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Feasibility and Equity of AI-Driven Models for Diabetic Retinopathy Screening in Sub-Saharan Africa: A Systematic Review and Meta-Analysis

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Abstract

Artificial intelligence (AI) has the potential to transform diabetic retinopathy (DR) screening, yet its feasibility and equity in low- and middle-income countries (LMICs), particularly sub-Saharan Africa (SSA), remain insufficiently examined. We conducted a systematic review and meta-analysis following PRISMA 2020 guidelines, searching PubMed and Google Scholar for peer-reviewed studies on AI-based DR screening in LMICs, with emphasis on SSA. Data on diagnostic performance, dataset composition, feasibility, and equity were extracted, and sensitivity and specificity were pooled using random-effects meta-analysis; qualitative synthesis identified infrastructural, economic, and ethical factors shaping implementation. Fifty studies met the inclusion criteria. Pooled specificity and sensitivity were 87.63% and 91.91%, respectively, both with very high heterogeneity (I^2 = 99.6% and 98.1%, respectively; $P < 0.001$), indicating that performance differences are unlikely to be due to chance alone. In LMIC validation settings, pooled specificity was higher (89.15%, 95% confidence interval (CI): 85.31-92.99; I^2 = 84.98%) but sensitivity was lower (91.23%, 95% CI: 88.14-94.31; I^2 = 96.4%) compared with high income countries (HIC) settings (specificity 82.80%, 95% CI: 75.35-90.25; I^2 = 99.81%; sensitivity 94.91%, 95% CI: 91.26-98.56; I^2 = 88.6%). This pattern suggests that models validated in LMICs may be more conservative in ruling out DR, whereas models validated in HICs may be more adept at detecting true positives. Key barriers to AI implementation in SSA included inadequate digital infrastructure, workforce shortages, high proprietary system costs, and underrepresentation of SSA researchers in leadership roles. Overcoming these challenges will require coordinated investment in local capacity, digital infrastructure, equitable research partnerships, and the adoption of open, transparent, and inclusive AI development, underpinned by cross-border governance. With such measures, AI could become a sustainable and equitable tool for reducing preventable vision loss across SSA and other resource-constrained regions.

Categories: AI applications, AI Ethics and Fairness, Algorithm Analysis
Keywords: sub-saharan africa, diabetic retinopathy, automated screening, artificial intelligence, equity, feasibility, low-and-middle-income countries

Introduction And Background

Diabetic retinopathy (DR) is a progressive retinal disease caused by prolonged hyperglycemia, leading to retinal capillary damage [1-3]. It remains one of the leading causes of preventable blindness worldwide, significantly impacting individuals' quality of life, productivity, and social participation, particularly among those aged 20 to 79 years living with diabetes mellitus (DM) [4,5]. Globally, approximately 285 million of the 589 million people living with DM exhibit signs of DR [6,7], with one-third experiencing vision-threatening forms such as macular edema (ME) [8]. This burden is projected to rise gradually, with the 11th edition of the International Diabetes Federation (IDF) Atlas estimating that by 2050, 853 million individuals will be living with DM [9,10], and that over 4 in 10 will be unaware they have the condition. This represents an increase of almost 45%, of whom one-third are expected to develop DR [11-13]. A substantial proportion of these new cases is anticipated to emerge from low-and middle-income countries (LMICs), particularly in Sub-Saharan Africa (SSA) [13,14], driven by lifestyle changes, an aging population, rapid urbanization, increasing levels of obesity and lack of physical activity, and persistent socioeconomic barriers that limit access to timely eye care services [15].

Additionally, SSA faces several critical challenges that hinder the effective screening, treatment, and management of DR [15,16]. Among the most significant barriers is the severe shortage of ophthalmologists, with the region averaging only 2.7 ophthalmologists per a million people, far below the World Health Organization (WHO) recommendation of 4 per a million people [17-19]. This workforce shortfall worsens the strain on already under-resourced healthcare systems, which often lack the infrastructure and financial capacity to support large-scale DR screening and treatment programs within SSA [20]. Furthermore, reliance on traditional DR screening methods persists across many SSA countries [16,21]. Traditional DR screening methods are frequently hindered by systemic limitations, including insufficient technological infrastructure, reliance on operator expertise, socioeconomic inequities, and linguistic or cultural barriers [20,21]. These limitations often result in delayed diagnoses and compromised clinical outcomes. However, the International Council of Ophthalmology (ICO) emphasizes that up to 95% of vision loss attributable to DR is preventable with early detection and timely intervention [22]. To this end, the ICO recommends at least annual dilated ophthalmic examinations for all individuals with diabetes, with retinal evaluations feasibly conducted via fundus photography, even in resource-limited settings.

These systemic constraints highlight the urgent need to integrate general eye care services with specialized diabetic eye care pathways to ensure continuity of care and effective DR management [23]. In parallel, the adoption of advanced digital health technologies, particularly artificial intelligence (AI)-driven systems, offers a transformative opportunity to strengthen DR screening, especially in underserved and resource-limited settings. Recent advances in deep learning have shown considerable promise in facilitating early and accurate diagnosis of DR [24-26], enhancing clinical decision-making processes [27,28], and expanding the reach of screening services to populations historically excluded from routine ophthalmic care [29-34]. These AI DR screening innovations represent a pivotal step toward addressing disparities in access, timeliness, and quality of DR detection on a global scale.

The role of AI in DR screening

AI is transforming ophthalmology by offering cost-effective, accurate, and scalable solutions for DR screening and management across clinical and community settings [16-19]. In high-income countries, ophthalmologists increasingly deploy Food and Drug Administration-approved autonomous AI tools such as LumineticsCore to detect more-than-mild DR (mtmDR) without human oversight, achieving sensitivity and specificity of 87% and 90%, respectively [19-22]. Similarly, EyeArt leverages cloud-based analysis to autonomously detect mtmDR with 97% sensitivity and 88% specificity, as well as vision-threatening DR (vtDR) with 97% sensitivity and 90% specificity, delivering results at the eye level [19,23-25]. Validated on over 500,000 patients and nearly 2 million retinal images, EyeArt demonstrates robust generalizability [24]. Other AI systems, such as RetmarkerDR, monitor DR progression by quantifying retinal biomarkers associated with underlying biological and pathological processes, and demonstrate strong performance in detecting proliferative DR [26,27]. Meanwhile, RetinaLyze provides cloud-based triage for DR, age-related macular degeneration, and glaucoma, accentuating the expanding role of AI across ophthalmic conditions [28,29].

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The integration of AI into ophthalmology has markedly enhanced the capabilities of ophthalmic imaging systems [30,31]. Increasingly, medical device manufacturers are embedding deep learning algorithms directly into imaging hardware and software, facilitating real-time image optimization and reducing dependence on operator expertise [32]. These advancements not only improve the diagnostic fidelity of retinal images but also enable more accurate and timely clinical decision-making. Moreover, AI-enhanced imaging platforms support remote expert consultations and tele-mentoring, expanding access to high-quality ophthalmic care in low-resource and underserved settings [33].

Beyond imaging and diagnostics, the integration of large language models (LLMs) into ophthalmology is redefining clinical support workflows [34]. Purpose-built systems such as LEME, EyeGPT, OphGLM, and RetinaChat, trained on specialized ophthalmic datasets that include diagnostic guidelines, peer-reviewed literature, and physician-patient interactions, can simplify complex clinical language and support decision-making for non-specialist providers [35,36]. In resource-limited regions, such as SSA, where over-referrals, long waiting times, and fragmented health records are common, LLMs offer scalable and context-adaptive solutions. These include automated triage, visual acuity screening support, generation of clinical summaries, and streamlined documentation workflows [37,38]. When effectively deployed, such tools can strengthen service delivery, improve diagnostic efficiency, and bridge persistent inequities in access to ophthalmic care [39,40].
However, realizing this potential requires more than technological progress. The translation of AI innovation from laboratory to clinical practice depends on both feasibility and equity, the capacity of health systems to integrate and sustain these technologies, and the fairness with which their benefits are distributed. These twin imperatives now define whether AI's clinical promise can be transformed into durable, population-level public health gains.

Feasibility of AI deployment

Feasibility extends beyond algorithmic precision to encompass the systemic readiness required to operationalize and sustain AI technologies. Despite strong diagnostic performance in controlled environments, real-world implementation in SSA remains hindered by infrastructural fragility, technical limitations, and ethical constraints [40-42]. Most AI models have been trained on datasets from high-income settings, reducing their generalizability to populations with different disease profiles, imaging quality, and comorbidities [43-45]. Achieving operational feasibility requires context-specific validation, the development of local data repositories, and low-cost, interoperable architectures tailored to regional conditions. Strengthening local capacity in AI development, deployment, and governance through collaborative, open-access frameworks and public-private partnerships will be essential for sustainable, autonomous implementation.

