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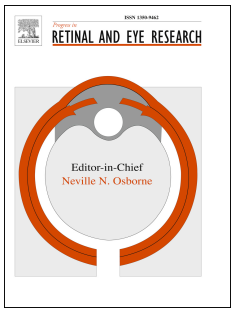

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Smartphone-Based Fundus Imaging in Global Eye Care: Closing the Gap

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Abstract

Smartphone-based fundus imaging (SBFI) is an emerging approach with potential relevance for global ophthalmic care, including in low- and middle-income countries and other resource-constrained settings. This scoping review, based on a structured literature search, synthesises current SBFI technology, clinical and teaching applications, implementation challenges and future directions. Analysing 30 hardware solutions (based on three principal technical designs) and 274 scientific publications and other relevant sources, we found that some SBFI devices can provide fields of view and image quality sufficient to support screening or triage for referable diabetic retinopathy, glaucoma-related optic nerve head changes, and selected retinopathy of prematurity applications. Reported sensitivity, specificity and gradability varied by disease, device, protocol, operator, and reference standard; no universal performance threshold could be inferred. After brief training, allied healthcare workers can acquire usable images in selected settings, suggesting that SBFI may support task-shifted screening and referral pathways. Artificial intelligence may further support scalability by assisting image-quality and protocol compliance assessment, frame selection, montage generation and disease classification. However, costs, maintenance requirements, data governance and domain shift remain important implementation considerations. Key challenges include variable image quality and fields of view, heterogeneous reporting, smartphone compatibility, regulatory compliance, photobiological safety verification, data security, and patient privacy. We therefore suggest minimum reporting standards to increase comparability across studies. Large-scale implementation and cost-effectiveness studies are needed to determine whether improved access to ophthalmic imaging can translate into sustainable and equitable eye-care services.

Smartphone-Based Fundus Imaging in Global Eye Care: Closing the Gap

Abstract

Smartphone-based fundus imaging (SBFI) is an emerging approach with potential relevance for global ophthalmic care, including in low- and middle-income countries and other resource-constrained settings. This scoping review, based on a structured literature search, synthesises current SBFI technology, clinical and teaching applications, implementation challenges and future directions. Analysing 30 hardware solutions (based on three principal technical designs) and 274 scientific publications and other relevant sources, we found that some SBFI devices can provide fields of view and image quality sufficient to support screening or triage for referable diabetic retinopathy, glaucoma-related optic nerve head changes, and selected retinopathy of prematurity applications. Reported sensitivity, specificity and gradability varied by disease, device, protocol, operator, and reference standard; no universal performance threshold could be inferred. After brief training, allied healthcare workers can acquire usable images in selected settings, suggesting that SBFI may support task-shifted screening and referral pathways. Artificial intelligence may further support scalability by assisting image-quality and protocol compliance assessment, frame selection, montage generation and disease classification. However, costs, maintenance requirements, data governance and domain shift remain important implementation considerations. Key challenges include variable image quality and fields of view, heterogeneous reporting, smartphone compatibility, regulatory compliance, photobiological safety verification, data security, and patient privacy. We therefore suggest minimum reporting standards to increase comparability across studies. Large-scale implementation and cost-effectiveness studies are needed to determine whether improved access to ophthalmic imaging can translate into sustainable and equitable eye-care services.

1. Introduction

Smartphone-based fundus imaging (SBFI) has emerged over the past decade as a low-cost and portable alternative to conventional desktop retinal cameras. With the rising global magnitude of vision-threatening diseases such as diabetic retinopathy (DR), glaucoma and retinopathy of prematurity (ROP), the demand for accessible and efficient solutions for early detection is urgent. Widespread availability of smartphone technology provides an opportunity to potentially bridge gaps in eye care, particularly in remote or underserved regions with limited access to specialised equipment and expertise. For this review, we define SBFI devices as devices essentially relying on the use of the smartphone's built-in camera for fundus image capturing (smartphone camera-based fundus imaging). Therefore, devices using smartphones primarily as display, computing or connectivity unit alone are classified separately as smartphone-enabled fundus imaging.

By integrating high-resolution smartphone cameras with special adapters, SBFI systems can acquire clinically useful fundus images in both adult and paediatric populations. Furthermore, this technology shows potential not only for disease screening in telemedical settings, but also for teaching purposes.(Campos et al., 2016; Dunn et al., 2021a) A growing body of research shows that images taken with SBFI devices are suitable for detection of DR, glaucoma, and ROP. Moreover, the portability and reported learnability of some systems may support their use in selected high-volume community screenings in resource-limited settings. The combination with artificial intelligence (AI) has also produced initial promising results, which might further increase efficiency and potential cost-effectiveness. Nevertheless, challenges ranging from image quality and limited fields of view to regulatory, data privacy, and medico-legal hurdles remain, emphasizing the importance of further research and structured implementation of SBFI programmes.

This review provides an overview of SBFI, from technical design and device comparisons to clinical validation studies and global implementation experiences. We discuss the role of SBFI in screening, documentation, and referral triage for DR, glaucoma, and ROP, many of which can be treated if detected early, as well as its integration into telemedicine programmes and future directions including the potential for large-scale integration into healthcare systems. In doing so, we aim to offer a roadmap for clinicians, researchers, and policymakers evaluating where SBFI may support fundus imaging, screening, and telemedical referral workflows within broader eye-care systems.

2. Comprehensive Overview and Background on Technical Applications

2.1 Background

SBFI uses smartphone cameras, usually combined with optical adapters and illumination systems, to capture fundus images. SBFI systems can rely on high-resolution sensors in smartphones, however, older models with inferior image quality and lower image resolution were also suitable for fundus imaging. Most SBFI approaches rely on external magnification lenses in addition to the smartphone's own optical system, simulating the function of a traditional indirect ophthalmoscope. Yet, there are a few technical approaches for SBFI where the concept of direct ophthalmoscopy is utilized without the need of an additional lens. A built-in or external light source is needed for proper retinal illumination. Utilization of the smartphone's light source can complicate medico-legal certification, as, by this, the smartphone becomes a medical device emitting light on the retina. Some systems use 3D-printed adapters, clip-on lenses, or beam splitters to align the smartphone camera, the illumination source, and the external lens.

There are multiple technical challenges and limitations including (1) Optical alignment requiring precise positioning of the (usually handheld) smartphone and lens system to ensure high image quality and avoid artefacts. (2) Lighting issues as excessive reflections and glare can degrade image quality. (3) Field of view limitations as even systems providing a relatively wide field of view are still inferior to many high-end retinal cameras. (4) Regulatory and clinical validation is a challenge as any SBFI systems must undergo regulatory approval, which varies between regions and countries and which can generate disproportionately high costs compared to the low-cost device.

Retinal image acquisition with smartphones may be performed using single still images, short image sequences, or video. Smartphone-native multi-frame functions, including features such as Live Photos, (Apple Inc., 2026) and comparable Android functions, such as Motion Photos with Top Shot on Google Pixel devices (Google LLC, 2026) and Motion Photo on Samsung Galaxy devices (Samsung Electronics Co., 2026), may allow selection of an alternative frame after acquisition. At least one clinical SBFI study used Apple's native iOS camera application in burst mode,(Idriss et al., 2021) a predecessor of the described multi-frame functions. However, most published SBFI studies have primarily used conventional video recording, followed by manual or automated selection of suitable retinal frames. (Ortiz et al., 2025; Russo et al., 2015a; Ryan et al., 2015; Scarpa et al., 2024)

2.2 Methods – Literature Search and Data Collection

This review was conducted as a scoping review with a structured literature search. The primary bibliographic search was performed in the web of science core collection

(search details in Supplement Appendix A.1), last updated on 6th of December 2025, screened 1979 publications for relevance, removed 51 duplicates and identified 363 potentially relevant articles through title screening, out of which after abstract screening and detailed revision 193 were included in our Review. 81 relevant articles and publications have additionally been included by cross-referencing and grey literature research.(Figure 1)

The web of science core collection was chosen as primary research database because the topic spans ophthalmology, vision science, biomedical engineering, and conference literature, as the review aimed to capture both clinical and technical/device oriented publications in a single searchable platform. We did not perform parallel full-database searches in MEDLINE/Pubmed, Embase, or Scopus. This should be considered a limitation of the review, as relevant studies might have been missed. For the grey-literature research, targeted searches in google and google scholar with device- and topic-specific terms were performed. As the process was limited to the most relevant results it was used to supplement, not to replace the structured database search (search details in Supplement Appendix A.1).

We aimed for transparency and reproducibility of the structured literature research and evidence base, but this was not a PRISMA-guided systematic review and we did not pre-register a protocol. To improve completeness of the technical device comparison, we also contacted SBFI manufacturers to provide details of the different devices. Manufacturer-provided information was used only for descriptive device characterization and where possible cross checked with available documentation including published studies, manufacturer official product information or regulatory listing. For the purposes of this review, we defined SBFI as approaches in which the smartphone camera serves as the image-capturing module. Systems in which the smartphone is used primarily as display, computing, or connectivity unit were classified separately as smartphone-enabled fundus imaging. The main technical review, tables, and comparative analysis were restricted to smartphone camera-based approaches, whereas smartphone-enabled systems were listed separately in Supplement Table A.1 to provide broader contextual overview without conflating fundamentally different device classes.

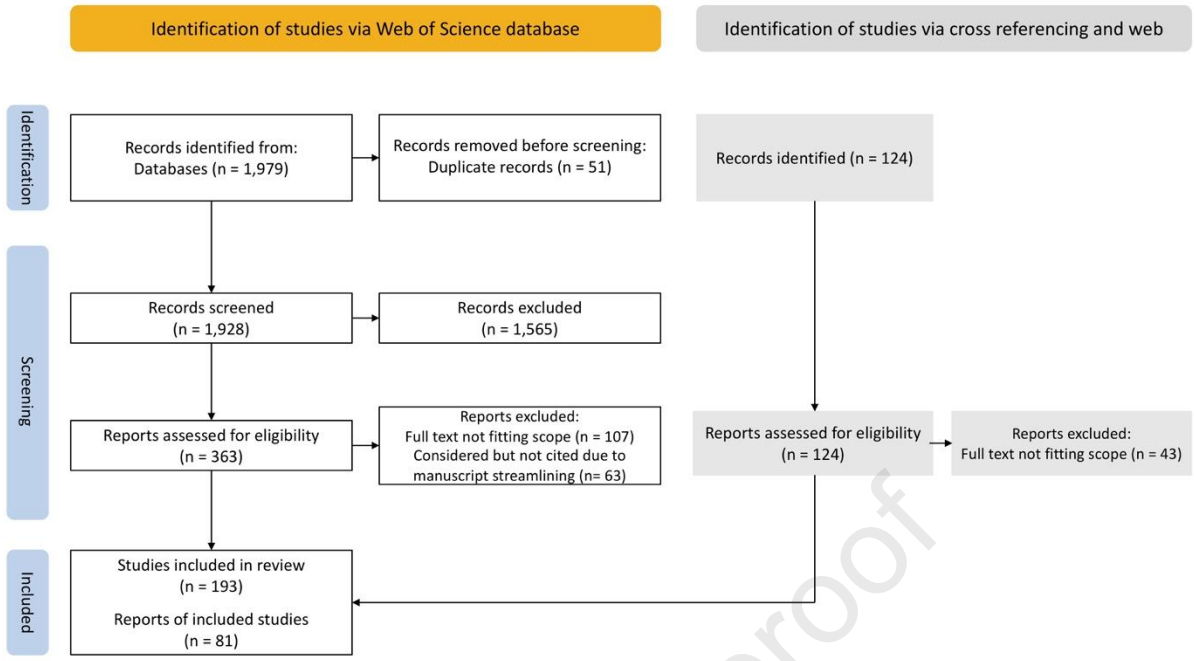


Figure 1: Flow chart illustrating the literature identification and screening process for this scoping review.

2.3 Results – Technical Approaches

This section outlines first the historical evolution of SBFI and then compares the dominant technical design principles. In total, 30 smartphone camera-based and smartphone-enabled adapters and approaches for SBFI were identified. Figure 3 presents smartphone camera-based devices with more than five publications that are commercially available as of 6 December 2025, together with example posterior pole images. Detailed specifications of those higher coverage smartphone camera-based devices with over five publications can be found in Table 1. Additional device information can be found in Supplement Table A.2. Smartphone camera-based devices not meeting these criteria and smartphone-enabled devices are listed in Supplement Figure A.1. Several early devices are retained in this review because of their historical and evidentiary relevance, not to imply current procurement availability.

2.3.1 Historical Evolution of Smartphone-Based Fundus Imaging

Early Do-It-Yourself Era (2010 – 2014)

The first demonstrations were essentially smartphone-assisted indirect ophthalmoscopy.(Lord et al., 2010) Investigators held a standard 20 D or 28 D lens in front of the patient's eye, illuminated the fundus with either the phone's flash or an external LED, and recorded video through the native camera app.(Bastawrous, 2012; Shanmugam et al., 2014) 3-D-printed or low-cost plastic housings soon appeared (e.g. DIYRetCam(Raju et al., 2016), early "MII RetCam" prototypes (MII Ret Cam Inc., India) (Sharma et al., 2016)), but there were no dedicated capture applications, no certifications, and alignment largely relied on operator skill.

First Commercial Clip-Ons with Coaxial Optics (2014 – 2018)

The launch of the Welch Allyn iExaminer (Welch Allyn, Inc., USA; now part of Baxter International Inc.) in 2013 and of the Peek Retina (Peek Vision Ltd, UK) in 2014 marked the move from lab projects to smartphone camera-based products. These represented the first solution wherein a regulated medical device was based on a consumer smartphone platform. Additional clip-on adapters such as D-Eye (D-EYE Srl, Italy), Paxos Scope (DigiSight Technologies, Inc., USA; later renamed Verana Health) and HEINE iC2 (HEINE Optotechnik GmbH & Co. KG, Germany) obtained CE marking and US Food and Drug Administration (FDA) clearance and bundled basic apps for still capture, cloud upload and rudimentary metadata tagging. Illumination was provided by the smartphone flash (D-EYE) or on-board LEDs arranged nearly coaxially with the camera. Field-of-view often remained relatively narrow (≈25°, except for Paxos Scope) and most adapters required pupil dilation for sufficient image quality.

Professional All-in-One Adapters (2018 –2025)

More professional systems introduced between 2018 and 2025 incorporate customized optics, annular or multi-path illumination, and sometimes even the smartphone itself. Examples include Remidio Fundus on Phone (FOP)/FOP-NM-10 (Remidio Innovative Solutions Pvt. Ltd., India), Phelcom Eyer (Phelcom Technologies, Brazil), and Volk VistaView (Volk Optical Inc., USA). The field of view (FOV) has expanded to approximately 45° - 55°, corneal reflections are largely suppressed, and many devices support non-mydriatic imaging, while also allowing dilated imaging when needed.

2.3.2 Technical Design Principles

Smartphone camera-based fundus imaging performance depends primarily on how illumination and image capture are optically arranged.(Figure 2) Direct approaches place the camera and light source nearly coaxially and are compact, but typically provide a narrower field of view and stronger pupil dependence. Indirect approaches use a condensing lens to create an aerial image and usually allow wider retinal coverage, at the cost of greater alignment demands and often dilation. More advanced systems use relay optics, beam splitters, or annular illumination to reduce corneal reflections and improve posterior-pole imaging through smaller pupils. Accordingly, differences in field of view, glare susceptibility, non-mydriatic usability, and ease of use are largely explained by optical design rather than by the smartphone camera alone.

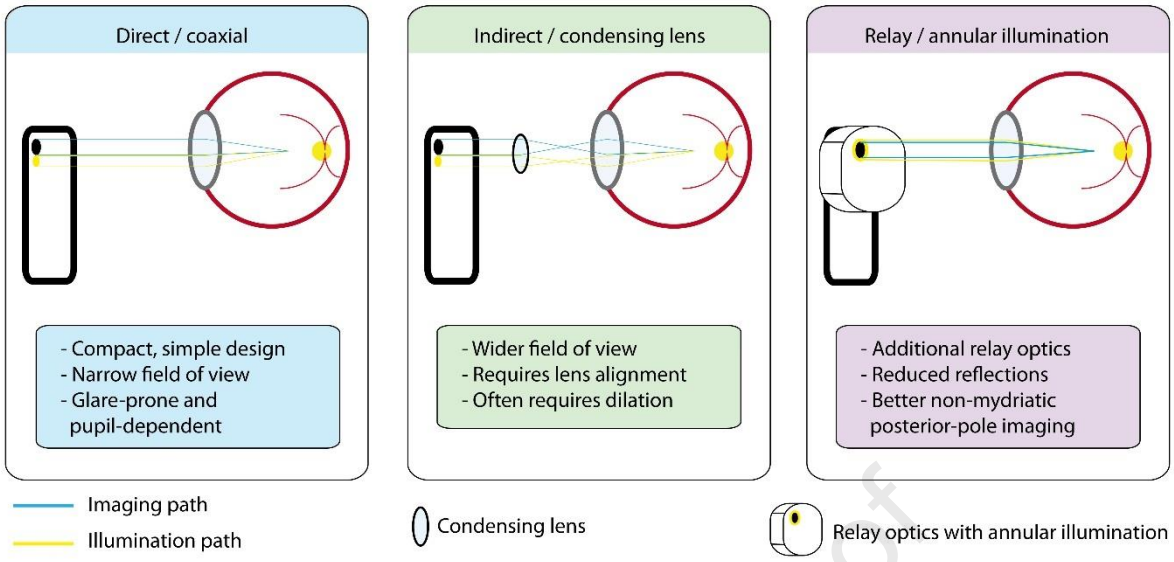


Figure 2: Simplified optical principles and designs of smartphone-based fundus imaging. Direct/coaxial approaches place camera and illumination pathways close to the same optical axis, resulting in compact and simple systems but typically narrower fields of view, greater pupil dependence, and more susceptibility to glare or corneal reflections. Indirect approaches use a separate condensing lens to form an aerial retinal image, allowing wider retinal coverage but requiring more precise lens alignment and often pupil dilation. Systems with relay optics, beam splitters, or annular illumination use additional optical elements to reduce reflections and improve posterior-pole imaging through smaller pupils, but at the expense of greater complexity, cost, and device size.

Direct-Ophthalmoscopy Adapters

These place the smartphone camera (or a relay lens) coaxially with an illumination source, eliminating the need for a condensing lens. Devices are ultra-compact and inexpensive and relatively easy to handle, but the trade-off is a limited field of view (10° - 20°) and strong dependence on pupil size. Image quality can drop significantly when the pupil is smaller than about 3.0 mm.(Bastawrous et al., 2016; Wintergerst et al., 2018) Typical representatives include Peek Retina, D-Eye, and the Welch Allyn iExaminer.

Indirect Single-Lens Adapters

In these approaches, a standard 20 D, 28 D, or 40 D lens creates an aerial image that is relayed to the smartphone camera. The optics mirror classical indirect ophthalmoscopy, delivering a wider field of view (30° - 69°). Learning curve and hand-eye coordination are more challenging as compared to direct-ophthalmoscopy approaches, and most systems still require pupil dilation, especially when working with lenses with lower condensing power (e.g. 20 D). Typical representatives include the Paxos Scope, MII RetCam, and oDocs visoScope (oDocs Eye Care Limited, New Zealand).

Adapters with Relay Optics, Beam Splitter or Annular Illumination

Devices introduced in the late 2010s, including the Remidio FOP-NM-10, Phelcom Eyer, and Volk VistaView, use multi-lens relays, beam splitters, or annular LED rings to deliver true coaxial or ring illumination that suppresses corneal reflection. These systems provide approximately 45° - 55° field of view and can capture diagnostic images in mesopic pupils (~3 mm), eliminating the need for dilation for images of the posterior pole in many scenarios. The extra optics increase cost and weight, and some products lock the user into specific smartphones.

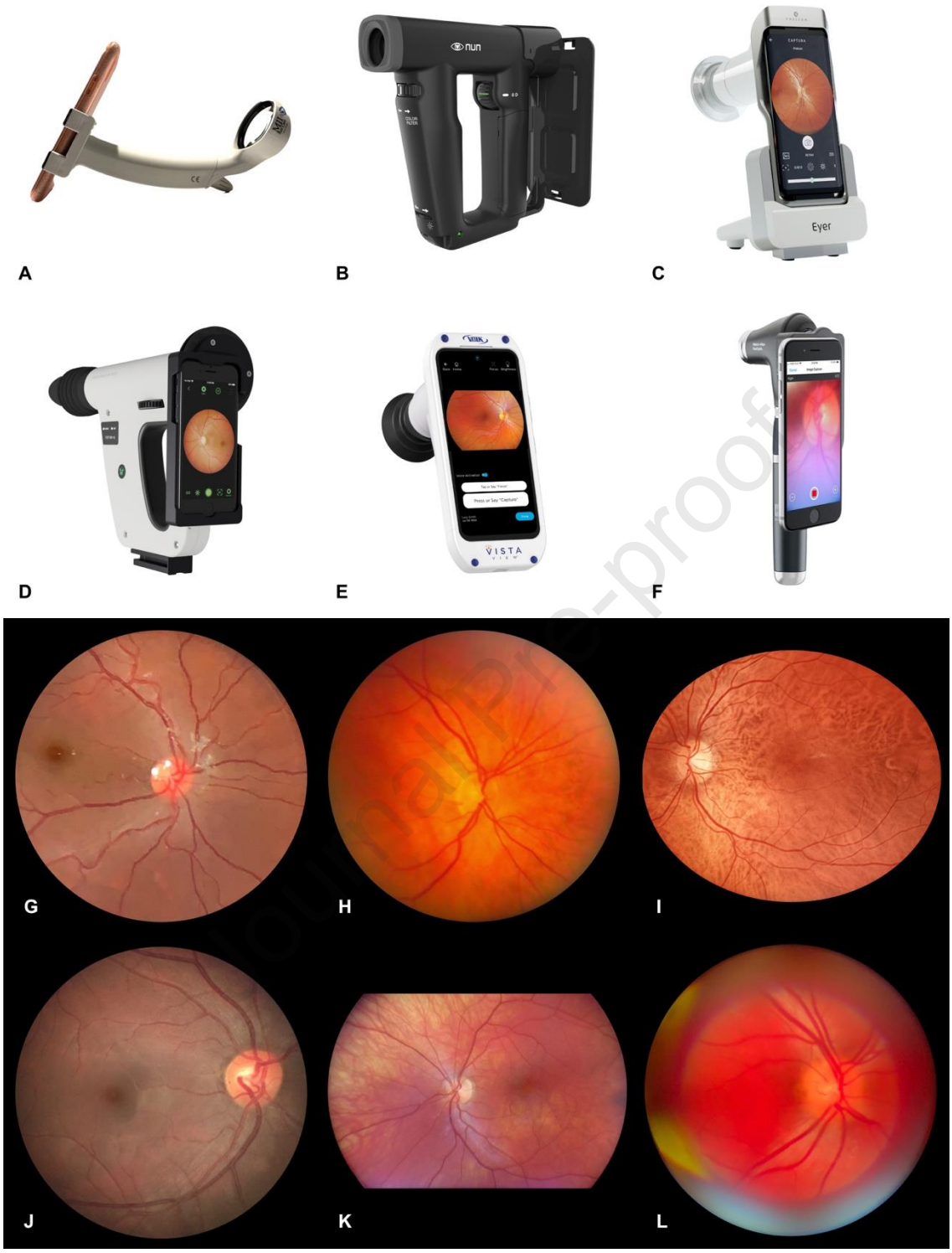


Figure 3: Example device and retinal image material of the most relevant and commercially available adapters in alphabetical manufacturer order: (A and G) MII Ret Cam device (MII Ret Cam Inc., Coimbatore, India) (B and H) oDocs nun Ophthalmoscope (oDocs Eye Care Limited, Dunedin, New Zealand) (C and I) Eyer system (Phelcom Technologies, São Carlos, Brazil). (D and J) Remidio FOP-NM 10 (Remidio Innovative Solutions Pvt. Ltd, Bangalore, India) (E and K) Volk VistaView (VOLK Optical Inc., Mentor, USA) (F and L) Welch Allyn PanOptic Plus iExaminer set (Welch Allyn, Inc.; now part of Baxter International Inc, Deerfield, USA).

***Table 1**. Overview on most relevant (more than 5 studies) technical approaches for smartphone camera-based fundus imaging*

Device Name (country of origin, date of release)	Com-mercial / available	Featured studies (total)	Illumination Source	Field of View (FOV)	Technical fundus examination approach	Certification	Pupil Dilation Required	Compatible Smartphones	Weight
Commercially available									
MII Ret Cam (MII Retcam Inc., India, 2015)	Yes/ Yes	15	Smartphone	40° – 69° (depending on lens 20D – 40D)	Indirect	CE	Yes	Universal	100g
oDocs nun (oDocs Eye Care Limited, New Zealand, 2018)	Yes/ Yes	12	Device	Non dilated = 5°, Dilated = 35°	Indirect + annular illumination + relay optics	CE, Medsafe, TGA	Optional	Universal (except Samsung Z and Note series and iPhone Pro Max series)	280g
Eyer (Phelcom Technologies, Brazil, 2019)	Yes/ Yes	39	Smartphone	45°	Indirect + annular & IR illumination + relay optics + beam splitter	ANVISA, FDA 510(k), ISO 13485	Optional	Samsung Galaxy S10 (integrated)	690g
Fundus on Phone - FOP NM-10 (Remidio, India, 2019)	Yes/ Yes	33	Device	40° – 45°	Indirect + annular & IR illumination + relay optics	CDSCO, CE, HSA	Optional	Universal	929g
Volk VistaView (Volk, USA, 2020)	Yes/ Yes	10	Device	55°	Indirect + relay optics	CE, FDA	Yes	Nokia XR20 (integrated)	560g
Pan Optic iExaminer plus (Welch Allyn, USA, 2018)	Yes/ Yes	29	Device	20°	Direct	CE, FDA	Optional	iPhone X, 11 Pro, 11 Pro Max, 12 Pro, Android smartphones[a]	340g
Not commercially available									
D-EYE (D-EYE Srl., Italy, 2016)	Yes/ No	50	Smartphone	10° – 20°	Direct	CE, FDA	Yes	iPhone 5s, SE, 6, 6 plus, 6s, 6s plus, 7, 8	11g
iC2 Funduscope (HEINE Optotechnik GmbH & Co. KG, Germany, 2018)	Yes/ No	7	Device	34°	Indirect + relay optics	CE, DIN EN ISO 15004-2 compliant	Yes	iPhone 5s, SE, 6, 6s, 7, 8	300g
Peek Retina (Peek Vision Ltd, UK, 2017-2020)	Yes/ No	25	Device	30°	Direct	CE	Yes	Universal	35g
Non-commercial									
Paxos Scope (DigiSight, USA, 2019)	planned/ No	18	Device	56° – 69° (depending on lens)	Indirect	CE	Yes	Universal	300g
oDocs Fundus (oDocs Eye Care Limited, New Zealand, 2015)	No/ No	13	Smartphone	40°	Indirect	None	N/A	Universal	Not reported
Volk iNview (Volk Optical Inc., USA, 2016)	Yes/ No	26	Device	50° – 55°	Indirect	CE, FDA, ISO 15004-2:2007(E) compliant	Yes	iPhone 5s, SE, 6, iPod touch	325g iPhone / 413g iPod touch
Ocular CellScope (University of California, Berkeley, USA, 2014)	No/ No	32	Device	55°	Indirect + annular illumination + relay optics + beam splitter	Not reported	Yes	iPhone 4, 4S, 5, 5S, 5C	Not reported
Self-made/3D-printed devices	No/ N/A	≥10	Varies	Varies	Indirect	None	Yes	Universal	Not reported
iPhone with Lens Attachment	No/ N/A	17	Smartphone	Varies	Indirect	None	Yes	iPhone models	Not reported

[a] According to devices smartphone and case selection guidelines

2.4. Certifications and Medico-Legal Aspects

2.4.1 Regulatory Approvals

Fundus imaging cameras that incorporate smartphones require careful navigation of certifications, approvals, and medico-legal compliance. These are important to enable clinical utilisation and patient impact.

Each region is subject to individual regulations and registration processes. For the entry into the EU market, manufacturers must demonstrate compliance with the EU Medical Device Regulation(*Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex*, n.d.) and obtain CE marking. For most devices this requires a conformity assessment by an EU Notified Body, such as TÜV SÜD. Device and actor information, vigilance reports and post-market surveillance data are progressively being captured in the EUDAMED database to improve transparency and oversight.

For the UK, the MHRA regulates the medical device market. Devices require conformity with the UK Medical Devices Regulations 2002 and typically a UKCA marking. The National Institute for Health and Care Excellence (NICE) in England provides guidelines for medical topics and provides evidence-based recommendations for medical technologies, including diagnostic devices.

If entering the United States market, FDA clearance is often required. In the United States, SBFI devices may require 510(k) clearance or, if no suitable predicate exists, De Novo classification for novel low to moderate risk devices. In Australia devices must undergo conformity assessment and be included in the Australian Register of Therapeutic Goods (ARTG) under the TGA. In New Zealand, SBFI devices must be notified to Medsafe’s Web Assisted Notification of Devices (WAND) database within the required timeframe.

India’s regulatory framework for medical devices, is primarily governed by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare. The pivotal regulation is the Medical Devices Rules, 2017 (MDR 2017), notified under the Drugs and Cosmetics Act, 1940, which sets forth the requirements for classification, manufacture, import, sale, and post-market surveillance of devices (MDR 2017, GSR 78(E); Chapter II, Rule 4).

Regulatory approval pathways are unevenly distributed across the commercially available smartphone camera-based SBFI systems with higher literature coverage, summarised in Table 1 and Supplement Table A.1. CE marking is the most frequently reported approval route, followed by FDA clearance for a smaller number of devices. Country-specific national approvals outside Europe and North America (e.g. CDSCO, ANVISA, HSA and Medsafe/TGA) are reported less frequently and are typically linked to the manufacturer's home or target market. This uneven landscape of approvals illustrates that market access is not harmonised across jurisdictions, which may strongly influence which SBFI systems become available for clinical use in different regions.

2.4.2 Medical Device Certification

Certification such as CE marking in the EU and UKCA Marking in the UK is often mandatory for marketing SBFI devices. Compliance with the essential safety and performance requirements is typically demonstrated by applying relevant standards, such as: (1) ISO 13485: Quality management systems for medical devices. (2) IEC 62304: Software lifecycle processes. (3) ISO 14971: Risk management. (4) IEC 60601-1: Electrical safety (if applicable). Additionally, standards specific to imaging devices may also apply, including (1) ISO 10993: Biocompatibility (if the device contacts skin or eyes), (2) interoperability standards as DICOM when integrating imaging into electronic health record (EHR) systems. For devices directing visible illumination into the eye, compliance with ophthalmic light-safety standards such as ISO 15004-2 is also relevant.

Certification burden is also not uniform across SBFI design classes. Passive optical adapters and simple mounting systems may primarily need to demonstrate mechanical safety, biocompatibility, and light-safety compliance where applicable, whereas more complex devices with powered illumination, integrated electronics, non-mydriatic capture assistance, embedded software, or autonomous AI-supported grading functions face additional requirements related to electrical safety, software lifecycle management, cybersecurity, and software-as-a-medical-device regulation. In practical terms, increasing technical complexity may improve usability and imaging performance, but it also tends to increase certification costs, documentation requirements, and time to market.

There is global variation for smart medical device regulation with each region having its own certification authorities, regulatory bodies, legal frameworks and medico-legal aspects. New SBFI devices may need to be submitted for evaluation. Key requirements of medical technologies evaluation programmes usually include: (1) Demonstrating clinical efficacy compared to existing solutions. (2) Evidence of cost-effectiveness for healthcare providers. (3) Meeting specific technical standards for the intended medical purpose.

2.4.3 Photobiological Safety

Photobiological safety deserves specific consideration in SBFI, particularly when consumer smartphone flash LEDs are used for indirect retinal photography. The relevant ophthalmic safety framework is ISO 15004-2, which specifies fundamental optical radiation safety requirements for ophthalmic instruments directing light into the eye. Available empirical data are reassuring but remain limited. Hong et al. reported that iPhone 6 indirect ophthalmoscopy was at least one order of magnitude below ISO 15004-2.2 safety limits, with a weighted retinal irradiance of 1.40 mW/cm² and a weighted retinal radiant exposure of 56.25 mJ/cm².(Hong et al., 2017) Solyman et al. investigated a sample of smartphones and found weighted irradiance values of 0.58–2.30 mW/cm², far below the reported ocular examination safety limit of 706 mW/cm², without measurable thermal effect. However, they also noted a relatively

high short-wavelength blue-light component, which may be relevant in prolonged or repeated examinations.(O. M. Solyman et al., 2022) Taken together, these findings suggest that smartphone flash LEDs used in typical indirect retinal photography are likely within accepted safety margins for brief screening exposures. Nevertheless, important uncertainties remain, including variability across phone models and brightness settings, cumulative exposure during repeated imaging or videography, differences between built-in smartphone flash and adapter-integrated LEDs, and the actual exposure durations encountered in field workflows. For large-scale screening deployment, these uncertainties support device-specific safety verification and adherence to applicable ophthalmic light-safety standards.

2.4.4 Data Protection and Cybersecurity

As SBFI devices obtain retinal images, they process sensitive personal health and biometric data. For compliant deployment, retinal images should be governed as highly sensitive medical and potentially biometric data, with clear policies on device ownership, data storage, transfer, access rights, retention, and deletion. Manufacturers and healthcare providers must therefore comply with applicable data protection laws in each country of use, including robust measures such as encryption and secure data transfer, especially for wireless transmission.

3. Image Quality and Protocol Compliance Assessment

3.1 Image Quality Assessment

Image quality assessment (IQA) and a standardized imaging approach are essential to ensure reliable examination and research results in SBFI. Reported rates of inadequate retinal image quality are as high as 3.7% for mydriatic and 19.7% for miotic eyes(Scanlon et al., 2003) when examining with non-mydriatic and mydriatic digital photographic screening cameras, highlighting the overall importance of image quality assessment.

Considering the potential use case of SBFI in telemedicine settings, image quality must meet standards to provide reliable patient screening.(Chalam et al., 2022) Media opacities as well as device issues can reduce the required retinal image quality. Successful IQA therefore requires standardized grading systems that can be automated to reduce the scarce resources of specialized human graders.(Pires Dias et al., 2014) Protocol compliance is the second critical step to ensure relevant anatomical fundus imaging for the disease under investigation, which guarantees the success of SBFI, especially when used as a telemedicine tool.

