist-supervised, patient-operated prototype that wirelessly streams real-time tympanic membrane images to a smartphone using a miniature illuminated camera. The device incorporates mixed-wavelength illumination, an optional in-ear temperature sensor, and a user-friendly mobile interface for screening and decision support. Its child-friendly, low-cost design prioritizes safety and supports diagnosis-first pediatric otitis care.

Embase, Cochrane CENTRAL, Web of Science, Scopus, IEEE Xplore (engineering/AI optics), trial registries (ClinicalTrials.gov and WHO ICTRP), Thai databases (ThaiJO and TCI), and grey literature (conference proceedings, theses, and preprints). Search strategies were constructed using controlled vocabulary and free-text terms for (otitis media OR middle-ear effusion) AND [(video otoscopy OR smartphone otoscope OR endoscopy) OR (short-wave infrared OR SWIR) OR (optical coherence tomography OR OCT) OR (artificial intelligence OR deep learning)], with pediatric filters and diagnostic terms applied. Reference lists of included studies and relevant reviews were hand-searched, and forward citation tracking was performed.

Study selection

Records were deduplicated and managed using Rayyan. Two reviewers independently screened titles/abstracts and then full texts against prespecified criteria, with calibration exercises (≥ 100 records) to align judgments. Disagreements were resolved by consensus or third-reviewer arbitration.

Data charting (extraction)

A piloted, standardized form captured: study identifiers; country/setting; population/age; technology class (video-AI, SWIR, OCT, adjunct tympanometry); reference standard; acquisition protocol and image-quality safeguards; outcomes (Se/Sp/Acc/PPV/NPV/AUC, κ /ICC, imageability); feasibility (training, time, costs); and sources of bias (spectrum, verification, operator dependence, device-specific factors).

Two reviewers independently charted each study with cross-checks; discrepancies were reconciled by consensus.

Methodological appraisal and management of validity threats

Because scoping reviews do not exclude by quality, we mapped methodological quality using design-appropriate tools (e.g., QUADAS-2 for diagnostic accuracy; tailored checklists for AI development/validation—dataset partitions, leakage safeguards, OOD robustness; feasibility reporting standards). We summarized internal validity risks (selection/spectrum bias, partial verification, indeterminate handling, operator/device dependence, small/imbalanced samples) alongside results, without down-weighting evidence post hoc. To enhance internal validity of the review process itself, we implemented: (i) preregistered protocol and locked eligibility; (ii) duplicate screening and extraction; (iii) calibration and κ reporting; (iv) a priori outcomes; (v) audit trail of amendments; and (vi) author contact when critical data were missing or unclear.

Synthesis and analysis

Findings were synthesized narratively and in evidence tables stratified by technology class (video-AI, SWIR, OCT) and by use-case (front-line screening/follow-up vs confirmatory assessment). We highlighted diagnostic performance alongside imageability and workflow requirements, and mapped implications for antimicrobial stewardship (diagnosis-first). Subgroup exploration considered age bands (e.g., < 5 y), setting (primary vs tertiary), reference standards (myringotomy vs

tympanometry), and handling of indeterminate images. Where appropriate, ranges and medians were reported; meta-analysis was not planned due to heterogeneity in devices, protocols, and reference standards.

Stakeholder consultation

To strengthen relevance and implementation traction, we convened a structured consultation with pediatric otolaryngologists, community pharmacists, engineers/AI developers, and policy stakeholders to verify interpretations, identify gaps (e.g., training, QA checklists), and refine practice/research recommendations.

Innovation development

Prototype development followed an iterative, multidisciplinary process involving otolaryngologists, pediatricians, biomedical engineers, and medical-device product designers. Expert reviews ensured ergonomic suitability and compliance with pediatric safety norms and relevant electrical/biocompatibility standards. The form factor emphasized a non-threatening appearance and short examination time to reduce distress in toddlers. Traceability matrices linked each specification to evidence and risk controls, reinforcing construct validity.

Internal validity safeguards comprised duplicate screening/extraction in the review; QUADAS-2 and AI-specific appraisal to identify spectrum, verification, and information biases; protocolized image acquisition; operator training; prespecified inclusion criteria for analyzable images; blinded dual interpretation; and audit-ready data capture. These controls minimized measurement error, observer and selection bias, and operator-dependent variability, supporting reproducibility of the developmental findings and readiness for subsequent clinical validation studies.

Ethics and Funding

As this scoping review analysed only published and archival data, ethics approval was not required. To enhance transparency and contextualize the findings, funding sources and declared conflicts of interest were systematically extracted from included studies and considered during evidence interpretation, thereby strengthening the credibility and internal validity of the review.

RESULTS

Key observations from scoping review

Direct visualization of the TM is fundamental to diagnosing AOM because bulging of the TM in the presence of MEE is the defining otoscopic sign that distinguishes AOM from OME; isolated redness or opacity without bulging is insufficient and risks antibiotic overuse. Evidence synthesized in a 2025 NEJM clinical practice review shows that bacteria are recovered from ~80% of middle-ear samples when the TM is bulging, that diagnosis

therefore relies primarily on otoscopic findings (ideally after cerumen removal), and that algorithms anchored on bulging + effusion improve diagnostic specificity while supporting observation (watchful waiting) in nonsevere cases¹⁶. These findings may inform future updates of international guidelines by reinforcing diagnosis-first criteria (bulging/MEE confirmed; careful technique; use of pneumatic otoscopy or tympanometry when needed) and by de-emphasizing nonspecific symptoms and legacy severity cut-points that lack proven interaction with treatment effect. For Thailand, adoption will likely include standardized TM visualization pathways in primary care and pharmacy practice—emphasizing cerumen management, image-quality checklists, adjunctive tympanometry access, structured safety-netting, and tele-otology escalation—while aligning antimicrobial decisions to confirmed AOM rather than presumed infection. Collectively, this evidence supports guideline updates that tighten diagnostic thresholds, curb unnecessary antibiotics, and formalize training and tools that ensure the TM is seen well before an AOM label is applied.

