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Prospective Validation of Deep-Learning Algorithms for Diabetic Retinopathy Screening: A Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2025 and was last updated on 31 May 2025.

INTRODUCTION

Review question / Objective To evaluate the prospective diagnostic accuracy of deep learning (DL) algorithms for diabetic retinopathy (DR) screening using fundus photographs, and to explore sources of heterogeneity (e.g., DR severity, image protocol, camera type, healthcare setting).

Condition being studied Diabetic retinopathy (DR), a microvascular complication of diabetes mellitus and a leading cause of preventable blindness among working-age adults globally.

METHODS

Participant or population Adults (age ≥ 18) undergoing fundus imaging for DR screening using DL algorithms.

Intervention Autonomous or assistive deep learning algorithms for fundus-based DR detection.

Comparator Expert human graders (retina specialists or ophthalmologists) using accepted grading protocols (e.g., ICDR, ETDRS).

Study designs to be included Prospective diagnostic accuracy studies.

Eligibility criteria Inclusion: Prospective studies applying DL to detect DR using fundus images, reporting 2x2 diagnostic metrics. Exclusion: Retrospective, pediatric, non-DL models, non-fundus modalities, reviews, conference abstracts.

Information sources PubMed, Embase, ClinicalTrials.gov; hand-searched bibliographies of included studies.

Main outcome(s) Pooled sensitivity and specificity for referable DR and vision-threatening DR, analyzed at patient and eye level.

Quality assessment / Risk of bias analysis QUADAS-2 tool applied by two independent

reviewers. Domains: patient selection, index test, reference standard, flow/timing.

Strategy of data synthesis Hierarchical bivariate random-effects meta-analysis. Meta-regression using 21 moderators. Forest plots and HSROC curves generated.

Subgroup analysis Moderators include DR subtype, image protocol, camera type, grading criteria, economic context, AI gradability, prevalence.

Sensitivity analysis Stratified by vendor involvement, regulatory status, ungradable image handling, and study design.

Language restriction No.

Country(ies) involved Taiwan.

Keywords diabetic retinopathy; deep learning; AI; screening; prospective; meta-analysis.

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