3.2 Conventional Fundus Photography Image Quality and Protocol Compliance Assessment

Ensuring the reliability of examination results depends on the correct assessment of quality parameters. The process of grading images is influenced by several factors

that can render an image ungradable. The conventional approach to assessing the overall quality of retinal images involves the use of generic image quality parameters, such as focus, clarity, and absence of artefacts, as well as structural image quality parameters, including field of view, optic disc visibility, and macular visibility. These parameters can be used for image quality detection and can be evaluated by human graders or used to train machine learning algorithms for IQA.(Pires Dias et al., 2014)

Protocol compliance also enhances diagnostic confidence by ensuring visualization of relevant fundus regions. When screening for DR, a minimum of a 2-field non-mydriatic fundus photography (Yan et al., 2023) or a wide field fundus camera can be used.(Ghasemi Falavarjani et al., 2017) For glaucoma screening, imaging modalities showing the optic disc can be sufficient.(B. Prakash and Selvathi, 2017)

3.3 Conventional Smartphone-Based Fundus Imaging Quality and Protocol Compliance Assessment

To ensure image comparability and overall reliable image quality despite a variety of SBFI devices, the implementation of a standardized evaluation and protocol compliance check is essential.(Ahn and Kim, 2024) IQA in SBFI should follow defined guidelines. Semi-quantitative scales for IQA established by Wintergerst et al. in 2020 include generic scales for the categories of contrast and illumination, sharpness, and reflective artefacts.(Wintergerst et al., 2020c) As SBFI systems typically have a limited field of view, an adapted Early Treatment Diabetic Retinopathy Study (ETDRS) 7-field fundus imaging technique (ETDRS RESEARCH GROUP, 1991) can ensure correct imaging of the relevant retinal areas for DR screening.(Wintergerst et al., 2020c) Conversely, imaging for glaucoma screening can be limited to the optic disc.(B. Prakash and Selvathi, 2017)

3.4 Automated Image Quality Assessment for Conventional Fundus Photography

Automated IQA enhances peripheral teleophthalmology retinal screening clinics. Research on automated IQA has been conducted for over ten years. Early approaches such as spatial techniques and wavelet transform techniques are human-dependent and not ideally generalizable.(Shi et al., 2022) Pires Dias et al. showed in 2014 high sensitivity and specificity in rating retinal images with neural networks for illumination, colour, focus and contrast.(Pires Dias et al., 2014) The introduction of deep learning (DL) algorithms has improved automated image quality assessment. The convolutional neural network (CNN) is one of the most popular systems used and does not require prior full human assessment as it does not depend on human scales but on hidden or latent image features,(Schmidhuber, 2015) allowing for improved performance compared to earlier approaches.(Shi et al., 2022)

A classification of non-gradable images into different categories was manually executed in many past studies, except for Shi et al who, in 2022, automatically

identified images as non-gradable due to artefacts or non-gradable due to abnormalities using the CNN architecture, allowing to request repeated imaging in case of artefacts, or rapid referral in the case of medical abnormalities.(Shi et al., 2022) Another approach for automated image quality assessment was performed by Karlsson et al. in 2021 allowing for fundus photography grading on a continuous scale and outperforming human graders in this approach.(Karlsson et al., 2021) Mobile image quality assessment using a CE-certified algorithm on mobile retinal cameras has also been shown to be able to detect reduced image quality, although in a diabetic retinopathy screening setting, 36% versus 16% of images were deemed non-evaluable by a human grader and patients therefore referred.(Wintergerst et al., 2022)

To ensure a good environment for the development and improvement of future automated IQA tools, in opposite to past datasets, image quality measures should be reported clearly alongside datasets, allowing for the inclusion of the needed data and reducing biases.(Gonçalves et al., 2024)

3.5 Adaptability to Smartphone-Based Fundus Imaging

To improve the comparability of image quality between different SBFI devices, standardised approaches to IQA and protocol compliance should be implemented. Manual or automated quality grading using algorithms that can grade fundus images based on structural parameters is warranted.

For manual IQA, the semi-quantitative image quality analysis scales of Wintergerst et al. from 2020 can be used,(Wintergerst et al., 2020c) leading to standardized assessments. Automated IQA conserves scarce human resources and supports the growth and widespread adoption of SBFI by providing automated feedback on image quality.(Wintergerst et al., 2020a)

In practical terms, future SBFI systems should ideally provide capture-time guidance, including live alignment cues, glare/reflection warnings, working-distance or focus indicators, real-time image-quality scoring, and field or quadrant mapping for multi-field or montage-based protocols. Such features could reduce failed acquisitions, improve protocol fidelity, and support more consistent performance across operators, particularly in task-shifted screening workflows.

Adapted DL algorithms may be able to immediately stratify reduced image quality into abnormality or artefact related issues, as described for conventional fundus imaging, allowing for re-examination or referral.(Shi et al., 2022) Considering the computing power required to perform automated image quality assessments, their resource requirements include a stable internet connection.

In conclusion, image quality and protocol compliance assessment in SBFI is an important step in streamlining examination success and allowing for improved usability of SBFI while maintaining its affordability. DL systems for IQA with lower computational requirements may soon match the improved computing power of

smartphones, allowing for immediate automated smartphone-based image quality and protocol compliance assessments even in regions without internet service.

4. Comprehensive Overview on Applications

Although SBFI has been investigated for a range of ophthalmic conditions, the published evidence is concentrated in DR, glaucoma, and ROP/paediatrics (see Table 2 for an evidence map summarising the strength, reference standards, and maturity of the literature across these applications). These areas were therefore selected for detailed review because they represent the largest and most developed bodies of SBFI literature and illustrate different screening, field-of-view, and image-acquisition requirements. The following sections will demonstrate the application of SBFI in these clinical subspecialties and will additionally highlight its application in teaching. Other diseases in which SBFI has been applied to include age-related macular degeneration and hypertensive retinopathy, as well as fundoscopy in emergency medicine.(Day et al., 2017; Muiesan et al., 2017; Negiloni et al., 2025; Savoy et al., 2024; Sayadia et al., 2022)

***Table 2**. Evidence map: the application of SBFI to diabetic retinopathy, glaucoma, and retinopathy of prematurity (Performance summaries should be interpreted as evidence for screening/triage use and not as proof of diagnostic equivalence across all devices, protocols, and care settings.)*

Application (target endpoint)	**Evidence base (study count, sample size, geography)**	**Reference standard (rigor tier)**	**Care setting and image-acquisition cadre**	**Imaging protocol (mydriasis; field coverage)**	**Image quality and reporting completeness (gradability; ungradable handling)**	**Implementation outcomes and evidence maturity (rank)**
Diabetic retinopathy (DR) (referable DR / DR screening triage)	16 studies; participant sample sizes range 60–900. Evidence is geographically concentrated in India (majority of studies), with additional studies from the USA, Brazil, Uganda, and Thailand; most evaluations are described as single-centre or programme-based, supporting generalisability primarily to similar screening/teleophthalmology contexts.	Robust–Moderate (Robust n=2, Moderate n=10, Weak n=4): Most studies compare SBFI against clinical ophthalmologist examination and/or conventional fundus photography graded using established DR criteria (masking/adjudication not consistently described). A minority of studies use specialist grading of smartphone images without an independent external comparator (Weak). The main diagnostic conclusions are driven primarily by the 12 robust/moderate studies using external clinical or imaging comparators.	Primarily outpatient eye/diabetes clinics and screening/teleophthalmology workflows. Image acquisition is most commonly performed by optometrists and ophthalmic staff/technicians, with some studies using ophthalmologists and supervised trainees/medical interns.	Predominantly mydriatic (non-mydriatic protocols reported in some studies): Most validation studies support posterior-pole-based detection/triage of referable DR/STDR, typically using macula ± disc imaging. Claims regarding detection of predominantly peripheral DR lesions beyond the posterior pole are supported only by extended-coverage protocols, such as multi-field, photomontage, or wide-field approaches.	Variable: Ungradable/gradability rates are reported in most studies (13/16), but definitions, reasons, and analytic handling are not consistently described. Imaging protocols (field selection/coverage, capture mode, dilation strategy) are heterogeneous, which limits direct comparability unless protocol compliance and quality-control procedures are explicitly described.	Implementation outcomes are variably reported: several studies include feasibility/process measures (e.g., screening workflow performance, image acquisition success), downstream pathway endpoints (referral completion, treatment uptake, time-to-treatment, visual outcomes) are not reported; evidence is largely limited to diagnostic/triage accuracy, feasibility/process measures, and gradability. Maturity: Moderate. The evidence base includes multiple studies across diverse care settings with broadly reproducible screening/triage performance (larger and more replicated than glaucoma/ROP), but important gaps remain in standardized reporting and longitudinal linkage-to-care outcomes.
Glaucoma / optic disc triage (glaucoma suspect/referral triage, not definitive diagnosis)	23 studies. Evidence spans small-to-moderate clinical/outreach cohorts (typically tens to a few hundred participants, up to 7,023 individuals) and includes dataset-/image-only studies (up to 5,716 images), limiting direct comparability across studies. Geographic	Moderate–Weak (Robust n=1, Moderate n=12, Weak n=10): Reference standards are heterogeneous and often rely on expert optic disc assessment (clinical examination and/or disc photography grading) and/or surrogate disc metrics (e.g.,vertical cup-to-disc ratio), with incomplete	Mixed clinic-based and outreach/remote screening contexts. Image acquisition is performed by a wide range of cadres including lay examiners/lay technicians, ophthalmic clinical officers, optometrists,	Both mydriatic and non-mydriatic: predominantly optic disc–centred imaging (disc and peripapillary retina); capture is performed as still images (and/or short videos with frame selection in a subset of workflows);	Variable to limited: Ungradable/gradability rates are inconsistently reported and can be substantial in some cohorts; definitions and analytic handling of ungradable images are often unclear. Reporting of optic-disc capture methodology and vertical	Implementation outcomes are largely limited to feasibility measures and diagnostic/triage performance; downstream confirmatory-testing completion, referral completion, and patient outcomes are not reported; workflow feasibility and acceptability are reported inconsistently. Maturity: Moderate. Evidence supports feasibility for triage, but heterogeneity in study design and limited

	coverage is broad (Africa, Europe, Asia, Oceania, North and South America), but heterogeneity in study designs and data sources constrains generalisability.	masking/adjudication in many reports. Comprehensive glaucoma case definitions incorporating structural and functional testing (e.g., optical coherence tomography and visual fields) are used only in a minority of studies (Robust when present).	and ophthalmologists/glaucoma specialists, reflecting intended use in both specialist and task-shifted screening environments.	diagnostic performance is sensitive to pupil size and media opacity, and field coverage requirements are narrower than for DR.	cup-to-disc quantification is heterogeneous, with incomplete standardization of image-quality criteria and protocol compliance elements that materially affect performance.	downstream/pathway evaluation constrain claims of readiness for clinical implementation.
Retinopathy of prematurity (ROP) (treatment-requiring ROP triage / tele-screening support)	10 studies. Evidence consists mainly of small feasibility/accuracy cohorts (typically 14–156 infants/patients; many reports are eye-based) plus image-only datasets (63–440 images). Studies are distributed across multiple regions (including India, USA, Germany, Nepal, Taiwan, Pakistan, Argentina/Colombia, and Brazil), but the evidence base remains relatively small, with limited pragmatic multicentre programme evaluations.	Moderate (Robust n=0, Moderate n=9, Weak n=1): Most studies benchmark against ROP-trained specialist examination (indirect ophthalmoscopy) and/or established widefield fundus imaging workflows (e.g., RetCam), with variable masking/adjudication. Some studies use imaging-only comparators focused on posterior-pole findings (e.g., plus disease) rather than a full clinical reference.	Predominantly hospital/ neonatal intensive care unit (NICU)-based ROP screening workflows. Image acquisition is most often performed by ROP-trained ophthalmologists; several studies also use non-physician trained photographers, and some use ophthalmology residents/trainees.	Mydriatic: indirect ophthalmoscopy–style imaging using a condensing lens system; assessment is focused on posterior pole findings (particularly plus disease); claims regarding zone/stage or more peripheral disease are more limited; field-of-view is often limited and wider coverage relies on multiple images and/or montage approaches, with emerging alternative widefield concepts reported.	Variable: Several studies report ungradable/poor-quality image rates, while others do not; definitions and analytic handling are inconsistently specified. Reporting commonly supports grading of posterior-pole vascular findings (especially plus disease), whereas documentation of peripheral features (zone/stage) is frequently limited by image quality/field coverage and should be explicitly addressed when interpreting diagnostic results.	Implementation outcomes are limited: studies report feasibility and agreement/accuracy for posterior-pole findings (particularly plus disease); programme-level endpoints (time-to-treatment, referral completion, treatment uptake, infant clinical outcomes) are not reported; safety/acceptability and workflow integration are reported inconsistently. Maturity: Moderate. Evidence supports tele-triage support with generally appropriate clinical comparators, but is constrained by smaller cohorts and limited pragmatic implementation and pathway-outcome studies.

Definitions for rigor tier and maturity rank are listed in the Supplement Appendix B.1.; STDR = sight-threatening diabetic retinopathy

4.1 Diabetic Retinopathy

4.1.1 Introduction - Diabetes, Diabetic Retinopathy and the Impact

Diabetic retinopathy is a priority application for SBFI because systematic screening requires retinal image acquisition at scale, whereas access to conventional fundus cameras remains limited in many low- and middle-income countries (LMICs). This challenge is particularly relevant because approximately three-quarters of people with diabetes live in LMICs, and diabetes prevalence in middle-income countries is projected to increase from 10.5% in 2021 to 21.1% by 2045.(Sun et al., 2023) A parallel increase in diabetes related complications is inevitable unless urgent measures are implemented to screen and treat them promptly.(Tomic et al., 2022) Undiagnosed diabetes also remains a concern and many are diagnosed only when complications occur.(Rajalakshmi et al., 2023) As an example, over half of the individuals with diabetes remain undiagnosed in India.(Anjana et al., 2017) Although most developed countries have implemented screening for diabetes and its complications, the health systems in most LMICs have limited resources allocated to preventive medicine. The rudimentary primary care systems are burdened with managing competing health priorities with limited resources. Therefore, simple, and affordable screening for diabetes and its complications needs to be developed and validated for implementation especially in middle-income countries. These constraints provide the rationale for evaluating SBFI as a potentially lower-infrastructure approach to retinal image acquisition within DR screening pathways.

DR is one the most common complications of diabetes and remains one of the five most common causes of global blindness.(Steinmetz et al., 2021) A meta-analysis published in 2021 estimated the global prevalence of DR to be 103 million with projections highlighting this figure to increase to 161 million by 2045.(Teo et al., 2021) Proliferative DR and diabetic macular oedema (DME) are the major sight-threatening forms of DR. As an asymptomatic condition at risk of progression to visual impairment, systematic screening for DR is essential.(Namperumalsamy et al., 2003) Smaller affluent countries that have established nation-wide systematic retinal screening for people with diabetes about a decade ago have started to experience decreasing incidence of DR related blindness.(Pieczynski et al., 2015)

4.1.2 Challenges in Traditional Diabetic Retinopathy Screening

Countries that established systematic DR screening for their population with diabetes took over a decade to transition from ophthalmoscopy and fundus examination to digital retinal colour photography using conventional mydriatic or non-mydriatic desktop fundus cameras.(Rajalakshmi et al., 2021a) However, such systematic screening services require trained manpower and are costly and, therefore, cannot be replicated in LMIC.(Pieczynski et al., 2015) Lack of public awareness of this condition, shortage of ophthalmologists, out of pocket expenses incurred by patients for their healthcare, lack of government policies and investment in infrastructure, and the sheer volume of individuals with diagnosed and undiagnosed diabetes are also

barriers for national implementation of similar programmes in LMIC.(Rajalakshmi et al., 2021b)

Therefore, more resource-friendly and yet robust DR screening programmes need to be implemented for global coverage. The key building blocks include developing a call-recall register, capturing retinal images with minimal investment in technological infrastructure, training non-ophthalmologists as graders for the retinal images or incorporation of AI, establishing a streamlined referral system for appropriate treatment and follow-up of those with vision-threatening DR, and ensuring a cost-effective sustainable model.(Wong and Tan, 2023) It is also important to improve patient awareness and education at the point of screening in order to support referral completion and treatment uptake.(Rajalakshmi et al., 2021b)

4.1.3 The Rise of Smartphone-Based Fundus Imaging for Diabetic Retinopathy Screening

Teleophthalmology has emerged as one practical strategy to address screening barriers, and hand-held fundus cameras are now accepted as part of teleophthalmology-based DR screening workflows.(Rajalakshmi et al., 2022; Ramasamy et al., 2021) In resource-limited settings, SBFI is a relevant lower-cost option for DR screening.(Bolster et al., 2015; Raj et al., 2025) Figure 4 shows examples of DR images acquired using SBFI as part of the teleophthalmology DR screening across diabetes care clinics in India. Several SBFI devices have received regulatory clearance in one or more jurisdictions, although their current commercial availability varies; device-specific regulatory and availability information is summarised in Table 1, Supplementary Table A.2, and Supplementary Figure A.1.

Landmark validation studies are summarised in Table 3, with additional studies presented in Supplementary Table B.1. Early clinical studies established the feasibility of mydriatic SBFI for DR screening and reported generally good agreement with conventional retinal photography or clinical examination.(Rajalakshmi et al., 2015; Russo et al., 2015a; Ryan et al., 2015; Sengupta et al., 2019) Subsequent evaluations across different devices and healthcare settings, including studies in the USA, Uganda, Brazil, Cameroon, and India, further supported the feasibility of SBFI-based DR screening, although performance varied according to device design, field of view, imaging protocol, and reference standard (Bilong et al., 2019; de Carvalho et al., 2025; Kim et al., 2018; Queiroz et al., 2020; Wintergerst et al., 2020c; Yusuf et al., 2022)

From 2019 onwards, studies extended validation to non-mydriatic, patient-led, and task-shifted acquisition approaches, with promising diagnostic performance, particularly when used by non-clinical field workers, while remaining dependent on image quality, pupil size, media clarity, and operator experience.(Kumari et al., 2022; Natarajan et al., 2019; Prathiba et al., 2020)

4.1.4 Accuracy and Reliability of Smartphone-Based Fundus Imaging

While many studies have shown that SBFI can achieve high sensitivity and specificity for detecting DR, the accuracy depends on image quality and field of view. Studies done comparing smartphone-based devices showed high specificities but varying sensitivities for detection of DR .(Karakaya and Hacisoftaoglu, 2020; Lu et al., 2022; Tan et al., 2020; Wintergerst et al., 2020c) Mydriatic SBFI improved field of view, enhanced image quality and hence the sensitivity and specificity for detecting referable DR was higher.(Rajalakshmi et al., 2015, 2018; Russo et al., 2015a; Sosale et al., 2020b) Non-mydriatic SBFI, showed slightly less sensitivity, especially in individuals with small pupils, dark iris and media opacities like cataract.(Prathiba et al., 2020; Sosale et al., 2020a)

Head-to-head comparisons confirmed that diagnostic performance is device-dependent. Specificity was generally high, whereas sensitivity, gradability, and image quality varied according to optical design, field of view, pupil dilatation, smartphone compatibility, and the reference standard used. (Karakaya and Hacisoftaoglu, 2020; Lu et al., 2022; Salongcay et al., 2022; Vaughan, 2024; Wintergerst et al., 2020c)

These points must be borne in mind while selecting SBFI devices for tele-ophthalmology DR screening services. One key limitation is the small field of view in most smartphone-based devices which can potentially lead to missing changes in the periphery of the retina.(Rajalakshmi et al., 2021a) Accordingly, the current validation literature supports smartphone-based detection and referral triage of referable DR/STDR primarily on the basis of posterior-pole imaging, whereas claims regarding peripheral lesion detection beyond the posterior pole should be restricted to studies using extended-coverage protocols such as multi-field, montage, or wide-field imaging. However, a 2024 study evaluated a smartphone-based wide field imaging device (58° field of view in a single field and a montage of 2 images providing a 90° field of view) could detect predominantly peripheral lesions of DR beyond the posterior pole in people with diabetes.(Rajalakshmi et al., 2024a; Sivaraman et al., 2021) SBFI with other devices such as CellScope Retina and MII-Ret Cam have also demonstrated the ability to image the peripheral retina.(Kim et al., 2018; Sharma et al., 2016) Against this background, defining a systematic imaging protocol and adhering to it is imperative, and key to ensure reliability and a high examination quality.(Wintergerst et al., 2020c) Accordingly, SBFI should currently be interpreted primarily as a screening/triage tool. Reported performance depends on the imaging protocol used and is influenced by field coverage, mydriasis status, photographer expertise, and the handling of ungradable images. One of the challenging areas is the variable output from devices, which complicates the development of AI algorithms - a crucial step in unlocking the full potential of SBFI.

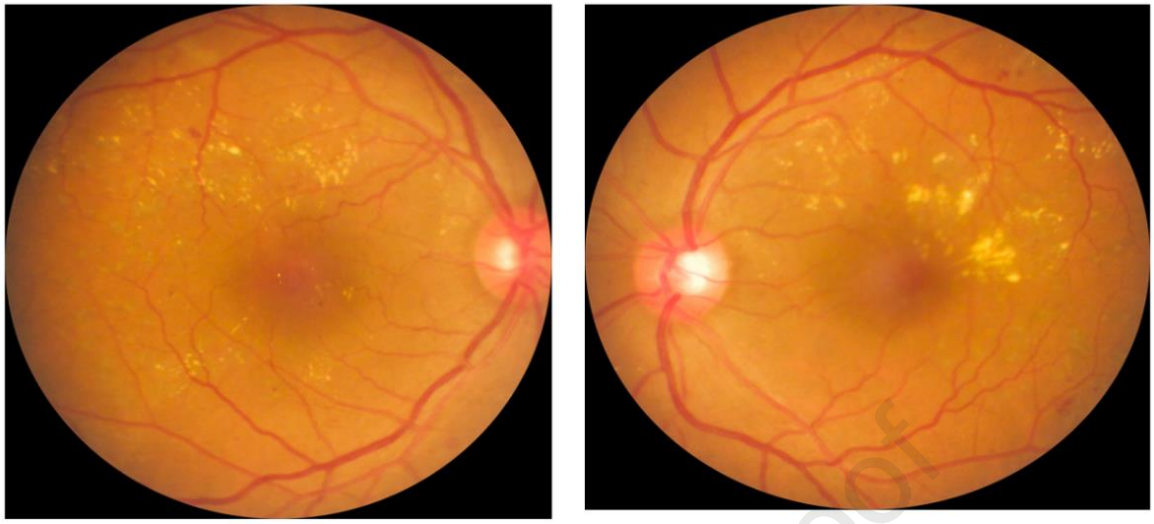


Figure 4: Diabetic retinopathy on Smartphone-based fundus imaging of bilateral diabetic macular oedema (Remidio FOP Non-mydriatic Camera (FOP-NM 10) 40 ° FOV)

***Table 3**. Smartphone-based fundus imaging for diabetic retinopathy detection (landmark studies)*

Study (Country)	Dataset size	Accuracy (manual analysis unless otherwise indicated)	Reference standard (rigor)	Device + Smartphone (pupil dilation/ no pupil dilation)	Photographer expertise	Ungrad-able Images (%)	AI used	Comments
Rajalakshmi et al., 2015 (India) (Rajalakshmi et al., 2015)	301 patients (602 eyes)	92.7% sensitivity, 98.4% specificity for detecting any DR ; 87.9% sensitivity, 94.9% specificity for STDR	Grading by 3 ophthalmologists on 7 field gold standard conventional fundus imaging (Robust)	Remidio M-FOP + android phone (pupil dilation)	Optometrists and ophthalmologists	Nil	No AI used	First study to compare conventional fundus imaging versus SBFI for all grades of severity of DR; high-rigor clinical validation
CAMRA study, Ryan et al., 2015 (India) (Ryan et al., 2015)	300 patients (600 eyes)	59% sensitivity, 100% specificity for sight-threatening DR	Grading by retina specialists on conventional fundus imaging (Moderate)	iPhone 5S with +20D lens (pupil dilation) in video mode	Optometrists and ophthalmologists	1.8%	No AI used	First study to compare three modes of imaging, non-mydriatic desktop, mydriatic smartphone and conventional desktop retinal; illustrates limitations
Sengupta et al., 2019 (India) (Sengupta et al., 2019)	135 patients (233eyes)	Grader 1- 93.1% sensitivity, 89.1% specificity Grader 2- 94.3% sensitivity, 94.5%specificity for detecting any DR (k=0.55)	grading by ophthalmologist on conventional fundus imaging (Topcon; Moderate)	Remidio M-FOP + android phone (pupil dilation)	Optometrists and ophthalmologists	1.7-2.1%	No AI used	Reproducible accuracy vs a standard tabletop camera with explicit two-grader performance reporting
Prathiba et al., 2020 (India) (Prathiba et al., 2020)	245 patients (490 eyes)	75.2% sensitivity, 95.2% specificity for detecting any DR; 82.9% sensitivity, 98.9% specificity for STDR	Grading by ophthalmologist on conventional fundus imaging (Moderate)	Remidio NM-FOP + iPhone (no pupil dilatation)	Optometrists and ophthalmologists	4.5%	No AI used	First study on non-mydriatic smartphone imaging for DR. Device uses Infrared and LED light
Wintergerst et al., 2020 (India) (Wintergerst et al., 2020c)	193 patients (381 eyes)	79% sensitivity, 99% specificity to detect any DR on indirect SBFI	Conventional fundus imaging and clinical examination by ophthalmologist (Moderate)	D eye, PEEK Retina, Paxos Scope, Do it yourself (pupil dilatation)	Optometrists and ophthalmologists	Not reported	No AI used	First study to compare 4 approaches of Smartphone-based fundus imaging; highlighting device-dependent variability in performance
Queiroz et al., 2020 (Brazil) (Queiroz et al., 2020)	627 patients	Not reported	N/A (Weak)	Phelcom Eyer + (pupil dilatation)	Nurses in diabetes centre	18.8%	No AI used	Primary-care deployment with nurse capture and a high ungradable rate, providing implementation realism
Yusuf et al., 2022 (Uganda) (Yusuf et al., 2022)	286 people with type 1 and type 2 diabetes	84% sensitivity, 79.9% specificity for detecting any DR	Grading by ophthalmologist on conventional fundus imaging (Moderate)	PEEK-Retina + Android phone (pupil dilatation)	Field health workers	1.4%	No AI used	Task-shifted acquisition by field health workers, supporting generalisability to LMIC screening workflows with very low ungradable rates
Rajalakshmi et al., 2024 (India) (Rajalakshmi et al., 2024a)	160 patients (318 eyes)	Sensitivity 92.7%, specificity 96.6% for STDR on the SBFI device.	Ultra-widefield (UWF) imaging with Optos Daytona camera (Moderate)	Remidio Vistaro (pupil dilatation)	Optometrists	1%	No AI used	First study to compare SBFI wide field fundus imaging and UWF imaging for detection of predominant peripheral DR lesions

4.2 Glaucoma

Glaucoma is a major cause of irreversible visual impairment and blindness, and an estimated 70–90% of affected individuals are unaware of their condition, highlighting the need for improved case detection.(Flaxman et al., 2017; Shen et al., 2008; Vijaya et al., 2005) A total of 64 million cases of glaucoma were estimated globally in 2013 and this is projected to reach 111.8 million cases by 2040.(Tham et al., 2014) The cup-to-disc ratio and disc colour (normal vs. pale) are simple ways to suspect and/or diagnose glaucoma and its severity. Teleophthalmology can help to facilitate this, however, progress is hindered due to the cost of medical equipment and limited availability of medical personnel. To address these challenges, a mobile, low-cost, digital device that is capable of capturing optic disc images of patients regardless of pupillary size is required. A potential solution may be the introduction of AI integrated SBFI to tele-ophthalmology screening to support automated quantification of optic disc feature.(Rodriguez-Una and Azuara-Blanco, 2018) The different smartphone imaging techniques and clinical implications are shown in Table 4 (landmark studies), Supplement Table C.1 (additional studies).

4.2.1 Technical Approaches for Smartphone-Based Optic Disc Evaluation

Image quality of the optic disc can be impaired without pupil dilation (e.g. by media opacities or pupillary light scattering). Therefore, pupil dilation is the preferred option for any SBFI application to detect glaucoma.(Wintergerst et al., 2018) However, non-mydriatic examination may need to be considered in cases with a shallow anterior chamber. A variety of SBFI solutions are available.

Early proof-of-concept studies demonstrated that optic disc images could be acquired using unmodified smartphones, simple external lenses, and direct-ophthalmoscopy-based adapters. These approaches established technical feasibility but were limited by pupil dependence, reflex artefacts, variable image quality, narrow fields of view, and, for unmodified smartphone configurations, the absence of device-specific regulatory approval.(Gunasekera and Thomas, 2019; Pujari et al., 2019c)

Another technical solution is to use adapters for SBFI that allow high image magnification and/or improved image resolution for optic disc evaluation. As a basic proof-of-concept approach, the optic disc was imaged using a 10× magnification lens and a 90D lens (Pujari et al., 2018) Similarly, attaching the D-EYE adapter to a smartphone allowed the capture of optic disc images without pupillary dilatation. (Russo et al., 2015a, 2016) Bastawrous et al. compared images acquired with a desktop retinal camera and a smartphone adapter (Peek Retina) used by a non-clinical photographer and found good agreement. The smartphone images were also remotely gradable.(Bastawrous et al., 2016) Similar findings were reported by Titoneli et al.(Titoneli et al., 2021) Furthermore, using D-EYE, Dao et al. noted moderate sensitivity and specificity for detecting optic nerve pathology and good agreement for determining the cup-to-disc ratio (CDR) between graders.(Dao et al., 2017) The reliability of D-EYE based glaucoma assessment can be increased by using 30-

second videos instead of still images.(Mittal et al., 2025) Clinical evaluations reported heterogeneous agreement and diagnostic performance for optic nerve pathology, cup-to-disc ratio assessment, and glaucoma classification across devices and reference standards.(Dao et al., 2017; Idriss et al., 2021; Muhsen et al., 2023; Saroya et al., 2024) Overall, smartphones and attachments may provide a lower-cost option for optic disc imaging, although diagnostic performance remains device-dependent.

4.2.3 Screening and Identification of Referable Glaucoma

Low-cost SBFI might fill part of the gaps left by traditional direct ophthalmoscopes in screening remote areas, (Figure 5, exemplary smartphone-based retinal photography of the posterior pole) with the added digital capability to store and share data for expert opinions from established medical centres.(Giardini et al., 2014; Wong and Tsai, 2021) Experts can examine the disc photographs and highlight the need for further re-evaluation, referral for in-person examination or need for other tests for glaucoma, which is of immense importance while screening any cohort.(Kim et al., 2024; B. Lin et al., 2022; Ramsey et al., 2020; Stratton et al., 2021; Wong and Tsai, 2021) Overall, the sensitivity and specificity of different devices in picking up accurate optic disc cupping irrespective of pupillary size varied from 46% to 100%. In an observation by Shah et al. during the Kumbh Mela religious gathering in India, the D-EYE adapter helped gather optic disc findings at screening sites, along with other systemic data points including ear health, oral health, cardiac, and neurological assessment.(Shah et al., 2018) Therefore, whether it is a hospital with a large outpatient load, a peripheral community screening, or screening in remote areas in India and Africa, SBFI might provide a viable low-cost solution for screening.(Rao, 2022; Smith et al., 2018) Beside optic nerve head examination and documentation in the adult population, SBFI can also assist in examining and documenting optic nerve heads in a paediatric population.(Pujari et al., 2019c)

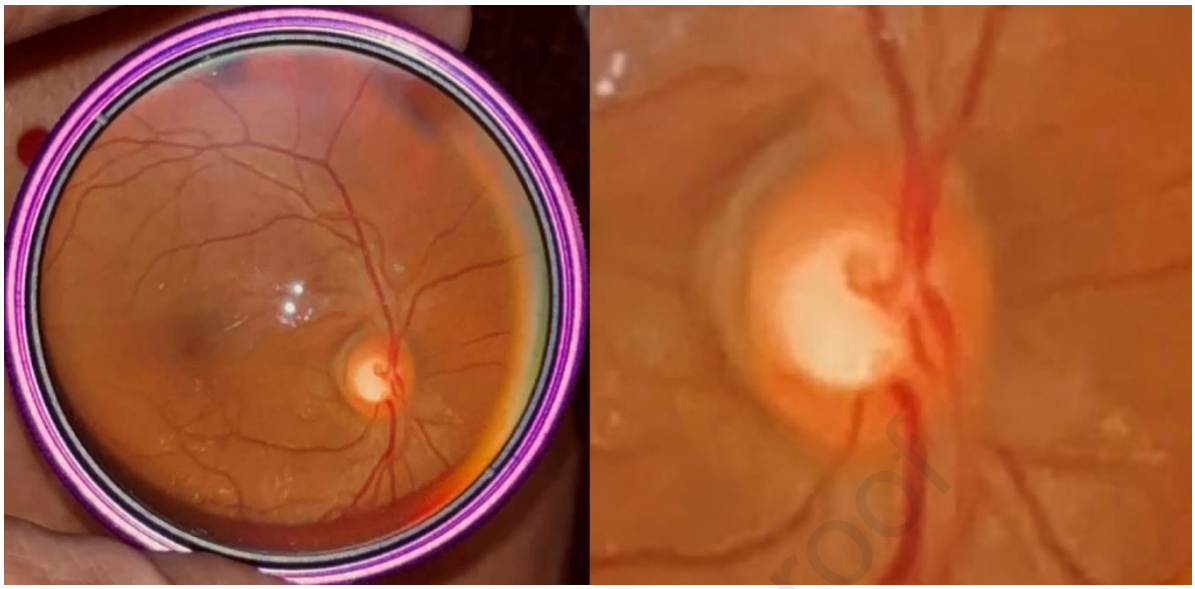


Figure 5: Exemplary Smartphone-based fundus imaging of the posterior pole (iPhone 16 + 20D lens). Left: complete image, right: magnification of the optic disc.

SBFI for glaucoma detection still has some limitations. First, there are no uniform methods for capturing details of the optic disc and its surroundings. Second, there is a lack of consistent methods for quantifying vertical cup-to-disc ratio across all smartphone imaging techniques. Third, there is a need for advanced lens systems to enhance image acquisition in cases of media opacities and to widen the field of view in non-mydriatic attachments. Lastly, advancements in the field of paediatric glaucoma imaging remain limited.