A consistent body of evidence¹¹⁻¹⁵ indicates that smartphone-coupled digital/video otoscopy augmented by AI-based image analysis is the most mature patient-operable approach for screening and differentiating otitis media in young children. Reported studies demonstrate adequate sensitivity and overall accuracy for detecting MEE and show strong feasibility for integration into tele-otology within primary care. Nevertheless, real-world performance is highly contingent on device quality and disciplined operating procedures—including a clear user manual, standardized positioning/angulation, a predefined image-quality checklist, pre-submission review, and explicit referral criteria for red-flag signs or indeterminate results. For suspected chronic MEE or when image quality is suboptimal, adding a physiological test such as tympanometry can enhance specificity and help avoid unnecessary treatment. In parallel, emerging advanced modalities—notably SWIR otoscopy and OCT otoscope—show promise for confirmatory assessment of MEE, but current limitations in cost, workflow complexity, and training requirements make them better suited to staffed service points rather than unsupervised home use. In summary, the most actionable, evidence-aligned pathway at present is a video-otoscopy/smartphone + AI workflow implemented under a diagnosis-first framework—i.e., confirm MEE plus tympanic-membrane inflammatory signs—backed by image-quality assurance, structured user education, and seamless referral pathways for at-risk patients or cases with inconclusive findings.

From Table 1, contemporary “in-ear digital visualization” technologies—most notably smartphone-coupled video otoscopy augmented with AI image analysis and, at the high end, SWIR otoscopy and OCT otoscope—demonstrate meaningful capability to screen for and classify MEE in children within a diagnosis-first framework, thereby helping to curb unnecessary antibiotic use in pediatric and primary-care pharmacy practice. The chief advantages of video-otoscopy

plus AI are its noninvasiveness, accessibility, reduction of inter-rater variability, and inherent compatibility with tele-otology. By contrast, SWIR/OCT provide fluid-specific optical/volumetric signatures that strengthen diagnostic confidence when confirmatory evidence is required. Important limitations remain. Internal validity is constrained by dependence on image quality and user technique, which increases indeterminate reads and depresses negative predictive value when images are interpreted in isolation. Generalizability is limited by evidence derived largely from specialty centers with modest samples, and by the cost and operational complexity of SWIR/OCT, which currently preclude widespread, unsupervised home use. A pragmatic clinical pathway is to deploy smartphone video-otoscopy as a front-line triage and follow-up tool under a standardized image-quality checklist and clear referral criteria, supplementing with tympanometry when images are suboptimal or risk is elevated, and reserving SWIR/OCT for high-certainty confirmation or pre-procedural assessment. Future work should prioritize multi-center external validation in primary care and younger children, development of AI that is robust to out-of-distribution inputs with expanded classes (e.g., true AOM, obstructing cerumen), real-world cost-effectiveness and acceptability evaluations, and miniaturization/cost-reduction of SWIR/OCT with user interfaces that mitigate operator dependence to enable safe, effective scale-up.

Figure 2 is a flowchart summarizing diagnostic technologies for acute otitis media AOM assessment. The frontline (screening/triage) stage utilizes video otoscopy with AI for TM image analysis, achieving pooled accuracy of 85–95%, suitable for point-of-care and tele-otology but dependent on image quality and user skill. The confirmatory stage employs SWIR and OCT otoscopy, both identifying middle-ear effusion with sensitivity/specificity of 80–91%, offering high diagnostic precision but limited by higher cost and complexity.

Evidence-Informed Design and Early Validation of a Pediatric Otitis Media Screening Device

Based on findings from the evidence synthesis, we conceptualized and developed a novel diagnostic device to improve screening and diagnosis of otitis media in pediatric patients. The minimum required specifications include a micro-camera capable of adjustable focus to capture all regions of the tympanic membrane, and an LED illumination system with sufficient intensity to enable high-quality image acquisition. The device specifications derived from the scoping review are displayed in Table 2.

The design process was guided by multidisciplinary collaboration and iterative expert validation. Consultations were conducted with medical device design specialists, otolaryngologists, pediatricians, and biomedical engineers to ensure the device met clinical, ergonomic, and safety requirements. Following the conceptual and structural optimization, the prototype underwent preliminary performance testing in a small cohort of healthy volunteers. The results demonstrated that the

device provided acceptable diagnostic accuracy and strong correlation with otoscopic assessments made by ear, nose, and throat specialists. These findings suggest that the device has promising potential for non-invasive, user-friendly, and reliable application in pediatric otitis media screening, warranting further clinical validation in a larger and more diverse population. Figure 3 shows the developed device and Figure 4 presents examples of tympanic membrane images. The image exhibits clear pixels and well-defined anatomic landmarks (e.g., malleus handle, light reflex), providing adequate visual quality for AOM assessment.

Emerging from the evidence synthesis, these concept designs translate key diagnostic evidence into a child-centred video otoscopy platform. Each incorporates an adjustable-focus miniature camera, uniform glare-controlled LED illumination, and soft single-use silicone ear tips within a familiar headset form, directly addressing the primary determinants of diagnostic accuracy identified in the review: complete TM visualization, stable focus, and consistent illumination. A paired smartphone application provides real-time imaging with automated quality checks (focus, angle, and obstruction) and standardized capture guidance to improve image quality and reduce observer variability among non-expert users. Pediatric-friendly ergonomics, including rounded contours, soft colors, and brief acquisition times—are intended to minimize anxiety and motion artefacts, thereby improving image acquisition in young children. The platform also supports tele-otology workflows through secure image sharing and optional AI-assisted interpretation, with AI functioning as a decision-support tool rather than a replacement for clinical judgement. Overall, the concept operationalizes the evidence into a practical, non-invasive screening solution that facilitates first-attempt acquisition of diagnostic-quality TM images, enabling guideline-concordant acute otitis media assessment while supporting appropriate antimicrobial stewardship.

DISCUSSION

The findings of this scoping review provide a coherent and actionable foundation for translating diagnostic evidence into community pharmacy practice and public health policy. Collectively, the evidence demonstrates that accurate identification of AOM requires direct visualization of the TM to confirm MEE and inflammatory changes before initiating antibiotic therapy. This “diagnosis-first” principle aligns with global antimicrobial stewardship goals and represents a necessary paradigm shift in primary care and pharmacy-based child health services. The synthesis highlights that video otoscopy, particularly smartphone-enabled systems augmented by AI for image interpretation—has achieved diagnostic performance approaching that of otolaryngologists when supported by quality assurance protocols and structured referral criteria. Advanced imaging modalities, such as SWIR otoscopy and OCT, further strengthen confirmatory accuracy but remain limited by cost and workflow complexity.