Equity in AI implementation

Equitable AI deployment requires more than technological access; it necessitates inclusion, representation, and accountability in both design and governance. Models trained predominantly on non-African datasets risk perpetuating diagnostic bias and amplifying inequities in eye care delivery [46-47]. Variability in image quality, device standards, and population-specific ocular features further affects model performance in SSA [48-49]. Beyond algorithmic bias, inequities in digital literacy, affordability, and infrastructure disproportionately disadvantage rural and marginalized populations. Ensuring fairness requires deliberate inclusion of African data in AI model training, transparent data governance that upholds privacy and sovereignty, and participatory development involving local clinicians, technologists, and patients.

Structural inequities compound these challenges; for example, researchers in SSA often face restricted access to datasets, limited representation in authorship, and underrepresentation in global AI leadership, resulting in systems misaligned with local clinical realities [50-51]. Without rigorous evaluation of feasibility and equity impacts, deployment risks reinforce rather than resolve existing disparities. Current assessments of AI-based DR screening have largely prioritized accuracy metrics [52-53], neglecting critical dimensions such as scalability, contextual adaptability, and equitable access.

There is an urgent need to design AI systems that are not only statistically robust but also socially responsive, grounded in the priorities, constraints, and values of the communities they serve. This review evaluates the feasibility and equity, the twin determinants of sustainable AI translation into clinical practice. It addresses two central questions: (1) what technical, infrastructural, clinical, and resource-related factors enable or hinder the implementation of AI-based DR screening in SSA; and (2) how AI models can be designed and deployed to ensure equitable access across the region's diverse socioeconomic and geographic settings. By interrogating these dimensions, the study seeks to advance the development of AI systems that are both feasible and just, bridging innovation with equitable, long-term improvements in vision health across resource-limited settings.

Materials and methods

This study employed a systematic literature search and meta-analysis guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 framework to ensure methodological transparency, completeness, efficiency, standardization, and reproducibility [54,55]. The various methods as per the framework are detailed as follows.

Literature search and strategy

We conducted a comprehensive literature search using publicly accessible research databases, including PubMed and Google Scholar, to ensure the inclusion of validated, relevant, and current sources. The search strategy centered on AI-based DR screening approaches, with a primary focus on LMICs, particularly in SSA. Additionally, studies from LMICs outside SSA and human-in control (HICs) were included when they provided relevant insights into contextual barriers, facilitators, or performance differentials of AI-driven DR screening across diverse health systems. The search strategy employed a combination of Medical Subject Headings (MeSH) and free-text keywords across the following thematic areas: “diabetic retinopathy,” “referable diabetic retinopathy,” “proliferative diabetic retinopathy,” “vision-threatening diabetic retinopathy,” “artificial intelligence,” “deep learning,” “machine learning,” “automated screening,” “low- and middle-income countries,” “Sub-Saharan Africa,” “healthcare equity,” and “high-income countries.”

PubMed - ("Diabetic Retinopathy"[MeSH] OR "diabetic retinopathy"[tiab] OR "referable diabetic retinopathy"[tiab] OR "proliferative diabetic retinopathy"[tiab] OR "vision-threatening diabetic retinopathy"[tiab]) AND ("Artificial Intelligence"[MeSH] OR "artificial intelligence"[tiab] OR "machine learning"[tiab] OR "deep learning"[tiab] OR "automated screening"[tiab]) AND ("Developing Countries"[MeSH] OR "low- and middle-income countries"[tiab] OR "Sub-Saharan Africa"[tiab]) AND ("Sub-Saharan Africa"[tiab] OR "high-income countries"[tiab]). For Google Scholar - "diabetic retinopathy" AND ("artificial intelligence" OR "machine learning" OR "deep learning") AND ("low- and middle-income countries" OR "Sub-Saharan Africa") AND ("high-income countries").

Eligibility criteria

This review included only peer-reviewed publications from January 1, 2015, to April 30, 2025, that met the following criteria: (1) written in the English language; (2) focused on DR, AI-based DR screening, or its implementation; and (3) specifically addressed LMICs, with a particular emphasis on SSA. Studies were required to (4) present original data and (5) include detailed implementation outcomes or analytical assessments related to DR screening feasibility, dataset composition, or healthcare equity. (6) To provide a broader context and comparative perspective, additional studies conducted in LMICs outside SSA and in HICs that offered relevant insights into barriers, enablers, and performance differences of AI-driven DR screening across diverse healthcare settings were also considered. Gray literature, editorials, and opinion pieces were excluded.

Data extraction, management, and risk assessment

Two independent reviewers extracted data from the selected final articles and examined the potential for publication bias. This included study characteristics, participant demographics, AI model details, performance metrics, implementation outcomes, feasibility data, and equity-related information. Disagreements were resolved through discussion and consultation with a third reviewer. Zotero library collection was utilized to store and organize the selected research articles, and an RStudio IDE was utilized for data extraction and analysis.

Assessment of publicly available DR imaging datasets

Publicly available DR imaging datasets used in the reviewed studies were assessed to evaluate their geographic representation, population diversity, and accessibility, focusing on datasets originating from or including SSA populations. This evaluation aimed to determine the extent to which existing datasets reflect SSA's demographic and clinical realities, which is critical for developing equitable and locally relevant AI models for SSA.

Feasibility assessment

The feasibility of AI-based DR screening in SSA was evaluated across four domains: (1) technological infrastructure (availability of computing resources, internet access, and imaging devices); (2) integration with clinical workflows (compatibility with existing diabetic eye care pathways); (3) human resources (availability of ophthalmologists, retinal specialists, and digitally trained healthcare workers); and (4) sustainability (cost-effectiveness and long-term viability). The country's income status (HICs or LMICs) data were analyzed to inform sustainability considerations.

Equity and ethical analysis

Equity considerations included assessing the representativeness of training and validation datasets regarding racial, ethnic, and demographic diversity, particularly for SSA populations. Potential biases in model development, performance, and generalizability were critically examined. Authorship patterns were analyzed to determine SSA researcher representation in leadership roles (e.g., first or senior authorship). Additionally, ethical frameworks reviewed across selected studies focused on fairness, transparency, inclusivity, and data sovereignty.

Data synthesis and analysis

We adopted a mixed-methods analytical framework to investigate the complex dimensions of feasibility and equity in AI-based DR screening. The quantitative component comprised the generation of summary statistics and meta-regression analyses of diagnostic accuracy metrics, specifically sensitivity and specificity, reported across studies included in our systematic review, enabling a structured appraisal of AI model performance. Concurrently, the qualitative component employed inductive thematic analysis to synthesize contextual factors, barriers and facilitators that shape the implementation of DR screening in SSA. By integrating these complementary approaches, we developed contextually grounded, actionable recommendations to support the equitable deployment of AI-driven DR screening strategies in SSA.

Review

Results

A total of 511 articles were identified through the literature search, comprising 506 from Google Scholar and five from PubMed. Following the PRISMA guidelines, 50 studies were ultimately included in this review. The selection process is detailed in Figure 1.

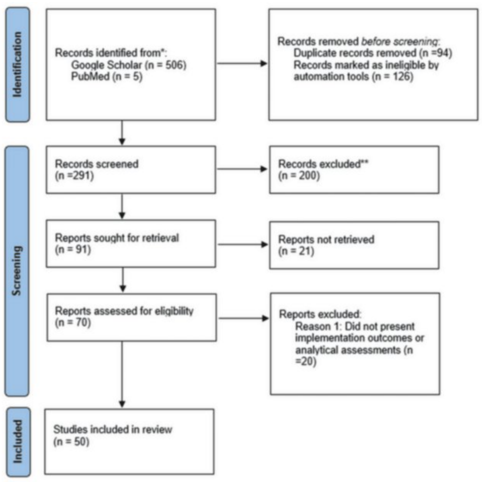

FIGURE 1: PRISMA flow diagram with included searches of databases.

PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Findings related to feasibility and equity

Table 1 provides a comparative overview of 50 studies, capturing the rapid evolution of AI-based models for DR screening. It details each system's technical specifications, training datasets, validation settings, access modes, deployment platforms, and performance metrics (sensitivity and specificity). The table also maps these characteristics across diverse geographic and economic contexts, including multiple SSA, LMICs outside SSA, and HICs that offered relevant insights into barriers, enablers, and performance differences of AI-driven DR screening across diverse healthcare settings.