Table 4. *Smartphone-based fundus imaging for glaucoma detection (landmark studies)*

Study (Country)	Dataset size	Accuracy (manual analysis unless otherwise indicated)	Reference standard (rigor)	Device + Smartphone (pupil dilation)	Photographer expertise	Ungrad-able Images	AI system	Comments
Bastawrous et al., 2016 (Kenya) (Bastawrous et al., 2016)	1460 adults (2,920 eyes)	Mean vCDR difference: −0.02 (95% CI, −0.20 to 0.17) in Bland-Altman analysis between SBFI and desktop fundus camera with expert grader and examiner.	CentreVue+ Digital Retinal System, Haag-Streit (Moderate)	Peek retina + Samsung SIII GT-I9300 (pupil dilation)	Ophthalmic clinical officer / lay technician	26%	No AI used	Large clinical validation with lay/clinical officer image acquisition supporting feasibility at scale.
Wintergerst et al., (2018) (Germany) (Wintergerst et al., 2018)	27 participants (54 eyes)	Mean vCDR ± SD on conventional monoscopic fundus photography and on dilated and undilated SBFI was 0.76 ± 0.14, 0.73 ± 0.13 and 0.68 ± 0.12, respectively.	Visucam 500, Carl Zeiss Meditec, Jena, Germany (with dilation; Moderate)	D-EYE adapter (2016) + Samsung Galaxy S4 (with and without pupil dilation)	Clinician	Not reported	No AI used	Direct evidence that pupil dilation improves capture success, image quality, and rim visualisation
LaMonica et al., (2021) (Samoa) (LaMonica et al., 2021)	206 participants	Intraclass correlation coefficients for the CDR and its difference were 0.84 (95% CI = 0.81-0.87) and 0.68 (95% CI = 0.59-0.75).	N/A (Weak)	PanOptic iExaminer + iPhone 6S (no pupil dilation)	Trained lay examiner	Not reported	No AI used	Remote workflow feasibility with trained laymen using non-mydriatic smartphone imaging
Idriss et al., (2021) (Uganda) (Idriss et al., 2021)	467 individuals (934 eyes)	The SBFI device showed 67.7% sensitivity and 96.7% specificity to detect vCDR of >0.5 using OCT as standard	Spectral Domain OCT vCDR (Moderate)	Paxos Scope + iPhone 6S (with dilation)	Ophthalmic clinical officer	14.8%	No AI used	Benchmarks smartphone vCDR against OCT-derived cupping, strengthening comparator rigor
Saroya et al., (2024) (Thailand) (Saroya et al., 2024)	185 participants (355 eyes)	Inter-rater reliability for vCDR measurement was poor or moderate between the three cameras (intraclass co-efficient 0.41 to 0.52)	Peek retina, Volk iNview, and Volk Pictor plus inter-comparison (Weak)	Peek retina, Volk iNview, and Volk Pictor plus inter-comparison (pupil dilation)	No previous fundus photography expertise	10% iNview, 15% Pictor plus, 37% Peek Retina	No AI used	Demonstrates poor vCDR agreement across handheld cameras, underscoring device-dependent measurement variability and limited interchangeability across platforms
Senthil et al., (2025) (India) (Senthil et al., 2025)	213 Patients	AI showed 92.02% accuracy, 91.36% sensitivity 94.12% specificity to detect referral wanted glaucoma	Clinical assessment, visual field tests, and SD-OCT (Robust)	Remidio Fundus on phone, FOP NM 10 (optional pupil dilation)	Non-eye care professionals	2.7%	Medios on-device AI	On-device glaucoma AI evaluated against clinical assessment plus visual fields and SD-OCT, representing one of the strongest comparator frameworks

4.3 Retinopathy of Prematurity and Paediatrics

Quality paediatric eye examinations present unique challenges compared to adult exams. History of symptoms is either impossible or highly unreliable, increasing the importance of objective imaging-based examination findings. Moreover, patients may not tolerate typical fundoscopic exams, which include bright light and objects held near the face. While posterior segment disease is rare in children, the stakes are higher given the potential for lifelong, significant ocular morbidity, and even mortality, from undetected eye disease. Some conditions that can arise in children which require fundus examination to diagnose include optic neuropathy, such as from papilledema or optic neuritis, retinoblastoma, Coats disease and retinopathy of prematurity (ROP).

ROP as a leading cause of preventable blindness in premature infants and is a high-stakes indication where fundus imaging is essential, yet access to established widefield contact imaging remains limited in many settings due to cost, infrastructure, and workforce requirements. SBFI has therefore been explored as a lower-cost and more portable option for documentation and tele-triage in selected NICU workflows.

The modern ROP diagnostic criteria are outlined in the International Committee of Retinopathy of Prematurity, Third edition (ICROP3); these are based on the zone, defined as the peripheral extent of vascularisation, stage, or severity of disease at the vascular border, and plus disease, defined as characteristic vascular tortuosity and dilation.

Traditional screening methods rely on in-person clinical examination by skilled sub-specialized ophthalmologists, who may not be routinely available in many parts of the world. Telemedicine services as effective in screening for treatment-requiring ROP are accepted, and are used widely around the world. However, these services still require expensive and bulky contact-based fundus cameras, which poses challenges in some resource-limited settings. Recent developments in SBFI have enabled exploration of more portable, lower-cost approaches for NICU-based documentation and tele-triage, although performance and feasibility remain device- and workflow-dependent. Figures 6–7 illustrate exemplary SBFI for ROP. This section synthesizes the existing literature on SBFI for ROP, as well as other paediatric ophthalmological applications, highlighting its effectiveness, challenges, and future directions.

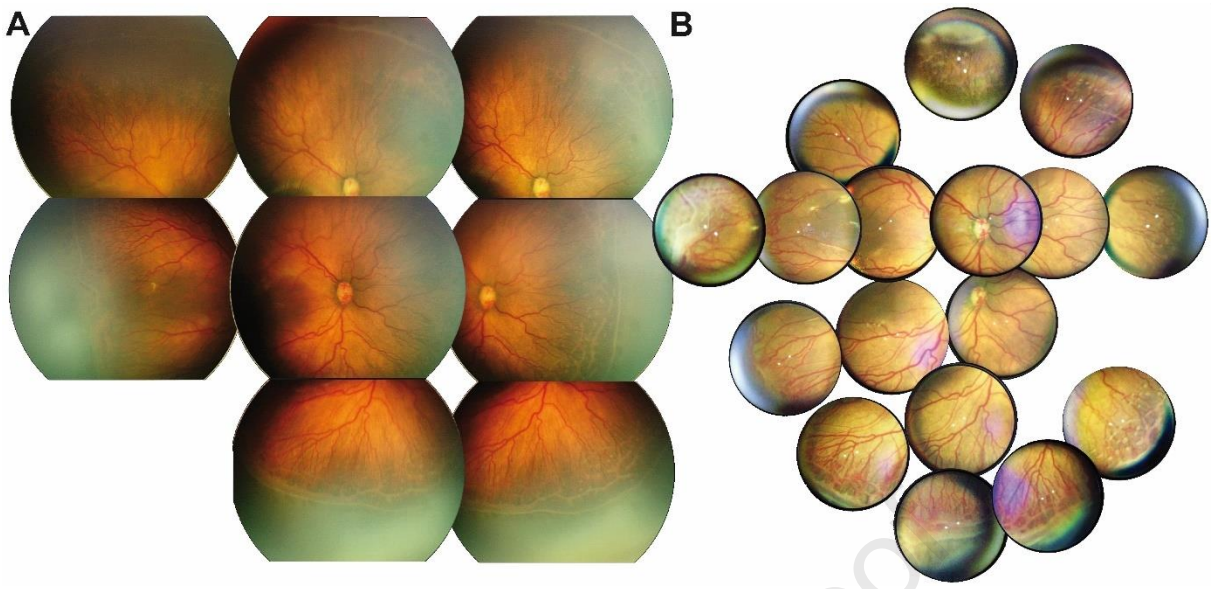


Figure 6: Comparison of composite retinal images. Conventional fundus imaging (A) and Smartphone-based fundus imaging (B; Paxos Scope equipped with an iPod touch 6th generation) were performed in the same eye under general anaesthesia. A wide-field-montage was created to give an impression of the dynamic field of view during live examination. Source (Wintergerst et al., 2019) The devices shown reflect the historical study setup and are no longer commercially available.

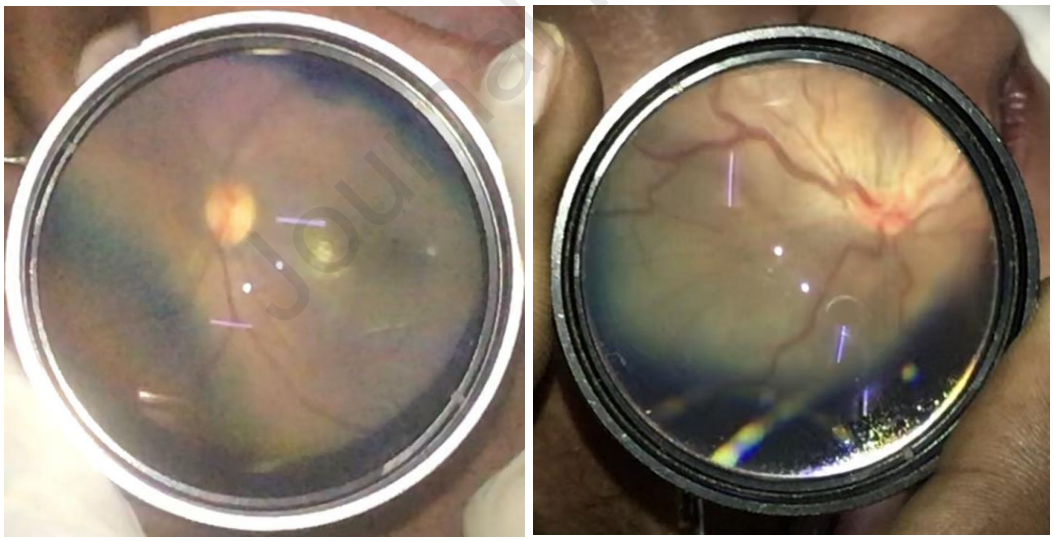


Figure 7: Sample images of Smartphone-based fundus imaging acquired for retinopathy of prematurity (ROP) screening acquired with a 28 dioptre lens, the MII Retcam Adapter, and smartphone. Left: An infant with no ROP and normal vessels. Right: An infant with plus disease who required treatment.

4.3.1 Smartphone-Based Imaging for Retinopathy of Prematurity

4.3.1.1 Device Design

ROP-specific SBFI systems should combine portability and affordability with sufficient image quality and retinal coverage for the intended screening or triage task.(Kirby et al., 2023) Most investigated approaches use an indirect-ophthalmoscopy design in which a 20D, 28D, or 40D condensing lens is positioned between the infant's eye and the smartphone camera, with near-coaxial illumination provided by the smartphone or an adapter. Different housings and mounting approaches have been developed to facilitate alignment and image acquisition. Although these configurations are relatively simple and portable, limited field of view and variable image quality can restrict assessment of peripheral ROP.

Alternative optical designs have aimed to improve illumination and retinal coverage. The RetinaScope uses a dual-lens optical system with annular illumination rather than a conventional condensing-lens configuration.(Patel et al., 2019b) More recently, Rossi et al. demonstrated a proof-of-concept ultra-widefield system using a contact-based lens and trans-pars-plana illumination, enabling imaging without pharmacological pupil dilation and reducing glare associated with coaxial illumination.(Rossi et al., 2024) However, this system is not commercially available and requires further clinical validation.

4.3.1.2 Validation and Accuracy for Retinopathy of Prematurity Screening

Landmark clinical validation studies are summarised in Table 5, with additional studies presented in Supplement Table D.1. Across nine accuracy studies, image acquisition was performed predominantly by physicians, while only three studies used non-physician photographers, and image gradability varied substantially across settings.(Adhikari et al., 2021; Choudhary et al., 2023)

Overall, reported performance was strongest for plus disease and referral-warranted ROP, whereas assessment of peripheral zone and stage was less consistent.(J.-Y. Lin et al., 2022; Patel et al., 2019a; Sharma et al., 2019) Some studies reported high agreement with indirect ophthalmoscopy or established widefield imaging, particularly when images were acquired by experienced clinicians, while others demonstrated important limitations in peripheral staging or image gradability.(Wintergerst et al., 2019) Performance therefore remains dependent on device design, imaging protocol, image quality, and operator expertise.

Current evidence suggests that SBFI may support posterior-pole documentation and tele-triage in selected settings.(Young et al., 2023) However, limited field of view and acquisition constraints can compromise complete peripheral assessment. Accordingly, SBFI should not be interpreted as equivalent to established widefield contact imaging for complete peripheral ROP staging unless supported by device-specific evidence. Studies without formal diagnostic-accuracy analyses further

support the feasibility of retinal documentation but do not establish equivalence with conventional ROP screening systems.(Kaur et al., 2020; Oluleye et al., 2016)

4.3.2 Other Paediatric Ophthalmology Applications

There were three other applications noted in the literature for SBFI, namely, screening for retinoblastoma, utility in the paediatric emergency room, and evaluating for non-accidental trauma.

Day et al. (2017)(Day et al., 2017) found that a smartphone attachment to the Welch Allyn PanOptic direct ophthalmoscope device was able to record clinically adequate fundus images non-mydriatically in 91.6% of patients. This may be useful to rapidly share images with consultant ophthalmologists for the diagnosis of optic disc pathology in the paediatric emergency department setting, if in-person consultation is unavailable, or the emergency physician is unable to interpret optic disc findings themselves. Similarly, earlier studies showed that the now-discontinued “D-EYE” system could record selected optic nerve findings. Pujari et al. (2019)(Pujari et al., 2019a) reported a historical proof-of-concept application in which an unmodified iPhone XS Max, a model no longer in production, was capable of capturing direct ophthalmoscopy images thanks to the co-axial lighting of the camera system; they were able to show a case example of such imaging with montaging showing a retinoblastoma, acquired during an exam under anaesthesia.

Jabir et al. (2022)(Jabir et al., 2022) evaluated ten articles in a systematic review of smartphone-based applications for retinoblastoma detection but most assessed the detection of leucocoria, which is outside the scope of this review for SBFI. Ademola-Popoola et al. (2017)(Ademola-Popoola and Olatunji, 2017) and Haddock et al. (2013)(Haddock et al., 2013) reported use of a smartphone camera with a 20D clinical lens to detect a variety of retinal diseases, including paediatric diseases such as retinoblastoma. Patel et al. (2019)(Patel et al., 2019b) used the above described “RetinaScope” device to image numerous paediatric retina diseases, including retinoblastoma, Coats disease, and others. Wintergerst et al. (2019) used a Heine iC2 to document Coats disease in a 7-year-old child (see Figure 8).(Wintergerst et al., 2020b)

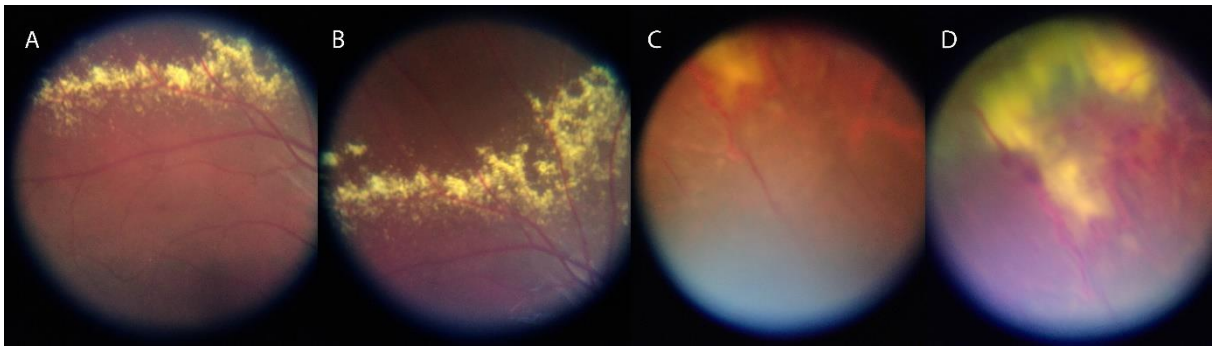


Figure 8: Smartphone-based retinal images (acquired with Heine iC2 using an iPhone 6) **from a 7-year-old child with Coats disease**. (A) and (B) exudates superior from the upper arcade; (C) and (D) massive exudation and telangiectasia of retinal vessels in the far superior-temporal periphery, which were also on fundus examination difficult to see. Source: Wintergerst et al. (2019)(Wintergerst et al., 2020b) The devices shown reflect the historical study setup and are no longer commercially available.

SBFI has been evaluated as a practical option for ROP-related documentation and tele-triage in selected settings, particularly for posterior-pole findings such as plus disease. However, limited field of view, variable image quality, and workflow constraints remain important barriers, and further pragmatic implementation studies are needed to define its role alongside established widefield imaging.

Finally, Solyman et al. (2022)(O. Solyman et al., 2022) reported using an SBFI system to document fundus imaging as part of their non-accidental trauma service. This is another critical application of this system, as accurate documentation of non-accidental trauma findings, including multi-layered retinal haemorrhages, has significant medico-legal implications. If standard fundus photography is not (readily) available, then their low-cost implementation of SBFI may be useful to providers who care for these delicate cases and vulnerable children in both high- and low-/middle-income countries.

***Table 5**. Smartphone-based fundus imaging for retinopathy of prematurity detection (landmark studies)*

Study (Country)	Dataset size	Accuracy (manual analysis unless otherwise indicated)	Reference standard (rigor)	Device + Smartphone (with or without pupil dilation)	Photographer expertise	Ungradable Images	Comments[a]
Sharma et al. (2019) (India) (Sharma et al., 2019)	20 patients (27 eyes)	Cohen's kappa 1.0 for referral-warranted ROP.	Clinical ophthalmologist examination (Moderate)	MII Retcam with a 20D lens and an iPhone 5S (with pupil dilation)	ROP trained ophthalmologist	10%	Referral-warranted ROP triage pilot, explicit exclusion of ungradable images, illustrating early feasibility
Patel et al. (2019) (United States) (Patel et al., 2019a)	27 patients (54 eyes)	Cohen's kappa 1.0, 0.85 for plus disease between two graders.	Clinical ophthalmologist examination (Moderate)	RetinaScope with a 54D lens and an iPhone 5s (with pupil dilation)	Ophthalmology resident	2%, 5% (2 graders)	High inter-grader agreement and low ungradable rates, supporting posterior-pole tele-triage feasibility
Wintergerst et al. (2019) (Germany) (Wintergerst et al., 2019)	14 patients (26 eyes)	Plus disease: Sensitivity 0.90, Specificity 1.00; ROP: Sensitivity 0.88, Specificity 0.93. No statistically significant difference between sensitivities of SBFI and Retcam (p = 0.41)	Clinical ophthalmologist examination and Retcam fundus photography (Moderate)	Paxos Scope with a Pan Retinal 2.2 or 40D lens and an iPod Touch 6th generation (with pupil dilation)	ROP trained ophthalmologist	Not reported	Direct comparison against RetCam and clinical evaluation with reported agreement for plus and stage
Adhikari et al. (2021) (Nepal) (Adhikari et al., 2021)	100 patients (200 eyes)	Sensitivity 87.5%, Specificity 81.6-82.1%	Clinical ophthalmologist examination (Moderate)	Paxos Scope + 20D lens + Google Pixel 3 (with pupil dilation)	Trained photographer	16%	Larger low-resource validation, trained photographer, substantial ungradable rate, illustrating potential feasibility and quality constraints in LMIC workflows
Lin et al. (2022) (Taiwan) (J.-Y. Lin et al., 2022)	71 patients (198 individual eye exams)	Cohen's kappa of 0.619 for plus disease. Could not grade zone or stage in any image	Retcam fundus photography (Moderate)	C3 Funduscam with a Volk 2.2 Pan Retinal lens and an iPhone 6s (with pupil dilation)	Trained photographer	8.6%	Smartphone images did not support zone/stage grading, illustrating limitations beyond plus-disease assessment (may be device-dependent)
Young et al. (2023) (India) (Young et al., 2023)	156 infants (312 eyes)	Sensitivity of 100%, specificity of 83% for treatment-requiring ROP; AI: Sensitivity 100%, specificity 58.6% for treatment-requiring ROP	Retcam fundus photography (Moderate)	MIO system with an iPhone 7 Plus or MII Retcam with a Samsung Galaxy M01 Core with a 28D lens (with pupil dilation)	Trained photographer	Not reported	Practice-relevant telescreening evaluation for treatment-requiring ROP with human grading + AI, including explicit referral-rule considerations affecting specificity

[a] Comments emphasize whether studies primarily support posterior-pole/plus-disease triage or broader zone/stage assessment.

4.4 Teaching

SBFI describes the use of the smartphone camera, usually with an external lens or adapter, to capture fundus images. Several educational studies refer to this as “smartphone fundus examination”, in this review we use the term SBFI for consistency.

4.4.1 The Crucial Role of Fundus Examination

Ocular fundus examination using direct fundus examination is an essential skill that has been identified by the International Council of Ophthalmology as one of the minimum clinical skills in ophthalmology (Parrish and Tso, 2006). Although rated as a core skill for clinicians (Benbassat et al., 2012), it enables practitioners from a range of specialties, including general practitioners, neurologists, and emergency physicians, to perform the essential examination of the patient’s fundus and decide whether further referral to an ophthalmologist is required.(Rodenbeck and Mackay, 2019) All students are likely to be exposed to ophthalmology first through direct fundus examination. While all specialties should be able to perform a basic retinal examination with direct fundus examination, ophthalmologists will continue their professional training with additional techniques. More importantly, direct fundus examination can provide rapid diagnosis where ophthalmologists are not readily available. Examinations of the optic disc, retina and vascular arcades are possible with direct fundus examination, allowing examiners to visualize possible changes associated with diabetes, hypertension or stroke risks with direct implications for systemic treatment.(Fraser-Bell et al., 2017; Klein et al., 2002; Wong, 2002; Yatsuya et al., 2010)

4.4.2 Current Use of Fundus Examination and the Role of SBFI

Fundus examination and direct fundus examination are less utilized in recent years outside of ophthalmology (Mackay et al., 2015), with rates being as low as 3% of patients receiving a fundus examination by general practitioners (Roberts et al., 1999), 4.5%-14% among emergency physicians (Bruce et al., 2011; Dunn et al., 2018) and 18% among neurologists.(Dalay et al., 2013) Reported barriers include low confidence, discomfort with close working distances, and concern about missing subtle retinal findings.(Dunn et al., 2023; Nagra et al., 2021; Qiu et al., 2025) Although direct fundus examination remains an essential diagnostic skill, SBFI may support and modernise fundus examination and teaching by making retinal visualization easier and more shareable.

4.4.3 Classic and SBFI-Based Teaching Approach for Fundus Examination and Retinal Diagnostics

Teaching direct fundus examination poses unique challenges, as examiners must get close to the patient and have a very limited field of view.(Mackay et al., 2015) Furthermore the teacher cannot follow how students actually visualize the fundus, unless they use special monitor equipment.(Schulz et al., 2016) SBFI can bridge

these gaps, as it allows students to more easily visualise fundus details, and teachers can check the students' imaging success simultaneously, as the retinal details are easily visible on the phone screen. First abstracts described the successful SBFI use in teaching either internal medicine residents or second year medical students in fundus examination using the "D-EYE" or "iExaminer" SBFI adapters in 2016 and 2017.(Campos et al., 2016; Stockslager et al., 2017)

Because retinal details are directly visible on the smartphone screen and can be mirrored to larger displays often featuring larger fields of view, SBFI facilitates supervised group teaching and immediate feedback without specialist monitoring equipment. (Russo et al., 2015b; Staniszewski et al., 2024; Wenting et al., 2017) Several studies also reported greater learner comfort, confidence, and preference for SBFI over direct fundus examination, with some studies showing improved examination performance and learning outcomes.(Hakimi et al., 2019; Kim and Chao, 2019; Nagra and Huntjens, 2019; Shetty et al., 2021; Wang et al., 2023; Wu et al., 2018)

4.4.4 Usability, Learning Curve, and Operator Variability in SBFI Training

Beyond their educational value, SBFI training studies also provide important implementation information on usability, learning curve, and operator variability. Across devices, image-acquisition success depends not only on theoretical understanding, but also on the optical design used, the level of supervision, and the examiner's ability to align the system, manage glare, and capture the intended retinal field reliably.

SBFI can be performed using a variety of devices and on undilated or dilated eyes. The simplest setup includes a phone with a light source and a 20D lens, which led to non-inferior training results in detecting retinal pathology in dilated eyes.(Kohler et al., 2021) This setup already yields promising results and may boost students' confidence.(Navarro et al., 2025) Complete devices like the now-discontinued D-EYE are associated with better student performance in identifying fundus pathologies than classic direct fundus examination, highlighting the system's viability for teaching.(Mamtora et al., 2018; Wu et al., 2018) High-end manufactured devices such as the PanOptic iExaminer also show higher diagnostic accuracy for optic disc diagnosis compared to a non-screen displaying fundus examination method.(Shikino et al., 2019)

Earlier Studies using now obsolete iPhone X or XS as direct ophthalmoscopy device demonstrated the feasibility of imaging and grading the optic disc compared with direct fundus examination. However this affordable setup might be inferior to more complex setups. (Ahmed et al., 2022; Gunasekera and Thomas, 2019; Pujari et al., 2019b) These studies provide historical evidence for attachment-free smartphone imaging but have limited relevance to current procurement and implementation, despite their hypothetical transmission to newer smartphone models. SBFI should

support rather than replace independent ophthalmoscopy skills in medical training.(Martins, 2019; Selvan and Pujari, 2019)

The available training literature suggests that different SBFI designs vary meaningfully in ease of use, image-acquisition time, and the amount of practice required for reliable fundus imaging, although most operators appear able to achieve high-quality image capture after a relatively short training period, regardless of prior experience.(Jansen et al., 2021; Sharma et al., 2020)

Taken together, these studies suggest that SBFI can often be learned within relatively short training periods, but that examination success, image quality, and acquisition time vary by device class and operator cadre. Direct approaches may offer simpler setup but narrower fields, whereas indirect or more optically complex systems may provide broader retinal coverage at the cost of greater alignment demands and a steeper learning curve.

4.4.5 Studies Demonstrating the Feasibility of Teaching Fundus Examination Using Smartphone-Based Fundus Imaging

Teaching studies generally support the feasibility of SBFI as a fundus examination training tool, with acceptance appearing to increase when device usability is better.(Dunn et al., 2021a; Nagra and Huntjens, 2019) Several studies also reported better diagnostic performance with SBFI than with traditional direct ophthalmoscopy, including direct-ophthalmoscopy-based smartphone adapters.(Dunn et al., 2021b, p. 2; Kim and Chao, 2019; Qader et al., 2022)

A recent review likewise concluded that SBFI can be a helpful teaching tool, while also noting practical considerations such as device selection, affordability, and curriculum integration.(Kherani et al., 2024). In particular, smartphone fundus examination may be easier to use than direct fundus examination and may therefore represent a valuable method for non-ophthalmologists.(Muiesan et al., 2017)

4.4.6 Metrics to Analyse SBFI Teaching Techniques

To improve comparability between teaching approaches, standardized evaluation tools should be used. One practical option is an adapted PU&PEOU questionnaire, which has already been applied to assess perceived training quality, ease of fundus visualization, confidence with the device, and intended future use of fundus examination after training.(Dunn et al., 2021a)

4.4.7 Integration of SBFI Teaching into College Programmes

While SBFI is a valid alternative to direct fundus examination, the current transition period requires that SBFI is taught alongside classic direct fundus examination. However, time is scarce in already constrained medical curricula.(Dunn et al., 2021b, p. 2; Kherani et al., 2024) Broader integration of SBFI in fundus examination teaching for medical students and non-ophthalmic specialties remains challenging, while it holds promising educational value. In the future, AI-guided teaching systems may

assist clinicians who perform fundus examination only irregularly in obtaining the best quality images.

In summary, SBFI offers a practical way to teach fundus examination and may improve learners´ confidence and performance compared with traditional direct fundus examination. Beyond undergraduate teaching, these educational advantages may also support workforce development in settings with limited ophthalmic capacity, where task-shifted image acquisition and telemedical referral pathways depend on operators who can obtain retinal images reliably.

Future work should therefore not only define standardized teaching protocols, but also examine how SBFI-based training translates into routine screening performance and implementation in low-resource care pathways. These educational aspects of SBFI are closely linked to AI-based decision support and to implementation in existing eye care infrastructure, as discussed in sections 5 and 6.

5. AI in Smartphone-Based Fundus Imaging

5.1 AI and Ophthalmology

In 2018, the first ever autonomous AI device to receive FDA authorisation in the United States was for DR screening(Abràmoff et al., 2018) and there are now multiple regulator approved devices available for DR screening.(Grzybowski et al., 2020) AI devices for the detection of suspected glaucoma and age-related macular degeneration are now entering the market.

Crucially the rising number of people with ophthalmological diseases is expected to disproportionately affect Africa and Asia.(Magliano and Boyko, 2021; Tham et al., 2014) With 76.2 ophthalmologists per million population in high-income countries compared to 3.6 per million population in low-income regions,(Resnikoff et al., 2020) task shifting by automated AI applications could help to increase health care access especially in underserved regions.

5.2 Opportunities for Smartphone-Based Fundus Imaging and Integrated AI Systems

AI may increase the practical value of SBFI, but its relevance in SBFI extends beyond automated pre-screening and diagnosis. In smartphone-based workflows, AI has the potential to support image-quality assessment, artefact detection, protocol-compliance checking, frame selection from video, image assembly/montage, and disease classification. This workflow perspective is particularly important in low-resource settings, where the utility of telemedical grading depends largely on acquisition quality. Algorithms working locally on the smartphone itself show early promising results for DR classification, (Engelmann et al., 2025) while earlier data shows that not all AI diagnostic tool solutions can be run on a smartphone alone. (Szymkowski et al., 2020)

A large proportion of AI systems developed in ophthalmology use ocular imaging as input data, most commonly retinal fundus photography and optical coherence tomography; for glaucoma-related applications, fundus-based optic disc imaging is also a common input modality, allowing for a potential transfer to SBFI systems, which can generate retinal fundus and optic disc images.(Nakahara et al., 2022; Natarajan et al., 2019; Sosale et al., 2020a)

5.3 Smartphone-Based Fundus Imaging Systems with AI-Supported Image Analysis

5.3.1 AI in Diabetic Retinopathy Detection

Automated detection of DR with the use of AI systems in teleophthalmology services can expedite referrals of those with STDR. The first study using AI with SBFI for automated detection of DR published in 2018 showed 95.8% sensitivity and 80.2% specificity for detection of referable DR, and 99.1% sensitivity and 80.4% specificity STDR.(Rajalakshmi et al., 2018)

Models specifically trained on smartphone-based retinal images reported improved accuracy in haemorrhage detection in DR.(Chandhakanond and Aimmanee, 2022) The availability of on-device AI that can provide instant diagnosis of DR has opened up access to tele-retinal screening in remote areas without internet connectivity.(Jain et al., 2021; Natarajan et al., 2019; Sosale et al., 2020b) On-device AI systems are validated and available for DR screening across countries in Asia and Europe,(Kemp et al., 2023; Rajalakshmi et al., 2024b) increasing use cases of AI based DR pre-screening. In the training of future algorithms, paired datasets of smartphone and table top cameras could serve as validation tools. For example, RetSyn is a novel dataset with potential use in this context. (Shuai et al., 2025)

5.3.2 AI in Glaucoma Assessment

Various studies show the possibility to detect glaucoma associated optic nerve head alterations with the help of AI-algorithms, even in SBFI images. Elloumi et al., developed a smartphone optic nerve head detection algorithm to detect disc images from retinal pictures. In different databases (partially based on SBFI using the iExaminer and D-EYE) a detection rate between 91% - 100% was shown.(Elloumi et al., 2018) Further, Mrad et al., observed the application provided more than 95% accuracy based on automated disc cupping detection using vessel distribution and displacement as a guide.(Mrad et al., 2022)

Similarly, smartphone applications like Yanbao can detect the optic disc and analyse the images to define the cup-disc ratio and neuroretinal rim changes.(Guo et al., 2020) Further processing using deep learning can increase glaucoma detection rate up to 90%.(Bragança et al., 2022) Different approaches including the use of a texture-based and model-based approach can localise and segment the optic disc in retinal images.(Mvoulana et al., 2019; Nakahara et al., 2022)

Such algorithms can also be deployed on-device.(Parthasarathy et al., 2021) In a comparative study by Rao et al., AI had a sensitivity and specificity of 93.7% and 85.6%, respectively, in detecting referable glaucoma compared to a comprehensive glaucoma workup.(Divya Parthasarathy Rao et al., 2024) The on-device application quantified vCDR and the clinically quantified ratios were comparable in Varshney et al. study.(Varshney et al., 2021) Yap et al. quantify the vCDR from public dataset, ultra-widefield, and smartphone images. (Yap et al., 2024) Scarpa et al.(Scarpa et al., 2020) analysed an automated disc size and cup segmentation from D-EYE SBFI Devices shot retinal videos. Nearly 95% accuracy in segmentation and good agreement in vCDR ratio calculation were shown.(Scarpa et al., 2020) Freire et al.(Freire et al., 2025) reported Dice indices of 95.52 for the disc and 85.30 for the images obtained with a Welch Allyn Panoptic ophthalmoscope. Together, these studies suggest that automated quantification of optic disc changes for glaucoma assessment is feasible in SBFI.(Martins et al., 2020; Neto et al., 2022). A recent smartphone-based AI model based on RETFound-Green, proposed in 2025 reports 82.5% sensitivity and 96.1% specificity for smartphone-based glaucoma assessment.(Kitema, 2025)

5.3.3 AI in Retinopathy of Prematurity Screening

Three studies in this review examined the use of AI applications for interpreting ROP in SBFI systems. The limited field of view of SBFI devices compared with contact wide-field fundus imaging may limit complete ROP grading. The available studies show high sensitivity but often lower specificity, indicating that implementation should be evaluated in terms of workflow burden, over-referral, and cost-effectiveness.

Subramaniam et al. (2023)(Subramaniam et al., 2023) showed the use of deep learning algorithms to interpret smartphone-based ROP images. They demonstrated a specificity of 1 and a sensitivity of 0.7143 for detection of plus disease with the deep learning system. Young et al. (2023)(Young et al., 2023) found that a deep learning algorithm to diagnose plus disease, and refer based on diagnosis of pre-plus or plus disease had a sensitivity of 100%, and specificity of 58.6% in identifying treatment-requiring ROP. The low specificity shows that there may be ‘over-referral’ using this AI system. Cost analysis comparing ‘over-referral’ with AI-enhanced SBFI systems compared to the increased cost of widefield digital fundus imaging and/or human graders may be fruitful in determining whether deployment of SBFI for ROP is reasonable in LMICs.