Table 1. Evidence Summary of Patient-Operable Otitis Tools for Pharmacy and Tele-Otology ^{v13-17}					
Study (Year)	Technology / Tool	Design & PICO (concise)	Key Outcomes	Self-Use Feasibility	Key Limitations
Preciado D, et al. (2020) (13)	OCT-otoscope	Design: Cross-sectional diagnostic accuracy (tertiary pediatric hospital, USA).	Se 90.9%, Sp 90.2%, Acc 90.6%, PPV 94.5%, NPV 84.2%.	Moderate–High at point-of-care under supervision; if miniaturized + app-assisted interpretation, could extend to home use with tele-otology support.	Internal: Imageability ~64% (risk of bias); low sensitivity for MEE subtype; operator-dependent UX/UI.
		P: Children undergoing tympanostomy.			Generalizability: Tertiary pre-op cohort → needs external validation in primary care and across devices.
		I: Pre-op OCT-otoscope imaging (standardized acquisition).			
		R: Intra-op myringotomy/confirmed MEE (gold standard).			
		O: Se/Sp/Accuracy/PPV/NPV; MEE type; inter/intra-reader; imageability.			
Khan MA, et al. (2020) (14)	AI on video oto-endoscopy (DenseNet-161)	Design: Model development/validation + reader study.	Acc ~95%, AUROC ~0.99; DenseNet-161 macro-F1 ≈0.951, acc ≈0.949; on 100-image web test: AI 87% vs physicians 74%.	High under supervision/tele-otology: upload images via app, immediate class + heatmap; best for screening/follow-up (not a stand-alone replacement when unclear/severe).	Internal: Strong dependence on image quality; only 3 classes (no true AOM/artefacts) → information bias; device/workflow-dependent; limited OOD testing.
		P: 2,484 oto-endoscopic images (normal/OME(MEE)/COM-perforation) + low-quality local set.			Generalizability: Needs multi-center external validation in younger children and varied hardware.
		I: Deep CNN (k-fold CV).			
		R: ENT-verified labels; compared with 17 physicians (web reader study).			
		O: Accuracy, AUROC, macro-F1; robustness; Grad-CAM.			

Kashani RG, et al. (2021) (15)	SWIR otoscopy + ML	Design: Paired diagnostic accuracy (pre-/intra-op).	Acc ~90.3%, Se ~90.5%, Sp ~90.1%, AUC ~0.96; physics rationale: SWIR penetrates TM; fluid strongly absorbs → high MEE contrast.	Moderate currently suited to supervised clinics; miniaturization + app could enable tele-otology/self-screening later.	Internal: Small/ imbalanced sample; reliance on external hardware (~500 g); image artefacts (cerumen/focus/hair).
		P: Children with suspected MEE before tympanostomy (Stanford).			Generalizability: Device/protocol-specific → needs external validation; hardware simplification for primary-care/home.
		I: SWIR + semantic segmentation + Random Forest.			
		R: Myringotomy (MEE yes/no).			
		O: Se/Sp/Accuracy/ AUC; compare RF vs threshold/DT; feasibility.			
Aftab M, et al. (2022) (16)	Video-otoendoscopy vs tympanometry	Design: Paired prospective cohort, multi-visit (real-world).	$\kappa \approx 0.38-0.52$; after excluding indeterminate: Se ~79.5%, Sp ~56.9%, Acc ~75.5%, PPV ~89.6%, NPV ~37.4% ; tympanometry more sensitive, video more specific; combination improves accuracy.	High for supervised screening/follow-up: record & tele-refer; works well in primary care/pharmacy with image-quality checklist and user guide.	Internal: User-skill dependent; low NPV when used alone (not for “rule-out”); possible spectrum bias.
		P: Ages 5–18 y with AOM/OME criteria (tertiary clinic, India).			Generalizability: Older children, single center → limited to younger ages/primary care; needs multi-center external validation.
		I: Video-otoendoscopy with OMGRADE (4 visits/21 days).			
		R: Same-day tympanometry (Jerger–Feldman).			
		O: Se/Sp/Acc/PPV/NPV + κ -agreement; image-quality factors.			

Othman D, et al. (2024) (17)	Video otoscope (Inventis) vs tympanometry (Grayson-Stadler)	Design: Retrospective diagnostic study (pediatric ENT clinic).	Se 79.5%, Sp 56.9%, PPV 89.6%, NPV 37.4%, Acc 75.5% (p<0.00001); best role = confirm MEE when image is clear; not suitable to rule- out alone → add tympanometry per indications.		
		P: 0–18 y with suspected persistent MEE; excluded acute AOM/TM perforation.			
		I: Video otoscope: positive/negative/ indeterminate (indeterminate excluded from calc).			
		R: Tympanometry reference.			
		O: Se/Sp/PPV/NPV/ Accuracy.			

Note: AOM (acute otitis media), OME (otitis media with effusion), MEE (middle-ear effusion), TM (tympanic membrane), Se (sensitivity), Sp (specificity), Acc (accuracy), PPV (positive predictive value), NPV (negative predictive value), AUC (area under the ROC curve), AI (artificial intelligence), CNN (convolutional neural network), SWIR (short-wave infrared), OCT (optical coherence tomography), RF (random forest), DT (decision tree), CV (cross-validation), OOD (out-of-distribution), QA (quality assurance), ENT (ear, nose, and throat/otolaryngology), PICO (population, intervention/index test, comparator/reference, outcomes), κ (Cohen's kappa for agreement), OMGRADE (otoscopic membrane grading score), and tele-otology (remote otologic consultation/assessment).

Translating these findings into community pharmacy practice requires operational models that balance safety, feasibility, and diagnostic validity. Within Thailand’s evolving universal health coverage framework, pharmacists occupy a uniquely accessible frontline position for pediatric ear-care triage, medication counseling, and antimicrobial stewardship. Evidence from this review underscores that, with proper training, quality-controlled imaging, and tele-otology support, community pharmacists can play a pivotal role in the early detection and referral of otitis media while reducing inappropriate antibiotic use. Therefore, the subsequent sections—Guidelines for the Application of Knowledge in Community Pharmacy Practice and Policy Recommendations for Public Health Decision-Makers—integrate these evidence-based insights into practical frameworks that align device innovation, professional capacity building, and national health priorities. Together, they delineate a scalable pathway toward safer, diagnosis-first pediatric ear care at the community level.