No	Study	AI system/model	Year	Training dataset	Origin of training dataset	Country of validation	Model of access	Platform type	Any DR Sens	Any DR Spec	RDR Sens	RDR Spec	VTDR/STDR Sens	VTDR/STDR Spec	mtmDR Sens	mtmDR Spec	DMI Sen
1	Abramoff et al. [22]	IDx-DR	2018	EyePACS & DIARETDB	USA & Finland	USA	Offline	Desktop	NR	NR	87.2	90.7	NR	NR	NR	NR	NR
2	Ipp et al. [24]	EyeArt	2021	EyePACS	USA & France	USA	Offline	Desktop	NR	NR	NR	NR	95.1	89	95.5	85	NR
3	He et al. [43]	Airdoc	2020	NR		China	Offline	Desktop	90.79	98.5	91.18	98.79	NR	NR	NR	NR	NR
4	Yang et al. [44]	AIDRScreening	2022	Chinese multicenter screening program	China	China	Offline	Desktop	NR	NR	86.72	95.84	NR	NR	NR	NR	NR
5	Bellemo et al. [56]	SELENA	2019	"Singapore National Diabetic Retinopathy Screening Program (SIDRP)	Singapore	Zambia	Offline	Desktop	NR	NR	92.25	89.04	99.42	NR	NR	NR	97.1
6	Ting et al. [57]	SELENA	2017	Singapore National Diabetic Retinopathy Screening Program (SIDRP)	Singapore	Singapore	Offline	Desktop	NR	NR	90.5	91.6	100	91.1	NR	NR	NR
7	Cleland et al. [58]	NR	2023	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
8	Nwaoha et al. [59]	NR	2024	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
9	Cleland et al. [60]	NR	2023	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
10	Amugongo et al. [61]	NR	2024	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
11	Sibal et al. [62]	NR	2024	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
12	Nunez do Rio et al. [63]	VISUHEALTH-AI DR	2022	Singapore Eye Research Institute (SERI)		India	Offline	Smartphone	NR	NR	72.07	85.65	NR	NR	NR	NR	NR
13	Hsieh et al. [64]	VeriSee	2021	National Taiwan University Hospital (NTUH) Dataset	Taiwan	Taiwan	Offline	Desktop	92.2	89.5	80.3	88.3	NR	NR	NR	NR	NR
14	Mathenge et al. [65]	NR	2022	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
15	Ephraim et al. [66]	NR	2024	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
16	Ozioko and Kamalakannan [67]	NR	2024	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
17	Nakayama et al. [68]	NR	2024	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
18	Hansen et al. [69]	Iowa Detection Program (IDP)	2015	MESSIDOR and EyePACS	USA & France	Kenya	Offline	Smartphone	91	69.9	NR	NR	NR	NR	NR	NR	NR
19	Achigbu et al. [70]	NR	2023	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
20	Dean et al. [71]	NR	2020	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
21	Mwangi [72]	NR	2020	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
22	Sosale et al. [73]	Medios AI	2020	EyePACS + mydriatic images captured at a tertiary diabetes center in India	USA & India	India	Offline	Smartphone	83.3	95.5	98.84	92.5	98.84	92.5	NR	NR	NR
23	Sosale et al. [74]	Medios AI	2020	EyePACS + mydriatic images captured at a tertiary diabetes center in India	USA & India	India	Offline	Smartphone	86.78	95.45	98.84	86.73	NR	NR	NR	NR	NR
24	Jain et al. [75]	Medios AI	2019	EyePACS + mydriatic images captured at a tertiary diabetes center in India	USA & India	India	Offline	Smartphone	89.13	94.43	100	89.55	NR	NR	NR	NR	NR
25	Raumviboonsuk et al. [76]	Google	2019	EyePACS & Messidor-2	USA & France	Thailand	NR	Desktop	NR	NR	94.3	98.5	NR	NR	NR	NR	95.3
	Ruamviboonsuk et			EyePACS &													

26	al. [77]	Google	2022	Messidor-2	USA & France	Thailand	NR	Desktop	NR	NR	NR	NR	91.4	95	NR	NR	NR
27	Gulshan et al. [78]	Google	2019	EyePACS & Messidor-2	USA & France	India	NR	Desktop	NR	NR	88.9	92.2	NR	NR	NR	NR	NR
28	Gulshan et al. [79]	Google	2016	EyePACS & Messidor-2	USA & France	USA	NR	Desktop	NR	NR	97.5	93.4	NR	NR	NR	NR	NR
29	Sobhi et al. [80]	DAPHNE	2020	NR	Saudi Arabia&China& Kenya	China	NR	Offline	Desktop	NR	NR	94.28	92.12	NR	NR	NR	NR
30	van der Heijden [81]	IDx-DR	2018	EyePACS & DIARETDB	USA & Finland	Netherlands	Offline	Desktop	NR	NR	91	84	64	95	NR	NR	NR
31	Al-Turk et al. [82]	DAPHNE	2020	EyePACS	USA	Kenya	Offline	Desktop	NR	NR	94.28	92.12	NR	NR	NR	NR	NR
32	Rajalakshmi et al. [83]	EyeArt	2018	EyePACS	USA & France	India	Both Offline and Online	Smartphone	95.8	80.2	99.3	68.8	99.1	80.4	NR	NR	75.8
33	Zhang et al. [84]	EyeWisdom	2022	A proprietary dataset from Chinese public hospitals	China	China	Offline	Desktop	98.23	74.45	92.96	93.32	80.47	97.96	NR	NR	NR
34	Ming et al. [85]	EyeWisdom	2021	EyePACs & PUMCH		China	Offline	Desktop	83.3	97.9	79.2	98.3	NR	NR	NR	NR	NR
35	Abdoola et al. [86]	Google AutoML Vision	2023	NR		South Africa	Offline	Desktop	NR	NR	85.7	87.5	NR	NR	NR	NR	NR
36	Bawankar et al. [87]	Bosch DR algorithm	2017	EyePACs + Bosch Eye Camera Dataset	USA & India	India	Offline	Smartphone	91.18	96.91	NR	NR	NR	NR	NR	NR	NR
37	Hao et al. [88]	EyeWisdom	2022	Chinese public hospitals (Peking Union Medical College Hospital; Eye Hospital, China Academy of Chinese Medical Sciences; and Beijing Friendship Hospital of Capital Medical University)	China	China	Offline	Desktop	81.2	94.3	NR	NR	NR	NR	NR	NR	NR
38	Ramachandran et al. [89]	Visiona	2017	EyePACS & Messidor-2	USA & France	New Zealand	Offline	Desktop	NR	NR	84.6	79.7	NR	NR	NR	NR	NR
39	Rogers et al. [90]	Pegasus	2021	EyePACS	USA	India	Offline	Desktop	NR	NR	93.4	94.2	NR	NR	NR	NR	NR
40	Ruan et al. [91]	Phoebus	2022	NR		China	Offline	Smartphone	NR	NR	82.1	97.4	NR	NR	NR	NR	88.2
41	Vaghefi et al. [92]	THEIA	2021	New Zealandâ€™s National Diabetic Retinopathy Screening program	New Zealand	New	Offline	Desktop	NR	NR	94	63	NR	NR	NR	NR	NR
42	Zhang et al. [93]	EyeWisdom	2021	EyePACs & PUMCH		China	Offline	Desktop	83.3	97.9	79.2	98.3	NR	NR	NR	NR	NR
43	Malerbi et al. [94]	PhelcomNet	2022	Itabuna Diabetes Campaign dataset	Brazil	Brazil	Online	Smartphone	90.48	90.65	97.8	61.4	NR	NR	90.23	85.06	NR
44	Malerbi et al. [95]	RAS/DRAS	2024	Itabuna Diabetes Campaign dataset	Brazil	Brazil	Online	Smartphone	90.48	90.65	NR	NR	NR	NR	90.23	85.06	NR
45	AbrÃ moff et al. [96]	Iowa Detection Program (IDP)	2016	NR	USA	France	Offline	Desktop	NR	NR	96.8	87	100	NR	NR	NR	NR
46	Milic et al. [97]	NR	2025	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
47	Dong et al. [98]	Airdoc	2022	A proprietary dataset from Chinese public hospitals	China	China	Online	Desktop	75.19	93.99	NR	NR	33.93	97.69	78.97	92.52	47.3
48	Arenas-Cavalli et al. [99]	DART	2021	TeleDxâ€™s proprietary archive	Chile	Chile	Online	Desktop	94.6	74.3	94.5	72.7	NR	NR	NR	NR	NR
49	Shah et al. [100]	IDx-DR	2020	EyePACS & DIARETDB	USA & Finland	Spain	Offline	Desktop	NR	NR	100	81.82	100	94.64	NR	NR	NR
50	Burgess et al. [101]	EyeStar	2020	EyePACS & APTOS 2019	USA & India	Malawi	Offline	Smartphone	NR	NR	100	76	NR	NR	NR	NR	NR

TABLE 1: Summary of evaluated studies on AI-based diabetic retinopathy screening.