Ortiz et al. (2025)(Ortiz et al., 2025) developed a three-step screening pipeline using SBFI videos obtained with a low-cost indirect ophthalmoscopy setup (smartphone and 20/28/40D condensing lens). The system first performs automated frame selection to identify high-quality fundus frames from the video, and then applies a binary classifier for ROP versus no ROP. In the diagnostic study (512 neonates; 524 videos), the model demonstrated high patient-level sensitivity (93.3%) but lower specificity (55.2%) in comparison to a panel of paediatric ophthalmologists. This

finding is indicative of a screening-first design that prioritises the avoidance of missed cases.

5.3.4 Summary of Findings on the Combination of SBFI and AI

Overall, the current evidence on SBFI combined with AI remains heterogeneous in both function and maturity. In Table 6 we have detailed the different AI models that have published performance data of AI analysis of retinal images captured with a smartphone-based camera. Most published studies are retrospective development or early validation studies, often based on limited datasets and performed under controlled conditions. A smaller number of systems have undergone prospective validation, while only one AI algorithm (Medios AI) according to manufacturer reports, has received regulatory approval for detection of referable DR in Singapore, the European Union, and India, but not in the United States.(Negiloni et al., 2025; Remidio Innovative Solutions Pvt. Ltd., 2024, 2023)

Importantly, AI in SBFI should not be viewed only as a diagnostic classifier. Automated image-quality assessment, artefact detection, protocol-compliance checking, and frame selection or montage support may be equally important for scalable deployment. Across all of these roles, robust external validation across devices, smartphone models, optics, populations, and care settings remains essential before broader implementation can be justified. Additional challenges, limitations, and future perspectives are discussed in section 7. Challenges, Limitations, and Future Perspectives .

***Table 6**. Summary of Smartphone-based fundus imaging with combined AI-supported image analysis for ophthalmic assessment*

Function of AI device	Smartphone camera / imaging device	Input data to AI device	AI device reported performance	AI device available*
Diabetic retinopathy				
DR detection(Hacisoftaoglu et al., 2020) [RD]	Multiple	Synthetic retinal images	Sensitivity**: 98.2% to 77.9%; Specificity**: 99.1% to 9.4%***	No
DMO detection(Malerbi et al., 2021) [RD]	Phelcom Eyer	Retinal images	Not reported	No
Referable DR detection(Kim et al., 2021) [PV]	RetinaScope with EyeArt	Retinal images	Sensitivity 87.0% and specificity 78.6%	Yes,
Referable DR detection(Natarajan et al., 2019; Divya P. Rao et al., 2024; Sosale et al., 2020b) [PV; RD; RD]	Remidio Non Mydriatic Fundus on Phone Camera	Retinal images	Sensitivity 95.30% - 100% and specificity 83.89% - 88.4%	Yes****
DR detection(Mueller et al., 2020) [RD]	iPod touch (6th generation, Apple Inc.) and Paxos Scope adapter (Verana Health Inc.)	Videos of retinal images	AUC = 0.84; AUC of the precision recall curve = 0.75	No
Glaucoma				
Cup-to-disc ratio estimate(Scarpa et al., 2024) [RD]	iPhone 5 or 6 with D-EYE adaptor	Optic disc videos	Pearsons rank correlation 0.93 between AI and reference standard	No
Glaucoma detection(Mrad et al., 2022) [RD]	iExaminer and iPhone4S	Optic disc images	Sensitivity 100%, specificity 100%	No
Glaucoma detection(Nakahara et al., 2022) [RD]	iPhone 8 with D-EYE adaptor	Optic disc images	AUC=0.842; AUC=0.900 for advanced glaucoma	No
Glaucoma detection(Bragança et al., 2022) [RD]	Smartphone with Welch Allyn direct ophthalmoscope	Optic disc images	AUC=0.965	No
Glaucoma detection(Yap et al., 2024) [RD]	Smartphone-based oDocs Nun IR camera	Optic disc images	MAE=0.084 when compared to reference standard	No
Referable glaucoma detection(Divya Parthasarathy Rao et al., 2024; Upadhyaya et al., 2025) [PV; PV]	Remidio Non Mydriatic Fundus on Phone Camera	Retinal / optic disc images	Sensitivity 91% - 93.7% and specificity 85.6% - 93%	Yes
Age-related macular degeneration (AMD)				
AMD progression predictor(Das et al., 2019) [PV]	OphthoAI IoMT headset	Retinal images	>92% (accuracy)	No
AMD detection(Sayadia et al., 2022) [RD]	Samsung S9 smartphone with optical lens	Retinal images	Not specified for smartphone-based images	No
Referable AMD detection(Savoy et al., 2024) [RD]	Remidio Non Mydriatic Fundus on Phone Camera	Retinal images	Sensitivity 91.25% and specificity 84.18%	No
Retinopathy of prematurity (ROP)				
Detecting ROP(Young et al., 2023) [PV]	1) MII Retcam and Samsung Galaxy 2) MIO system with iPhone7 Plus	Retinal images	Sensitivity 0.81 and specificity 0.92 for detection of referable ROP**	No
Plus disease staging(Subramaniam et al., 2023) [RD]	Smartphone camera + Volk 28D/20D lens	Retinal images	AUC 0.9754, accuracy 0.96, specificity 1, sensitivity 0.7143	No
Detecting ROP(Ortiz et al., 2025) [RD]	Smartphone + indirect ophthalmoscopy	Retinal videos	Patient-level sensitivity 93.3%, specificity 55.2%	No

*AI, artificial intelligence; DR, diabetic retinopathy; DME, diabetic macular oedema; AUC, area under the curve; MAE, mean absolute error.; PV = prospective validation; RD = retrospective development.; *commercially ** Reported range of results as FOV decreases from 100% to 20%; *** Combined result from both SBFI cameras; **** AI device (EyeArt) not licensed for use with smartphone camera*

6. Implementation in Existing Eye Care Infrastructure

6.1 Applicability in Clinical Settings

SBFI may support tele-ophthalmology workflows for remote screening, documentation, referral triage, and selected monitoring applications. Such programmes may also be used in community screening, outreach clinics, and other settings where access to conventional retinal imaging or specialist assessment is limited.(Ahn and Kim, 2024; Barbieri et al., 2024; Davidson et al., 2024; Malerbi et al., 2022; Malerbi and Andrade, 2022; Penha et al., 2023; Vishwanath et al., 2023) Due to their low-cost, mobile, and delegable nature, SBFI programmes may be particularly useful in resource-limited settings, remote or rural areas where access to specialized ophthalmic care is limited. A SBFI strategy could also be employed in non-traditional environments such as emergency rooms, nursing homes, or even in patient's homes.(Ahn and Kim, 2024; Ay and Kose, 2023; Davidson et al., 2024; Korn Malerbi et al., 2020; Varo et al., 2023; Vishwanath et al., 2023)

Based on the intended application and available healthcare cadres and financial resources, in each clinical application a decision for one of the three basic technical principles for SBFI devices must be made. The relevant differences in field of view, ease of use, training requirements, pupil dilatation, and cost are described in Section 2 and summarised in Table 1.

For the establishment of a tele-ophthalmology programme with SBFI, certain conditions must be met. Considering that retinal image acquisition often represents an early step in screening and referral pathways, there are necessary subsequent steps that should be granted, above all, the capacity of treating such individuals when necessary. Generally, screening campaigns in underserved areas tend to increase the demand for treatment, and reference services should have the capacity of absorbing the created demand. In that sense, the basic principles of screening, initially formulated in 1968 (Box 1 in Wilson and Jungner, 1968, WHO(Wilson and Jungner, 1968)) and further consolidated(Dobrow et al., 2018), should be taken into account.

Several ocular conditions fall into the category of diseases that merit screening and could benefit from SBFI, such as DR, glaucoma, ROP and age-related macular degeneration.(Baatiema et al., 2023; Melo et al., 2024b; Mintz et al., 2022; Wintergerst et al., 2019, 2020c)

Across the published validation literature, the most mature evidence base for SBFI supports telemedical screening and referral triage for referral-/treatment-warranted DR and ROP, where image-based decisions closely align with established photography-based workflows. By contrast, evidence for glaucoma is more heterogeneous when relying on optic nerve head photographs alone, with reported performance spanning a wide range across devices and settings and being strongly influenced by image gradability, pupil dilation status, and the chosen reference

standard. Accordingly, SBFI appears best positioned today as a first-line triage tool for DR/ROP programmes, whereas smartphone-based optic disc imaging may serve as an initial triage step for glaucoma suspicion, provided that programmes explicitly link this first-line assessment to downstream confirmatory examinations (e.g., ophthalmological fundoscopic examination, IOP measurement, perimetry).

Besides disease screening, there are other situations in which SBFI could play an important role, including tele-consultation for ocular urgencies and emergencies, such as retinal vascular occlusions, retinal detachment or acute optic nerve disorders, or several medical conditions with ocular manifestations such as increased cranial pressure or hypertensive emergencies.(Ahn and Kim, 2024; Chaichan et al., 2023; Kalic et al., 2023; Mbanugo et al., 2023; Mohammadpour et al., 2017) The deployment of SBFI programmes should only take place in regions where there is need of detecting diseases for which SBFI has demonstrated sufficient screening/triage performance in device- and protocol-specific validation studies, such as the above-mentioned examples. There are several ocular conditions that currently lack clinical validation for this method.

Minimal infrastructure requirements must be met for the deployment of SBFI programmes, for both disease screening and tele-consultation, including electricity supply and data transmission structure such as broadband internet or at least stable 3G.(Vishwanath et al., 2023) As for human resources, there is a minimal requirement of trained personnel for image acquisition (where the screening takes place) and specialized professionals for image reading (in a clinic / hospital / reading centre) and treatment delivery (clinic / hospital).

With all the above conditions met, the literature suggests that SBFI programmes are most plausibly justified in underserved and resource-constrained settings(Barbieri et al., 2024; Queiroz et al., 2020), particularly where portability(Malerbi et al., 2022; Penha et al., 2023; Malerbi and Andrade, 2022), task-shifting, and telemedical referral pathways address clear access barriers. (Ahn and Kim, 2024; Ay and Kose, 2023; Davidson et al., 2024; Korn Malerbi et al., 2020; Vishwanath et al., 2023) Economic implications are discussed separately in Section 7.12.

6.2 Implementation Strategy and Key Requirements

Every programme involving SBFI requires evaluation of the process from many aspects, including feasibility, clinical outcomes, financial and human resources, ease of access, equity, cultural barriers, and patient satisfaction.(Mohammadpour et al., 2017; Wintergerst et al., 2020a) As for human resources, capacity building, teamwork, training, and standardisation across different levels of care are required, involving physicians and appropriately trained non-physician personnel.(Davidson et al., 2024; Melo et al., 2024b; Queiroz et al., 2020; Varo et al., 2023) A functioning referral pathway should be agreed upon from inception by all stakeholders. The identification of barriers and development of strategies to overcome them should also

be part of the programme design. The funding / cost-compensation of a programme is also essential for its success and completion, and financial planning should be created involving every aspect of the programme, including equipment, services, and structure for data storage and transmission.

The implementation of SBFI programmes needs careful planning, with special attention to the objectives of the programme and the geographical area, intended targeted population and diseases which could be detected and treated. If the programme is intended as a tool for primary care, such as DR screening, all the subsequent steps must be planned from inception, with a continuum of care from community to tertiary care.(Melo et al., 2024a) Another critical issue involves, even before the programme begins, alignment among all stakeholders, including those responsible for public health, infrastructure, funding, and care delivery. Such initial planning must foresee all the clinical workflow and the referral pathway, involving inclusion criteria and desired outcomes, ideally with data collection throughout the process to assess programme quality, outcomes, and opportunities for improvement. To support translation into practice, the key programme-design and implementation requirements discussed in this section are summarised in Supplement Table E.1 as a concise implementation checklist.

Training paramedical personnel in SBFI is another crucial step in setting-up telemedical SBFI programmes. While it is time- and personnel-intensive to conduct such trainings in person, resource-efficient alternatives might be online e-learning approaches, where theoretical and practical knowledge on SBFI, the screened disease(s), and the screening workflow are taught in a systematic and structured manner. Regardless of the training format, personnel should demonstrate the theoretical and practical competency required for the intended purpose. Online e-learning approaches may offer a resource-efficient alternative to conventional face-to-face training and warrant further evaluation in SBFI implementation studies with standardized educational and imaging-quality outcomes.

The imaging protocol of a SBFI programme must be standardized, including the minimal number of required images per eye / fundus region, the correct framing, the field of view, and quality standards. Such standardization depends on the chosen equipment and the disease which is screened for. The equipment choice for a given programme should ideally take into consideration the properties of each device, regarding image quality, field of view, the ocular condition of interest and cost-effectiveness, among other variables. The relevant trade-offs between retinal coverage, image detail, acquisition time, and image quality may favour SBFI solutions with a wider field of view for DR and ROP screening, whereas systems with a more limited field of view but higher image detail may be preferable for glaucoma assessment. Further details are discussed in Section 2 and summarised in Table 1.(Vishwanath et al., 2023)

The imaging protocol standardization is of paramount importance not only for image acquisition, but also for image reading and interpretation. For example, for

telemedical DR screening, an imaging protocol for SBFI of the posterior pole and the peripheral retina should be employed, as it has been established and published by Wintergerst et al.(Wintergerst et al., 2020c) Consequently, compliance with the imaging protocol should also be monitored.(Wintergerst et al., 2020c) The classification system used by the readers should be previously agreed, allowing a reading protocol compatible with predefined referral criteria and thresholds.(Nakayama et al., 2021) Evaluation of image quality/gradability by the readers may also determine if a given patient is referred: pathways should therefore be defined for ungradable images and incidental findings like cataracts. (Queiroz et al., 2020) Even if certain outcomes are not contemplated in a given strategy, a referral pathway must be clear to all stakeholders (including photographers, readers and the specialist who receive referrals) from the beginning.

An adequate image quality is a major factor upon which the success of the screening strategy is dependent.(Li et al., 2011) The key factors determining image quality in fundus photographs are often the optics of the system, characteristics of the eye being imaged (including possible media opacities and pupil dilation), patient cooperation, and ability/training of the photographer.(Ahn and Kim, 2024; Malerbi et al., 2023; Vishwanath et al., 2023) Hence, the design of a SBFI programme should also determine the pupil dilation strategy: it has been established that, for certain conditions, such as DR, pupil dilation allows better quality images, improving the efficiency of the programme (especially for peripheral retinal images). The training of photographers is also essential for obtaining high-quality images, increasing the efficiency of SBFI programmes.(Wintergerst et al., 2020c) There are reports of good results of initiatives which have trained healthcare personnel without previous experience in ocular imaging.(Jansen et al., 2021; Queiroz et al., 2020) Whatever approach is used, ensuring sufficient image quality for the intended use is important. Means to assess image quality in terms of focus, reflex artefacts, contrast, illumination, and image alignment are published, and allowing for standardized image quality assessment; therefore, those parameters should be used to monitor image quality in SBFI programmes.(Jansen et al., 2021; Wintergerst et al., 2020c, 2018)

The choice of the device for image acquisition in any SBFI programme should ideally involve equipment which has already undergone clinical validation, to optimize the success of the programme. There are several examples of clinically validated devices or mounted sets for SBFI for various retinal conditions, generally tested against a gold-standard / clinical reference.(de Oliveira et al., 2023; Rajalakshmi et al., 2015; Russo et al., 2015a; Wintergerst et al., 2020c, 2019) Depending if a certain product is registered as a medical device or not, regulatory issues should also be taken into account during the planning of the programme.(Ahn and Kim, 2024) Ease of use and learning speed should be a concern as well.(Jansen et al., 2021; Vishwanath et al., 2023) In addition to the choice of devices, as in any initiative involving telemedicine and transmission of sensitive data, special care should be taken regarding data protection and patient privacy.(Ahn and Kim, 2024; Robles et al., 2023)

Teleophthalmology programmes may be designed for synchronous (real-time) or asynchronous (store-and-forward) image interpretation, with the possibility of results at the point of care in the former. Notwithstanding the technical challenges, it is expected that the point-of-care approach will have a positive impact on patient adherence.(Malerbi et al., 2023; Melo et al., 2024b) Combination with AI may further assist in providing such a point-of-care solution with readily available grading results.

As previously pointed out, SBFI can easily be integrated into teleophthalmology systems for remote DR screening of people with diabetes in rural and remote areas, improving access and regular follow-ups of underserved populations annually.(Pradeepa et al., 2019) Embedding telemedical DR screening with SBFI directly into primary-care and endocrinology workflows could offer a practical “one-stop” solution: retinal photographs can be captured opportunistically during routine diabetes visits by trained nurses or medical assistants, then forwarded for remote grading. This co-location leverages existing patient touch-points, could lower no-show rates, and might increase cost-effectiveness. Periodic quality audits could be used to ensure sufficient image quality and the integration of generated reports into the existing electronic medical record systems must be considered. Also, for such an integrated approach, clear referral pathways should be defined. When these caveats are addressed, primary-care and endocrine practices could become effective, cost-efficient gateways for equitable DR prevention.

Figure 9 provides a flowchart for such an example workflow. Cloud based storage of retinal images captured using smartphone-based devices during community outreach DR screening programmes, can allow for remote access by certified ophthalmologists / graders to provide diagnosis of DR. SBFI devices can also be connected with Wi-Fi for use in tele-ophthalmology/rural screening. A wide-ranging advantage is the feasibility and effectiveness of utilising SBFI for DR screening in diabetes care centres. As diabetologists manage and optimise glycaemic control and other risk factors and also screen for other complications of diabetes, integrating SBFI for DR screening facilitates a holistic approach.(Rajalakshmi et al., 2022)

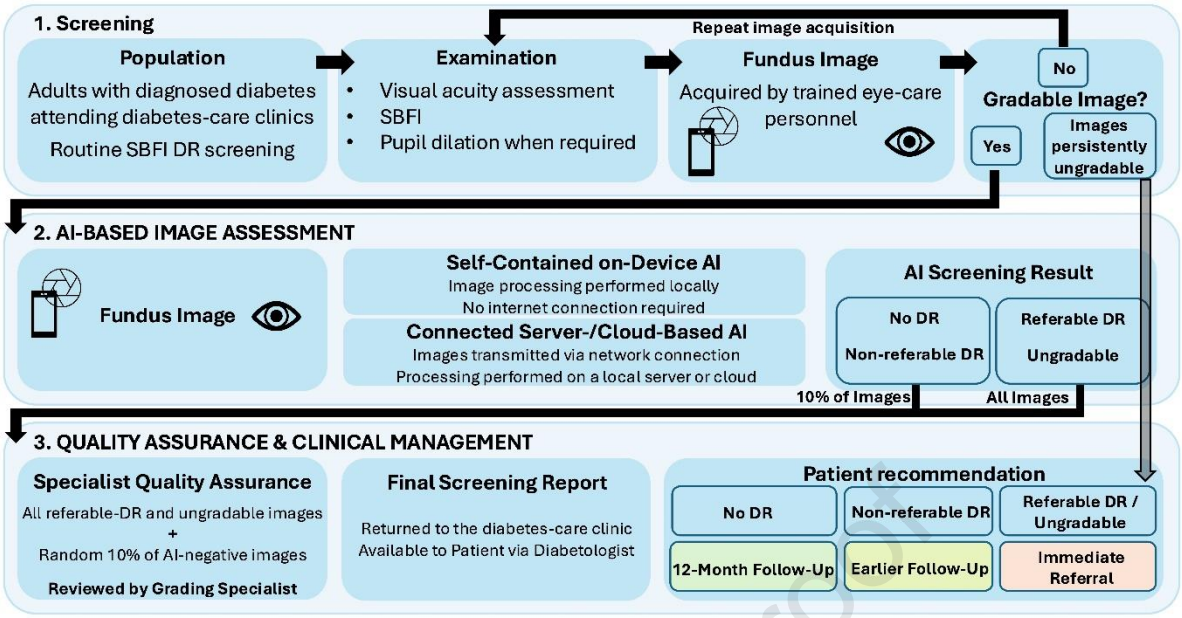


Figure 9: Example tele-ophthalmology flow-chart for diabetic retinopathy (DR) screening with Smartphone-based fundus imaging in India (Rajalakshmi et al., 2022)

6.3 Selected Examples of Implementation

Although SBFI has been investigated for more than a decade, published evidence of durable implementation remains limited. A small number of pioneering programmes have been reported to progress beyond pilot stages and become integrated into routine eye-care services, whereas many others remained temporary pilots or proof-of-concept initiatives. In some cases, it was difficult to assess how much a first pilot study has moved to a full-scale long-term programme implemented in existing infrastructure. Where possible programmes / pilot study authors were contacted to verify the actual stage of implementation.

Varo and colleagues evaluated the utility of a low-cost, portable SBFI solution to screen fundus pathology in an adult population in a public referral hospital in southern Mozambique, whose ophthalmology services are provided by an ophthalmology technician. Patients with suspected retinal pathology are referred to Maputo's central hospital, where the only fully trained ophthalmologist in the country provided clinical assistance, by the time of the publication.(Varo et al., 2023) For that pilot study, a telemedicine platform was created and remote image evaluation was performed by two ophthalmologists in Spain. Images were collected by two general practitioners with no experience in ocular imaging; after a 3-hour practical training, 90% of images were of sufficient quality for interpretation.(Varo et al., 2023) The longer-term continuation of this pilot programme was not reported and could not be verified for this review.

Melo and colleagues reported the creation of a dedicated workflow for SBFI screening of DR in an underserved state capital in north-eastern Brazil, and also the experience of fundus evaluation in rural areas of the same north-eastern Brazilian

state.(Melo et al., 2024b, 2024a) The initiative that took place in the state's capital was a public-private partnership, involving public health primary care units and outsourced private providers for specialized care; after a few months, the programme was discontinued due to low patient attendance rates, which jeopardized the financial sustainability of the initiative. In their paper, the authors discuss the causes for drawbacks, the main reason being a combination of patient turnout lower than expected with the fee-for-service financial model.(Melo et al., 2024a) In their rural initiative, the authors also reported issues with low attendance rates, highlighting the importance of health education, of raising awareness and of advocacy for the success of such initiatives, proposing measures including use of TV, radio and internet campaigns, along with local communication by primary care personnel during home visits.(Korn Malerbi and Barreto Melo, 2022; Melo et al., 2024b)

Queiroz and colleagues(Queiroz et al., 2020) described the feasibility and implementation of a low-cost DR tele-ophthalmological screening strategy with SBFI, with images obtained by a team of nurses with no previous experience in ocular imaging in an urban, primary care setting.(Queiroz et al., 2020) The nurses underwent a four-hour training about image protocol and acquisition by an ophthalmologist and, thereafter, relied on continuous remote feed-back given by the specialist as images were being interpreted. The learning curve of image acquisition was evaluated according to the rate of patients with dilated pupils whose images allowed clinical decision; from the 7th day onward, such rate was maintained above 80%. Examination duration per patient had an average time of 2.5 $\pm$ 1.7 min. No information was available on whether the service continued beyond the study period.

Lodhia and colleagues conducted a qualitative study in Kenya to evaluate a smartphone-based ophthalmic system called “the Portable Eye Examination Kit” (Peek).(Lodhia et al., 2016) They applied semi structured interviews with healthcare professionals and patients who underwent fundus imaging at a temporary clinic, all of whom expressed being satisfied with that SBFI system, having perceived it to be fast, convenient and able to reach a large population. The system was also deemed to have generated a lot of interest among the communities, having therefore been considered as an opportunity for increasing awareness of eye health within the population. Overall, health care personnel demonstrated a good understanding of the utility of the system, having perceived the system to be a capabilities enhancer, a social enabler and able to improve communication between providers themselves as well as with their patients, through the provision of diagnostic and decision support. Ultimately, the authors concluded that the system acted as a means to strengthen eye care delivery.(Lodhia et al., 2016) However, the Peek system was discontinued in the meantime.

In a pilot study performed at rural screening camps in Nepal, Collon and colleagues evaluated the impact of SBFI on detection and management of ocular diseases, having demonstrated the feasibility of using such devices in that setting. They described the hectic nature of the screening camps, with cases of protocol non-adherence, and emphasized that several patients had mature cataracts, which

precluded adequate fundus photography. The authors described that image interpretation was performed by both technicians and physicians, with low agreement among those professionals; they suspected that the discrepancy was due to minimal training in and exposure to posterior segment pathology for technicians, inadequate examination tools available to technicians, among other factors.(Collon et al., 2020) Media opacities were also the most common finding in another initiative reported by Kim and colleagues, performed in Vietnam, which also counted on image interpretation by two different professionals: local optometrists and remote physicians.(Kim et al., 2024) The authors considered that their project attained resource efficiency in measuring the prevalence of ophthalmic conditions, and stated that the SBFI system helped in quickly identifying patients who required medical intervention, facilitating their appropriate referral.

Another pilot study with SBFI, undertaken in South Sudan during a humanitarian project, attained sufficient fundus image quality for the investigation of patients with conditions such as Burkitt lymphoma, Kala Azar, malnutrition, tuberculosis, HIV, Usher syndrome and hypertension.(Furdova et al., 2017) Finally, Caceres and colleagues performed a proof of concept study in the Pacific islands of Vanuatu, having confirmed the feasibility of deploying SBFI for DR screening in that resource-limited environment. The authors emphasized that the portability of the equipment allowed the team to travel across three different islands in Vanuatu without requiring extensive equipment.(Caceres et al., 2023)

In India, rural vision technicians (Essilor's Eye Mitra opticians) trained in SBFI performed DR screening and on-device AI analysis. Using the Remidio SBFI device equipped with on-device Medios AI, non-specialist personnel were able to capture retinal images and identify referable DR in the field.(Bahl and Rao, 2022) In initial screening camps across two villages, 250 adults over 40 years old were examined, yielding good-quality retinal photos in 197 individuals and detecting 7 cases of referable DR. Although the existing network of 4,000 Eye Mitra opticians may provide a platform for future scale-up, the initial screening camps do not themselves demonstrate sustained implementation.

Another example of attempted scale-up has been described in publicly available programme material from Samsung's Galaxy Upcycling initiative, reported in collaboration with the International Agency for the Prevention of Blindness (IAPB) and Yonsei University Health System. According to this 2022 program report repurposed Galaxy smartphones were used as low-cost fundus imaging devices in outreach settings in Vietnam and later expanded to India, Morocco, and Papua New Guinea.("Samsung's EYELIKE™ Fundus Camera Repurposes Galaxy Smartphones to Improve Access to Eye Care," n.d.) However, because this information derives from a corporate/newsroom source rather than a peer-reviewed implementation study, it should be interpreted as descriptive programme information rather than independently verified long-term implementation evidence.

Teleophthalmology based DR screening using SBFI with and without AI integration is being followed across 48 branches of Diabetes Specialities Centres in 32 cities in India. These are single physician diabetes care clinics where SBFI is performed by trained eye technicians for all individuals with diabetes visiting the centres.(Rajalakshmi et al., 2021a) Along with the blood test reports, the SBFI eye diagnosis report is available within half hour after imaging, for the diabetologist. This physician-based model enables holistic screening for various complications of diabetes. Following direct confirmation from the authors, these SBFI-based screening services were still operating as of 6 December 2025.

In southern India 4 technically different approaches of SBFI were compared to conventional fundus imaging (7-field colour fundus photographs) and clinical examination with indirect ophthalmoscopy.(Wintergerst et al., 2020c) Based on this first field trial, a telemedical DR screening programme using SBFI has been developed and integrated in the eye care. A dedicated app for patient medical record management and for acquisition, data management, transfer, grading, and storage of smartphone-based retinal images in a telemedical setting has been developed. An AI for automated analysis of SBFI videos for detection of sight-threatening DR has been developed.(Mueller et al., 2020). According to information provided by the authors and verified on 6 December 2025, SBFI-based DR screening was continuing through rural screening camps conducted at least twice monthly in southern India.

Countries with SBFI studies and with first pilot implementations of SBFI in existing eye care are displayed in Figures 10 and 11. Taken together, these examples show that SBFI has repeatedly demonstrated technical and clinical feasibility, but sustained implementation remains uncommon and incompletely documented. Most reports describe pilots or temporary outreach initiatives, while only a small number provide evidence of continued routine use. Long-term data on utilisation, financing, referral completion, treatment uptake, and patient outcomes remain scarce.

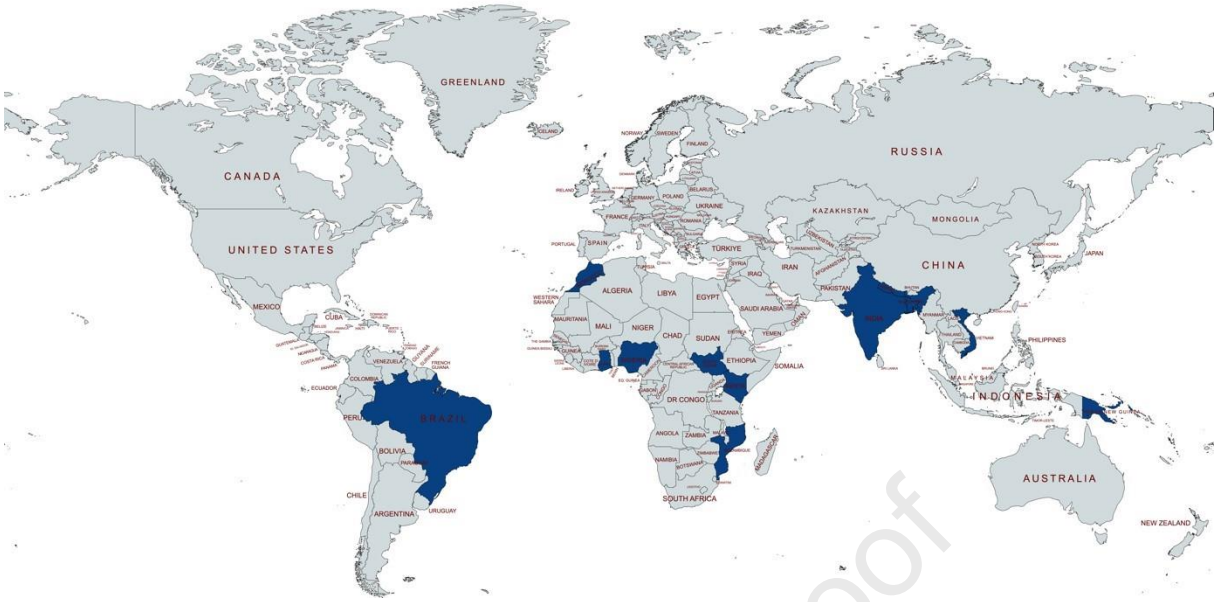


Figure 10: Countries with first attempts of implemented Smartphone-based fundus imaging programmes: Bangladesh, Brazil, Ghana, India, Kenya, Morocco, Mozambique, Nepal, Nigeria, Papua, New Guinea, South Sudan, Vanatu, Vietnam

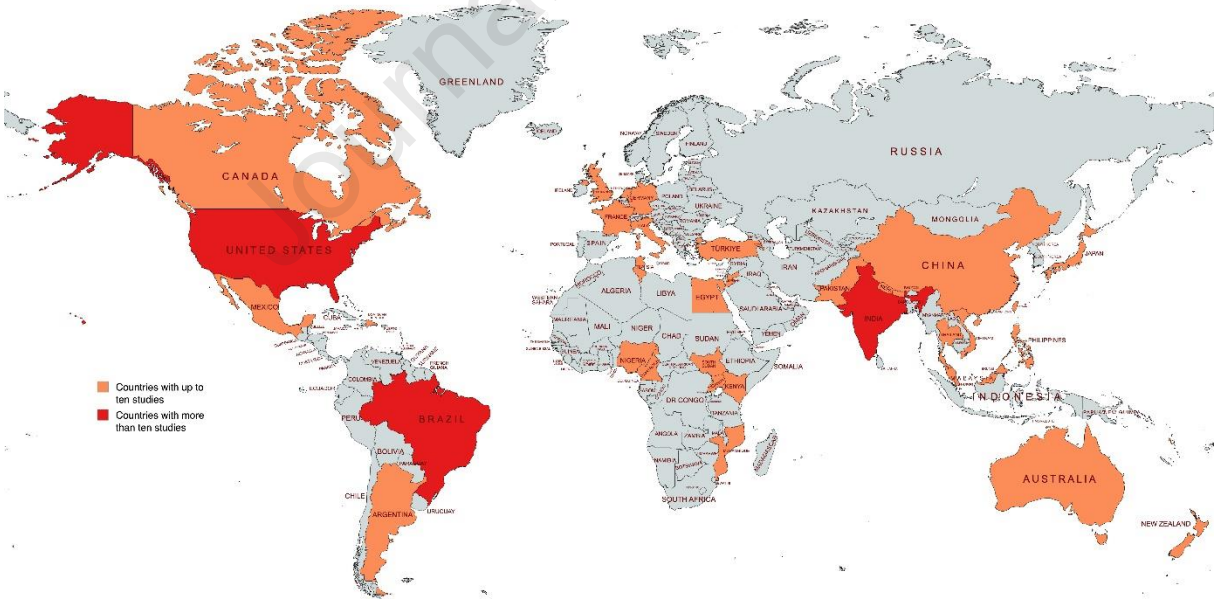


Figure 11: Geographic distribution of Smartphone-based fundus imaging publications included in this review. Included publications originated from 37 countries. Countries are grouped according to the number of included publications conducted in each country (1–10; >10), with India, Brazil, and the United States representing the three countries with more than ten publications. Countries without identified publications are shown in grey. Multinational publications were counted once for each participating country.

7. Challenges, Limitations, and Future Perspectives

SBFI represents a rapidly evolving approach to fundus imaging that may expand access to retinal photography and telemedical screening in selected settings, depending on device design, imaging protocol, and available care pathways. However, the full scope of SBFI's capacity remains only partially realized as important challenges remain. These include hardware limitations, regulatory hurdles, data security considerations, training strategies and workforce development, image quality and imaging protocol compliance, the combination with AI, integration in existing infrastructure and the full eye care continuum, achieving scalability and sustainable service models, evidence limitations, and the demonstration of cost-effectiveness. This section outlines the details of these hurdles and how they can be addressed.