Guidelines for the Application of Knowledge in Community Pharmacy Practice

Drawing upon the evidence synthesis and policy framework presented in this review, the implementation of self-use otoscopic tools within community pharmacy practice should operationalize the diagnosis-first principle—emphasizing screening and follow-up rather than definitive diagnosis in all cases. Evidence indicates that smartphone-based video otoscopy, supported by AI-assisted image analysis, currently represents the most feasible and evidence-aligned front-line approach for early differentiation of otitis media in young

children, while SWIR and OCT otoscopy serve as confirmatory technologies for complex or indeterminate cases. Accordingly, pharmacists should apply these tools within a standardized, stepwise workflow that prioritizes image quality, structured evaluation, and timely referral.

Service delivery should begin with clearly defined eligibility and exclusion criteria, targeting children with mild ear pain, nasal congestion, or cough without acute danger signs, and excluding those with severe pain, high fever, vomiting, vertigo, or suspected complications. A five-step standardized process is recommended: (1) brief assessment of symptoms and risk factors such as recurrent infection or language delay; (2) safe removal of cerumen or external obstructions; (3) caregiver-assisted image or video capture via smartphone otoscope following a predefined quality checklist; (4) structured evaluation using standardized forms; and (5) a management plan emphasizing symptom monitoring, analgesia, and referral if images or symptoms are inconclusive or high-risk. Crucially, the confirmation of middle-ear effusion prior to antibiotic prescribing remains the central diagnostic safeguard—fully aligned with global antimicrobial stewardship standards.

To ensure internal validity, each step must be quality-assured through measurable performance indicators such as image usability, inconclusive result rate, consultation time, referral proportion, and short-term clinical outcomes (48–72 hours). Randomized image audits and expert network reviews are recommended to minimize inter-observer variability, while AI interpretation tools should function solely as decision-support aids, not diagnostic substitutes. Pharmacists must



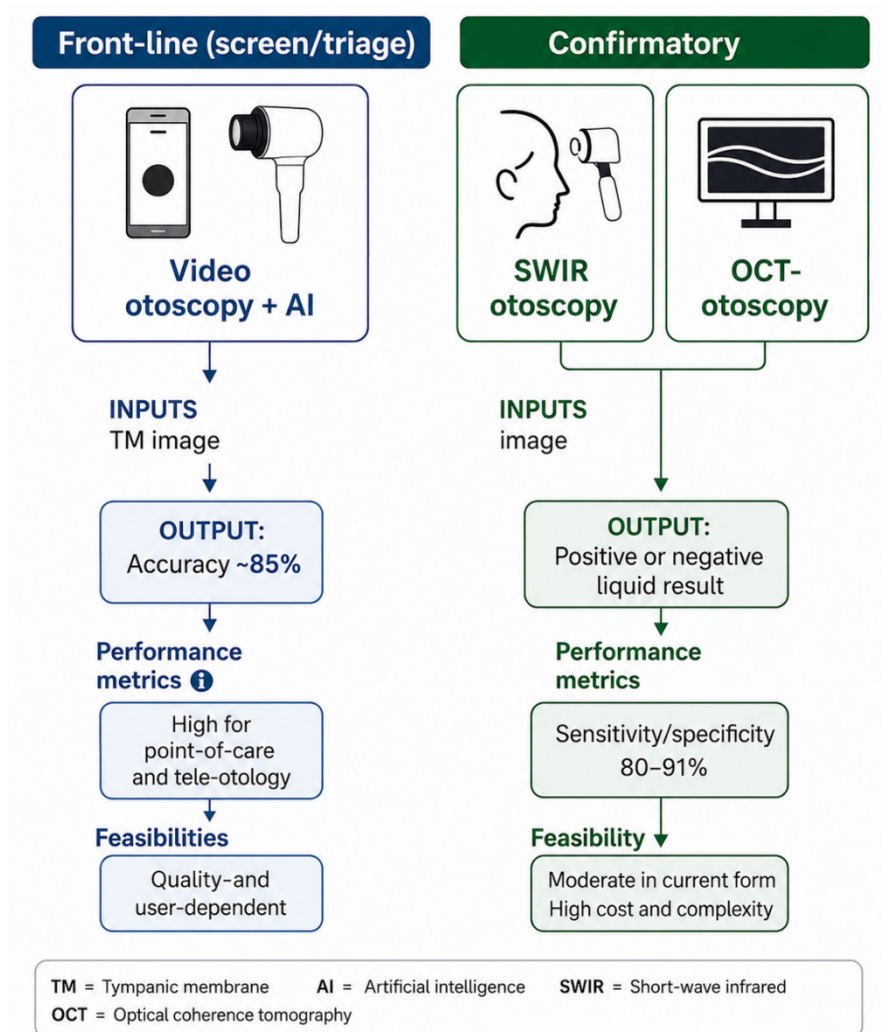


Figure 2. Summarizes diagnostic technologies for acute otitis media (AOM) assessment.

also communicate diagnostic uncertainty using standardized caregiver scripts, maintaining transparency and trust.

Safety, ethics, and professional scope must remain integral. Pharmacies should obtain short-form consent for image capture, uphold PDPA-compliant data handling, and maintain infection control through single-use speculum tips and device cleaning protocols. The pharmacist's professional role should focus on screening, education, symptomatic management, and referral coordination, rather than definitive diagnosis. In practice, the minimum equipment set should include a certified video otoscope, auxiliary lighting, positioning aids, a structured data form, and reference image guides distinguishing usable from unusable images. Portable tympanometry may supplement screening in high-risk or unclear cases to strengthen diagnostic accuracy. Finally, continuous professional development through annual refresher training, inter-facility peer review, and national data monitoring will sustain quality and scalability. Long-term success will depend on the availability of affordable,

user-friendly devices, robust tele-otoscopy integration, and national standardization of workflows and evaluation metrics, as outlined in the proposed primary-care and pharmacy-driven national program for pediatric otitis media. This integrated, evidence-based model will enable Thai community pharmacists to deliver safe, accurate, and cost-effective ear health services while advancing rational antibiotic use and public trust in pharmacy-based care.