Key for accuracy columns: Any DR Spec, specificity for detecting any stage of diabetic retinopathy (DR); RDR Sens, sensitivity for detecting referable diabetic retinopathy (RDR); RDR Spec, specificity for detecting RDR; VTDR/STDR Sens, sensitivity for detecting vision-threatening diabetic retinopathy (VTDR) or sight-threatening diabetic retinopathy (STDR). mtmDR Sens, sensitivity for detecting moderate to more severe diabetic retinopathy; DME Sens, sensitivity for detecting diabetic macular edema (DME); DME Spec, specificity for detecting DME. PDR Sens, sensitivity for detecting proliferative diabetic retinopathy (PDR); PDR Spec, specificity for detecting PDR; NR, not recorded; AI, artificial intelligence.

Technical limitations

This study identifies a fundamental technical constraint in AI-based DR screening related to the origin and composition of training and validation datasets. These elements critically shape model performance, robustness, generalizability, and algorithmic fairness, particularly when deployed in real-world, heterogeneous populations. As depicted in Figure *2a*, the majority of AI systems have been trained and developed on datasets sourced predominantly from HICs and a limited few LMICs outside of SSA. In contrast, Figure *2b* illustrates the pronounced underrepresentation of SSA-derived data within the AI development pipeline, highlighting a significant gap in both geographic and demographic inclusivity. This data asymmetry poses significant risks of algorithmic bias and undermines the clinical applicability of these models across SSA populations.

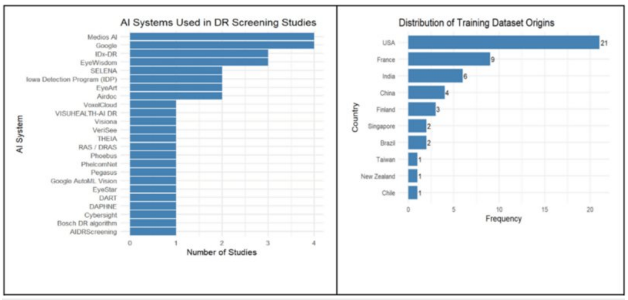

FIGURE 2: (a) The figure summarizes AI-models/systems in the surveyed systems; whereas (b) on the right displays how various training dataset origins.

AI, artificial intelligence.

For example, Bellemo et al. [56] evaluated the SELENA+ model in Zambia using local retinal images, despite the model having been trained exclusively on data from the Singapore National Diabetic Retinopathy Screening Programme. Although the validation yielded promising results, performance fell short of that reported in the original study by Ting et al. [57], in which both training and testing datasets were geographically aligned. This performance gap likely reflects differences in patient demographics, disease phenotypes, image quality, clinical workflows, and healthcare infrastructure, factors that directly influence model inference.
Supporting this, Cleland et al. [58] noted that most AI models for DR screening in LMICs lack meaningful representation from SSA populations, thereby limiting their generalizability and reliability in those settings. Nwaoha et al. [59] and Cleland et al. [60] further argue that the absence of contextually relevant datasets and digital infrastructure in SSA hinders AI adoption and undermines diagnostic accuracy. Similarly, Amugongo et al. [61] and Sibal et al. [62] call for equitable and localized AI design, warning that deploying non-contextualized models not only perpetuates algorithmic bias but also erodes trust in these systems.

Similarly, studies by Nunez do Rio et al. [63] and Hsieh et al. [64] employed models trained on data from Singapore and Taiwan, respectively. In these studies [63,64], the authors emphasize the importance of the similar context of datasets to the one on which the algorithm was trained and quality of captured images in real-world community settings in determining the success of any AI system used for non-mydriatic DR screening. Together, these findings underscore the spatial and temporal limitations of current AI models, which tend to perform reliably only in settings that closely mirror their original training environments. This highlights the critical need for the development of region-specific datasets, particularly for SSA, along with local validation of AI models and the design of context-aware systems. Such measures are essential to ensure that DR screening tools are not only technically robust, but also ethically responsible and clinically effective within SSA contexts. This necessity is further emphasized by the fact that the majority of AI systems reviewed in this study were developed using datasets from HICs and validated predominantly in non-SSA LMICs, Figure *3* raising concerns about their generalizability and equity in real-world SSA settings.

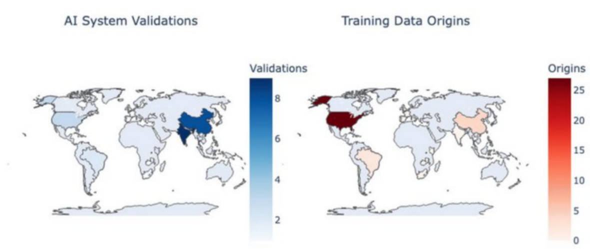

FIGURE 3: AI systems validation vs training data origins.

AI, artificial intelligence.

Infrastructural limitations

Persistent infrastructural deficits, such as fragmented health information systems, unreliable electricity, limited internet access, and the absence of interoperable electronic health records (EHRs) and trusted research environments (TREs), continue to hinder the scalable implementation of AI-based DR screening in SSA [65-68]. The unavailability of essential diagnostic hardware, including fundus cameras and optical coherence tomography (OCT), further compounds these limitations. Mathenge et al. [65] emphasize how workforce shortages and inadequate imaging infrastructure constrain DR screening efforts, while Ephraim et al. [66] document the compounding effects of infrastructural and financial barriers on the uptake of AI-driven medical technologies. In rural Nigeria, Ozioko and Kamalakannan [67] highlight the destabilizing role of poor power supply and weak data ecosystems, while Nakayama et al. [68] underscore that device availability and stable network connectivity are prerequisites for functional AI deployments in remote or resource-limited settings.

These challenges are echoed in broader AI implementation literature. For example, Milic [97] critiques the premature adoption of opaque AI systems in SSA, pointing to under-resourced digital infrastructure and fragile health system integration as ethical and practical concerns. Dong et al. [98] also report significant variability in AI performance and usability in Chinese community health centers in part due to inconsistent device quality and connectivity issues. These challenges are likely to be amplified in the SSA. Similarly, Abdoola and Kruse [86] show that despite promising algorithmic performance, infrastructural weaknesses in South Africa limit the reach and reliability of DR screening initiatives, particularly in rural provinces.

Despite these constraints, tailored innovations offer a glimpse of feasibility. In Kenya, Hansen et al. [69] demonstrated the viability of deploying the Iowa Detection Program through a smartphone-enabled, offline-compatible model. This approach effectively reduced dependency on continuous internet access and grid electricity, enabling scalable DR screening in community settings. Likewise, Malerbi et al. [94,95] explored the integration of handheld fundus cameras with AI algorithms, validating their use in mobile screening units and low-connectivity environments. These examples underscore the potential of context-adapted AI systems that are designed with infrastructural realities in mind.

Nevertheless, the widespread success of AI-based DR screening in SSA demands more than isolated technological adaptations. It requires sustained investment in digital and health infrastructure, enhanced digital literacy among health workers, and the strategic alignment of AI tools with national health information systems. As emphasized by Arenas-Cavalli et al. [99], even well-performing AI systems encounter scale-up limitations in under-resourced health systems without institutional readiness. To ensure equitable access and sustainable integration, AI-based retinal screening technologies must be embedded within broader frameworks of health system strengthening, local capacity building, and inclusive digital transformation.

Clinical capacity and human resources

Clinically, the successful deployment of AI-based DR screening systems in SSA hinges on sustained clinical oversight and sufficient workforce capacity. Mathenge et al. [65] highlight systemic limitations, notably the scarcity of trained personnel and imaging tools. Similarly, Achigbu et al. [70] report a critical shortage of ophthalmologists across the region, hindering both implementation and quality assurance. Dean et al. [71] further argue that integrating AI into SSA's health systems requires parallel investment in ethical training, clinical competencies, and governance structures. Clinicians, particularly ophthalmologists, must be equipped to interpret and ethically manage AI outputs within settings often constrained by limited oversight. Together, these studies emphasize that without deliberate investment in workforce development and regulatory frameworks, AI systems risk exacerbating rather than alleviating diagnostic gaps in SSA.

Economic sustainability

Economic sustainability remains a critical challenge in implementing AI-based DR screening in SSA. Nakayama et al. [68] highlight that proprietary AI tools often involve prohibitive upfront costs and ongoing expenses for software updates, maintenance, and technical support, making them inaccessible primarily to resource-constrained health systems, such as those in the SSA. Ephraim et al. [66] share this concern, noting that many SSA countries lack the necessary infrastructural and financial capacity to support the digital infrastructure required for AI deployment. However, despite these challenges, emerging evidence demonstrates potential for cost-effectiveness when AI is strategically integrated.