7.1 Hardware Limitations and Future Technological Improvements

SBFI has matured into a potential alternative to conventional retinal cameras. Yet, several hardware constraints inherent to different optical designs can limit its application. First, multi-camera smartphones can complicate optical alignment. Unless the acquisition software can identify and lock onto the correct sensor that aligns with the optical axis of the adapter, inadvertent switching among lenses can degrade focus, illumination co-axiality and field of view. Multi-camera smartphones therefore might cause variable performance in clinical use with universal SBFI adapters. This may be mitigated by robust application programming that enables correct sensor selection and provides users with device-specific guidance for high-quality SBFI imaging across different smartphones.

Universal smartphone adapters can support prolonged device usability across changing phone availability and may reduce the need to follow rapid smartphone turnover. However, other designs rely more strongly on model-specific integration to achieve stable alignment and ease of use. While such model-specific solutions may improve optical performance and usability, they can also increase vendor lock-in and reduce procurement flexibility and long-term sustainability, particularly where replacement smartphones are inconsistent across LMIC sites.

Field of view remains another critical bottleneck. Among the commercially available devices with higher literature coverage summarised in Table 1, reported fields of view varied substantially, and four of six devices provided a single shot field of view of at least 40°, adequate for posterior-pole screening, but insufficient for also including peripheral regions in one single image. On-device montaging that stitches contiguous frames and wide-field optics could address this limitation by artificially increasing the field of view.(Kim et al., 2018; Rajalakshmi et al., 2024a; Rossi et al., 2024; Sivaraman et al., 2021) However, on-device stitching requires smartphone processor chips capable of such tasks. In general, in-built computational capability resembles a

limitation when advanced post-processing or AI are intended to run locally on the smartphone. Yet, recent mobile chip developments offer prospects of solving this problem. Field of view should therefore be regarded as a disease- and workflow-defining parameter rather than a simple technical specification: narrow-field systems may be adequate for optic-disc or posterior-pole triage, whereas peripheral DR lesion detection and full ROP staging generally require multi-field, montage-based, or wider-field approaches, with corresponding increases in acquisition time, protocol complexity, and training demands.

Standardization and device compatibility are additional challenges. The SBFI field includes various devices and attachments, e.g., condensing lens plus smartphone, 3D-printed adapters, or one-piece commercial integrated optical attachments. There is no universal standard for smartphone imaging, as each system has different image resolution, field of view, and even storage formats. This lack of standardization complicates comparisons and regulatory approval(Ahn and Kim, 2024; Hunt et al., 2021). Additionally, compatibility issues arise as smartphones evolve - new phone designs or operating systems may not support older SBFI adapters, raising sustainability concerns.

Material durability, though less discussed, is essential for sustained deployment in dusty, humid or hospital environments requiring frequent disinfection. Material used for 3-D-printed adapters is usually susceptible to solvents(Głowacki et al., 2022), which could result in warping and constrained optical alignment. Therefore, similar standards as for other medical devices should be applied and SBFI adapters should therefore be manufactured from chemically inert materials and should have sealed seams.

Image quality itself will likely further profit from forthcoming sensor and optical advances.(Blahnik and Schindelbeck, 2021) For example, 1-inch-type smartphone sensors promise improved low-light signal-to-noise ratio, which might allow sufficient fundus imaging with less illumination intensities. Off-axis time-of-flight modules, although unable to focus on the virtual aerial retinal image, could serve as range-finders that guide users to the correct working distance.

Another challenge with devices relying on smartphone illumination is significant glare, leading to poor patient cooperation and low-quality images. Some developers, like MII Ret Cam Inc., have addressed this issue in their MII Ret Cam Pro iOS software, which allows flash intensity control. However, the MII Ret Cam Pro Android app lacks this feature due to limitations in the Android system. These developments unfold within a broader trend toward comprehensive smartphone-based eye care. Commercial prototypes already extend slit-lamp examination and documentation to smartphone-based systems,(Dutt et al., 2021) and validated visual-acuity assessments(Rono et al., 2018) are implemented in large field studies. Beyond these individual components, integrated smartphone-based platforms that enable both anterior segment documentation and fundus imaging have already been described, supporting the feasibility of broader mobile ophthalmic examination workflows.

(Rubegni et al., 2024) Future developments may further consolidate these functions into more resource-efficient end-to-end examination platforms, potentially spanning visual acuity testing,(Bastawrous et al., 2015) anterior segment imaging, fundus imaging, intraocular pressure assessment, and visual field testing.

7.2 Regulatory and Device Certification Hurdles

Certification remains the principal non-technical hurdle for SBFI.(Ahn and Kim, 2024) Although the relevant approval frameworks and standards are outlined in Section 2.5, their practical consequence is that even low-cost SBFI systems may face substantial documentation, conformity-assessment, and market-entry costs. These burdens can be disproportionate for simple adapters intended for low-resource settings, where the public-health benefit of rapid deployment may outweigh only marginal device risks.(World Health Organization, 2022)

A risk-stratified approach would treat non-invasive optical housings, passive mounting hardware and low-intensity illumination sources (i.e. International Electrotechnical Commission's 62471 Risk Group 1) as self-certifiable accessories, while reserving third-party review for components that encompass higher energy delivery to the eye or incorporate diagnostic algorithms. In practice this means complete SBFI adapters without embedded analytics could follow a manufacturer's declaration of conformity, whereas software that claims autonomous disease grading, or light emitting products exceeding photobiological safety thresholds, would still require notified-body scrutiny.(Ahn and Kim, 2024; Torous et al., 2022) Additionally, ill-equipped regulatory authorities in some LMICs could rely on regulatory work from another country's jurisdiction to save costs and speed-up certification processes.(World Health Organization, 2022) Framing requirements along such functional lines would preserve patient safety, accommodate do-it-yourself and ultra-low-cost solutions, and accelerate scale-up in regions facing the largest retinal-disease backlogs.

7.3 Data Security and Privacy Considerations

Retinal images encode a person's vascular fingerprint alongside explicit diagnostic findings. A breach could therefore compromise both biometric identity and health status. Against this background, SBFI workflows should consequently be engineered with the same safeguards that govern other high-risk medical data, recognising that the attack surface spans the smartphone itself, the internet connection, the cloud (if applicable) and the reading-centre.

Security controls should follow the data's life-cycle. On the capture device, the operating system must be fully patched, extraneous apps purged and unused radios disabled (Bluetooth/Wi-Fi Hotspot).(Bromwich and Bromwich, 2016) Single-purpose phones minimise residual exposure. To prevent inadvertent disclosure, image-capture devices should not use personal photo galleries, and automatic synchronization to consumer cloud services should be disabled by default. Images

should instead be stored only within a secured clinical application environment with controlled export, encrypted storage, and auditable access. During transit, uploads require end-to-end encryption with certificate pinning so that only the intended back end can decrypt the payload. In storage, strong cryptography and access logging that meets OWASP Application Security Verification Standard and ISO/IEC 27001 guidelines are required.(“ISO/IEC 27001:2022,” n.d.; OWASP Foundation, 2019) Pseudonymising identifiers once the image leaves the smartphone could further assist, yet this can complicate longitudinal medical record-keeping.(Kohlmayer et al., 2019) Finally, role-based authentication and cryptographic integrity checks can ensure that only authorised clinicians or algorithms can open, modify or analyse the data.

While all these measures are meaningful, implementing all of them can present significant challenges to low-cost approaches in resource-limited health care systems.(Kohlmayer et al., 2019) A pragmatic “good-enough” security approach should prioritise open-source, low-cost, high-impact controls: a dedicated smartphone with built-in storage encryption, removal of consumer apps, and automatic pseudonym assignment, with data stored in a securely encrypted format using well-established cryptographic standards.(Syzdykova et al., 2017) Data should be accessible only with role-based authentication and transferred only via trusted internet connections. This architecture delivers the critical triad of device hardening, encryption, and role-based data-access, while preserving a seamless SBFI screening process in low-resource settings. In addition, compliant deployment requires governance measures such as role-based user administration, audit trails, staff training, defined data-retention periods, secure deletion procedures, and compliance with applicable national data-protection and medical-data regulations.

7.4 Optimising Training Strategies and Workforce Development

Optimizing SBFI training is not only an educational issue, but a core implementation requirement, particularly in task-shifted and resource-constrained screening programmes where image-acquisition success directly determines downstream referral quality. A resilient SBFI workforce must be built through task-shifting from ophthalmologist to medical assistants and trained community health workers.(Bastawrous et al., 2016; Burton et al., 2021; Jansen et al., 2021) Training programmes on SBFI should be embedded as modules in existing curricula and local trainers should be identified for long-term capacity building in resource-constrained settings.(Sadikin et al., 2024) Reliable scale-up depends on uniform competency benchmarks and should combine theoretic didactic content with hands-on sessions as well as long term competency maintenance.(Sultan et al., 2025) Online e-learning courses represent a less personnel- and cost-intensive alternative to conventional face-to-face training and have shown good results in SBFI teaching.(Frehywot et al., 2013; Huemmer et al., 2024; Strehlow et al., 2024). Embedding brief in-app instructions and reminders, decision check-lists and troubleshooting guides could deliver “just-in-time” refreshers that sustain performance during routine screening.

Finally, programmes should incorporate basic device-maintenance modules and supply multilingual, culturally and gender-sensitive training materials tailored to local clinical guidelines.(Sultan et al., 2025)

7.5 Ensuring Sufficient Image Quality and Protocol Compliance

A consensus on established SBFI standards for image quality and examination protocol compliance is important to assure minimum quality standards and to achieve comparability across different studies.(Wintergerst et al., 2020a) Such image quality protocols include focus, contrast/illumination, reflex artefacts, usable field of view (in cases of optical un-alignment a dark peripheral crescent can become evident), and alignment with the examined anatomical structure (e.g. macula, optic nerve head).(Wintergerst et al., 2020c) Beside this, examination protocol compliance standards are equally important and evaluate examination completeness of the intended retinal area (e.g. 7-field-imaging). Wintergerst et al. published image quality and examination protocol compliance standards for DR screening using SBFI(Wintergerst et al., 2020c), that align with general retinal-imaging literature.(Taylor et al., 2009)

At minimum, SBFI programmes and validation studies should report the imaging scheme used, the device field of view, image-quality outcomes including focus, contrast/illumination, reflex artefacts, usable field of view, gradable and ungradable image rates with explicit reasons for ungradability, repeat-capture rates, and protocol-compliance success for the intended retinal fields, since these parameters are critical for judging how image-quality limitations affect performance in clinical screening workflows.

Programmes should embed these benchmarks already at the training stage, requiring trainees to meet predefined minimum criteria during a practical examination and receive explicit instruction in recognizing common quality lapses. Mandatory refresher courses and log-book audits could then preserve competence, while audits during routine programmes could flag systemic drift before it compromises clinical validity.

Automated quality-control algorithms, as already outlined in section 3.5, could further streamline oversight.(Karlsson et al., 2021) Running either in the cloud or, as on-device computation improves, directly on the smartphone, these modules could grade each image for image quality and each examination for fulfilment of protocol compliance and directly flag shortcomings which would allow the examiner to provide better image material right away.

7.6 Minimum Reporting Standard for SBFI Validation Studies

Published SBFI evidence is currently difficult to compare directly because studies often use heterogeneous imaging protocols, quality/grading scales, and reference

standards, which limits generalisability and slows regulatory and programme-level decision making.

To improve comparability, future SBFI studies should adopt a minimum reporting standard that, at a minimum, specifies the imaging system (adapter/device, smartphone model, software version, and field of view), acquisition protocol (mydriatic strategy, retinal fields/number of images, operator cadre and training), and image quality/protocol compliance procedures, including a defined IQA framework (if present) and transparent reporting of gradable vs ungradable rates with reasons.

Studies should also report a clear reference standard and masked grading workflow, and provide diagnostic outcomes (e.g., sensitivity/specificity and agreement statistics, ideally with confidence intervals) separately for all images and gradable images, while documenting the data pathway where telemedicine transmission is involved.

A consensus reporting standard for SBFI would most plausibly need to be developed through an international multi-stakeholder process, for example a Delphi-based consensus exercise involving clinicians, biomedical engineers, industry stakeholders, reading-centre experts, programme implementers and regulators.

7.7 Challenges for Combination with AI

There are a number of challenges related to the uptake and use of SBFI with integrated AI. The broader challenges include ethico-legal and data privacy concerns, infrastructure and connectivity challenges, clinician and patient trust, algorithmic bias and determining actual impact.

Regarding algorithmic bias, the majority of data used to train AI algorithms in ophthalmology are from high-income country populations.(Khan et al., 2021) This therefore means there is a risk that AI devices trained using these data will work well in high-income country populations but not on under-represented populations from LMICs. This could lead to a widening of global health inequities and has been called “health data poverty”.(Ibrahim et al., 2021)

A major barrier is domain shift. AI models that are trained using limited sets of smartphone–adapter combinations, illumination geometries, compression pipelines and populations may perform poorly when applied to different devices or under-represented groups. Robust deployment therefore requires validation across different smartphone models, optical systems, pupil dilation strategies, and populations. Additionally, a decision must be made between on-device and cloud-based inference. On-device workflows are appealing in areas with poor connectivity, but they limit model size and update cycles. In contrast, cloud workflows can support more complex models, but they introduce latency, connectivity, and governance issues.

When considering challenges more specifically related to SBFI with integrated AI, a key issue is whether SBFI can provide retinal images of sufficient quality to enable accurate AI-supported diagnoses. The field of view of retinal images captured with SBFI is reduced compared with traditional retinal cameras, and indeed publications showed that a decreasing field of view substantially reduced performance of the AI model.(Hacisoftaoglu et al., 2020; Sosale et al., 2020b) This is less of an issue for glaucoma diagnosis, which generally requires only optic disc images and may in part explain why the majority of SBFI devices and integrated AI are for glaucoma detection (Table 6).

Some groups have begun recording continuous SBFI video rather than capturing individual frames, which can make it quicker and more reliable for non-expert operators to sweep across the retina and collect diagnostically useful material.(Mueller et al., 2020) The downside is that pulling out and grading individual images from video is labour-intensive. Emerging deep-learning approaches that process entire video streams rather than isolated frames could both streamline post-processing and deliver real-time diagnostic feedback, alleviating the current bottleneck of manual frame extraction.(Ortiz et al., 2025; Scarpa et al., 2024, 2020)

The primary opportunity with SBFI and integrated AI is to enable non-eye specialists to provide high-quality ophthalmic diagnostics to underserved populations. In order for SBFI and integrated AI to be used outside of academically led projects and in clinical practice, regulatory approval will be required. This is an expensive and time-consuming process which is generally led by commercial groups. However, the large financial markets for medical AI diagnostics are in high-income countries (e.g. USA and Europe) where the business case for the use of SBFI and integrated AI is less clear. Therefore, it remains to be seen whether any groups will make the required investment in a smartphone camera with an integrated AI model to enable wider clinical adoption. Without this, implementation of these devices may continue to be limited.

If SBFI and integrated AI analysis were successfully implemented it is likely they would contribute towards earlier diagnosis of eye diseases. However, if access to ophthalmologists and treatment for these conditions is not simultaneously made more accessible to underserved populations, integrated SBFI and AI diagnostics will have a limited impact on the prevention of vision loss. Improved AI-supported diagnostics must therefore be accompanied by improved access to effective treatment.

To address the under representation of LMIC populations in data used to train AI algorithms, efforts are needed to collect, curate and store well labelled and high-quality ocular imaging data from under-represented populations. This will be challenging and expensive but is important to ensure that the development of AI devices in ophthalmology is equitable and benefits populations globally, not just those in high-income countries.

The combination of SBFI and integrated AI diagnostics may improve access to ophthalmic imaging and support screening and referral pathways for underserved populations, but its long-term impact will depend on validation, implementation, regulation and access to downstream care.(Antonio-Aguirre et al., 2025)

7.8 Challenges for Integration in Existing Infrastructure

Integrating SBFI into established systems of care requires more than hardware deployment. Task-shifting from ophthalmologists to trained technicians or nurses is key, as there are countries with as little as one fully trained ophthalmologist, especially in sub-Saharan Africa.(“Data on Ophthalmologists Worldwide - International Council of Ophthalmology,” 2021; Queiroz et al., 2020; Varo et al., 2023) Even if images obtained in the realm of SBFI programmes may help with disease detection, and interpreted by specialists elsewhere or by automated systems, there will always be the need for the presence of specialists in order to deliver treatment, even if those specialists are part of workforces from abroad.

This setup must be matched by point-of-care diagnostic workflows that - ideally - feed seamlessly into legacy electronic health-record systems (e.g. of the eye care provider conducting the SBFI service, the primary care physicians, endocrinologists). However, patient’s health records are often paper in LMICs, which can lead to fragmentation of data.(Syzdykova et al., 2017) Integration in existing primary care health care infrastructure has proven effective and is also recommended by the WHO; however, it can also come with significant challenges.(*Global Strategy on Digital Health 2020-2025*, 2021; Melo et al., 2024a)

Furthermore, technical infrastructure in many LMICs remains fragile. On-device-first architectures that cache patient data locally, encrypt it, and synchronise automatically once bandwidth becomes available can mitigate intermittent connectivity, while scheduled batch uploads reduce cellular costs. However, the downside would be a significant delay in image grading. On-device-algorithms could solve this problem, given sufficient local computation power on the smartphone.(Natarajan et al., 2019) Equally, unreliable mains power (which is even an issue in larger health care facilities) can necessitate battery banks, solar chargers, and (spare) device-rotation so screening sessions continue during grid outages.(*Energizing Health*, 2023)

Hardware logistics for SBFI are relatively favourable: smartphones can be sourced from multiple non-specialist vendors, and low-value adapters are small enough for hand-carry importation. Another advantage of SBFI over conventional fundus imaging is fewer dependence on service chains: most adapters are so simple and cheap, that - economically speaking - it does not make sense to perform expensive repairs. Minor issues (e.g. alignment / calibration of the optical system) can usually easily be solved directly by the operator (if trained accordingly) or via contacting the manufacturer and getting instructions on how to solve the issue. Universal smartphone adapters can also support the prolonged SBFI device use in dependence of the available smartphones, avoiding to follow rapid smartphone

turnover rates, while different physical limitations of multi-camera smartphones require specialised software for the intended use.

One key limitation is the pupil dilation required for sufficient image quality and / or peripheral retinal examination by many SBFI adapters.(Wintergerst et al., 2018) This, however, is problematic in screenings conducted by paramedical staff only. The possibility of pupil dilation depends upon several circumstances, including the availability of a physician to manage the very rare but possible adverse effects of pharmacological mydriasis.(Pandit and Taylor, 2000) On the other hand, non-mydriatic programmes are recognized for a higher patient satisfaction, with positive impact on patient adherence.(Malerbi et al., 2023) Further, diabetic autonomic neuropathy in people with longer duration of diabetes can affect the physiological mydriasis even in a dark room. Depending on the device, good quality images may be obtained for most individuals by trained photographers even without dilation, making a staged mydriasis strategy an interesting choice.(Malerbi et al., 2023) Possible further solutions include focusing on SBFI approaches which also deliver sufficient image quality without pupil dilation and - if the patient agrees and is properly informed about the possible risks - using only mild pupil dilation to mitigate risks while maintaining functionality.(Raman et al., 2021)

Finally, programme success hinges on patient uptake and sustainability. Text message recalls,(Rono et al., 2021) community awareness campaigns and embedded health-education materials could address generic attendance barriers, while explicit equity targets should steer services toward under-represented groups.(Burton et al., 2021) Environmental stewardship should also be considered: solar charging and responsible e-waste disposal can help limit the carbon footprint as SBFI scales across diverse healthcare settings.(Van Der Zee et al., 2024)

7.9 Integrating Screening into the Full Eye Care Continuum

Effective SBFI programmes must extend far beyond image capture: they must guarantee referral-loop closure so that every patient in need of referral / treatment identified in the screening is flagged and monitored throughout the whole referral-loop. Automated appointment generation and text message reminders have proven efficacy in this regard, as demonstrated by a school-based vision-impairment initiative in Kenya, where reminder cascades cut no-show rates markedly.(Rono et al., 2021, 2018) Embedding community health workers in the notification process could not only sustain adherence but also enhance local acceptance of the screening service.(Burton et al., 2021)

Patient compliance can be a significant challenge, so the design of a screening programme must contain a clear strategy of recruiting, due to the risk of low attendance.(Melo et al., 2024a) One possible strategy is to actively invite patients from known databases (for example, individuals with diabetes from a certain area) to be screened. Alternatively, the invitation or image acquisition may take place when those individuals come to a local clinic for a general practitioner encounter or to get

prescriptions filled. Another approach is to have a community healthcare agent obtaining ocular images while visiting patients' homes.(Melo et al., 2024a) Communication campaigns, local advocacy and other measures to raise awareness and improve health education, addressed not only to patients, but also to families, caregivers, and healthcare personnel, and the support by political stakeholders or organizations such as the International Diabetes Federation, World Health Organization, and the International Agency for the Prevention of Blindness, could help increase patient attendance, being also important for achieving adequate coverage of programmes, as well for helping convince financing of current and future programmes.(Korn Malerbi and Barreto Melo, 2022; Melo et al., 2024a) The careful analysis of the programme as a whole also allows evaluation of patient satisfaction, which is crucial to adherence.(Gunasekeran et al., 2024)

Beside this, downstream capacity planning is equally important. It is necessary not to oversee whether sufficient infrastructure for potentially required referral or follow-up treatment is available and functional (e.g. for DR: laser treatment, intravitreal injection, vitreoretinal surgery).(Wilson and Jungner, 1968) It is also useful to forecast possible downstream load generated by screening volumes to ensure treatment capacities are available. Also, low-vision and rehabilitation pathways should be considered.

The possibility of tele-consultation during the screening for borderline or complex cases should be provided, to reduce unnecessary referrals and associated costs.(Pieczynski et al., 2021) Where treatment fees threaten uptake, linking screening outcomes to insurance pre-authorization, voucher schemes or social funds (where possible) could remove a major financial barrier and reinforces continuity of care.(Kacker et al., 2022; *World report on vision*, 2019)

Finally, outcome surveillance must close the loop.("Screening programmes: a short guide. Increase effectiveness, maximize benefits and minimize harm.," 2020) Programmes should monitor post-treatment and overall long-term outcomes to recalibrate SBFI-specific referral thresholds where necessary, and to ensure that screening translates into measurable, long-term visual benefits.

7.10 Achieving Scalability and Sustainable Service Models

Scalable SBFI must fit heterogeneous care architectures - from stand-alone screening camps to integration within primary-care and endocrinology clinics - and should ideally interact seamlessly with (future) national e-health backbones.(Bolster et al., 2015; Zimmer-Galler et al., 2015)

Although low-cost, SBFI services produce costs which cannot be carried by NGO on the long-term.(Burton et al., 2021) Insurance coverage or social funds might be a solution for some country contexts, but often, the required treatments produce out-of-pocket costs. Therefore, sustainable cost-compensation models must be developed for each healthcare- / country-context in which SBFI is integrated.(Burton et al., 2021) First, SBFI services should be aligned with existing insurance codes or public-

health funding streams to sustain operations beyond pilot grants. Embedding data from SBFI programmes in country-specific electronic health record platforms can not only prevent parallel information systems but might also ease access to national healthcare funds / insurance budgets.(Zimmer-Galler et al., 2015) Further, cost-effectiveness evidence should be provided to assist with integration of SBFI programmes in national health services (see section 7.12 for more details).(Ahn and Kim, 2024; Rachapelle et al., 2013) Second, if no such coverage is available, country-specific cost-compensations must be developed.

Costs could be further reduced by benefiting from synergies (e.g. for cloud services and AI) when building (cross-country) collaborations on SBFI programmes (Tan et al., 2023)

An additional consideration to reduce costs is to extend smartphones product life-cycle by using “outdated” / refurbished smartphones in the context of SBFI, which might also increase awareness in high-income countries for SBFI and on how beneficial the donation of an outdated smartphone could be for people in LMICs (e.g. Samsung’s EYELIKE programme). Using lightweight software supporting a broad range of smartphone versions is important to lower the barrier for refurbished-phones and for prolonging hardware life cycles. Samsung’s EYELIKE is also a good example of potential public-private partnerships, which might assist to mitigate financial and scalability issues at the same time. Tiered collaborations in which private manufacturers supply adapters, telecom providers donate data bundles, and ministries of health undertake trainings could spread financial burdens across multiple actors.(Bak et al., 2025) Further, outcome-based financing (pay-for-performance contracts with predefined coverage or sight-loss-averted targets that need to be met) might allow optimizing cost-effectiveness.(Clarke et al., 2018)

Also, hardware availability influences scalability: local assembly and/or 3-D printing could ease equipment built-up to scale-up programmes, shorten supply chains and build technical capacity (e.g. Remidio in India). Open-source designs could further facilitate this approach.(Raju et al., 2016)

Finally, proof of scalability by successful existing programmes, online e-learning platforms that cut training expenses, and demonstrated cost-effectiveness could strengthen the case for integrating SBFI into routine services and for moving from pilot projects to sustainable implementation at regional or national scale.

7.11 Evidence Limitations

Published evidence shows sufficient operational feasibility in terms of feasible learning curves, device robustness, and availability of required medico-legal certifications for many SBFI adapters (see Table 1). For example, general practitioners in Mozambique produced 90% gradable images after just a three-hour course,(Varo et al., 2023) Brazilian medical assistants reached ≥ 80% pass-rate by their seventh screening day, with mean acquisition times of 2.5 min per patient(Queiroz et al., 2020) and medical assistants in Germany and India achieved

sufficient image quality and examination times for posterior pole examination within a 30 minutes training(Jansen et al., 2021) and for peripheral examination in a three-day training. However, more evidence is required for newer / less studied models and long-term data on device robustness is necessary. One major operational hurdle for many manufacturers and device designers are medico-legal certifications (see section 7.2), as they imply significant costs. These financial regulatory issues can represent a relevant obstacle for commercialization, especially in low-resource settings.

Evidence for diagnostic accuracy is limited by small, usually single-centre cohorts (especially for paediatrics) and heterogeneous study protocols (in terms of imaging protocol and grading scales). Studies show that SBFI is in principle feasible both with and without pupil dilation (depending on the intended application and used device), however, image quality and diagnostic accuracy can be reduced without pupil dilation.(Wintergerst et al., 2018) This can be the case especially in countries such as India where the iris is darker in colour and a greater number of people have media opacities due to cataract.(Prathiba et al., 2020) Therefore, a stepped approach for pupil dilation only in eyes where images cannot be captured sufficiently otherwise can be considered (see also section 7.8).

Overall, the evidence supports the use of several SBFI devices for telemedical DR screening and referral triage, although diagnostic performance varies by device, imaging protocol, and reference standard.(Lu et al., 2022; Wintergerst et al., 2020c) Mydriatic studies such as Rajalakshmi et al. 2015(Rajalakshmi et al., 2015) (Remidio M-FOP, India) achieved 92.7% sensitivity / 98.4% specificity for any DR and 87.9% / 94.9% for sight-threatening DR, while non-mydriatic versions of the same hardware still delivered 82.9% / 98.9% for sight-threatening DR.(Prathiba et al., 2020) For non-mydriatic studies, a reference standard including peripheral retinal images and / or clinical examination is important. Validation spans high- and low-income settings: CellScope in the USA (93% sensitivity)(Kim et al., 2018), PEEK-Retina in Uganda (84% sensitivity, 80% specificity)(Yusuf et al., 2022) and Paxos Scope in India (79% sensitivity, 99% specificity).(Wintergerst et al., 2020c) Comparative head-to-head work in Indian outreach clinics showed that four technically divergent adapters all reached ≥ 99% specificity, with SBFI approaches based on indirect-ophthalmoscopy yielding the highest sensitivity.(Wintergerst et al., 2020c)

Diagnostic accuracy for telemedical glaucoma detection varies across devices, pupils status and countries: dilated SBFI in Uganda detected vCDR > 0.5 with 67.7% sensitivity yet 96.7% specificity versus OCT.(Idriss et al., 2021) In Germany, assessment of CDR on dilated smartphone photos correlated strongly with assessment on conventional photography (r = 0.91) while undilated images only reached r = 0.70, confirming the mydriatic advantage.(Wintergerst et al., 2018) Non-mydriatic protocols from Italy(Russo et al., 2016) and the USA(B. Lin et al., 2022) nevertheless showed substantial agreement with slit-lamp grading and generated referral scores that separated glaucomatous from normal eyes (ICC = 0.509).

Diagnostic accuracy for telemedical ROP screening is overall high: Cohen's κ reached 1.0 for referral-warranted ROP in Mumbai(Sharma et al., 2019) and for plus disease in California(Patel et al., 2019a). In Germany(Wintergerst et al., 2019) and Nepal(Adhikari et al., 2021), sensitivities / specificities of 88% / 93% and 87% / 82% were achieved for any ROP, while a multicentre Indian tele-screening study captured every treatment-requiring ROP case (100% sensitivity, 83% specificity) with smartphone images alone.(Young et al., 2023) For ROP in particular, interpretation should remain bounded by field-of-view limitations and the distinction between posterior-pole assessment and full peripheral staging.

Overall, the available evidence supports SBFI primarily as a screening and triage tool for DR, glaucoma suspect/referral, and selected ROP applications, with performance that remains device-, protocol-, and context-dependent. Of note, studies on SBFI should consistently report the photographer expertise and the rate of ungradable images, as this information is required for comparison across studies.

However, the generation of evidence for clinical workflow utility for the whole referral-loop is hampered as all applications for SBFI lack long-term outcome data. Therefore, longitudinal studies for all relevant SBFI applications (DR, glaucoma, ROP) are warranted. Beside this, future studies should analyse the effect of SBFI programmes on the rate of missed cases and the efficiency of referral and treatment-initiation.

Evidence of operational feasibility, diagnostic accuracy, and clinical workflow utility has been shown in different country contexts, suggesting SBFI is in principle generalizable to a variety of world regions, cultural contexts, and ethnicities.

7.12 Demonstrating Cost-Effectiveness

The cost of acquiring devices varies substantially across SBFI approaches and is listed, where known, in Supplement Tables A.1 and A.2. However, the total programme cost depends not only on the price of the device itself, but also on personnel, training, the dilation strategy, data transfer, maintenance, replacement cycles and the capacity for downstream referral and treatment.

Smartphone-based screening for DR offers the clearest case for an economic evaluation because DR combines a very large, rapidly growing adult population at risk (80% of the people with diabetes live in LMICs(International Diabetes Federation, 2025)), strong evidence that systematic photography-based screening followed by laser or intravitreal therapy prevents vision loss,(Pasquel et al., 2016) and an extensive literature showing that even conventional tele-ophthalmology for DR is already cost-effective in LMICs.(Avidor et al., 2020; Rachapelle et al., 2013)

By contrast, glaucoma requires additional tests such as intra-ocular pressure and visual-field assessment (at least if comprehensive screening is intended), as fundus photographs alone are insufficient for diagnosis of early disease, which inflates programme costs and yields more uncertain economic returns.(Burr et al., 2007)

ROP is currently screened for only by ophthalmologists. Given sufficient diagnostic accuracy and feasibility of the overall approach, telemedical smartphone-based ROP screening by medical assistants may therefore be a more cost-effective alternative to the current situation where ophthalmologists must perform the screening themselves. However, ROP affects a far smaller cohort. Consequently, DR offers the largest public-health payoff and the most robust data inputs for modelling, making it the most defensible primary focus for cost-effectiveness analyses of SBFI, with glaucoma and ROP considered as secondary, emerging applications.

In practice, the economic value of SBFI hinges on the performance of the entire screening process, encompassing image gradability, referral completion, treatment uptake and the associated costs of false positives and false negatives, rather than image acquisition alone.

Despite widespread pilot use, only fragmentary economic evidence exists - one Tanzanian programme reported a per-patient screening cost of USD 5 with SBFI versus USD 27 using a Topcon camera,(Parisi et al., 2016) but no comprehensive cost-utility studies have yet been published. Formal SBFI-specific cost-utility and incremental cost-effectiveness ratio (ICER)-based analyses do not yet appear to be available, and the current evidence base is therefore insufficient to support robust policy conclusions on comparative cost-effectiveness across different implementation contexts.

Consequently, rigorous cost-effectiveness evidence is urgently required. A robust analysis should compare three strategies: (1) no organized DR screening (status quo in many LMICs), (2) standard tele-ophthalmology using conventional retinal cameras or ophthalmologist examination, and (3) SBFI-based screening conducted by primary-level staff with remote or automated grading. Secondary comparisons may test alternative screening intervals (annual vs. biennial) or hybrid models that triage with SBFI and confirm positives with conventional imaging.(Pasquel et al., 2016)

A state-transition (Markov) model is recommended to capture the lifetime course of DR, linking yearly screening outcomes (true/false positives, true/false negatives) to downstream transitions between no DR, non-proliferative DR, proliferative DR, and blindness. Analyses should be run from both the healthcare provider perspective (direct programme, diagnostic and treatment costs) and the societal perspective (patient expenses and productivity losses). Primary output should be the ICER as cost per quality-adjusted life-year (QALY) gained. Secondary metrics (cost per blindness case averted or per sight-year saved) can aid policy interpretation.(Maberley et al., 2003)

Key inputs include SBFI test performance (published pooled estimates for handheld fundus cameras are approximately 85% sensitivity and 91% specificity overall (Kanclerz et al., 2021; Palermo et al., 2022; Sengupta et al., 2019; Tan et al., 2020)), device and training costs, DR prevalence and progression rates, treatment efficacy of laser and anti-VEGF (dependent on availability), health-state utilities for vision loss,

and country-specific wage data for productivity estimates. A lifetime horizon with 3% annual discounting can capture long-term benefits and half-cycle corrections can avoid temporal bias.(Edejer, 2003) Uncertainty must be explored through one-way and probabilistic sensitivity analyses. Critical variables should include screening uptake, follow-up adherence, device cost, test accuracy, treatment uptake and treatment effectiveness. Threshold analyses must then identify break-points where SBFI ceases to be cost-effective. Task-shifting to nurses, integration with diabetes clinics, AI integration, and economies of scale could all lower the ICER, whereas poor follow-up or low utilization could negate economic gains.(Nguyen et al., 2016)

Community outreach programmes for DR screening where the entire population in that area is screened for diabetes followed by DR screening using SBFI in those with diabetes may yield a low percentage of DR detection, although it can help in detecting DR in undiagnosed diabetes.(Rajalakshmi et al., 2021b) Targeted screening strategies that prioritise higher-risk individuals could enhance programme effectiveness and should be incorporated into future economic models where feasible. (Pramod Kumar et al., 2023)

Rigorous country-specific cost-utility studies are needed to confirm cost-effectiveness and to guide scale-up. Nevertheless, the available data indicate that SBFI could be an economically viable pathway to relatively widespread DR screening in LMICs, with glaucoma and ROP remaining promising but less mature use-cases.