Policy Recommendations for Public Health Decision-Makers

Grounded in the synthesized evidence, we recommend the establishment of a national, primary-care- and pharmacy-driven pediatric otitis media program that operationalizes a diagnosis-first framework integrated with tele-otoscopy. The program should be underpinned by comprehensive, end-to-end national standards encompassing device specifications, clinical workflows, financing mechanisms, and performance evaluation. Minimum technical requirements for smartphone-

Table 2. Specifications of the novel pediatric otitis media screening device informed by the scoping review			
Subsystem / Part	Minimum Specification (concise)	Evidence/Reference (from scoping review)	Specific Reason (why it matters)
Imaging sensor (micro-camera)	Adjustable focus; captures entire TM with visible landmarks	Diagnostic performance of video otoscopy hinges on image quality and full-TM visualization; smartphone video otoscopy ± AI is most decision-ready (accuracy ≈80–95%).	Ensures the malleus, light reflex, and annulus are clearly seen—prerequisites to confirm MEE and TM inflammation for AOM decision-making.
Optics & field of view	Wide enough FoV to include pars tensa in a single frame; minimal distortion	Review emphasizes imageability/quality pass rate as a key limiter in real-world use.	Reduces missed bulging or retrotympenic fluid located peripherally; lowers need for repeat attempts.
Illumination (LED)	Integrated, even, glare-controlled LED with sufficient intensity for clear capture	Image quality (focus/lighting/angle) is the dominant driver of diagnostic accuracy and indeterminate rates.	Prevents shadows and specular glare that mask bulging/effusion; supports consistent color assessment.
Tip & patient interface	Soft, smooth, single-use speculum; child-friendly form; non-invasive depth stop	Safety and usability standards; pharmacy/primary-care pathways stress single-use tips and safe insertion.	Minimizes discomfort/fear in 1–4-year-olds; reduces infection risk; standardizes insertion depth for reproducible images.
Stabilization & guidance	On-device alignment guide and on-screen angulation prompts; basic anti-shake	Structured workflows with positioning/angulation guidance improve imageability and agreement.	Helps novice operators capture usable images on the first attempt; decreases inconclusive reads.
Image-quality checkpoint (software)	Pre-capture checklist (focus, lighting, angle, cerumen) with pass/fail prompts	The review recommends a predefined image-quality checklist to raise usable-image rates.	Improves internal validity by filtering poor inputs before clinical interpretation/tele-referral.
AI decision-support (optional)	On-device/app classifier highlighting landmarks and suggesting “indeterminate/ refer”	AI on otoscopic images can match/ exceed generalists but is image-quality dependent; use as support, not replacement.	Reduces inter-rater variability; standardizes triage while preserving clinician oversight.
Tele-otology integration	Secure export (FHIR/HL7-ready), stills + short clips; audit trail	Tele-otology workflow is a key implementation path in primary care/ pharmacy.	Enables rapid expert review; supports watchful waiting and timely escalation.
Safety & hygiene	Cleanable body; IP-rated splash resistance; PDPA-compliant data handling	Programmatic guidance stresses infection control, consent, and data privacy in community settings.	Protects patients and caregivers; enables scale in pharmacies/clinics without safety trade-offs.
Adjunct compatibility	Optional pairing with portable tympanometry for unclear cases	Combining video otoscopy with tympanometry improves accuracy; video alone has lower NPV when images are borderline.	Increases specificity for MEE; reduces inappropriate antibiotics when the image is indeterminate.
Training & UX	Short, pictorial user guide; child-friendly UI; caregiver-assisted capture	Operator training and workflow discipline are major determinants of real-world accuracy.	Improves first-pass success in toddlers; decreases repeat attempts and anxiety.