Cleland et al. [58] found that AI-based DR screening can outperform standard care economically in LMICs if implemented efficiently. Mathenge et al. [65] reported that AI-assisted triaging significantly improved referral uptake in Rwanda, resulting in both clinical and financial benefits. Similarly, Mwangi [72] used cost-effectiveness modeling in Kenya to show that AI integration can expand access while remaining sustainable within public health frameworks. Nakayama et al. [68] also suggest that telemedicine-enabled AI could alleviate pressure on overstretched ophthalmic services. Collectively, these studies emphasize the importance of locally adapted, strategically funded AI solutions in ensuring long-term cost-effectiveness and enhancing health system resilience in SSA.

Authorship and data ownership

The review reveals enduring structural inequities in research ownership and leadership, particularly within SSA (Table *2*). Despite increasing validation of studies within SSA, especially in Rwanda, Zambia, Kenya, and South Africa, the first and senior authors remain predominantly affiliated with institutions in HICs. Among the 50 studies reviewed, 56.2% of senior authors were based in HICs, while only 43.8% were from LMICs. The regional disparity is even more pronounced: 97.9% of senior authors were located outside SSA, with just 2.1% from within the region, as illustrated in Figure *4a*. Figure *4b* further illustrates this imbalance, showing that although first authorship is evenly split between HICs and LMICs (50% each), only 14% of first authors are affiliated with SSA institutions, compared to 86% based elsewhere. These findings highlight a persistent concentration of research leadership outside SSA and highlight the ongoing marginalization of local voices in shaping research agendas relevant to the region.

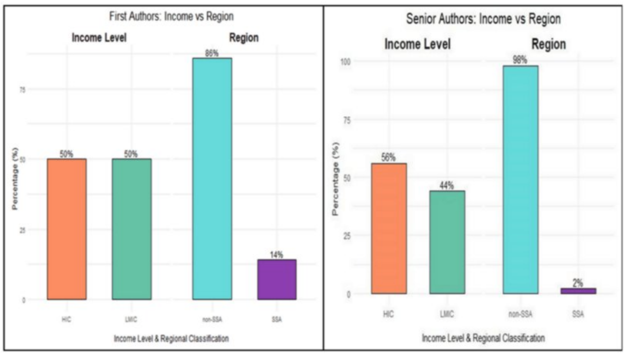

FIGURE 4: Describes the researcher affiliation: (a) on the left, the first author association globally, whereas in (b), the senior author association globally is described.

SSA, sub-Saharan Africa; LMIC, low- and middle-income country; HIC, human-in control.

No.	First author	Study title	First author affiliation	First author affiliation country	First author country income	Senior author	Senior author affiliation	Senior author affiliation country	Senior author country income
1	Sosale et al. [73]	Simple, mobile-based artificial intelligence algorithm in the detection of diabetic retinopathy (SMART) study	Diabetology, Diacon Hospital, Bangalore	India	LMIC	Muralidhar Naveenam	Ophthalmology, Retina Institute of Karnataka, Bangalore, India	India	LMIC
2	Sosale et al. [74]	Medios, An offline, smartphone-based artificial intelligence algorithm for the diagnosis of diabetic retinopathy	Diabetology, Diacon Hospital, Bangalore	India	LMIC	Muralidhar Naveenam	Ophthalmology, Retina Institute of Karnataka, Bangalore, India	India	LMIC
3	Natarajan et al. [16]	Diagnostic accuracy of community-based diabetic retinopathy screening with an offline artificial intelligence system on a smartphone	Aditya Jyot Foundation for Twinkling Little Eyes, Mumbai	India	LMIC	Sobha Sivaprasad	Moorfields Eye Hospital, London, United Kingdom	United Kingdom	HIC
4	Jain et al [75]	"Use of offline artificial intelligence in a smartphone-based fundus camera for community screening of diabetic retinopathy	Dept. of Vitreoretina, Aditya Jyot Foundation for Twinkling Little Eyes, Mumbai, Maharashtra	India	LMIC	Sundaram Natarajan	Aditya Jyot Foundation for Twinkling Little Eyes, Mumbai	Singapore	LMIC
5	Ting et al. [57]	Development and validation of a deep learning system for diabetic retinopathy and related eye diseases using retinal images from multiethnic populations with diabetes	Singapore National Eye Centre	Singapore	HIC	Tien Y. Wong	Singapore National Eye Centre	Singapore	HIC
6	Bellemo et al. [56]	Artificial intelligence using deep learning to screen for referable and vision-threatening diabetic retinopathy in Africa: a clinical validation study	Singapore National Eye Centre	Singapore	HIC	Daniel S W Ting	Singapore Eye Research Institute, Singapore National Eye Centre, Singapore	Singapore	HIC
		Deep learning							

7	Ruamviboonsuk et al. [76]	versus human graders for classifying diabetic retinopathy severity in a nationwide screening program	College of Medicine, Rangsit University, Bangkok	Thailand	LMIC	Dale R. Webster	Google AI, Google, Mountain View, CA, USA	USA	HIC
8	Gulshan et al. [78]	Performance of a deep-learning algorithm vs manual grading for detecting diabetic retinopathy in India	Google Research, Mountain View, California	USA	HIC	Dale R Webster	Google Research, Mountain View, California	USA	HIC
9	Gulshan et al [79]	Development and validation of a deep learning algorithm for detection of diabetic retinopathy in retinal fundus photographs	Google Research, Mountain View, California	USA	HIC	Dale R. Webster	Google AI, Google, Mountain View, CA, USA	USA	HIC
10	Ruamviboonsuk et al. [77]	Real-time diabetic retinopathy screening by deep learning in a multisite national screening programme: a prospective interventional cohort study	Department of Ophthalmology, College of Medicine, Rangsit University, Rajavithi Hospital, Bangkok, Thailand	Thailand	LMIC	Dale R. Webster	Google AI, Google, Mountain View, CA, USA	USA	HIC
11	Al-Turk et al. [82]	Evidence based prediction and progression monitoring on retinal images from three nations	Department of Statistics, King Abdulaziz University, Jeddah	Saudi Arabia	HIC	Hongying Lilian Tang	Department of Computer Science, University of Surrey, Guildford, Surrey	UK	HIC
12	Rajalakshmi et al. [83]	Automated diabetic retinopathy detection in smartphone-based fundus photography using artificial intelligence	Dr. Mohan's Diabetes Specialities Centre & Madras Diabetes Research Foundation, WHO Collaborating Centre for Noncommunicable Diseases Prevention and Control & IDF Centre of Excellence in Diabetes Care & ICMR Centre for Advanced Research on Diabetes, Chennai, Tamil Nadu	India	LMIC	Viswanathan Mohan	Dr. Mohan's Diabetes Specialities Centre & Madras Diabetes Research Foundation	India	LMIC
13	Zhang et al. [84]	Artificial intelligence-enabled screening for diabetic retinopathy: a real-world, multicenter and prospective study	Department of Endocrine and Metabolic Diseases, Shanghai Institute of Endocrine and Metabolic Diseases, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine; Shanghai National Clinical Research Center for Metabolic Diseases; Key Laboratory for Endocrine and Metabolic Diseases of the National Health Commission; Shanghai National Center for Translational Medicine, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine	China	LMIC	Weiqing Wang	Department of Endocrine and Metabolic Diseases, Shanghai Institute of Endocrine and Metabolic Diseases, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China; Shanghai National Clinical Research Center for metabolic Diseases, Key Laboratory for Endocrine and Metabolic Diseases of the National Health Commission of the PR China, Shanghai National Center for Translational Medicine, Ruijin Hospital, Shanghai Jiao Tong University	China	LMIC