8. Conclusions

Over the past decade, SBFI technologies have steadily improved and have been evaluated for screening, referral triage and teaching applications. However, their current use remains limited relative to the global need for retinal imaging, and evidence of sustained large-scale impact on eye-care delivery remains scarce. Our review indicates that SBFI may support fundus imaging workflows, particularly in resource-limited settings where access to conventional imaging equipment and specialist care is limited. Its main current value lies in expanding access to image acquisition and telemedical referral pathways for conditions such as diabetic retinopathy, glaucoma suspect identification and referral, and selected retinopathy of prematurity applications. The integration of AI may further support scalability through image-quality assessment, workflow support, and automated grading, but its impact in clinical practice will depend on robust validation, implementation, and access to downstream care.

The SBFI validation literature supports telemedical screening and referral triage in DR and selected ROP applications. In contrast, evidence for glaucoma based on optic nerve head photographs alone is more heterogeneous, and photographic assessment generally requires downstream confirmatory testing. Implementation remains constrained by variable image quality, limited fields of view, training requirements, regulatory and medico-legal considerations, data security, patient privacy, and economic and logistical barriers. The sustainability and scalability of

SBFI programmes depend not only on device performance, but also on integration into clinical workflows, referral completion, downstream treatment capacity, cost-effectiveness analyses, and country-specific reimbursement models.

The heterogeneity of existing studies on SBFI limits direct comparability. Future studies should consistently report the imaging system, acquisition protocol, image quality with gradability rates and reasons for ungradable images, reference standards, grading workflows, and core diagnostic performance metrics. Continued technological advances may improve image acquisition and on-device analysis, but large-scale, multicentre implementation studies remain necessary to assess effectiveness, reliability, long-term utilisation, patient outcomes, and economic viability across diverse populations and healthcare settings.

Ultimately, SBFI should be considered a potentially valuable part of wider eye-care pathways, rather than a stand-alone solution. Its contribution will depend on whether improved access to retinal imaging can be translated into sustainable screening, referral and treatment pathways, particularly for underserved populations.

12. Supplements

Supplement Appendix A.1*. Search Phrases and Approaches*

(Web of Science Core Collection) – Main Database research

(Smartphone based fundus imaging)

OR

(

(

smartphone OR *iPhone* OR (*mobile* AND imag*) OR (*mobile* AND *phone*) OR *mHealth* OR *eHealth* OR "PEEK" OR “D-EYE” OR "D Eye" OR *Welch* OR *iExaminer* OR *oDocs* OR *Eyego* OR "Eye go" OR *Paxos* OR *iNview* OR "iC2”

)

AND

(*retina* OR “optic nerve” OR *glaucoma* OR *fundus* OR *fundos* OR *ophthalmo* OR (“disc” AND (*photo* OR *foto* OR *imag*)))

)

OR (smartphone retinal photography) OR (smartphone fundus imaging) OR (smartphone retinal imaging) OR (smartphone fundus photography)

(Google and Google Scholar) – Supplementary search Approach

(smartphone retinal imaging)

OR (smartphone fundus imaging)

OR (smartphone fundus camera)

OR (smartphone retinal photography)

OR (smartphone ophthalmoscopy)

OR (retinal imaging adapter smartphone)

OR (smartphone-based retinal imaging)

OR (mobile fundus camera)

OR (mobile retinal imaging)

Additional targeted searches were performed using identified device names, manufacturer names, and key terms related to certification, technical specifications, and regulatory status.

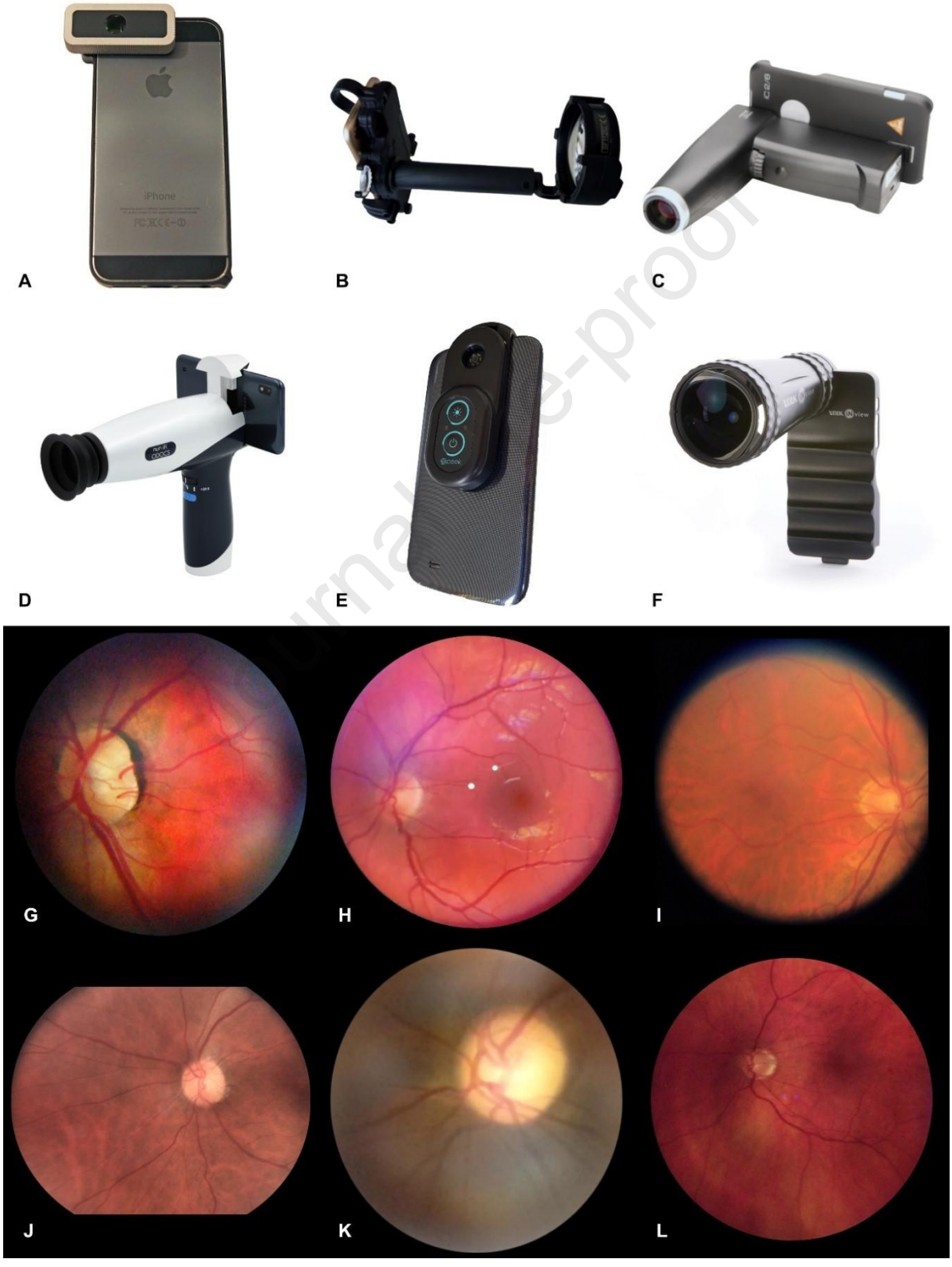
Backward cross-referencing of included studies was also performed.

Supplementary searches were exploratory and used to identify additional publications, technical documentation, certification/regulatory information, and device specifications not captured by the primary Web of Science search. Not intended to constitute a fully exhaustive systematic grey-literature search.

***Supplement Appendix B.1**. Definitions for rigor tier and maturity rank (used in Table 2):*

Reference standard rigor: Robust: an external reference standard appropriate for the target endpoint, applied independently of the index test, with key safeguards against bias (e.g., masking to index test results; clearly described diagnostic criteria; and, for image-based reference standards, multi-grader assessment and/or adjudication/reading-centre processes). Moderate: an external reference standard appropriate for the endpoint, but with incomplete safeguards (e.g., single-grader/examiner, limited/no masking or adjudication, and/or incomplete reporting of criteria). Weak: reference standard absent, unclear, not independent of the index test, or not appropriate for the endpoint (e.g., index images graded without an external comparator; unmasked comparisons with substantial incorporation/observer bias risk; comparisons to another SBFI method without an external ground truth). Mixed: substantial heterogeneity across included studies, spanning two adjacent tiers (Robust–Moderate or Moderate–Weak); the stated range reflects the distribution of reference standards used in the evidence base. Maturity rank (application-level evidence maturity; not device maturity): High: multiple studies with reasonably representative populations and reproducible performance across settings, including at least some multi-site/programmatic evidence and generally complete reporting of protocol and image-quality handling (including gradability and handling of ungradable images), with emerging evidence on workflow and/or linkage-to-care outcomes. Moderate: evidence supports feasibility and diagnostic/triage performance, but generalisability is constrained by single-centre designs, enriched populations, heterogeneous protocols, and/or incomplete reporting; implementation and patient-relevant outcomes are limited. Emerging: evidence is dominated by pilots/feasibility studies or narrowly selected datasets with small sample sizes and/or weak/inconsistently applied reference standards; external validity, reporting completeness, and downstream/pathway outcomes are largely absent.

Supplement Figure A.1. Overview on additional smartphone-based and associated fundus imaging devices *in alphabetical manufacturer order: (A and G) D-EYE (D-EYE Srl., Italy, 2016) (B and H) Paxos Scope (DigiSight, USA, 2019) (C and I) Heine iC2 Funduscope (HEINE Optotechnik GmbH & Co. KG, Germany, 2018). (D and J) oDocs nun IR ((oDocs Eye Care Limited, New Zealand, 2020) (E and K) Peek Retina ((Peek Vision Ltd, UK, 2017-2020) (F and L) Volk iNview (Volk, USA, 2016).*



Supplement Table A.1 *Additional smartphone camera-based fundus imaging devices with limited academic coverage (<5 studies), legacy/discontinued systems and smartphone-enabled fundus imaging devices in which the smartphone is not used as the image-capturing module*

Device Name (country of origin, date of release)	Com-mercial / available	Featured studies (total)	Illumi-nation Source	Smartphone camera-based/ enabled	Available Software / AI	Field of View (FOV)	Technical fundus examination approach	Certifi-cation	Price	Pupil Dilation Required	Compatible Smart-phones	Weight	Notes
Commercially available smartphone camera - based													
C3 Fundus Cam (C3 Med-Tech, India, 2019)	Yes/ on request	1	Device	Smartphone camera-based	No commercial software, community-based solutions. No AI.	40°	Indirect	Not yet FDA approved	"Afford-able. Low-cost"	Yes	Universal	N/A	Designed for ease of use with a wide FOV; specific details may vary.
Fundus Link (C-MER RAINS Optics Limited, Hong Kong, 2018)	Yes/ Yes	0	Device	Smartphone camera-based	Fundus Link android app for capture, no AI	34,5°	Indirect + relay optics	Accredited by ISO13485:2016 and FDA listed	N/A	No	Universal	N/A	Specific details may vary; designed for affordability and accessibility.
Jaiz RetiCam (Jaiz-ARIS, India, 2016)	Yes/ Yes	2	Smartphone	Smartphone camera-based	None	30°	Indirect	None	INR 20.000, exclude-ing lens	Yes	Single camera smartphones	N/A	Specific details may vary; designed for ease of use in various settings.
Jaiz RetiCam 2.0 (Jaiz-ARIS, India, 2020)	Yes/ Yes	0	Device	Smartphone camera-based	None	30°	Indirect + relay optics	None	INR 25.000, exclud-ing lens	Yes	Multi camera smartphones	N/A	-
oDocs visoScope 2.0 (oDocs Eye Care Limited, New Zealand, 2020)	Yes/ Yes	2	Smartphone	Smartphone camera-based	oDocs Capture iOS app, no AI, / oDocs nun IR software (Google Play Store) optional	45°	Indirect	CE marked, TGA & Medsafe registered	$280	Yes	Universal, except for Samsung Z and Note series, iPhone Pro Max series	100g	Open-source design with a focus on affordability and accessibility.
Not commercially available smartphone camera - based													
HopeScope (Helios	Yes/ No	1	Device	Smartphone camera-based	HopeScope Android and iOS	40°	Indirect	None	N/A	Yes	Universal	N/A	Specific details may vary; designed for

Ophthalmics, India, 2015)					apps for image capture, no AI								portability and ease of use.
Non-commercial smartphone camera-based													
EyeFundusScope (Frauenhofer AICOS, Portugal, 2020)	No/No	5	Smartphone	Smartphone camera-based	Android app including patient management and on-device AI, CADx Software	45°	Indirect + IR illumination + relay optics + beam splitter	None	N/A	No	Samsung Galaxy S8	N/A	
EYELIKE (LabSD, Inc. South Korea, 2019)	No/N/A	1	N/A	Smartphone camera-based	Android and Web application, AI based decision support system	>55°	N/A	Class I Medical Device	N/A	Yes	Samsung Galaxy Smartphones	389,3g	Upcycled Smartphone-based, AA Battery powered
oDocs visoScope 20/30D 3D Print (oDocs Eye Care Limited, New Zealand, NA	No/ Yes	0	Smartphone	Smartphone camera-based	N/A	N/A	Indirect	None	Free 3D print Download, excluding Lens	N/A	iPhone 5, 5S, 5C, SE, 6, 6S, 6, 6S, 7, 8	N/A	-
i-Spot (unknown, Indonesia, 2021)	N/A/ N/A	1	Device	Smartphone camera-based	None	30°	Indirect	None	N/A	Yes	Universal	N/A	Specific details may vary; designed for versatility.
Slit-lamp-Dependent Devices	No/ N/A	4	Uses slit-lamp's illumination	Smartphone camera-based	None	Varies	Indirect	None	Varies	Usually	Universal	N/A	Converts existing slit-lamps for fundus imaging; quality depends on the slit-lamp used.
Commercially available smartphone-enabled													
oDocs nun IR (oDocs Eye Care Limited, New Zealand, 2020)	Yes/ Yes	17	Device	Smartphone-enabled	None	45° – 55°	Indirect + infrared illumination + relay optics	CE, Medsafe, TGA	$4200	Optional	Samsung A and S series	531g	-
Eyer 2 (Phelcom Technologies, Brazil, 2025)	Yes/ Yes	0	Smartphone	Smartphone-enabled	EyerMaps AI heatmap algorithm for	55°	Indirect + infrared illumination +	FDA 510(k) Exempt	$9000	Optional	Samsung Galaxy S21 (integrated)	710g	Features non-mydriatic imaging;

					Screening, EyerCloud for report and storage		relay optics + beam splitter	(ongoing process for clearance), ISO 13485					specific details may vary.
Volk Viva (Volk, USA, 2024)	Yes/ Yes	0	Device	Smartphone-enabled	inbuilt software, pre-installed on the device, enabling seamless image capture, viewing, and management	45° in Miosis	Indirect + infrared illumination + relay optics	CE, FDA	$7500	No	Samsung Galaxy A23 (integrated)	600g	-
Not commercially available smartphone-enabled													
Remidio Vistaro (Remidio, India, 2021)	Yes/ No	3	Device	Smartphone-enabled	Automatic image capture algorithm	45°	Indirect + annular illumination + relay optics	None	Discontinued	No	Universal	N/A	Non-mydriatic imaging with high-resolution capabilities; designed for ease of use without dilation.

Supplement Table A.2 *Additional details on most relevant (more than 5 studies) technical approaches for Smartphone-based fundus imaging*

Device Name (country of origin, date of release)	Available Software / AI	Price (if applicable prior to marked exit)	Notes
Commercially available			
MII RetCam (MII Retcam Inc., India, 2015)	MII Ret Cam Pro App for iOS and Android	$380 / $550 [a]	Designed for retinal images in ROP suspect children.
oDocs nun (oDocs Eye Care Limited, New Zealand, 2018)	oDocs nun IR software (Google Play Store) optional	$1200	-
Eyer (Phelcom Technologies, Brazil, 2019)	EyerMaps AI heatmap algorithm for Screening, EyerCloud for report and storage	$7999	Features non-mydriatic imaging; specific details may vary.
Fundus on Phone -FOP NM-10 (Remidio, India, 2019)	Medios DR on-device AI algorithm, Remidio FOP app	$4972	Non-mydriatic imaging, infrared with medical-grade LED illumination; high-quality imaging without dilation.
Volk VistaView (Volk, USA, 2020)	Voice activation app for image capture integrated into Device	$2200	Offers a wide FOV with high-quality optics; suitable for detailed retinal examinations.
Pan Optic iExaminer plus (Welch Allyn, USA, 2018)	Welch Allyn iExaminer Pro app	$1048	Attaches to Welch Allyn ophthalmoscopes for digital imaging.
Not commercially available			
D-EYE (D-EYE Srl, , Italy, 2016)	D-EYE ImageVault™ cloud storage and ImageSelect™ capture editor. No AI.	Discontinued ($435)	Portable and attaches directly to the smartphone; relies on the phone's light source. * HIPAA compliant
iC2 Funduscope (HEINE Optotechnik GmbH & Co. KG, Germany, 2018)	iC2 iOS App with capture and email functions, no AI	Discontinued ($1200)	Professional-grade device with high-quality optics.
Peek Retina (Peek Vision Ltd, UK, 2017-2020)	None	Discontinued	Portable device designed for use in diverse environments.
Volk iNview (Volk, USA, 2016)	Volk iNview App on iOS App store	Discontinued ($800)	Offers a wide FOV with high-resolution imaging.
Non-commercial			
Paxos Scope (Digisight, USA, 2019)	None	N/A	-
oDocs Fundus (oDocs Eye Care Limited, New Zealand, 2015)	N/A	Free 3D print Download	-
Ocular CellScope (University of California, Berkley, USA, 2014)	Ocular CellScope App	Device constructor estimation $1000	-
Self-made / 3D-printed devices	Open-source community-based solutions	< $100	Customizable and low-cost; quality depends on design and assembly.
iPhone with Lens Attachment	None	~ $80 for 20D lens	Simple setup using a condensing lens; image quality varies based on technique.

***Supplement Table B.1**. Smartphone-based fundus imaging for diabetic retinopathy detection (additional studies)*

Study (Country)	Dataset size	Accuracy (manual analysis unless otherwise indicated)	Reference standard (rigor)	Device + Smartphone (pupil dilation/ no pupil dilation)	Photographer expertise	Ungrad-able Images (%)	AI used	Comments
Russo et al., 2015 (USA) (Russo et al., 2015a)	120 patients (240 eyes)	85% sensitivity for DR, kappa agreement=k=0.78	Clinical examination by an ophthalmologist (Moderate)	D-EYE adapter + iPhone (pupil dilation) in video mode	Optometrists	3.75%	No AI used	Lesser field of view
Rajalakshmi et al. 2018 (India) (Rajalakshmi et al., 2018)	296 patients (592 eyes)	AI showed 95.8% sensitivity, 80.2% specificity for detecting any DR; 99.1% sensitivity, 80.4% specificity for STDR	Ophthalmologist grading on conventional retinal and SBFI images (Moderate)	Remidio NM-FOP + iPhone (pupil dilatation)	Optometrists	1.7%	EyeArt AI	First study on use of AI with SBFI
Kim et al., 2018 (USA) (Kim et al., 2018)	71 patients	Sensitivity 93.3%, specificity 56.8% (k=0.63) for referral-warranted DR	Grading by retina specialists on 7 field conventional fundus imaging and clinical examination (Robust)	CellScope Retina + iPhone (pupil dilatation)	Medical interns and ophthalmologists	Not reported	No AI used	Automated 100° retinal photomontages from five overlapping images
Natarajan et al., 2019 (India) (Natarajan et al., 2019)	231 patients	100% sensitivity, 85.2% specificity for referable DR detection by AI	Ophthalmologists grading of DR of smartphone images vs. AI grading (no ground truth; Weak)	Remidio NM-FOP + iPhone (pupil dilatation)	Field health workers	7.8%	On-device Medios AI	First study on use of on-device AI with SBFI in community settings
Sosale et al., 2020 (India) (Sosale et al., 2020a)	900 patients	Sensitivity 93%, specificity 92.5% for referable DR detection	AI diagnosis compared with the image diagnosis of five retina specialists (Weak)	Remidio NM-FOP-10 + iPhone (no pupil dilatation)	Trained camera technician	0.8%	On-device Medios AI	
Sosale et al., 2020 (India) (Sosale et al., 2020b)	297 patients	98.84% sensitivity, 86.73% specificity for detecting referable DR by AI	Grading by retina specialist on smartphone-based retinal image (Weak)	Remidio NM-FOP + iPhone (pupil dilatation)	Trained eye technicians	2.3%	On-device Medios AI	
Kumari et al., 2022 (India) (Kumari et al., 2022)	60 patients	Sensitivity for DR: 88.39% (k=0.77), sensitivity for DME: 93.67% (k=0.91)	Grading by ophthalmologist on conventional fundus imaging (Moderate)	Volk iNview + iPhone (pupil dilatation)	Imaging by patients themselves and by technician	11.6%	No AI used	First study on Selfie fundus imaging during the Covid-19 pandemic
Lu et al., 2022 (Thailand) (Lu et al., 2022)	185 participants (355 eyes)	PEEK-Retina: 16.7% sensitivity, 95.7% specificity; iNview: 71.6% sensitivity, 81.8% specificity; Pictor Plus: 76.5% sensitivity, 90.5% specificity, for any DR	Clinical examination by ophthalmologist (Moderate)	Pictor Plus, PEEK-eye, iNview (pupil dilatation)	Optometrists and ophthalmologists	Not reported	No AI used	Comparison of 3 hand-held cameras - 2 smartphone-based and 1 non-smartphone-based for both DR and AMD patients

Supplement Table C.1. *Smartphone-based fundus imaging for glaucoma detection (additional studies)*

Study (Country)	Dataset size	Accuracy (manual analysis unless otherwise indicated)	Reference standard (rigor)	Device + Smartphone (pupil dilation)	Photographer expertise	Ungradable Images (%)	AI system	Comments
Russo et al., (2016) (Italy) (Russo et al., 2016)	110 participants	Smartphone vCDR estimation agreement with standard slit-lamp: 72.4% of POAG eyes, 66.7% of OH eyes.	Slit-lamp indirect biomicroscopy with 90D lens (Moderate)	D-EYE + iPhone 5S (no pupil dilation)	Glaucoma specialist	2.72%	No AI used	SBFI shows substantial agreement with slit-lamp examination
Titoneli et al., (2021) (Brazil) (Titoneli et al., 2021)	50 participants (100 eyes)	Very good agreement for vCDR between SBFI and conventional fundus camera (ICC = 0.82 and 0.83; $p < 0.001$ for examiners 1 & 2).	Topcon fundus camera (Moderate)	Designed optical system + Samsung Galaxy S7 (pupil dilation)	Trained nurses	10% (overall)	No AI used	
Varshney et al., (2021) (India) (Varshney et al., 2021)	25 participants (50 eyes)	The fundus on phone AI provided vCDR values which correlated well with the clinical findings with an ICC of 0.86 (Pearson's correlation coefficient 0.76; $P < 0.001$).	Glaucoma expert and OCT measurements (Moderate)	Remidio fundus on phone (no pupil dilation)	Glaucoma specialist	-	Medios on-device AI	OCT overestimated clinical and AI predicted values
Nakahara et al., (2022) (Japan) (Nakahara et al., 2022)	73 patients 89 subjects (73+89 eyes)	AROC was 98.9% / 84.2% with fundus camera / smartphone respectively. In advanced glaucoma AROC was 99.3%/90%.	Fundus camera (Moderate)	D-EYE + iPhone 8 (pupil dilation)	Experienced optometrists	-	ResNet algorithm	Glaucoma diagnosis is possible using deep learning assessment on SBFI images
Mrad et al., (2022) (Tunisia) (Mrad et al., 2022)	DRISHTI database, DRIONS database, RIAMP dataset of 16 people	Automated glaucoma diagnosis showed 99% accuracy, 100% sensitivity and 96.77% specificity with DRISHTI database; 95% / 95% / 97.52% respectively with DRIONS database; 100% / 100% / 100% respectively in the smartphone RIAMP dataset.	Predefined datasets and Topcon retinal camera (Moderate)	iExaminer + iPhone 4S	-	-	No AI used	Proposed a fast and accurate method of glaucomatous disc detection using SBFI
Bragança et al., (2022) (Brazil) (Bragança et al., 2022)	1000 volunteers: 500 healthy, 500 glaucoma (2000 eyes)	90% accuracy for DL based glaucoma diagnosis within the BrG smartphone captured dataset.	Other public datasets (Weak)	Welch Allyn panoptic ophthalmoscope + iPhone 6s	Nonmedical professional	-	CNN based algorithm	The smartphones provide new datasets which are reliable for algorithm testing and to diagnose glaucoma reliably

				(no pupil dilation)				
Muhsen et al., (2023) (Jordan) (Muhsen et al., 2023)	90 patients (90 eyes)	D-EYE ophthalmoscopy of normal vCDR was acceptable (sensitivity 85.8%–96.4%; specificity 51.4%–96.4%). For ONH pathologies agreement with expert slit lamp expert examination was poor.	Slit-lamp fundus examination (Moderate)	D-EYE + iPhone 6 (pupil dilation)	Ophthalmologist	Nil	No AI used	In glaucomatous eyes, the D-EYEs sensitivity, specificity, and inter-examiner agreement was low
Kim et al., (2024) (Vietnam) (Kim et al., 2024)	7,023 individuals (13,615 eyes)	Amongst the screened patients 10.17% were identified with glaucomatous discs.	N/A (Weak)	EYELIKE digital ophthalmoscope + Galaxy S7 and S8 (pupil dilation)	Trained doctor	-	No AI used	SBFI can rapidly screen avoidable blindness cases. Study includes Glaucoma, AMD and other eye diseases
Rao et al., (2024) (India) (Divya Parthasarathy Rao et al., 2024)	282 participants (549 eyes)	AI showed 93.7% sensitivity and 85.6% specificity to diagnose referable glaucoma on smartphone fundus images.	Table-top Fundus camera (Moderate)	Remidio fundus on phone (no pupil dilation)	-	45 eyes of 39 participants	Medios on-device AI	The AI integrated SBFI provides reliable alternatives to in person expert screening for referral decisions
Yap et al., (2024) (Singapore) (Yap et al., 2024)	151 patients	The Deep Learning vCDR estimation showed a mean absolute error of 0.040 for REFUGE public dataset, 0.068 for ultra-widefield fundus images and 0.084 for SBFI images.	REFUGE database, ultra-widefield images (Moderate)	oDocs Nun IR portable camera (pupil dilation)	Optometrist	32.9% to 35.8% for smartphone-based images	CNN based algorithm.	Peripapillary atrophy didn't influence the quantification of vCDR by the deep learning network
Scarpa et al., (2024) (Italy) (Scarpa et al., 2024)	15 healthy, and 15 glaucoma subjects	Pearson correlation co-efficient of 0.93 for automated vCDR vs expert calculation. AI's accuracy was 0.93, sensitivity 1 and specificity 0.88.	Expert opinion (Weak)	D-EYE + iPhone 5 and 6	-	-	CNN based algorithm.	Automated relevant frame selection from retinal videos and segmentation of the cup, disc and vCDR
Dao D et al., (2017) (USA) (Dao et al., 2017)	122 eyes (61 patients)	Sensitivity & specificity in mydriatic and non-mydriatic smartphone fundus videos for disc pathologies and varied from 46% to 84% amongst general and neuro-ophthalmologist.	N/A (Weak)	D-EYE system (with and without pupil dilation)	-	-	-	The D-EYE system showed moderate sensitivity and specificity for detecting optic nerve pathology while having good agreement with clinical determination of CDR
Ramsey et al., (2020) (Samoa) (Ramsey et al., 2020)	206 participants	The risk of glaucoma was identified in 16% participants. Moderately strong agreement was noted between different graders (k=0.53). The intraclass coefficients for	N/A (Weak)	PanOptic iExaminer + iPhone 6S (without	Lay examiner	-	-	

		CDR and its differences was 0.84 and 0.68.		pupil dilation)				
Scarpa et al., (2020) (Italy) (Scarpa et al., 2020)	5 healthy and 5 glaucoma subjects	On a limited number of subjects, the automated analysis showed perfect agreement with manual analysis with an accuracy of >/- 96%	N/A (Weak)	D-EYE	-	-	-	
Parthasarathyet al., (2021) (Asian and Caucasian population) (Parthasarathy et al., 2021)	5716 images, set A: 626 images of Asian eyes, set B: 389 images of Caucasian eyes	The deep learning algorithm had a sensitivity of 97% specificity of 92% and AUC of 0.97 for referable glaucoma in set A. Similarly, in set B, a sensitivity of 96%, specificity of 82% and AUC of 0.93 was noted.	N/A (Weak)		-	-	The deep learning algorithm showed high sensitivity (97%) and specificity (92%) in detecting referable glaucoma during on-device testing	Smartphone imaging integrated with on-device deep learning algorithm can detect referable glaucoma
Stratton et al., (2021) (El Salvador) (Stratton et al., 2021)	273 participants	CDR showed moderate reliability and good agreement with expert opinion, picture based screening of risk of glaucoma compared to clinical examination showed a positive predictive value of 45.1% and negative predictive value of 87.7%	Expert grading (Moderate)	PanOptic iExaminer +iPhone 6S (without pupil dilation)	Trained non-specialist	6.8%	-	
Lin et al., (2022) (USA) (B. Lin et al., 2022)	236 eyes (210 normal and 26 glaucomatous)	The likelihood referral for normal and glaucomatous eyes was 1.671 and 2.565 respectively with intraclass coefficient of 0.509	N/A (Weak)	D-EYE (without pupil dilation)	-	21.2%	-	Using smartphones, the referral of glaucomatous eyes for further workup was higher compared to normal eyes

***Supplement Table D.1**. Smartphone-based fundus imaging for retinopathy of prematurity detection (additional studies)*

Study (Country)	Dataset size	Accuracy (manual analysis unless otherwise indicated)	Reference standard (rigor)	Device + Smartphone (with or without pupil dilation)	Photographer expertise	Ungradable Images
Goyal et al. (2019) (India) (Goyal et al., 2019)	28 eyes	Not reported	N/A (Weak)	Either an MIIRetcam or custom PVC pipe with 20D, 28D, 40D lens mounted to an iPhone 5S (with pupil dilation)	ROP trained ophthalmologist	10.80%
Choudhary et al. (2023) (Pakistan) (Choudhary et al., 2023)	63 images (eyes / patients not reported)	Cohen's kappa 0.65,1.00 for stage, 0.84, 1.0 for plus across two graders	Clinical ophthalmologist examination (Moderate)	28D lens + iPhone 11 (with pupil dilation	ROP trained ophthalmologist	1.58%, 3.17% (2 graders)
Subramaniam et al. (2023) (Argentina and Colombia)(8) (Subramaniam et al., 2023)	440 images (patients not reported)	Human graders agreed vessel appearance improved with image pre-processing; AI: Specificity 1.0, Sensitivity 0.7143 for plus disease detection using deep learning algorithms	Clinical ophthalmologist examination (Moderate)	20D or 28D lens with a smartphone camera (type not specified) (with pupil dilation)	ROP trained ophthalmologist	Not reported
Ribeiro Sant'Ana et al. (2025) (Brazil) (de Sant'Ana et al., 2025)	142 eyes	Sensitivity 82%, Specificity 100%	Clinical ophthalmologist examination (Moderate)	Modified version Phelcom Eyer with an Samsung S9 smartphone	Clinical ophthalmologist	0%

***Supplement Table E.1**. Practical checklist for the design and implementation of smartphone-based fundus imaging (SBFI) programmes*

Domain	Key question / requirement
Indication	Is the target population clearly defined, and is the programme intended for DR screening, glaucoma suspect/referral triage, ROP support, or another specific indication?
Device	Has the SBFI device been selected with a clear justification regarding field of view, mydriatic/non-mydriatic use, smartphone compatibility, cost, and local availability?
Protocol	Is the imaging protocol predefined, including dilation strategy, retinal fields/number of images, repeat-capture rules, and handling of ungradable images?
Training	Are the image-acquisition personnel identified and trained? Are competency benchmarks and supervision procedures in place?
Image quality / gradability	Are image-quality assessment (IQA) criteria, gradability thresholds, and protocol-compliance checks clearly defined?
Data governance	Is a secure workflow for image storage and transfer implemented, including access control, encryption, retention/deletion policy, and compliance with applicable privacy regulations?
Grading	Is the interpretation pathway defined, including human grading, teleophthalmology, AI-supported triage where applicable, and management of ungradable or suspicious findings?
Referral	Is there a clear referral pathway for positive, suspicious, or ungradable cases, including documentation of referral completion?
Treatment capacity	Is confirmatory examination and treatment capacity available for referred patients, and can the receiving service absorb the expected demand?
Monitoring	Are programme-level indicators predefined, such as image gradability, referral completion, treatment uptake, time-to-treatment, and, where feasible, clinical outcomes and cost metrics?