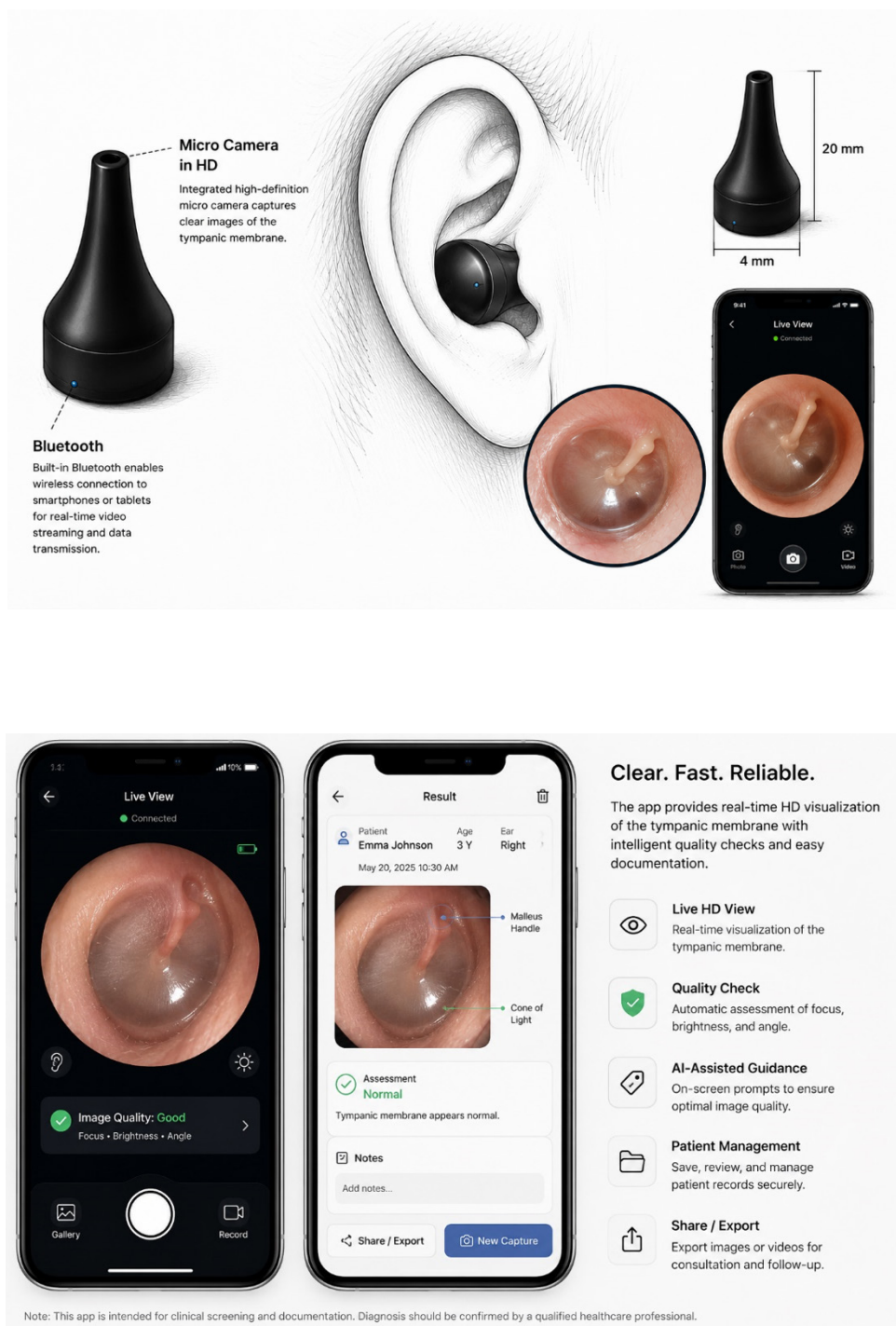


Figure 3.Proposed application functions are conceptual and have not yet undergone full clinical validation.

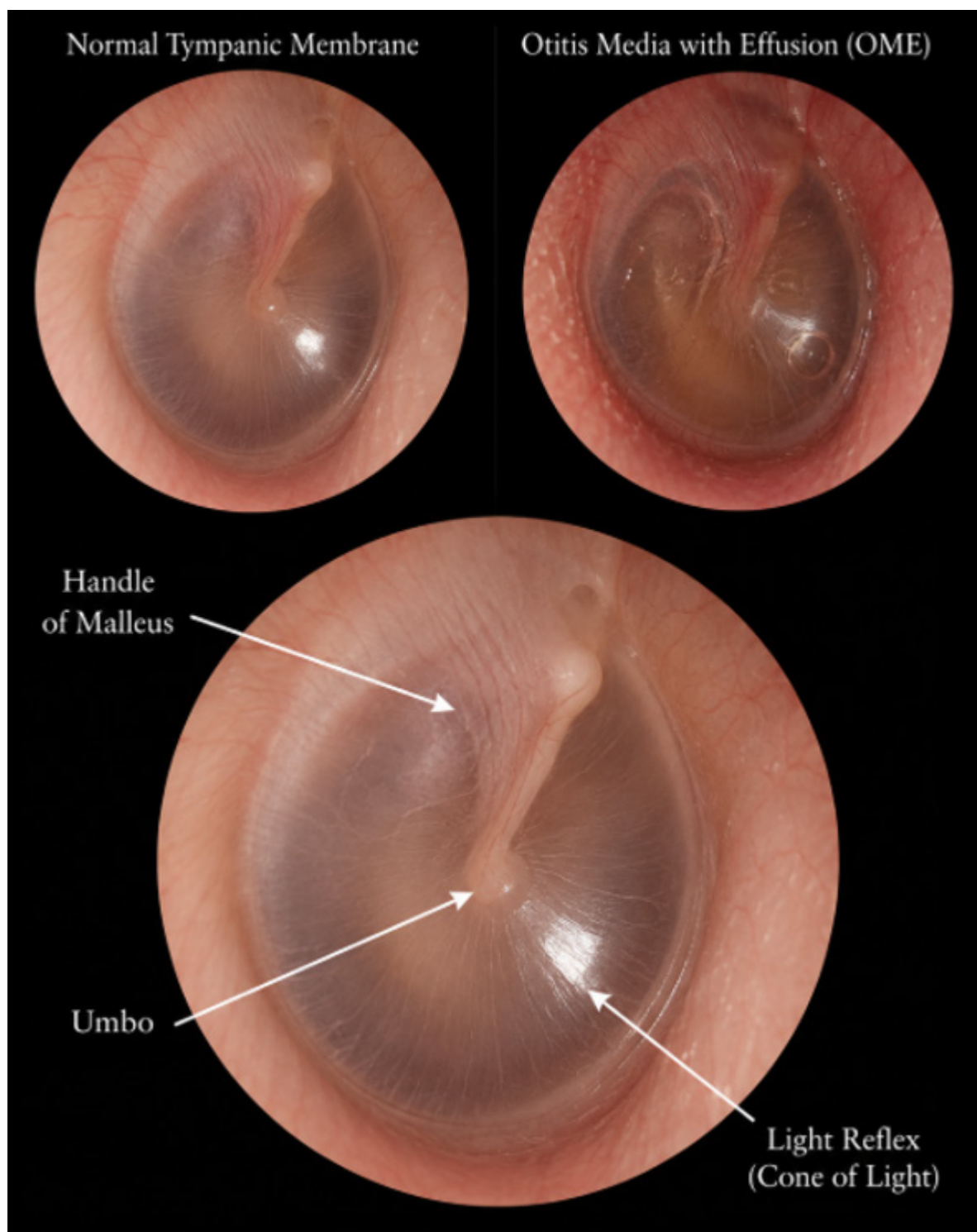


Figure 4. Representative tympanic membrane images and key anatomical landmarks relevant to otitis media assessment
Note: Normal tympanic membrane, demonstrating clear visualization of the handle of the malleus and cone of light. These landmarks enable accurate assessment of membrane integrity and facilitate differentiation between normal findings, acute otitis media, and middle-ear effusion.

connected video otoscopes—including image resolution, field of view, luminance, durability, and the use of single-use specula—should be formally defined. Alongside these, an auditable image-quality checklist and a standardized service pathway for screening, follow-up, and referral should be implemented, embedding watchful waiting, analgesic management, and antimicrobial stewardship, with explicit contraindications for home use and emergency referral triggers to prevent delayed care.