							School of Medicine, Shanghai, China		
14	Ming et al. [86]	Evaluation of a novel artificial intelligence-based screening system for diabetic retinopathy in community of China: a real-world study	Department of Ophthalmology, Clinical Research Center, Henan Eye Hospital, Henan Provincial People's Hospital, Henan Eye Institute, People's Hospital of Zhengzhou University, Zhengzhou"	China	LMIC	Bo Lei	Department of Ophthalmology, Henan Eye Hospital, People's Hospital of Zhengzhou University	China	LMIC
15	Yang et al. [44]	Performance of the AIDRScreening system in detecting diabetic retinopathy in the fundus photographs of Chinese patients: a prospective, multicenter, clinical study	State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University; Guangdong Provincial Key Laboratory of Ophthalmology and Visual Science, Guangzhou	China	LMIC	Xiaofeng Lin	State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangdong Provincial Key Laboratory of Ophthalmology and Visual Science, Guangzhou	China	LMIC
16	Nunez do Rio et al. [63]	Evaluating a deep learning diabetic retinopathy grading system developed on mydriatic retinal images when applied to non-mydriatic community screening	Institute of Ophthalmology, University College London; Section of Ophthalmology, King's College London, London	United Kingdom	HIC	Rajiv Raman	Sankara Nethralaya, 18, College Road, Chennai 600006	India	LMIC
17	Abràmoff et al. [96]	Improved automated detection of diabetic retinopathy on a publicly available dataset through integration of deep learning	Department of Ophthalmology and Visual Sciences, University of Iowa Hospitals & Clinics, Iowa City	USA	HIC	Meindert Niemeijer	IDx LLC, Iowa City, Iowa, United States	USA	HIC
18	Abràmoff et al. [22]	Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices	Department of Ophthalmology and Visual Sciences, University of Iowa, Iowa City, IA 52242, USA	USA	HIC	James C Folk	Department of Ophthalmology and Visual Sciences, University of Iowa, Iowa City & Veterans Administration Medical Center, Iowa City	USA	HIC
19	He et al. [43]	Artificial intelligence-based screening for diabetic retinopathy at community hospital	Department of Ophthalmology, Shanghai Shibei Hospital of Jing'an District, Shanghai, China	China	LMIC	Jili Chen	Department of Ophthalmology, Shanghai Shibei Hospital of Jing'an District, Shanghai, China	China	LMIC
20	Ramachandran et al. [89]	Diabetic retinopathy screening using deep neural network	Eye Department, Dunedin Hospital, Dunedin, New Zealand	New Zealand	HIC	Graham A Wilson	Eye Department, Dunedin Hospital, Dunedin	New Zealand	HIC
21	Hsieh et al. [64]	Application of deep learning image assessment software VeriSee™ for diabetic retinopathy screening	Department of Ophthalmology, National Taiwan University Hospital, Taipei, Taiwan	Taiwan	HIC	Mingke Chen	Acer Inc., New Taipei	Taiwan	HIC
22	Vaghefi et al. [92]	THEIA™ development, and testing of artificial intelligence-based primary triage of diabetic retinopathy screening	Toku Eyes, Auckland; School of Optometry & Vision Science, University of Auckland	New Zealand	HIC	D Squirrell	Toku Eyes, Auckland & Department of Ophthalmology, Auckland	New Zealand	HIC

		images in New Zealand							
23	Rogers et al. [90]	Evaluation of an AI system for the detection of diabetic retinopathy from images captured with a handheld portable fundus camera: the MAILOR AI study	Pegasus (Visulytix Ltd.), London	United Kingdom	HIC	N. Jaccard	Unaffiliated, London, UK	UK	HIC
24	Burgess et al. [101]	Efficacy of automated point-of-care screening for diabetic retinopathy in Southern Malawi	VisionQuest Biomedical, Albuquerque, New Mexico, United States	USA	HIC	Philip Burgess	Faculty of Health & Life Sciences, University of Liverpool, Liverpool, United Kingdom	UK	HIC
25	Hansen et al. [69]	Results of automated retinal image analysis for detection of diabetic retinopathy from the Nakuru study Kenya.	Clinical Services, Orbis International, New York, NY	USA	HIC	Wanjiku Mathenge	Department of Ophthalmology, Rwanda Military Hospital, Kigali, Rwanda	Rwanda	LMIC
26	Abdoola et al. [86]	Evaluation of Google AutoML novel artificial intelligence in detecting referable diabetic retinopathy in South Africa	Department of Ophthalmology, University of KwaZulu-Natal, Durban	South Africa	LMIC	CH Kruse	Department of Ophthalmology, University of KwaZulu-Natal, Durban	South Africa	LMIC
27	Hao et al. [88]	Clinical evaluation of AI-assisted screening for diabetic retinopathy in rural areas of midwest China	Department of Ophthalmology, Heji Hospital, Changzhi Medical College, Changzhi	China	LMIC	Shengfu Fan	Department of Foreign Languages, Changzhi Medical College, Changzhi	China	LMIC
28	Bawankar et al. [87]	Sensitivity and specificity of automated analysis of single-field non-mydriatic fundus photographs by Bosch DR algorithm-comparison of mydriatic fundus photography for screening in undiagnosed diabetic retinopathy	Sri Sankaradeva Nethralaya, Guwahati	India	LMIC	Suneet Sood	Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia, Johor Bahru	Malaysia	HIC
29	Hansen et al. [69]	Results of automated retinal image analysis for detection of diabetic retinopathy from the Nakuru Study, Kenya	NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Trust & UCL Institute of Ophthalmology, London	UK	HIC	Tunde Peto	"NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology, London, United Kingdom"	United Kingdom	HIC
30	Ruan et al. [91]	A new handheld fundus camera combined with visual artificial intelligence	Dept. of Ophthalmology, Shanghai General Hospital, Shanghai	China	LMIC	Feng-Hua Wang	"Department of Ophthalmology, Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine; Shanghai Key Laboratory of Ocular Fundus Diseases, Shanghai	China	LMIC

		facilitates diabetic retinopathy screening	Jiao Tong University, Shanghai				Engineering Center for Visual Science and Photomedicine; National Clinical Research Center for Eye Diseases, Shanghai 200025, China"		
31	Zhang et al. [84]	The validation of deep learning-based grading model for diabetic retinopathy	Peking Union Medical College Hospital (CAMS) Beijing, China	China	LMIC	You-xin Chen	"Department of Ophthalmology, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Beijing; Key Laboratory of Ocular Fundus Diseases, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China"	China	LMIC
32	Dong et al. [98]	Evaluation of an Artificial intelligence system for the detection of diabetic retinopathy in Chinese community healthcare centers	Department of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University	China	LMIC	Jiangfeng Zou	Department of Ophthalmology, Dongguan Tungwah Hospital, Dongguan, China	China	LMIC
33	Arenas-Cavalli et al. [99]	Clinical validation of an artificial intelligence-based diabetic retinopathy screening tool for a national health system	TeleDx, Santiago	Chile	LMIC	Rodrigo Donoso	Department of Ophthalmology, Universidad de Chile, Santiago, Chile	Chile	LMIC
34	Malerbi et al. [94]	Diabetic retinopathy screening using artificial intelligence and handheld smartphone-based retinal camera	Department of Ophthalmology and Visual Sciences, Federal University of São Paulo, São Paulo, Brazil	Brazil	LMIC	Rubens Belfort Jr	"Department of Ophthalmology and Visual Sciences, Federal University of São Paulo, São Paulo; Instituto Paulista de Estudos e Pesquisas em Oftalmologia (IPEPO), Vision Institute, São Paulo, Brazil"	Brazil	LMIC
35	Malerb et al. [95]	Automated identification of different severity levels of diabetic retinopathy using a handheld fundus camera and single-image protocol	Singapore National Eye Centre	Singapore	HIC	Caio V Regatieri	Federal University of São Paulo, São Paulo, Brazil	Brazil	LMIC
36	Ipp et al. [24]	Pivotal evaluation of an artificial intelligence system for autonomous detection of referrable and vision-threatening diabetic retinopathy	The Lundquist Institute, Harbor-UCLA Medical Center, Torrance, California	USA	HIC	Kaushal Solanki	Eyenuk Inc, Los Angeles, California, United States	United States	HIC
		Validation of automated screening for referable Diabetic					FISABIO Oftalmología		