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process

During the critical internal review of this work the authors used the LLM ChatGPT in order to identify potential areas of improvement. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

13. References

Abràmoff, M.D., Lavin, P.T., Birch, M., Shah, N., Folk, J.C., 2018. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. npj Digital Med 1, 39. https://doi.org/10.1038/s41746-018-0040-6

Ademola-Popoola, D.S., Olatunji, V.A., 2017. Retinal imaging with smartphone. Niger J Clin Pract 20, 341–345. https://doi.org/10.4103/1119-3077.201428

Adhikari, S., Bajimaya, S., Ranjitkar, E.P., 2021. Validation of smartphone-based screening for retinopathy of prematurity in a low-resource setting. J AAPOS 25, 274.e1-274.e5. https://doi.org/10.1016/j.jaapos.2021.04.010

Ahmed, Y., Pereira, A., Rai, Amrit S., Leung, V.C., Ahmed, A., Rai, Amandeep S., 2022. Prospective evaluation of medical student accuracy conducting direct ophthalmoscopy with an unmodified iPhone X. Int Ophthalmol 42, 3933–3940. https://doi.org/10.1007/s10792-022-02377-4

Ahn, S.J., Kim, Y.H., 2024. Clinical Applications and Future Directions of Smartphone Fundus Imaging. Diagnostics (Basel) 14. https://doi.org/10.3390/diagnostics14131395

Anjana, R.M., Deepa, M., Pradeepa, R., Mahanta, J., Narain, K., Das, H.K., Adhikari, P., Rao, P.V., Saboo, B., Kumar, A., Bhansali, A., John, M., Luaia, R., Reang, T., Ningombam, S., Jampa, L., Budnah, R.O., Elangovan, N., Subashini, R., Venkatesan, U., Unnikrishnan, R., Das, A.K., Madhu, S.V., Ali, M.K., Pandey, A., Dhaliwal, Rupinder Singh, Kaur, T., Swaminathan, S., Mohan, V., Anjana, R.M., Deepa, M., Pradeepa, R., Mahanta, J., Narain, K., Das, H.K., Adhikari, P., Rao, P.V., Saboo, B., Kumar, A., Bhansali, A., John, M., Luaia, R., Reang, T., Ningombam, S., Jampa, L., Budnah, R.O., Elangovan, N., Subashini, R., Venkatesan, U., Unnikrishnan, R., Das, A.K., Madhu, S.V., Ali, M.K., Pandey, A., Dhaliwal, R S, Kaur, T., Swaminathan, S., Mohan, V., Sudha, V., Parvathi, S.J., Jayashri, R., Velmurugan, K., Borah, P.K., Rao, S.B., Padhiyar, J.M., Sharma, S., Lalramenga, P., Das, S.K., Singh, T.B., Kaki, T., Basaiawmoit, M.R., Shukla, D.K., Rao, M.N., Joshi, P.P., Dhandania, V.K., Joshi, S.R., Yajnik, C.S., 2017. Prevalence of diabetes and prediabetes in 15 states of India: results from the ICMR–INDIAB population-based cross-sectional study. The Lancet Diabetes & Endocrinology 5, 585–596. https://doi.org/10.1016/S2213-8587(17)30174-2

Antonio-Aguirre, B., Gadiraju, A., Ownagh, V., Vajzovic, L., 2025. Novel artificial intelligence applications for pediatric retina. CURRENT OPINION IN OPHTHALMOLOGY 36, 456–461. https://doi.org/10.1097/ICU.0000000000001168

Apple Inc., 2026. Take and edit Live Photos [WWW Document]. Apple Support. URL https://support.apple.com/en-gb/104966 (accessed 7.19.26).

Avidor, D., Loewenstein, A., Waisbourd, M., Nutman, A., 2020. Cost-effectiveness of diabetic retinopathy screening programs using telemedicine: a systematic review. Cost Eff Resour Alloc 18, 16. https://doi.org/10.1186/s12962-020-00211-1

Ay, I.E., Kose, F., 2023. Ocular health screening among care-center residents with disabilities: a smartphone adaptive fundus camera cross-sectional study. Eur Rev Med Pharmacol Sci 27, 620–627. https://doi.org/10.26355/eurrev_202301_31063

B. Prakash, N., Selvathi, D., 2017. An Efficient Detection System For Screening Glaucoma InRetinal Images. Biomed. Pharmacol. J. 10, 459–465. https://doi.org/10.13005/bpj/1130

Baatiema, L., Sanuade, O., Allen, L., Abimbola, S., Hategeka, C., Koram, K., Kruk, M., 2023. Health system adaptions to improve care for people living with non-communicable diseases during COVID-19 in low- middle income countries: A scoping review. JOURNAL OF GLOBAL HEALTH 13. https://doi.org/10.7189/jogh.13.06006

Bahl, A., Rao, S., 2022. Diabetic retinopathy screening in rural India with portable fundus camera and artificial intelligence using eye mitra opticians from Essilor India. Eye (Lond) 36, 230–231. https://doi.org/10.1038/s41433-020-01350-8

Bak, M.A.R., Horbach, D., Buyx, A., McLennan, S., 2025. A scoping review of ethical aspects of public-private partnerships in digital health. npj Digit. Med. 8, 129. https://doi.org/10.1038/s41746-025-01515-3

Barbieri, V.D.O.A., Nakayama, L.F., Barbieri, G.A., Da Silva, S.E.R., Karmouche, D.C.J., Shinzato, M.N.O., Nakagawa, R.E., Regatieri, C.V., Malerbi, F.K., 2024. Transition from an in-person to a telemedicine diabetic retinopathy screening program. ABO 87. https://doi.org/10.5935/0004-2749.2023-0200

Bastawrous, A., 2012. Smartphone Fundoscopy. Ophthalmology 119, 432-433.e2. https://doi.org/10.1016/j.ophtha.2011.11.014

Bastawrous, A., Giardini, M.E., Bolster, N.M., Peto, T., Shah, N., Livingstone, I.A.T., Weiss, H.A., Hu, S., Rono, H., Kuper, H., Burton, M., 2016. Clinical Validation of a Smartphone-Based Adapter for Optic Disc Imaging in Kenya. JAMA Ophthalmol 134, 151–158. https://doi.org/10.1001/jamaophthalmol.2015.4625

Bastawrous, A., Rono, H., Livingstone, I., Weiss, H., Jordan, S., Kuper, H., Burton, M., 2015. Development and Validation of a Smartphone-Based Visual Acuity Test (Peek Acuity) for Clinical Practice and Community-Based Fieldwork. JAMA OPHTHALMOLOGY 133, 930–937. https://doi.org/10.1001/jamaophthalmol.2015.1468

Benbassat, J., Polak, B.C.P., Javitt, J.C., 2012. Objectives of teaching direct ophthalmoscopy to medical students. Acta Ophthalmologica 90, 503–507. https://doi.org/10.1111/j.1755-3768.2011.02221.x

Bilong, Y., Katte, J.-C., Koki, G., Kagmeni, G., Obama, O.P.N., Fofe, H.R.N., Mvilongo, C., Nkengfack, O., Bimbai, A.M., Sobngwi, E., Mbacham, W., Mbanya, J.C., Bella, L.A., Sharma, A., 2019. Validation of Smartphone-Based Retinal Photography for Diabetic Retinopathy Screening. Ophthalmic Surg Lasers Imaging Retina 50, S18–S22. https://doi.org/10.3928/23258160-20190108-05

Blahnik, V., Schindelbeck, O., 2021. Smartphone imaging technology and its applications. Advanced Optical Technologies 10, 145–232. https://doi.org/10.1515/aot-2021-0023

Bolster, N.M., Giardini, M.E., Bastawrous, A., 2015. The Diabetic Retinopathy Screening Workflow: Potential for Smartphone Imaging. J Diabetes Sci Technol 10, 318–324. https://doi.org/10.1177/1932296815617969

Bragança, C.P., Torres, J.M., Soares, C.P. de A., Macedo, L.O., 2022. Detection of Glaucoma on Fundus Images Using Deep Learning on a New Image Set Obtained with a Smartphone and Handheld Ophthalmoscope. Healthcare (Basel) 10. https://doi.org/10.3390/healthcare10122345

Bromwich, M., Bromwich, R., 2016. Privacy risks when using mobile devices in health care. CMAJ 188, 855–856. https://doi.org/10.1503/cmaj.160026

Bruce, B.B., Lamirel, C., Wright, D.W., Ward, A., Heilpern, K.L., Biousse, V., Newman, N.J., 2011. Nonmydriatic Ocular Fundus Photography in the Emergency Department. N Engl J Med 364, 387–389. https://doi.org/10.1056/NEJMc1009733

Burr, J., Mowatt, G., Hernández, R., Siddiqui, M., Cook, J., Lourenco, T., Ramsay, C., Vale, L., Fraser, C., Azuara-Blanco, A., Deeks, J., Cairns, J., Wormald, R., McPherson, S., Rabindranath, K., Grant, A., 2007. The clinical effectiveness and cost-effectiveness of screening for open angle glaucoma: a systematic review and economic evaluation. Health Technol Assess 11. https://doi.org/10.3310/hta11410

Burton, M., Ramke, J., Marques, A., Bourne, R., Congdon, N., Jones, I., Tong, B., Arunga, S., Bachani, D., Bascaran, C., Bastawrous, A., Blanchet, K., Braithwaite, T., Buchan, J., Cairns, J., Cama, A., Chagunda, M., Chuluunkhuu, C., Cooper, A., Crofts-Lawrence, J., Dean, W., Denniston, A., Ehrlich, J., Emerson, P., Evans, J., Frick, K., Friedman, D., Furtado, J., Gichangi, M., Gichuhi, S., Gilbert, S., Gurung, R., Habtamu, E., Holland, P., Jonas, J., Keane, P., Keay, L., Khanna, R., Khaw, P., Kuper, H., Kyari, F., Lansingh, V., Mactaggart, I., Mafwiri, M., Mathenge, W., McCormick, I., Morjaria, P., Mowatt, L., Muirhead, D., Murthy, G., Mwangi, N., Patel, D., Peto, T., Qureshi, B., Salomao, S., Sarah, V., Shilio, B., Solomon, A., Swenor, B., Taylor, H., Wang, N., Webson, A., West, S., Wong, T., Wormald, R., Yasmin, S., Yusufu, M., Silva, J., Resnikoff, S., Ravilla, T., Gilbert, C., Foster, A., Faal, H., 2021. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. LANCET GLOBAL HEALTH 9, E489–E551. https://doi.org/10.1016/S2214-109X(20)30488-5

Caceres, J., Zhang, Y., Boe, L., Zhou, Y., Besirli, C., Paulus, Y., Rosenthal, J., 2023. Diabetic Retinopathy Screening Using a Portable Retinal Camera in Vanuatu. OPTH Volume 17, 2919–2927. https://doi.org/10.2147/OPTH.S410425

Campos, C., Pedley, C., Wofford, J., Feiereisel, K., Koch, A., Velez, R., 2016. USING SMARTPHONE TECHNOLOGY TO PERFORM FUNDUSCOPIC EXAMINATION: A PROMISING TEACHING TOOL. JOURNAL OF GENERAL INTERNAL MEDICINE 31, S854–S854.

Chaichan, S., Laovirojjanakul, W., Kotruchin, P., 2023. FUNDOSCOPIC EXAMINATION USING A SMARTPHONE CAMERA: A REVIEW OF EFFECTIVENESS AND FEASIBILITY IN DETECTING HYPERTENSIVE RETINOPATHY IN HYPERTENSIVE CRISIS PATIENTS. JOURNAL OF HYPERTENSION 41, E186–E187. https://doi.org/10.1097/01.hjh.0000914568.85839.70

Chalam, K.V., Chamchikh, J., Gasparian, S., 2022. Optics and Utility of Low-Cost Smartphone-Based Portable Digital Fundus Camera System for Screening of Retinal Diseases. Diagnostics (Basel) 12. https://doi.org/10.3390/diagnostics12061499

Chandhakanond, P., Aimmanee, P., 2022. Hemorrhage segmentation in mobile-phone retinal images using multiregion contrast enhancement and iterative NICK thresholding region growing. Sci Rep 12, 21513. https://doi.org/10.1038/s41598-022-26073-6

Choudhary, R.A., Hashmi, S., Tayyab, H., 2023. Smartphone-based fundus imaging for evaluation of Retinopathy of Prematurity in a low-income country: A pilot study. Pak J Med Sci 39, 638–643. https://doi.org/10.12669/pjms.39.3.7053

Clarke, L., Chalkidou, K., Nemzoff, C., 2018. Development Impact Bonds Targeting Health Outcomes. CGD Policy Paper 133, CGD Policy Paper.

Collon, S., Chang, D., Tabin, G., Hong, K., Myung, D., Thapa, S., 2020. Utility and Feasibility of Teleophthalmology Using a Smartphone-Based Ophthalmic Camera in Screening Camps in Nepal. Asia Pac J Ophthalmol (Phila) 9, 54–58. https://doi.org/10.1097/01.APO.0000617936.16124.ba

Dalay, S., Umar, F., Saeed, S., 2013. Fundoscopy: a reflection upon medical training? The Clinical Teacher 10, 103–106. https://doi.org/10.1111/j.1743-498X.2012.00630.x

Dao, D., Shah, N., Tamhankar, M., Tapino, P., Pan, W., Ying, G., Willett, K., VanderBeek, B., Brucker, A., 2017. Smartphone Ophthalmoscopy (D-Eye System) for Detection of Optic Nerve Pathology and Cup-to-Disc Ratio in an Outpatient Clinical Setting. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 58.

Das, A., Rad, P., Choo, K., Nouhi, B., Lish, J., Martel, J., 2019. Distributed machine learning cloud teleophthalmology IoT for predicting AMD disease progression. FUTURE GENERATION COMPUTER SYSTEMS-THE INTERNATIONAL JOURNAL OF ESCIENCE 93, 486–498. https://doi.org/10.1016/j.future.2018.10.050

Data on Ophthalmologists Worldwide - International Council of Ophthalmology, 2021.

Davidson, S., de Souza, W.J., Eggleton, K., 2024. Use of a smartphone-based, non-mydriatic fundus camera for patients with red flag ophthalmic presentations in a rural general practice. JOURNAL OF PRIMARY HEALTH CARE. https://doi.org/10.1071/HC24040

Day, L.M., Wang, S.X., Huang, C.J., 2017. Nonmydriatic Fundoscopic Imaging Using the Pan Optic iExaminer System in the Pediatric Emergency Department. Academic Emergency Medicine 24, 587–594. https://doi.org/10.1111/acem.13128

de Carvalho, J.X., Malerbi, F.K., Bortoto, S.F., de Matos, M.R., Cavalcante, C. das G.D., Andrade, E.A.S., Vieira, G.B., Queiroz, M.S., 2025. Integrating Nursing-Teleophthalmology Improves Diabetic Retinopathy Screening in Primary Healthcare, Reducing Unnecessary Referrals to Specialist Healthcare. INTERNATIONAL JOURNAL OF NURSING PRACTICE 31. https://doi.org/10.1111/ijn.70016

de Oliveira, J.A.E., Nakayama, L.F., Zago Ribeiro, L., de Oliveira, T.V.F., Choi, S.N.J.H., Neto, E.M., Cardoso, V.S., Dib, S.A., Melo, G.B., Regatieri, C.V.S., Malerbi, F.K., 2023. Clinical validation of a smartphone-based retinal camera for diabetic retinopathy screening. Acta Diabetol 60, 1075–1081. https://doi.org/10.1007/s00592-023-02105-z

de Sant'Ana, V.R., do Vale Lucio, K.C., Fogaca, A.J., Bonini, N.B., Jorge, E.C., 2025. Smartphone-based retinal camera modified for ROP screening. INTERNATIONAL JOURNAL OF RETINA AND VITREOUS 11. https://doi.org/10.1186/s40942-025-00725-x

Dobrow, M.J., Hagens, V., Chafe, R., Sullivan, T., Rabeneck, L., 2018. Consolidated principles for screening based on a systematic review and consensus process. CMAJ 190, E422–E429. https://doi.org/10.1503/cmaj.171154

Dunn, H., Kang, C., Marks, S., Witherow, J., Dunn, S., Healey, P., White, A., 2021a. Perceived usefulness and ease of use of fundoscopy by medical students: a randomised crossover trial of six technologies (eFOCUS 1). BMC MEDICAL EDUCATION 21. https://doi.org/10.1186/s12909-020-02469-8

Dunn, H., Marks, S., Teo, K.Z., Dunn, S.M., Healey, P.R., White, A.J., 2021b. eFOCUS 2: A randomised crossover trial of smartphone fundoscopy and direct ophthalmoscopy aiming to improve optic disc interpretation by medical students with e-learning support. Clin Exp Ophthalmol 49, 704–713. https://doi.org/10.1111/ceo.13977

Dunn, H., Teo, K.Z., Smyth, J.W.P., Weerasinghe, L.S., Pampapathi, P., Costello, J., Keay, L., White, A.J., McCluskey, P., Fraser, C.L., 2018. FUNDUS PHOTOGRAPHY IN THE EMERGENCY DEPARTMENT: FOTO-ED AUSTRALIA. CLINICAL AND EXPERIMENTAL OPHTHALMOLOGY.

Dunn, H.P., Kang, C.J., Marks, S., Dunn, S.M., Healey, P.R., White, A.J., 2023. Optimising fundoscopy practices across the medical spectrum: A focus group study. PLoS One 18, e0280937. https://doi.org/10.1371/journal.pone.0280937

Dutt, S., Nagarajan, S., Vadivel, S., Baig, A., Savoy, F., Ganapathy, V., Dominic, M., Sivaraman, A., Rao, D., 2021. Design and Performance Characterization of a Novel, Smartphone-Based, Portable Digital Slit Lamp for Anterior Segment Screening Using Telemedicine. TRANSLATIONAL VISION SCIENCE & TECHNOLOGY 10. https://doi.org/10.1167/tvst.10.8.29

Edejer, T.T.-T. (Ed.), 2003. Making choices in health: WHO guide to cost-effectiveness analysis. World Health Organization, Geneva.

Elloumi, Y., Akil, M., Kehtarnavaz, N., 2018. A mobile computer aided system for optic nerve head detection. Comput Methods Programs Biomed 162, 139–148. https://doi.org/10.1016/j.cmpb.2018.05.004

Energizing Health: Accelerating Electricity Access in Health-Care Facilities, 1st ed. ed, 2023. . World Health Organization, Geneva.

Engelmann, J., Kitema, G.F., Morley, M., Sevgi, M., Ong, A.Y., Ruffell, E., Merle, D.A., Gago, L., Wagner, S., Keane, P.A., 2025. RETFound-Mobile: Running a high-performance retinal foundation model on a regular smartphone. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 66.

ETDRS RESEARCH GROUP, 1991. Grading Diabetic Retinopathy from Stereoscopic Color Fundus Photographs—An Extension of the Modified Airlie House Classification. Ophthalmology 98, 786–806. https://doi.org/10.1016/S0161-6420(13)38012-9

Flaxman, S.R., Bourne, R.R.A., Resnikoff, S., Ackland, P., Braithwaite, T., Cicinelli, Maria V, Das, A., Jonas, J.B., Keeffe, J., Kempen, J.H., Leasher, J., Limburg, H., Naidoo, K., Pesudovs, K., Silvester, A., Stevens, G.A., Tahhan, N., Wong, T.Y., Taylor, H.R., Bourne, R., Ackland, P., Arditi, A., Barkana, Y., Bozkurt, B., Braithwaite, T., Bron, A., Budenz, D., Cai, F., Casson, R., Chakravarthy, U., Choi, J., Cicinelli, Maria Vittoria, Congdon, N., Dana, R., Dandona, R., Dandona, L., Das, A., Dekaris, I., Del Monte, M., Deva, J., Dreer, L., Ellwein, L., Frazier, M., Frick, K., Friedman, D., Furtado, J., Gao, H., Gazzard, G., George, R., Gichuhi, S., Gonzalez, V., Hammond, B., Hartnett, M.E., He, M., Hejtmancik, J., Hirai, F., Huang, J., Ingram, A., Javitt, J., Jonas, J., Joslin, C., Keeffe, J., Kempen, J., Khairallah, M., Khanna, R., Kim, J., Lambrou, G., Lansingh, V.C., Lanzetta, P., Leasher, J., Lim, J., Limburg, H., Mansouri, K., Mathew, A., Morse, A., Munoz, B., Musch, D., Naidoo, K., Nangia, V., Palaiou, M., Parodi, M.B., Pena, F.Y., Pesudovs, K., Peto, T., Quigley, H., Raju, M., Ramulu, P., Rankin, Z., Resnikoff, S., Reza, D., Robin, A., Rossetti, L., Saaddine, J., Sandar, M., Serle, J., Shen, T., Shetty, R., Sieving, P., Silva, J.C., Silvester, A., Sitorus, R.S., Stambolian, D., Stevens, G., Taylor, H., Tejedor, J., Tielsch, J., Tsilimbaris, M., Van Meurs, J., Varma, R., Virgili, G., Wang, Y.X., Wang, N.-L., West, S., Wiedemann, P., Wong, T., Wormald, R., Zheng, Y., 2017. Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. The Lancet Global Health 5, e1221–e1234. https://doi.org/10.1016/S2214-109X(17)30393-5

Fraser-Bell, S., Symes, R., Vaze, A., 2017. Hypertensive eye disease: a review. Clinical Exper Ophthalmology 45, 45–53. https://doi.org/10.1111/ceo.12905

Frehywot, S., Vovides, Y., Talib, Z., Mikhail, N., Ross, H., Wohltjen, H., Bedada, S., Korhumel, K., Koumare, A.K., Scott, J., 2013. E-learning in medical education in resource constrained low- and middle-income countries. Hum Resour Health 11, 4. https://doi.org/10.1186/1478-4491-11-4

Freire, T.P., Braz Junior, G., de Almeida, J.D.S., Rodrigues Junior, J.R.D., 2025. Cup and Disc Segmentation in Smartphone Handheld Ophthalmoscope Images with a Composite Backbone and Double Decoder Architecture. VISION 9. https://doi.org/10.3390/vision9020032

Furdova, Alena, Furdova, Adriana, Krcmery, V., 2017. Our experience with smartphone and spherical lens for the eye fundus examination during humanitarian project in Africa. Int J Ophthalmol 10, 157–160. https://doi.org/10.18240/ijo.2017.01.25

Ghasemi Falavarjani, K., Tsui, I., Sadda, S.R., 2017. Ultra-wide-field imaging in diabetic retinopathy. Vision Research 139, 187–190. https://doi.org/10.1016/j.visres.2017.02.009

Giardini, M.E., Livingstone, I.A.T., Jordan, S., Bolster, N.M., Peto, T., Burton, M., Bastawrous, A., 2014. A smartphone based ophthalmoscope. Annu Int Conf IEEE Eng Med Biol Soc 2014, 2177–2180. https://doi.org/10.1109/EMBC.2014.6944049

Global Strategy on Digital Health 2020-2025, 1st ed. ed, 2021. . World Health Organization, Geneva.

Głowacki, M., Mazurkiewicz, A., Słomion, M., Skórczewska, K., 2022. Resistance of 3D-Printed Components, Test Specimens and Products to Work under Environmental Conditions—Review. Materials 15, 6162. https://doi.org/10.3390/ma15176162

Gonçalves, M.B., Nakayama, L.F., Ferraz, D., Faber, H., Korot, E., Malerbi, F.K., Regatieri, C.V., Maia, M., Celi, L.A., Keane, P.A., Belfort, R., 2024. Image quality assessment of retinal fundus photographs for diabetic retinopathy in the machine learning era: a review. Eye 38, 426–433. https://doi.org/10.1038/s41433-023-02717-3

Google LLC, 2026. Get a great photo every time with Top Shot [WWW Document]. Pixel Camera Help. URL https://support.google.com/pixelcamera/answer/9937175?hl=en (accessed 7.21.26).

Goyal, A., Gopalakrishnan, M., Anantharaman, G., Chandrashekharan, D.P., Thachil, T., Sharma, A., 2019. Smartphone guided wide-field imaging for retinopathy of prematurity in neonatal intensive care unit - a Smart ROP (SROP) initiative. Indian J Ophthalmol 67, 840–845. https://doi.org/10.4103/ijo.IJO_1177_18

Grzybowski, A., Brona, P., Lim, G., Ruamviboonsuk, P., Tan, G.S.W., Abramoff, M., Ting, D.S.W., 2020. Artificial intelligence for diabetic retinopathy screening: a review. Eye 34, 451–460. https://doi.org/10.1038/s41433-019-0566-0

Gunasekera, C.D., Thomas, P., 2019. High-Resolution Direct Ophthalmoscopy With an Unmodified iPhone X. JAMA Ophthalmol 137, 212–213. https://doi.org/10.1001/jamaophthalmol.2018.5806

Gunasekeran, D.V., Miller, S., Hsu, W., Lee, M.L., Wong, H.T., Lee, M.T., Lamoureau, E., Ting, D.S.W., Tan, G.S.W., Wong, T.-Y., 2024. National Use of Artificial Intelligence for Eye Screening in Singapore. NEJM AI 1. https://doi.org/10.1056/AIcs2400404

Guo, F., Li, W., Zhao, X., Qiu, J., Mai, Y., 2020. A mobile app for Glaucoma diagnosis and its possible clinical applications. BMC Med Inform Decis Mak 20, 128. https://doi.org/10.1186/s12911-020-1123-2

Hacisoftaoglu, R.E., Karakaya, M., Sallam, A.B., 2020. Deep Learning Frameworks for Diabetic Retinopathy Detection with Smartphone-based Retinal Imaging Systems. Pattern Recognit Lett 135, 409–417. https://doi.org/10.1016/j.patrec.2020.04.009

Haddock, L.J., Kim, D.Y., Mukai, S., 2013. Simple, inexpensive technique for high-quality smartphone fundus photography in human and animal eyes. J Ophthalmol 2013, 518479. https://doi.org/10.1155/2013/518479

Hakimi, A.A., Lalehzarian, S.P., Lalehzarian, A.S., Dallalzadeh, L.O., Boodaie, B.D., Oggoian, R., Hakim, M.A., 2019. The utility of a smartphone-enabled ophthalmoscope in pre-clinical fundoscopy training. Acta Ophthalmologica 97. https://doi.org/10.1111/aos.13934

Hong, S.C., Wynn-Williams, G., Wilson, G., 2017. Safety of iPhone retinal photography. J Med Eng Technol 41, 165–169. https://doi.org/10.1080/03091902.2016.1264491

Huemmer, S.E., Patnaik, J.L., Ybarra, S., Congdon, N., Cherwek, D.H., Wilson, M.W., 2024. Teleophthalmology Through Online Mentorship Over a 20-Year Period: Education and Capacity Building. JCO Glob Oncol e2400297. https://doi.org/10.1200/GO-24-00297

Hunt, B., Ruiz, A.J., Pogue, B.W., 2021. Smartphone-based imaging systems for medical applications: a critical review. J. Biomed. Opt. 26. https://doi.org/10.1117/1.JBO.26.4.040902

Ibrahim, H., Liu, X., Zariffa, N., Morris, A.D., Denniston, A.K., 2021. Health data poverty: an assailable barrier to equitable digital health care. The Lancet Digital Health 3, e260–e265. https://doi.org/10.1016/S2589-7500(20)30317-4

Idriss, B.R., Tran, T.M., Atwine, D., Chang, R.T., Myung, D., Onyango, J., 2021. Smartphone-based Ophthalmic Imaging Compared With Spectral-domain Optical Coherence Tomography Assessment of Vertical Cup-to-disc Ratio Among Adults in Southwestern Uganda. J Glaucoma 30, e90–e98. https://doi.org/10.1097/IJG.0000000000001779

International Diabetes Federation, 2025. IDF_Atlas_11th_Edition_2025, Diabetes Atlas.

ISO/IEC 27001:2022, n.d.

Jabir, A., Zaheer, H., Zaheer, M., Zaheer, E., Birdsong, R., 2022. Detection and Diagnosis of Retinoblastoma: Can Mobile Devices Be the Next Step Toward Early Intervention? CUREUS JOURNAL OF MEDICAL SCIENCE 14. https://doi.org/10.7759/cureus.30074

Jain, A., Krishnan, R., Rogye, A., Natarajan, S., 2021. Use of offline artificial intelligence in a smartphone-based fundus camera for community screening of diabetic retinopathy. Indian J Ophthalmol 69, 3150–3154. https://doi.org/10.4103/ijo.IJO_3808_20

Jansen, L.G., Shah, P., Wabbels, B., Holz, F.G., Finger, R.P., Wintergerst, M.W.M., 2021. Learning curve evaluation upskilling retinal imaging using smartphones. Sci Rep 11, 12691. https://doi.org/10.1038/s41598-021-92232-w

Kacker, S., Macis, M., Gajwani, P., Friedman, D.S., 2022. Providing vouchers and value information for already free eye exams increases uptake among a low-income minority population: A randomized trial. Health Economics 31, 541–551. https://doi.org/10.1002/hec.4463

Kalic, H., Broddin, B., Kramer, S., Mostard, G., Buijs, J., van Twist, D., 2023. SMARTPHONE-BASED OPHTHALMOSCOPY TO DIAGNOSE HYPERTENSIVE CRISIS IN THE EMERGENCY DEPARTMENT: A PILOT STUDY. JOURNAL OF HYPERTENSION 41, E124–E124. https://doi.org/10.1097/01.hjh.0000940024.18895.e3

Kanclerz, P., Tuuminen, R., Khoramnia, R., 2021. Imaging Modalities Employed in Diabetic Retinopathy Screening: A Review and Meta-Analysis. Diagnostics (Basel) 11. https://doi.org/10.3390/diagnostics11101802

Karakaya, M., Hacisoftaoglu, R.E., 2020. Comparison of smartphone-based retinal imaging systems for diabetic retinopathy detection using deep learning. BMC Bioinformatics 21, 259. https://doi.org/10.1186/s12859-020-03587-2

Karlsson, R.A., Jonsson, B.A., Hardarson, S.H., Olafsdottir, O.B., Halldorsson, G.H., Stefansson, E., 2021. Automatic fundus image quality assessment on a continuous scale. Computers in Biology and Medicine 129, 104114. https://doi.org/10.1016/j.compbiomed.2020.104114

Kaur, R., Singh, H., Samria, S., Kumar, N., Parachuri, N., Sharma, R., Bandello, F., Loewenstein, A., Bilong, Y., Hafeez Faridi, M., Sharma, A., 2020. MII RetCam assisted smartphone-based fundus imaging (MSFI)-A boon for paediatric retinal imaging. Eye (Lond) 34, 1307–1309. https://doi.org/10.1038/s41433-020-0822-3

Kemp, O., Bascaran, C., Cartwright, E., McQuillan, L., Matthew, N., Shillingford-Ricketts, H., Zondervan, M., Foster, A., Burton, M., 2023. Real-world evaluation of smartphone-based artificial intelligence to screen for diabetic retinopathy in Dominica: a clinical validation study. BMJ Open Ophthalmol 8. https://doi.org/10.1136/bmjophth-2023-001491

Khan, S.M., Liu, X., Nath, S., Korot, E., Faes, L., Wagner, S.K., Keane, P.A., Sebire, N.J., Burton, M.J., Denniston, A.K., 2021. A global review of publicly available datasets

for ophthalmological imaging: barriers to access, usability, and generalisability. The Lancet Digital Health 3, e51–e66. https://doi.org/10.1016/S2589-7500(20)30240-5

Kherani, I.Z., Kritzinger, J., Micieli, J.A., Wong, J.C.Y., 2024. Evaluating smartphone fundoscopy as a pedagogical tool in medical education: a narrative review. Can J Ophthalmol 59, e425–e430. https://doi.org/10.1016/j.jcjo.2023.07.024

Kim, J., Yoon, S., Kim, H.Y.S., 2024. Prevalence of Selected Ophthalmic Diseases Using a Smartphone-Based Fundus Imaging System in Quang Tri and Thai Nguyen, Vietnam. Healthc Inform Res 30, 162–167. https://doi.org/10.4258/hir.2024.30.2.162

Kim, T.N., Aaberg, M.T., Li, P., Davila, J.R., Bhaskaranand, M., Bhat, S., Ramachandra, C., Solanki, K., Myers, F., Reber, C., Jalalizadeh, R., Margolis, T.P., Fletcher, D., Paulus, Y.M., 2021. Comparison of automated and expert human grading of diabetic retinopathy using smartphone-based retinal photography. Eye (Lond) 35, 334–342. https://doi.org/10.1038/s41433-020-0849-5

Kim, T.N., Myers, F., Reber, C., Loury, P., Loumou, P., Webster, D., Echanique, C., Li, P., Davila, J.R., Maamari, R.N., Switz, N.A., Keenan, J., Woodward, M.A., Paulus, Y.M., Margolis, T., Fletcher, D.A., 2018. A Smartphone-Based Tool for Rapid, Portable, and Automated Wide-Field Retinal Imaging. Trans. Vis. Sci. Tech. 7, 21. https://doi.org/10.1167/tvst.7.5.21

Kim, Y., Chao, D.L., 2019. Comparison of smartphone ophthalmoscopy vs conventional direct ophthalmoscopy as a teaching tool for medical students: the COSMOS study. OPTH Volume 13, 391–401. https://doi.org/10.2147/OPTH.S190922

Kirby, R., Malik, A., Palamountain, K., Gilbert, C., TPP Survey Meeting Participants, 2023. Improved screening of retinopathy of prematurity (ROP): development of a target product profile (TPP) for resource-limited settings. BMJ OPEN OPHTHALMOLOGY 8. https://doi.org/10.1136/bmjophth-2022-001197

Kitema, G.F., 2025. Developing a high-performance, smartphone-ready glaucoma AI model with RETFound-Green. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 66.

Klein, R., Sharrett, A.R., Klein, B.E.K., Moss, S.E., Folsom, A.R., Wong, T.Y., Brancati, F.L., Hubbard, L.D., Couper, D., 2002. The association of atherosclerosis, vascular risk factors, and retinopathy in adults with diabetes. Ophthalmology 109, 1225–1234. https://doi.org/10.1016/S0161-6420(02)01074-6

Kohler, J., Tran, T.M., Sun, S., Montezuma, S.R., 2021. Teaching Smartphone Funduscopy with 20 Diopter Lens in Undergraduate Medical Education. Clin Ophthalmol 15, 2013–2023. https://doi.org/10.2147/OPTH.S266123

Kohlmayer, F., Lautenschläger, R., Prasser, F., 2019. Pseudonymization for research data collection: is the juice worth the squeeze? BMC Med Inform Decis Mak 19, 178. https://doi.org/10.1186/s12911-019-0905-x

Korn Malerbi, F., Barreto Melo, G., 2022. Feasibility of screening for diabetic retinopathy using artificial intelligence, Brazil. Bull World Health Org 100, 643–647. https://doi.org/10.2471/BLT.22.288580

Korn Malerbi, F., Lelis Dal Fabbro, A., Botelho Vieira Filho, J.P., Franco, L.J., 2020. The feasibility of smartphone based retinal photography for diabetic retinopathy screening among Brazilian Xavante Indians. Diabetes Res Clin Pract 168, 108380. https://doi.org/10.1016/j.diabres.2020.108380

Kumari, S., Venkatesh, P., Tandon, N., Chawla, R., Takkar, B., Kumar, A., 2022. Selfie fundus imaging for diabetic retinopathy screening. Eye (Lond) 36, 1988–1993. https://doi.org/10.1038/s41433-021-01804-7

LaMonica, L.C., Bhardwaj, M.K., Hawley, N.L., Naseri, T., Reupena, M.S., Cooper, M.L., Cotran, P.R., Roh, S., Ramsey, D.J., 2021. Remote Screening for Optic Nerve

Cupping Using Smartphone-based Nonmydriatic Fundus Photography. J Glaucoma 30, 58–60. https://doi.org/10.1097/IJG.0000000000001680

Li, H., Horton, M., Bursell, S., Cavallerano, J., Zimmer-Galler, I., Tennant, M., Abramoff, M., Chaum, E., DeBuc, D., Leonard-Martin, T., Winchester, M., 2011. Telehealth Practice Recommendations for Diabetic Retinopathy, Second Edition. TELEMEDICINE AND E-HEALTH 17, 814–837. https://doi.org/10.1089/tmj.2011.0075

Lin, B., Markatia, Z., Mittal, A., Sanchez, V., Patel, N., Robles, R., Blake, R., Iyer, S., Sherwood, M., 2022. Evaluating a Smartphone-Based Optic Nerve Imaging Device as a Glaucoma Screening Tool in an Outpatient Clinic Setting. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 63.