Service delivery should be formalized under a nationwide initiative titled “Pharmacy-led Ear Screening”, deployed through accredited community pharmacies, subdistrict health-promoting hospitals, and primary-care clinics. These service points would utilize structured assessment forms, integrate tele-otology consultation, and, where feasible, incorporate portable tympanometry for indeterminate or high-risk cases to enhance diagnostic accuracy. A national digital health platform, compliant with PDPA and interoperable through FHIR/HL7 standards, should support secure image and metadata uploads, automate pre-submission quality assurance (focus, lighting, angle checks), and facilitate centralized monitoring.

Sustainable workforce capacity should be achieved through a national e-learning micro-credential curriculum, combined with quarterly randomized image audits and standardized caregiver education modules. Financial support from the National Health Security Office (NHSO) should include reimbursement for video-based ear screening, pharmacist and tele-otology consultations, and tympanometry when indicated. Cost-efficiency can be reinforced by regional pooled procurement and incentives for domestic medical device manufacturing, such as tax benefits and expedited registration.

The framework should embed ethical and safety safeguards, including short-form consent for image capture, strict infection-control practices, and clear delineation of the pharmacist's scope—limited to screening, health education, symptom management, and referral coordination, without issuing final diagnoses in complex cases. To promote health equity, the program should allocate basic otoscopy equipment kits to rural pharmacies and subdistrict hospitals, establish mobile ear clinic services, and maintain free consultation channels for low-income families or children at developmental risk.

Program monitoring and evaluation should employ measurable indicators, including the proportion of usable images, indeterminate results, time per case, appropriate referrals, antibiotic use consistent with guidelines, follow-up visits, cost per outcome, caregiver satisfaction, and real-world AI and QA module performance. A phased 12–36-month implementation roadmap is proposed:

- Phase 1 (0–6 months): Establish standards, training curricula, and select pilot provinces.

- Phase 2 (6–18 months): Conduct pooled procurement, workforce training, pilot service launch, and initiate data capture.
- Phase 3 (18–36 months): Evaluate impact, refine financial models, scale to regional health networks, and foster innovation and local production.

This integrated, evidence-informed strategy offers a cost-effective, sustainable model for improving pediatric ear health services, reducing unnecessary antibiotic prescriptions, and enhancing the quality and equity of child healthcare delivery within Thailand's universal health coverage framework.

From a regulatory and health-system standpoint, the proposed pharmacy-based screening model has been deliberately designed to align with Thailand's existing medical-device governance and Universal Health Coverage (UHC) service architecture, thereby strengthening its internal and external validity. The screening device is conceptualized as a non-invasive, low-to-moderate risk medical device intended for image acquisition and decision support rather than autonomous diagnosis and would be expected to require evaluation under the applicable Thai Food and Drug Administration medical-device registration pathway, with classification determined by its final intended use and risk profile, including conformity assessment, quality management system requirements, and post-market surveillance proportional to device risk. Importantly, the workflow explicitly constrains clinical interpretation to structured screening outputs (e.g., image quality pass/fail, indeterminate flags, referral prompts), which minimizes diagnostic overreach and preserves role fidelity, reducing the risk of misclassification bias at the point of care.

At the service level, integration within community pharmacy practice is consistent with the NHSO mandate to expand preventive, screening, and referral-based services under UHC, particularly for common pediatric conditions that drive avoidable antibiotic use and downstream healthcare costs. Pharmacists function as accessible first-contact providers responsible for standardized assessment, caregiver education, and referral coordination, while definitive diagnosis and treatment decisions remain with physicians or otolaryngologists through established referral or tele-consultation pathways. This separation of functions enhances internal validity by ensuring that observed outcomes—such as referral appropriateness, reduced empirical antibiotic dispensing, and timely escalation of high-risk cases—can be attributed to the screening workflow rather than to unregulated diagnostic decision-making.

Within Thailand's UHC framework, this model is realistic and scalable because it builds upon existing reimbursable pharmacy services, leverages nationwide primary-care and telemedicine infrastructure, and emphasizes cost-effective early triage rather than resource-intensive specialist access. By embedding quality-assured image acquisition, predefined referral thresholds, and

stewardship-oriented decision support into routine pharmacy workflows, the model supports rational medicine use while remaining compatible with regulatory scope, financing mechanisms, and workforce capacity. Collectively, these design choices mitigate implementation bias, enhance reproducibility across settings, and position pharmacy-based otitis media screening as a feasible and internally coherent component of Thailand's diagnosis-first pediatric care strategy.

CONCLUSION

This scoping review minimized bias through a preregistered protocol, locked eligibility, duplicate screening and extraction with calibrated agreement, predefined outcomes, and an audit trail, yielding internally coherent, reproducible synthesis. Across technologies, the most decision-ready pathway is smartphone video-otoscopy ($\pm$ AI) used under a diagnosis-first framework with a strict image-quality checklist and explicit referral rules; estimates of accuracy are plausible but hinge on imageability and operator discipline. SWIR and OCT provide strong confirmatory signal for middle-ear effusion yet require external validation in primary care, simplified workflows, and cost reduction before broad deployment. Overall, the evidence supports confirming effusion and TM inflammatory signs before antibiotics, integrating tympanometry when images are indeterminate or risk is high, and reserving advanced optics for confirmation—conclusions that remain robust after accounting for spectrum, verification, and operator-dependence risks.

AUTHORS' CONTRIBUTIONS

Janyut Srihirun conceptualized the design-oriented components of the study, led the visual and device-form factor development, contributed to prototype conceptualization, and participated in data interpretation related to usability, ergonomics, and implementation feasibility. Janyut Srihirun also contributed to drafting and revising sections related to device design, figures, and visual presentation. **Chanida Chantim** provided

clinical expertise in otolaryngology, contributed to defining diagnostic criteria and clinical relevance, advised on tympanic membrane assessment and otitis media differentiation, and critically reviewed the manuscript for clinical accuracy and applicability within pediatric care pathways. **Minchaya Boonyaharn** contributed to background research, preliminary data collection, literature screening support, and assisted in organizing evidence tables and figures under supervision. Minchaya Boonyaharn also supported manuscript formatting and reference management. **Prayuth Poowaruttanawiwit** conceptualized and led the overall study, including formulation of the research question, scoping review methodology, and diagnosis-first conceptual framework. Prayuth Poowaruttanawiwit supervised the literature search strategy, data extraction, methodological appraisal, and synthesis, and led the integration of pharmacy practice, antimicrobial stewardship, and health-system perspectives. He also oversaw the innovative development process, ensured internal validity safeguards, coordinated stakeholder consultation, and led the drafting, critical revision, and final approval of the manuscript. All authors contributed to manuscript review and approved the final version. The corresponding author takes responsibility for the integrity of the work as a whole.