37	Shah et al. [100]	retinopathy with an autonomous diagnostic artificial intelligence system in a Spanish population	1Dx Technologies Inc, Coralville, IA, USA	USA	HIC	Cristina Peris Martinez	Medica (FOM), Valencia; University of Valencia, Spain	Spain	HIC
38	van der Heijden et al. [81]	Validation of automated screening for referable diabetic retinopathy with the IDx-DR device in the Hoorn Diabetes Care System	1Department of General Practice and Elderly Care Medicine, VU University Medical Centre, Amsterdam, the Netherlands	Netherlands	HIC	Giel Nijpels	"Department of General Practice and Elderly Care Medicine & Amsterdam Public Health Research Institute, VU University Medical Centre, Amsterdam, the Netherlands"	The Netherlands	HIC
39	Cleland et al. [58]	Artificial intelligence for diabetic retinopathy in low-income and middle-income countries: a scoping review	Eye Department, Kilimanjaro Christian Medical Centre, Moshi	Tanzania	LMIC	Covadonga Bascaran	International Centre for Eye Health, LSHTM, London	UK	HIC
40	Nwaoha et al. [59]	Factors associated with the uptake and utilization of diabetic retinopathy screening services in sub-Saharan Africa: a scoping review	Department of Public Health, Univ. of Limerick	Ireland	HIC	Nuha Ibrahim	Dept. of Public Health, Univ. of Limerick	Ireland	HIC
41	Cleland et al. [60]	Artificial intelligence-supported diabetic retinopathy screening in Tanzania: rationale and design of a randomised controlled trial	International Centre for Eye Health, LSHTM + KCMC*	United Kingdom	HIC	Matthew J. Burton	International Centre for Eye Health, LSHTM	United Kingdom	HIC
42	Amugongo et al. [61]	Machine intelligence in Africa: a survey	Technical University of Munich,	Germany	HIC	Hamidou Tembine	Technical University of Munich,	Germany	HIC
43	Sibal et al. [62]	Artificial intelligence needs assessment survey in Africa	UNESCO	France	HIC	Davor Orlic	International Artificial Intelligence Research Centre (IRCAI)	UK	HIC
44	Ephraim et al. [66]	Application of medical artificial intelligence technology in Sub-Saharan Africa: Prospects for medical laboratories	Dept. of Medical Laboratory Science, School of Allied Health Sciences, University of Cape Coast	Ghana	LMIC	Tivani Phosa Mashamba-Thompson	Health Systems & Public Health, Faculty of Health Sciences, University of Pretoria	South Africa	LMIC
45	Milic et al. [97]	The role of artificial intelligence in strengthening healthcare delivery in Sub-Saharan Africa: challenges and opportunities	High Medical College of Professional Studies "Milutin Milankovic", Belgrade	Serbia	LMIC				
46	Nakayama et al. [68]	Artificial intelligence for telemedicine diabetic retinopathy screening: a review	Institute for Medical Engineering & Science, MIT, Cambridge, MA	USA	HIC	Paolo S. Silva	Philipines Eye Research Institute, University of Philippines	Phillipines	LMIC
47	Achigbu et al. [70]	Assessing the barriers and facilitators of access to diabetic retinopathy screening in Sub-Saharan Africa: a literature review	Federal University Teaching Hospital, Owerri	Nigeria	LMIC	Adrianna Murphy	London School of Hygiene & Tropical Medicine	United Kingdom	HIC

48	Dean et al. [71]	Ophthalmology training in sub-Saharan Africa: a scoping review	University of Cape Town, Cape Town	South Africa	LMIC	Matthew J. Burton	International Centre for Eye Health, LSHTM, London	United Kingdom	HIC
49	Mwangi et al. [72]	Diabetic retinopathy in Kenya: assessment of services and interventions to improve access	London School of Hygiene & Tropical Medicine (PhD thesis)	Kenya	LMIC				
50	Mathenge et al. [65]	Impact of artificial intelligence assessment of diabetic retinopathy on referral service uptake in a low-resource setting: the RAIDERS randomized trial	Rwanda International Institute of Ophthalmology, Kigali	Rwanda	LMIC	Nicolas Jaccard	Orbis International, New York, New York	USA	HIC

TABLE 2: Author affiliations and country income classifications.

Ethical concerns and potential for bias

To characterize variability in AI performance, we conducted a stratified forest plot analysis according to the income status of the validation dataset (Figure 5). Overall, pooled specificity was 87.63% (95% CI 84.13-91.14) and pooled sensitivity was 91·91% (89.32-94.50), with heterogeneity exceeding 98% for both metrics ($P < 0.001$), indicating that differences between studies were unlikely to be attributable to chance alone. In LMIC validation settings, pooled specificity was higher at 89.15% (85.31-92.99; I^2=84.98%), whereas pooled sensitivity was lower at 91.23% (88.14-94.31; I^2=96·40%). In HIC settings, the pattern was reversed: pooled specificity was 82.80% (75.35-90.25; I^2=99.81%), while pooled sensitivity reached 94.91% (91.26-98.56; I^2=88.60%). These differences suggest that models validated in LMIC datasets may be more conservative in ruling out disease, whereas models validated in HIC datasets appear more effective at identifying true positives. Persistently, high heterogeneity within both subgroups suggests substantial contextual variation, including differences in dataset provenance, image quality, grading standards, and clinical workflows. Together, these findings emphasize the need for robust local validation and highlight the challenges of generalizing AI-driven retinal screening tools across diverse global health systems..

Al Turk et al. [82] exemplify this issue, demonstrating variability in algorithmic performance across datasets from three countries, thereby highlighting concerns about generalizability and equitable applicability. Furthermore, Rajalakshmi et al. [83] critique the use of non-representative training data and the opacity of proprietary algorithms, noting their potential to reinforce systemic health disparities. Real-world deployments in China and South Africa, documented by Zhang et al. [84], Ming et al. [85], and Abdoola et al. [86], expose operational challenges such as limited infrastructure, inconsistent data quality, and inadequate access to follow-up care, all of which disproportionately affect rural and underserved populations. Zhang et al. [93] and Arenas-Cavalli et al. [99] highlight the complexities of scaling AI tools across national health systems, where real-world validations often uncover performance inconsistencies not evident in initial development phases.

Device- and setting-specific limitations, as reported by Ruan et al. [91] and Malerbi et al. [94,95], further contribute to misclassification risk. Milic [97] raises critical ethical concerns about deploying opaque AI systems in underresourced SSA, where health system fragility can exacerbate inequitable outcomes. Meanwhile, foundational work by Abràmoff et al. [96] emphasizes the importance of open-access datasets and transparent validation processes to mitigate bias and overfitting in early-stage AI development.

Performance discrepancies are also evident in proprietary systems such as Medios AI, which was trained on the EyePACS dataset. External validation in India showed wide variability in specificity, ranging from 85.2% to 95.45% [73-75], highlighting the model's limited generalizability in LMICs that were underrepresented during training. Similarly, the Google DR algorithm, trained on EyePACS and Messidor, demonstrated a specificity of 93.4% in U.S. validation, which changed to 94.3% in Thailand and 88.9% in India [76-79], reinforcing the challenges of transferring models across distinct healthcare ecosystems.

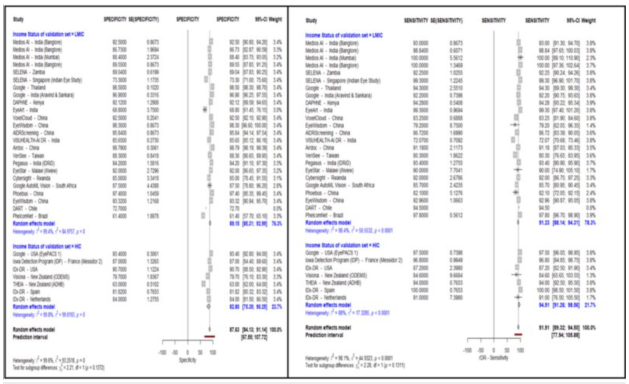

FIGURE 5: Forest plots of pooled specificity and sensitivity for AI-based DR screening systems, stratified by income classification of the validation set.

AI, artificial intelligence; DR, diabetic retinopathy.

In contrast, AI systems developed and validated within HICs, such as IDx-DR, exhibited more consistent diagnostic performance. Validations in Spain and the Netherlands, as reported by Shah et al. [80] and Heijden et al. [81], yielded sensitivities exceeding 91% and specificities above 84%, reflecting the advantage of geographic alignment between development and deployment contexts. Collectively, these findings emphasize the necessity for ethical AI development grounded in transparency, inclusivity, and rigorous cross-context validation to prevent the amplification of existing inequities in global eye care delivery.

Discussion

This systematic review provides a comprehensive synthesis of the current state of AI in DR screening, with an emphasis on LMICs, particularly SSA. From an initial search yielding 511 studies, 50 met the inclusion criteria, enabling a rigorous analysis across technical, infrastructural, economic, clinical, and ethical domains.

Technical limitations

One of the central findings of this study is the pronounced geographic and demographic disconnect between the datasets used to train AI models and the populations in which these tools are ultimately deployed. A substantial proportion of models are developed using data from HICs or LMICs outside SSA, thereby limiting their external validity and contextual relevance within SSA. This misalignment heightens the risk of algorithmic bias, potentially undermining both clinical utility and health equity. For example, Bellemo et al. [56] reported marked performance degradation of the SELENA+ model when deployed in Zambia compared to its performance in its original development setting in Singapore (Ting et al. [57]). Such discrepancies mirror evidence from multiple studies [72-77], which highlight the fragility of model performance when confronted with novel demographic or epidemiological contexts.

Supporting this, Cleland et al. [58] found that most AI models developed for DR screening in LMICs lack meaningful representation from SSA cohorts, undermining their reliability in these settings. Further compounding the challenge, Nwaoha et al. [59] and Cleland et al. [60] stress that the absence of contextually relevant datasets, coupled with insufficient digital infrastructure, severely constrains both AI adoption and diagnostic accuracy in SSA. Similarly, Amugongo et al. [61] and Sibal et al. [62] advocate for human-centered design approaches that embed local expertise and lived realities into AI systems, warning that the deployment of non-contextualized models risks perpetuating algorithmic injustice and eroding trust among patients and clinicians.

These findings reveal that the ethical deployment of AI for DR screening in SSA hinges on aligning with the WHO's six guiding AI ethics framework principles. Locally validated datasets are essential to protect clinical autonomy, ensure patient safety, and enhance transparency. Co-development with regional stakeholders fosters accountability, while addressing SSA's data underrepresentation advances equity. Long-term sustainability demands cross-border governance and strong digital infrastructure. Without these measures, non-contextualized AI risks perpetuating diagnostic inequities and eroding trust. Ethically grounded, region-specific AI systems are therefore not only technically advantageous but also critical for equitable, safe, and sustainable health outcomes in SSA. These concerns echo the calls of multiple studies [101-103] for an ethical reorientation of AI development towards inclusivity, transparency, and contextual relevance, aligning global principles with regional realities.

Infrastructural limitations

Infrastructural deficits remain a critical barrier to the scalability of AI-based DR screening in SSA. Persistent weaknesses, fragmented health data systems, limited internet connectivity, unreliable electricity, and the absence of core digital infrastructure such as EHRs and TREs undermine implementation. These challenges are compounded by a shortage of diagnostic imaging equipment, particularly fundus cameras and OCT devices, which constrains both screening reach and diagnostic accuracy [65-68].

Evidence from multiple studies underscores the multifaceted barriers to AI implementation in SSA. Mathenge et al. [65] cite shortages of trained personnel and imaging tools, while Ephraim et al. [66] report that fiscal and infrastructural limitations often confine AI deployments to short-lived pilots. In rural areas, Ozioko and Kamalakannan [67] identify fragile data ecosystems and unreliable power as key constraints, and Nakayama et al. [68] highlight the need for stable connectivity and functional diagnostic equipment. Although offline-capable, smartphone-based systems show promise, their use remains limited. Embedding AI DR screening within national telemedicine platforms and primary health care networks, alongside investment in solar-powered mobile units with offline AI capabilities, could extend reach and equity. Without sustained investment in digital infrastructure, diagnostic hardware, and workforce capacity, AI initiatives in low-resource settings will struggle to scale or deliver equitable health outcomes [104-108].

Clinical capacity and human resources

The deployment of AI-based DR screening in SSA hinges on strengthening human resource capacity and ensuring sustained clinical oversight. The region's ophthalmologist-to-population ratio, 2.7 per million versus the WHO-recommended 4, stresses the fragility of specialist coverage, particularly for problematic or borderline cases [70]. AI must operate as a decision-support tool that complements rather than replaces clinical judgment. However, severe shortages of trained personnel and diagnostic equipment [65] undermine both service delivery and quality assurance within SSA. Without regulatory oversight, institutional accountability, and skilled interpretation, AI risks degrading care quality and eroding patient trust.

Effective adoption requires parallel investment in clinical competencies, algorithmic literacy, and governance frameworks [71]. A tiered triage model, in which trained ophthalmic technicians review AI-flagged cases and escalate uncertain results to remote ophthalmologists, could help offset workforce shortages. Establishing regional training programs in AI interpretation and ethics for all eye care professionals would further strengthen human-AI collaboration. Targeted investment in infrastructure, supportive policy, and cross-border coordination is not ancillary but foundational to equitable, scalable, and sustainable implementation. These measures reflect a growing consensus [109-111] that strategic investment in human capital is indispensable for achieving meaningful and fair health outcomes in low-resource settings.

Economic sustainability

Economic sustainability remains a major barrier to scaling AI-based DR screening in SSA. Many proprietary systems entail substantial upfront costs and recurring expenses for licensing, software updates, maintenance, and user support, costs that are prohibitive for resource-constrained health systems [68]. These financial burdens intersect with infrastructural deficits such as limited internet bandwidth, unreliable power supply, and insufficient workforce training [66], reinforcing the perception that AI is financially untenable in low-resource settings.

Emerging evidence, however, indicates that when strategically integrated into existing service models, AI can deliver cost-effectiveness gains and operational efficiencies. Cleland et al. [58] showed that locally adapted deployment, through selective automation, decentralized screening, and integration with referral pathways, can outperform standard care in LMICs.

In Rwanda, Mathenge et al. [65] found that AI-assisted triaging improved referral uptake while reducing unnecessary specialist consultations, generating measurable financial benefits. In Kenya, Mwangi [72] demonstrated that AI-enabled screening could expand coverage within existing health budgets by averting downstream costs of late-stage DR treatment. Telemedicine-enabled AI, as described by Nakayama et al. [68], offers further savings by enabling task-shifting: non-specialist health workers conduct preliminary screenings, escalating only complex cases to ophthalmologists. This decentralized model can lower costs, reduce waiting times, and improve rural access, addressing key priorities for SSA health systems.

Authorship and data ownership

The authorship trends identified in this review reveal persistent and deeply embedded inequities in research ownership and leadership within AI-based DR screening studies, particularly as they pertain to SSA. While the number of studies validated within SSA settings is increasing, particularly in Rwanda, Zambia, Kenya, and South Africa, these advances have not been matched by proportional gains in local research leadership. The analysis shows that 56.2% of senior authors were based in HICs, compared to only 43.8% in LMICs. The disparity becomes even more severe when considering regional representation, with 97.9% of senior authors located outside SSA, with only 2.1% from within the SSA region.

Although first authorship appeared more balanced between HICs and LMICs (50% each), only 14% of first authors were affiliated with SSA institutions. This pattern points to a structural bottleneck in which local scientists may contribute to data collection and operational research activities, but decision-making power, agenda setting, and senior authorship, often linked to funding control, remain concentrated in institutions outside the SSA region. These authorship trends highlight the urgent need for structural reforms in how global health AI research is conceived, funded, and executed. Without a deliberate redistribution of research leadership, the promise of AI in improving DR screening equity will be undermined by inequities in the very processes that generate the evidence base. Ensuring that SSA researchers lead and shape the research conducted in their contexts is both a matter of scientific integrity and an ethical imperative for global health.

Ethical concerns and potential for bias

Marked variability in AI model performance across settings raises critical concerns about fairness and clinical reliability. Forest plot analysis stratified by income status of the validation set showed pooled specificity of 87.63% (95% CI: 84.13-91.14) and sensitivity of 91.91% (95% CI: 89.32-94.50), with very high heterogeneity (I^2 = 99.6% and 98.1%, P < 0.001), indicating that differences are unlikely due to chance. In LMIC validation settings, specificity was higher (89.15%) but sensitivity lower (91.23%) than in HIC settings (specificity 82.80%, sensitivity 94.91%), suggesting LMIC-validated models may be more conservative in ruling out disease, while HIC-validated models are more adept at detecting true positives. Such disparities highlight the risk that models optimized for one context may systematically over- or under-diagnose in another. Persistent heterogeneity within both subgroups points to the influence of contextual factors, dataset origin, image quality, and workflow integration, highlighting the need for region-specific validation protocols. To ensure equity and generalizability, AI developers and policymakers should require local performance benchmarking and calibrate model thresholds to the epidemiological and operational realities of the target health system.

Conclusions

This systematic review highlights both the transformative potential and the enduring challenges of AI-based DR screening in SSA. While AI technologies have demonstrated high diagnostic accuracy and the potential to expand screening coverage, their real-world implementation remains constrained by infrastructural fragility, workforce shortages, and inequities in data representation and research leadership. Most AI models are trained on datasets from high-income countries, which reduces generalizability and contributes to lower sensitivity and specificity in LMIC settings. These technical limitations intersect with systemic barriers, including unreliable electricity, limited internet connectivity, high device costs, and inadequate regulatory oversight, which undermine feasibility and long-term sustainability. Moreover, inequities in data ownership, authorship, and research funding reflect deeper structural imbalances that risk perpetuating dependency and bias in global health innovation. Sustainable and equitable deployment of AI-based DR screening in SSA will require coordinated investment in digital infrastructure, low-cost imaging technologies, and local capacity for AI development, maintenance, and governance. Establishing inclusive data-sharing frameworks and transparent regulatory standards that align with regional ethical and legal norms will be crucial to ensuring clinical trust and accountability. This review provides the first comprehensive synthesis of both the feasibility and equity of AI-driven DR screening in SSA, identifying critical infrastructural, technical, and ethical barriers while delineating actionable pathways for sustainable, equitable implementation. For policymakers, it highlights the need for investment in local infrastructure, capacity building, and data governance; for researchers, it calls for a paradigm shift from algorithmic validation toward real-world, equity-oriented implementation science. With sustained investment, ethical governance, and regional ownership, AI can transition from a promising innovation to a practical, equitable tool for preventing avoidable blindness and advancing universal eye health across Africa.

Appendices

Data Availability

All data generated or analyzed during this study are either included in this article or are available from the corresponding author on reasonable request for any data not explicitly presented in the paper.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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