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None.

CONFLICT OF INTEREST

None to declare.

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References

1. Danishyar A, Ashurst JV. Acute Otitis Media. [Updated 2023 Apr 15]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470332/>
2. Hidaka H, Ito M, Ikeda R, Kamide Y, Kuroki H, Nakano A, et al. Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan - 2022 update. *Auris Nasus Larynx*. 2023 Oct;50(5):655-699. doi: 10.1016/j.anl.2022.12.004. Epub 2022 Dec 27. PMID: 36577619.
3. Leung AKC, Wong AHC. Acute otitis media in children. *Recent Pat Inflamm Allergy Drug Discov*. 2017;11(1):32-40. doi: 10.2174/1874609810666170712145332. PMID: 28707578.
4. Shaikh N. Otitis media in young children. *N Engl J Med*. 2025 Apr 10;392(14):1418-1426. doi: 10.1056/NEJMcp2400531. PMID: 40214033.
5. Poowaruttanawiwit P, Anantasirijinda P, Intamao W, Rachapradit N, Srihirun J, Chantim C, et al. Identifying the specification of differential diagnosis tool for ear inflammation within the context of Thai community pharmacy. *TJPP*. 2021;24:29-40.
6. Folino F, Caruso M, Bosi P, Aldè M, Torretta S, Marchisio P. Acute otitis media diagnosis in childhood: still a problem in 2023? *Ital J Pediatr*. 2024 Jan 25;50(1):19. doi: 10.1186/s13052-024-01588-y. PMID: 38273404; PMCID: PMC10809769.
7. Jamal A, Alsabea A, Tarakme M, Safar A. Etiology, diagnosis, complications, and management of acute otitis media in children. *Cureus*. 2022 Aug 15;14(8):e28019. doi: 10.7759/cureus.28019. PMID: 36134092; PMCID: PMC9471510.
8. Lieberthal AS, Carroll AE, Chonmaitree T, Ganiats TG, Hoberman A, Jackson MA, et al. The diagnosis and management of acute



- otitis media. *Pediatrics*. 2013 Mar;131(3):e964-99. doi: 10.1542/peds.2012-3488. Epub 2013 Feb 25. Erratum in: *Pediatrics*. 2014 Feb;133(2):346. Dosage error in article text. PMID: 23439909.
9. El Feghaly RE, Nedved A, Katz SE, Frost HM. New insights into the treatment of acute otitis media. *Expert Rev Anti Infect Ther*. 2023 May;21(5):523-534. doi: 10.1080/14787210.2023.2206565. Epub 2023 Apr 28. PMID: 37097281; PMCID: PMC10231305.
 10. Tangkaikiatkajai M, Chongtrakul P, Chueamongkol W, Yossombat K, Suraphan S, Pijaroensap S, et al., editors. *Rational Use of Medicines Guideline for Community Pharmacies: Primary Care Symptom Management Manual* [Internet]. 1st ed. Bangkok (Thailand): Panchaya Ltd.; 2024 [cited 2025 Sep 25]. 688 p. Thai. Available from: <https://cpat.or.th/assets/uploads/contents/1032/250307034733.pdf>
 11. Buus N, Nygaard L, Berring LL, Hybholt L, Kamionka SL, Rossen CB, et al. Arksey and O'Malley's consultation exercise in scoping reviews: A critical review. *J Adv Nurs*. 2022 Aug;78(8):2304-2312. doi: 10.1111/jan.15265. Epub 2022 Apr 22. PMID: 35451517; PMCID: PMC9545832.
 12. McGowan J, Straus S, Moher D, Langlois EV, O'Brien KK, Horsley T, et al. Reporting scoping reviews-PRISMA ScR extension. *J Clin Epidemiol*. 2020 Jul;123:177-179. doi: 10.1016/j.jclinepi.2020.03.016. Epub 2020 Mar 27. PMID: 32229248.
 13. Preciado D, Nolan RM, Joshi R, Krakovsky GM, Zhang A, Pudik NA, et al. Otitis media middle ear effusion identification and characterization using an optical coherence tomography otoscope. *Otolaryngol Head Neck Surg*. 2020 Mar;162(3):367-374. doi: 10.1177/0194599819900762. Epub 2020 Jan 21. PMID: 31959053; PMCID: PMC7289273.
 14. Khan MA, Kwon S, Choo J, Hong SM, Kang SH, Park IH, et al. Automatic detection of tympanic membrane and middle ear infection from oto-endoscopic images via convolutional neural networks. *Neural Netw*. 2020 Jun;126:384-394. doi: 10.1016/j.neunet.2020.03.023. Epub 2020 Apr 1. PMID: 32311656.
 15. Kashani RG, Młyńczak MC, Zarabanda D, Solis-Pazmino P, Huland DM, Ahmad IN, et al. Shortwave infrared otoscopy for diagnosis of middle ear effusions: a machine-learning-based approach. *Sci Rep*. 2021 Jun 15;11(1):12509. doi: 10.1038/s41598-021-91736-9. PMID: 34131163; PMCID: PMC8206083.
 16. Aftab M, Jain S, Malik R, Kumar P, Gola RK, Singh S. Correlation between video-otoendoscopy and tympanograms of patients with acute middle ear infections. *Indian J Otolaryngol Head Neck Surg*. 2022 Dec;74(Suppl 3):3893-3900. doi: 10.1007/s12070-021-02701-x. Epub 2021 Jun 30. PMID: 34226866; PMCID: PMC8242284.
 17. Othman D, Alashkar M, Bitar MA. Accuracy of video otoscopy in predicting the presence of middle ear effusion in children compared to tympanometry: A diagnostic study. *Cureus*. 2024 Nov 5;16(11):e73098. doi: 10.7759/cureus.73098. PMID: 39650911; PMCID: PMC11621397.