Lin, J.-Y., Kang, E.Y.-C., Banker, A.S., Chen, K.-J., Hwang, Y.-S., Lai, C.-C., Huang, J.-L., Wu, W.-C., 2022. Comparison of RetCam and Smartphone-Based Photography for Retinopathy of Prematurity Screening. Diagnostics (Basel) 12. https://doi.org/10.3390/diagnostics12040945

Lodhia, V., Karanja, S., Lees, S., Bastawrous, A., 2016. Acceptability, Usability, and Views on Deployment of Peek, a Mobile Phone mHealth Intervention for Eye Care in Kenya: Qualitative Study. JMIR mHealth uHealth 4, e30. https://doi.org/10.2196/mhealth.4746

Lord, R.K., Shah, V.A., San Filippo, A.N., Krishna, R., 2010. Novel Uses of Smartphones in Ophthalmology. Ophthalmology 117, 1274-1274.e3. https://doi.org/10.1016/j.ophtha.2010.01.001

Lu, L., Ausayakhun, S., Ausayakuhn, S., Khunsongkiet, P., Apivatthakakul, A., Sun, C.Q., Kim, T.N., Lee, M., Tsui, E., Sutra, P., Keenan, J.D., 2022. Diagnostic accuracy of handheld fundus photography: A comparative study of three commercially available cameras. PLOS Digit Health 1, e0000131. https://doi.org/10.1371/journal.pdig.0000131

Maberley, D., Walker, H., Koushik, A., Cruess, A., 2003. Screening for diabetic retinopathy in James Bay, Ontario: a cost-effectiveness analysis. Canadian Medical Association Journal, Canadian Medical Association Journal.

Mackay, D.D., Garza, P.S., Bruce, B.B., Newman, N.J., Biousse, V., 2015. The demise of direct ophthalmoscopy: A modern clinical challenge. Neur Clin Pract 5, 150–157. https://doi.org/10.1212/CPJ.0000000000000115

Magliano, D., Boyko, E.J., 2021. IDF diabetes atlas, 10th edition. ed. International Diabetes Federation, Brussels.

Malerbi, F., Cardoso, V., Santos, L., Melo, G., 2023. Point-of-care Diabetic Retinopathy screening with a low-cost portable retinal camera, artificial intelligence and staged mydriasis in a rural, underserved area. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE.

Malerbi, F.K., Andrade, R.E., 2022. Real-World diabetic retinopathy screening with a handheld fundus camera in a high-burden setting. Acta Ophthalmologica 100. https://doi.org/10.1111/aos.15170

Malerbi, F.K., Andrade, R.E., Morales, P.H., Stuchi, J.A., Lencione, D., de Paulo, J.V., Carvalho, M.P., Nunes, F.S., Rocha, R.M., Ferraz, D.A., Belfort, R.J., 2022. Diabetic Retinopathy Screening Using Artificial Intelligence and Handheld Smartphone-Based Retinal Camera. J Diabetes Sci Technol 16, 716–723. https://doi.org/10.1177/1932296820985567

Malerbi, F.K., Mendes, G., Barboza, N., Morales, P.H., Montargil, R., Andrade, R.E., 2021. Diabetic Macular Edema Screened by Handheld Smartphone-based Retinal Camera and Artificial Intelligence. J Med Syst 46, 8. https://doi.org/10.1007/s10916-021-01795-8

Mamtora, S., Sandinha, M.T., Ajith, A., Song, A., Steel, D.H.W., 2018. Smart phone ophthalmoscopy: a potential replacement for the direct ophthalmoscope. Eye (Lond) 32, 1766–1771. https://doi.org/10.1038/s41433-018-0177-1

Martins, J., Cardoso, J.S., Soares, F., 2020. Offline computer-aided diagnosis for Glaucoma detection using fundus images targeted at mobile devices. Comput Methods Programs Biomed 192, 105341. https://doi.org/10.1016/j.cmpb.2020.105341

Martins, T.G.D.S., 2019. Smartphone Disc Photography Versus Standard Stereoscopic Disc Photography as a Teaching Tool. J Glaucoma 28, e174. https://doi.org/10.1097/IJG.0000000000001383

Mbanugo, T.H., Mezue, W.C., Emejulu, J.-K.C., Uche, E.O., Chikani, M.O., Iloabachie, I., Onyia, E., Okpalauwaekwe, U., 2023. Smartphone Ocular Fundal Photography in the Diagnosis of Raised Intracranial Pressure: A Novel Adaptation to Neurosurgical Practice. Cureus 15, e38246. https://doi.org/10.7759/cureus.38246

Melo, G.B., Malerbi, F.K., De Medeiros, J.N., Grauslund, J., 2024a. A comprehensive strategy of diabetic retinopathy screening in a public health system: Identifying and overcoming obstacles for implementation. Diabetes Epidemiology and Management 13, 100192. https://doi.org/10.1016/j.deman.2023.100192

Melo, G.B., Nakayama, L.F., Cardoso, V.S., Dos Santos, L.A., Malerbi, F.K., 2024b. Synchronous Diagnosis of Diabetic Retinopathy by a Handheld Retinal Camera, Artificial Intelligence, and Simultaneous Specialist Confirmation. Ophthalmology Retina 8, 1083–1092. https://doi.org/10.1016/j.oret.2024.05.009

Mintz, J., Labiste, C., DiCaro, M.V., McElroy, E., Alizadeh, R., Xu, K., 2022. Tele-ophthalmology for age-related macular degeneration during the COVID-19 pandemic and beyond. J Telemed Telecare 28, 670–679. https://doi.org/10.1177/1357633X20960636

Mittal, A., Sanchez, V., Azad, N.S., Zuyev, Y., Robles, R., Sherwood, M., 2025. The Utility of a Smartphone-Based Retinal Imaging Device as a Screening Tool in an Outpatient Clinic Setting: Protocol for an Observational Study. JMIR RESEARCH PROTOCOLS 14. https://doi.org/10.2196/52650

Mohammadpour, M., Heidari, Z., Mirghorbani, M., Hashemi, H., 2017. Smartphones, tele-ophthalmology, and VISION 2020. Int J Ophthalmol 10, 1909–1918. https://doi.org/10.18240/ijo.2017.12.19

Mrad, Y., Elloumi, Y., Akil, M., Bedoui, M., 2022. A Fast and Accurate Method for Glaucoma Screening from Smartphone-Captured Fundus Images. IRBM 43, 279–289. https://doi.org/10.1016/j.irbm.2021.06.004

Mueller, S., Karpova, S., Wintergerst, M.W.M., Murali, K., Shanmugam, M.P., Finger, R.P., Schultz, T., 2020. Automated Detection of Diabetic Retinopathy from Smartphone Fundus Videos, in: Fu, H., Garvin, M.K., MacGillivray, T., Xu, Y., Zheng, Y. (Eds.), Ophthalmic Medical Image Analysis, Lecture Notes in Computer Science. Springer International Publishing, Cham, pp. 83–92. https://doi.org/10.1007/978-3-030-63419-3_9

Muhsen, S., Roto, A., Al-Sabbagh, M.Q., Al-Huneidy, L., AlRamahi, N., Alhalaybeh, N., Kotkot, D., Alkiswani, S., Al-Ani, A., Abu-Yaghi, N., 2023. Smartphone ophthalmoscopy versus slit-lamp biomicroscopy for optic nerve head evaluation: A digital apparatus into medical education. Eur J Ophthalmol 33, 341–351. https://doi.org/10.1177/11206721221113827

Muiesan, M.L., Salvetti, M., Paini, A., Riviera, M., Pintossi, C., Bertacchini, F., Colonetti, E., Agabiti-Rosei, C., Poli, M., Semeraro, F., Agabiti-Rosei, E., Russo, A., 2017. Ocular fundus photography with a smartphone device in acute hypertension. J Hypertens 35, 1660–1665. https://doi.org/10.1097/HJH.0000000000001354

Mvoulana, A., Kachouri, R., Akil, M., 2019. Fully automated method for glaucoma screening using robust optic nerve head detection and unsupervised segmentation based cup-to-disc ratio computation in retinal fundus images. COMPUTERIZED MEDICAL IMAGING AND GRAPHICS 77. https://doi.org/10.1016/j.compmedimag.2019.101643

Nagra, M., Huntjens, B., 2019. Smartphone ophthalmoscopy: patient and student practitioner perceptions. J Med Syst 44, 10. https://doi.org/10.1007/s10916-019-1477-0

Nagra, M., Konstantopoulos, A., Pardhan, S., 2021. Smartphone ophthalmoscopy: a potential way forward for non-ophthalmology medics in the COVID-19 era. BMJ INNOVATIONS 7, 237–239. https://doi.org/10.1136/bmjinnov-2020-000472

Nakahara, K., Asaoka, R., Tanito, M., Shibata, N., Mitsuhashi, K., Fujino, Y., Matsuura, M., Inoue, T., Azuma, K., Obata, R., Murata, H., 2022. Deep learning-assisted (automatic) diagnosis of glaucoma using a smartphone. Br J Ophthalmol 106, 587–592. https://doi.org/10.1136/bjophthalmol-2020-318107

Nakayama, L.F., Gonçalves, M.B., Ferraz, D.A., Santos, H.N.V., Malerbi, F.K., Morales, P.H., Maia, M., Regatier, C.V.S., Belfort, R., 2021. The Challenge of Diabetic Retinopathy Standardization in an Ophthalmological Dataset. J Diabetes Sci Technol 15, 1410–1411. https://doi.org/10.1177/19322968211029943

Namperumalsamy, P., Nirmalan, P.K., Ramasamy, K., 2003. Developing a Screening Program to Detect Sight-Threatening Diabetic Retinopathy in South India. Diabetes Care 26, 1831–1835. https://doi.org/10.2337/diacare.26.6.1831

Natarajan, S., Jain, A., Krishnan, R., Rogye, A., Sivaprasad, S., 2019. Diagnostic Accuracy of Community-Based Diabetic Retinopathy Screening With an Offline Artificial Intelligence System on a Smartphone. JAMA Ophthalmol 137, 1182–1188. https://doi.org/10.1001/jamaophthalmol.2019.2923

Navarro, F., Khallouk, J., Blot, S., Guellab, Y., Tran, T.H.C., 2025. Smartphone Funduscopic Examination by Medical Students: The FUSOMED Project. JOURNAL FRANCAIS D OPHTALMOLOGIE 48. https://doi.org/10.1016/j.jfo.2025.104613

Negiloni, K., Baskaran, P., Rao, D.P., Maitray, A., Savoy, F.M., Suresh, S., Mahalingam, M., Vighnesh, M.J., Rajendran, A., 2025. Advancing AMD screening with an offline, AI-powered smartphone-based fundus camera: A prospective, real-world clinical validation. EYE 39, 2548–2554. https://doi.org/10.1038/s41433-025-03902-2

Neto, A., Camara, J., Cunha, A., 2022. Evaluations of Deep Learning Approaches for Glaucoma Screening Using Retinal Images from Mobile Device. Sensors (Basel) 22. https://doi.org/10.3390/s22041449

Nguyen, H.V., Tan, G.S.W., Tapp, R.J., Mital, S., Ting, D.S.W., Wong, H.T., Tan, C.S., Laude, A., Tai, E.S., Tan, N.C., Finkelstein, E.A., Wong, T.Y., Lamoureux, E.L., 2016. Cost-effectiveness of a National Telemedicine Diabetic Retinopathy Screening Program in Singapore. Ophthalmology 123, 2571–2580. https://doi.org/10.1016/j.ophtha.2016.08.021

Oluleye, T.S., Rotimi-Samuel, A., Adenekan, A., 2016. Mobile Phones for Retinopathy of Prematurity Screening in Lagos, Nigeria, Sub-Saharan Africa. European Journal of Ophthalmology 26, 92–94. https://doi.org/10.5301/ejo.5000666

Ortiz, A., Patino, S., Torres, J., Marmol, J., Serafin, C., Dodhia, R., Saidman, G., Schbib, V., Pena, B., Monteoliva, G., Martinez-Castellanos, M.A., Weeks, W.B., Ferres, J.M.L., 2025. AI-Enabled Screening for Retinopathy of Prematurity in Low-Resource Settings. JAMA NETWORK OPEN 8. https://doi.org/10.1001/jamanetworkopen.2025.7831

OWASP Foundation, 2019. Application Security Verification Standard v4.0.

Palermo, B.J., D'Amico, S.L., Kim, B.Y., Brady, C.J., 2022. Sensitivity and specificity of handheld fundus cameras for eye disease: A systematic review and pooled analysis.

Survey of Ophthalmology 67, 1531–1539. https://doi.org/10.1016/j.survophthal.2021.11.006

Pandit, R.J., Taylor, R., 2000. Mydriasis and glaucoma: exploding the myth. A systematic review. Diabetic Medicine 17, 693–699. https://doi.org/10.1046/j.1464-5491.2000.00368.x

Parisi, S., Bastawrous, A., Philippin, H., Sawers, N., Burton, M., Gomes, M., 2016. Economic evaluation of Peek (Portable Eye Examination Kit) for diabetic retinopathy screening. European Journal of Public Health 26. https://doi.org/10.1093/eurpub/ckw164.036

Parrish, R., Tso, M., 2006. Principles and Guidelines of a Curriculum for Ophthalmic Education of Medical Students. Klin Monatsbl Augenheilkd 223, S1–S19. https://doi.org/10.1055/s-2006-951844

Parthasarathy, D., Hsu, C., Eldeeb, M., Jinapriya, D., Shroff, S., Shruthi, S., Pradhan, Z., Deshmukh, S., Savoy, F., 2021. Development and performance of a novel "offline" deep learning (DL)-based glaucoma screening tool integrated on a portable smartphone based fundus camera. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 62.

Pasquel, F.J., Hendrick, A.M., Ryan, M., Cason, E., Ali, M.K., Narayan, K.M.V., 2016. Cost-effectiveness of Different Diabetic Retinopathy Screening Modalities. J Diabetes Sci Technol 10, 301–307. https://doi.org/10.1177/1932296815624109

Patel, T.P., Aaberg, M.T., Paulus, Y.M., Lieu, P., Dedania, V.S., Qian, C.X., Besirli, C.G., Margolis, T., Fletcher, D.A., Kim, T.N., 2019a. Smartphone-based fundus photography for screening of plus-disease retinopathy of prematurity. Graefes Arch Clin Exp Ophthalmol 257, 2579–2585. https://doi.org/10.1007/s00417-019-04470-4

Patel, T.P., Kim, T.N., Yu, G., Dedania, V.S., Lieu, P., Qian, C.X., Besirli, C.G., Demirci, H., Margolis, T., Fletcher, D.A., Paulus, Y.M., 2019b. Smartphone-Based, Rapid, Wide-Field Fundus Photography for Diagnosis of Pediatric Retinal Diseases. Trans. Vis. Sci. Tech. 8, 29. https://doi.org/10.1167/tvst.8.3.29

Penha, F.M., Priotto, B.M., Hennig, F., Przysiezny, B., Wiethorn, B.A., Orsi, J., Nagel, I.B.F., Wiggers, B., Stuchi, J.A., Lencione, D., de Souza Prado, P.V., Yamanaka, F., Lojudice, F., Malerbi, F.K., 2023. Single retinal image for diabetic retinopathy screening: performance of a handheld device with embedded artificial intelligence. Int J Retina Vitreous 9, 41. https://doi.org/10.1186/s40942-023-00477-6

Pieczynski, J., Chair of Ophthalmology, University of Warmia and Mazury, Olsztyn, Warszawska, Poland, The Voivodal Specialistic Hospital, Olsztyn, Zolnierska, Poland, Grzybowski, A., Chair of Ophthalmology, University of Warmia and Mazury, Olsztyn, Warszawska, Poland, Department of Ophthalmology, Poznan City Hospital, Poznan, Poland, 2015. Diabetic Retinopathy Screening Methods and Programmes Adopted in Different Parts of the World – Further Insights. European Ophthalmic Review 09, 161. https://doi.org/10.17925/EOR.2015.09.02.161

Pieczynski, J., Kuklo, P., Grzybowski, A., 2021. The Role of Telemedicine, In-Home Testing and Artificial Intelligence to Alleviate an Increasingly Burdened Healthcare System: Diabetic Retinopathy. Ophthalmol Ther 10, 445–464. https://doi.org/10.1007/s40123-021-00353-2

Pires Dias, J.M., Oliveira, C.M., Da Silva Cruz, L.A., 2014. Retinal image quality assessment using generic image quality indicators. Information Fusion 19, 73–90. https://doi.org/10.1016/j.inffus.2012.08.001

Pradeepa, R., Rajalakshmi, R., Mohan, V., 2019. Use of Telemedicine Technologies in Diabetes Prevention and Control in Resource-Constrained Settings: Lessons Learned from Emerging Economies. Diabetes Technology & Therapeutics 21, S2-9-S2-16. https://doi.org/10.1089/dia.2019.0038

Pramod Kumar, T.A., Sivaprasad, S., Venkatesan, U., Mohan, V., Anjana, R.M., Unnikrishnan, R., Cherian, J., Giridhar, A., Gopalakrishnan, M., Rajalakshmi, R., 2023. Role of cystatin C in the detection of sight-threatening diabetic retinopathy in Asian Indians with type 2 diabetes. Journal of Diabetes and its Complications 37, 108545. https://doi.org/10.1016/j.jdiacomp.2023.108545

Prathiba, V., Rajalakshmi, R., Arulmalar, S., Usha, M., Subhashini, R., Gilbert, C.E., Anjana, R.M., Mohan, V., 2020. Accuracy of the smartphone-based nonmydriatic retinal camera in the detection of sight-threatening diabetic retinopathy. Indian J Ophthalmol 68, S42–S46. https://doi.org/10.4103/ijo.IJO_1937_19

Pujari, A., Lomi, N., Goel, S., Yadav, S., Mukhija, R., Kumar, P., Kumar, A., 2019a. Unmodified iPhone XS Max for fundus montage imaging in cases of retinoblastoma. Indian J Ophthalmol 67, 948–949. https://doi.org/10.4103/ijo.IJO_2144_18

Pujari, A., Mukhija, R., Chawla, R., Phuljhele, S., Saxena, R., Sharma, P., 2018. Smartphone-based evaluation of the optic nerve head. Indian J Ophthalmol 66, 1617–1618. https://doi.org/10.4103/ijo.IJO_394_18

Pujari, A., Selvan, H., Goel, S., Ayyadurai, N., Dada, T., 2019b. Smartphone Disc Photography Versus Standard Stereoscopic Disc Photography as a Teaching Tool. J Glaucoma 28, e109–e111. https://doi.org/10.1097/IJG.0000000000001251

Pujari, A., Selvan, H., Goel, S., Dada, T., 2019c. Direct Smartphone Disc Video Documentation for Pediatric Glaucomas During Evaluation Under Anesthesia. J Glaucoma 28, e143–e144. https://doi.org/10.1097/IJG.0000000000001294

Qader, A., Er, H., Sow, C., 2022. The effectiveness of smartphone ophthalmoscope compared to direct ophthalmoscope as a teaching tool. ASIA PACIFIC SCHOLAR 7, 22–34. https://doi.org/10.29060/TAPS.2022-7-4/OA2735

Qiu, J.-N., Luo, J., Xie, M.-Y., 2025. Application of smartphone ophthalmoscope in ophthalmic clinical practice and teaching. INTERNATIONAL JOURNAL OF OPHTHALMOLOGY 18, 951–957. https://doi.org/10.18240/ijo.2025.05.22

Queiroz, M.S., de Carvalho, J.X., Bortoto, S.F., de Matos, M.R., das Graças Dias Cavalcante, C., Andrade, E.A.S., Correa-Giannella, M.L., Malerbi, F.K., 2020. Diabetic retinopathy screening in urban primary care setting with a handheld smartphone-based retinal camera. Acta Diabetol 57, 1493–1499. https://doi.org/10.1007/s00592-020-01585-7

Rachapelle, S., Legood, R., Alavi, Y., Lindfield, R., Sharma, T., Kuper, H., Polack, S., 2013. The Cost–Utility of Telemedicine to Screen for Diabetic Retinopathy in India. Ophthalmology 120, 566–573. https://doi.org/10.1016/j.ophtha.2012.09.002

Raj, A., Singla, A., Sidana, S., 2025. Preventive and therapeutic strategies via health care delivery system to minimize sight-threatening diabetic retinopathy: a narrative review. CURRENT DIABETES REPORTS 25. https://doi.org/10.1007/s11892-025-01591-5

Rajalakshmi, R., Arulmalar, S., Usha, M., Prathiba, V., Kareemuddin, K.S., Anjana, R.M., Mohan, V., 2015. Validation of Smartphone Based Retinal Photography for Diabetic Retinopathy Screening. PLoS One 10, e0138285. https://doi.org/10.1371/journal.pone.0138285

Rajalakshmi, R., Mohammed, R., Vengatesan, K., PramodKumar, T.A., Venkatesan, U., Usha, M., Arulmalar, S., Prathiba, V., Mohan, V., 2024a. Wide-field imaging with smartphone based fundus camera: grading of severity of diabetic retinopathy and locating peripheral lesions in diabetic retinopathy. Eye (Lond) 38, 1471–1476. https://doi.org/10.1038/s41433-024-02928-2

Rajalakshmi, R., PramodKumar, T.A., Naziyagulnaaz, A.S., Anjana, R.M., Raman, R., Manikandan, S., Mohan, V., 2024b. Leveraging Artificial Intelligence for Diabetic Retinopathy Screening and Management: History and Current Advances. Seminars in Ophthalmology 1–8. https://doi.org/10.1080/08820538.2024.2432902

Rajalakshmi, R., Prathiba, V., Arulmalar, S., Usha, M., 2021a. Review of retinal cameras for global coverage of diabetic retinopathy screening. Eye (Lond) 35, 162–172. https://doi.org/10.1038/s41433-020-01262-7

Rajalakshmi, R., Prathiba, V., Rani, P.K., Mohan, V., 2021b. Various models for diabetic retinopathy screening that can be applied to India. Indian J Ophthalmol 69, 2951–2958. https://doi.org/10.4103/ijo.IJO_1145_21

Rajalakshmi, R., Subashini, R., Anjana, R.M., Mohan, V., 2018. Automated diabetic retinopathy detection in smartphone-based fundus photography using artificial intelligence. Eye (Lond) 32, 1138–1144. https://doi.org/10.1038/s41433-018-0064-9

Rajalakshmi, R., UmaSankari, G., Prathiba, V., Anjana, R.M., Unnikrishnan, R., Venkatesan, U., JebaRani, S., Shanthirani, C.S., Sivaprasad, S., Mohan, V., 2022. Tele-Ophthalmology Versus Face-to-Face Retinal Consultation for Assessment of Diabetic Retinopathy in Diabetes Care Centers in India: A Multicenter Cross-Sectional Study. Diabetes Technology & Therapeutics 24, 556–563. https://doi.org/10.1089/dia.2022.0025

Rajalakshmi, R., Vasconcelos, J.C., Prevost, A.T., Sivaprasad, S., Deepa, M., Raman, R., Ramasamy, K., Anjana, R.M., Conroy, D., Das, T., Hanif, W., Mohan, V., SMART India Study Collaborators, 2023. Burden of undiagnosed and suboptimally controlled diabetes in selected regions of India: Results from the SMART India population-level diabetes screening study. Diabet Med 40, e15165. https://doi.org/10.1111/dme.15165

Raju, B., Raju, N.S.D., Akkara, J.D., Pathengay, A., 2016. Do it yourself smartphone fundus camera - DIYretCAM. Indian J Ophthalmol 64, 663–667. https://doi.org/10.4103/0301-4738.194325

Raman, R., Ramasamy, K., Rajalakshmi, R., Sivaprasad, S., Natarajan, S., 2021. Diabetic retinopathy screening guidelines in India: All India Ophthalmological Society diabetic retinopathy task force and Vitreoretinal Society of India Consensus Statement. Indian Journal of Ophthalmology 69, 678–688. https://doi.org/10.4103/ijo.IJO_667_20

Ramasamy, K., Mishra, C., Kannan, N., Namperumalsamy, P., Sen, S., 2021. Telemedicine in diabetic retinopathy screening in India. INDIAN JOURNAL OF OPHTHALMOLOGY 69, 2977–2986. https://doi.org/10.4103/ijo.IJO_1442_21

Ramsey, D., LaMonica, L., Bhardwaj, M., Naseri, T., Reupena, M., Cooper, M., Cotran, P., Roh, S., Hawley, N., 2020. Smartphone-based Nonmydriatic Fundus Imaging for Remote Glaucoma Screening. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 61.

Rao, D., 2022. Revolutionizing retinal disease screening using “intelligent” smartphones. ACTA OPHTHALMOLOGICA 100. https://doi.org/10.1111/j.1755-3768.2022.15372

Rao, Divya P., Savoy, F.M., Sivaraman, A., Dutt, S., Shahsuvaryan, M., Jrbashyan, N., Hambardzumyan, N., Yeghiazaryan, N., Das, T., 2024. Evaluation of an AI algorithm trained on an ethnically diverse dataset to screen a previously unseen population for diabetic retinopathy. Indian J Ophthalmol 72, 1162–1167. https://doi.org/10.4103/IJO.IJO_2151_23

Rao, Divya Parthasarathy, Shroff, S., Savoy, F.M., S, S., Hsu, C.-K., Negiloni, K., Pradhan, Z.S., P V, J., Sivaraman, A., Rao, H.L., 2024. Evaluation of an offline, artificial intelligence system for referable glaucoma screening using a smartphone-based fundus camera: a prospective study. Eye (Lond) 38, 1104–1111. https://doi.org/10.1038/s41433-023-02826-z

Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex, n.d.

Remidio Innovative Solutions Pvt. Ltd., I., 2024. Remidio’s Revolutionary AI on a smartphone for Referable Diabetic Retinopathy (DR) Receives EU MDR Class II Regulatory Approval [WWW Document]. PR Newswire. URL https://www.prnewswire.com/ae/news-releases/remidios-revolutionary-ai-on-a-

smartphone-for-referable-diabetic-retinopathy-dr-receives-eu-mdr-class-ii-regulatory-approval-301753950.html (accessed 4.1.26).

Remidio Innovative Solutions Pvt. Ltd., I.S.P., 2023. India brings early Diabetic Retinopathy detection to the last mile with Artificial Intelligence [WWW Document]. PR Newswire. URL https://www.prnewswire.com/in/news-releases/india-brings-early-diabetic-retinopathy-detection-to-the-last-mile-with-artificial-intelligence-302247453.html (accessed 4.1.26).

Resnikoff, S., Lansingh, V.C., Washburn, L., Felch, W., Gauthier, T.-M., Taylor, H.R., Eckert, K., Parke, D., Wiedemann, P., 2020. Estimated number of ophthalmologists worldwide (International Council of Ophthalmology update): will we meet the needs? Br J Ophthalmol 104, 588–592. https://doi.org/10.1136/bjophthalmol-2019-314336

Roberts, E., Morgan, R., King, D., Clerkin, L., 1999. Funduscopy: a forgotten art? Postgraduate Medical Journal 75, 282–284. https://doi.org/10.1136/pgmj.75.883.282

Robles, R., Patel, N., Neag, E., Mittal, A., Markatia, Z., Ameli, K., Lin, B., 2023. A Systematic Review of Digital Ophthalmoscopes in Medicine. CLINICAL OPHTHALMOLOGY 17, 2957–2965. https://doi.org/10.2147/OPTH.S423845

Rodenbeck, S.J., Mackay, D.D., 2019. Examining the ocular fundus in neurology. Curr Opin Neurol 32, 105–110. https://doi.org/10.1097/WCO.0000000000000637

Rodriguez-Una, I., Azuara-Blanco, A., 2018. New Technologies for Glaucoma Detection. ASIA-PACIFIC JOURNAL OF OPHTHALMOLOGY 7, 394–404. https://doi.org/10.22608/APO.2018349

Rono, H., Bastawrous, A., Macleod, D., Mamboleo, R., Bunywera, C., Wanjala, E., Gichuhi, S., Burton, M., 2021. Effectiveness of an mHealth system on access to eye health services in Kenya: a cluster-randomised controlled trial. LANCET DIGITAL HEALTH 3, E414–E424.

Rono, H.K., Bastawrous, A., Macleod, D., Wanjala, E., Di Tanna, G.L., Weiss, H.A., Burton, M.J., 2018. Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial. The Lancet Global Health 6, e924–e932. https://doi.org/10.1016/S2214-109X(18)30244-4

Rossi, A., Toslak, D., Erol, M., Rahimi, M., Son, T., Chan, R., Yao, X., 2024. Affordable ultra-widefield smartphone PedCam for comprehensive pediatric retinal examination. BIOMEDICAL OPTICS EXPRESS 15, 6171–6182. https://doi.org/10.1364/BOE.537633

Rubegni, G., Cartocci, A., Tognetti, L., Tosi, G., Salfi, M., Caruso, A., Castellino, N., Orione, M., Cappellani, F., Fallico, M., D'Esposito, F., Russo, A., Gagliano, C., Avitabile, T., 2024. Design of a new 3D printed all-in-one magnetic smartphone adapter for fundus and anterior segment imaging. Eur J Ophthalmol 11206721241246187. https://doi.org/10.1177/11206721241246187

Russo, A., Mapham, W., Turano, R., Costagliola, C., Morescalchi, F., Scaroni, N., Semeraro, F., 2016. Comparison of Smartphone Ophthalmoscopy With Slit-Lamp Biomicroscopy for Grading Vertical Cup-to-Disc Ratio. J Glaucoma 25, e777-781. https://doi.org/10.1097/IJG.0000000000000499

Russo, A., Morescalchi, F., Costagliola, C., Delcassi, L., Semeraro, F., 2015a. Comparison of Smartphone Ophthalmoscopy With Slit-Lamp Biomicroscopy for Grading Diabetic Retinopathy. American Journal of Ophthalmology 159, 360-364.e1. https://doi.org/10.1016/j.ajo.2014.11.008

Russo, A., Morescalchi, F., Costagliola, C., Delcassi, L., Semeraro, F., 2015b. A Novel Device to Exploit the Smartphone Camera for Fundus Photography. J Ophthalmol 2015, 823139. https://doi.org/10.1155/2015/823139

Ryan, M.E., Rajalakshmi, R., Prathiba, V., Anjana, R.M., Ranjani, H., Narayan, K.M.V., Olsen, T.W., Mohan, V., Ward, L.A., Lynn, M.J., Hendrick, A.M., 2015. Comparison

Among Methods of Retinopathy Assessment (CAMRA) Study: Smartphone, Nonmydriatic, and Mydriatic Photography. Ophthalmology 122, 2038–2043. https://doi.org/10.1016/j.ophtha.2015.06.011

Sadikin, I.S., Lestari, Y.D., Victor, A.A., 2024. The role of cadre in the community on diabetic retinopathy management and its challenges in low-middle income countries: a scoping review. BMC Public Health 24, 177. https://doi.org/10.1186/s12889-024-17652-5

Salongcay, R.P., Aquino, L.A.C., Salva, C.M.G., Saunar, A.V., Alog, G.P., Sun, J.K., Peto, T., Silva, P.S., 2022. Comparison of Handheld Retinal Imaging with ETDRS 7-Standard Field Photography for Diabetic Retinopathy and Diabetic Macular Edema. Ophthalmol Retina 6, 548–556. https://doi.org/10.1016/j.oret.2022.03.002

Samsung Electronics Co., Ltd., 2026. How to enable Motion Photos on a Galaxy phone [WWW Document]. Samsung Support. URL https://www.samsung.com/ae/support/mobile-devices/enable-motion-photos-on-my-samsung-phone/ (accessed 7.21.26).

Samsung's EYELIKE^{TM} Fundus Camera Repurposes Galaxy Smartphones to Improve Access to Eye Care [WWW Document], n.d. URL https://news.samsung.com/sg/samsungs-eyelike-fundus-camera-repurposes-galaxy-smartphones-to-improve-access-to-eye-care-2 (accessed 5.5.25).

Saroya, J., Lu, L., Ausayakhun, Somsanguan, Ausayakhun, Sakarin, Khunsongkiet, P., Apivatthakakul, A., Sun, C.Q., Kim, T.N., Lee, M., Tsui, E., Sutra, P., Keenan, J.D., 2024. Comparison of Three Handheld Fundus Cameras for Assessment of the Vertical Cup-To-Disk Ratio. Ophthalmic Epidemiol 31, 311–314. https://doi.org/10.1080/09286586.2023.2260877

Savoy, F.M., Rao, D.P., Toh, J.K., Ong, B., Sivaraman, A., Sharma, A., Das, T., 2024. Empowering Portable Age-Related Macular Degeneration Screening: Evaluation of a Deep Learning Algorithm for a Smartphone Fundus Camera. BMJ Open 14, e081398. https://doi.org/10.1136/bmjopen-2023-081398

Sayadia, S.B., Elloumi, Y., Kachouri, R., Akil, M., Abdallah, A.B., Bedoui, M.H., 2022. Automated method for real-time AMD screening of fundus images dedicated for mobile devices. Med Biol Eng Comput 60, 1449–1479. https://doi.org/10.1007/s11517-022-02546-8

Scanlon, P.H., Malhotra, R., Thomas, G., Foy, C., Kirkpatrick, J.N., Lewis-Barned, N., Harney, B., Aldington, S.J., 2003. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. Diabetic Medicine 20, 467–474. https://doi.org/10.1046/j.1464-5491.2003.00954.x

Scarpa, F., Berto, A., Colonna, A., Scarpa, A., 2020. Development of an automated analysis for glaucoma screening of videos acquired with smartphone ophthalmoscope. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 61.

Scarpa, F., Berto, A., Tsiknakis, N., Manikis, G., Fotiadis, D., Marias, K., Scarpa, A., 2024. Automated analysis for glaucoma screening of retinal videos acquired with smartphone-based ophthalmoscope. HELIYON 10. https://doi.org/10.1016/j.heliyon.2024.e34308

Schmidhuber, J., 2015. Deep learning in neural networks: An overview. Neural Networks 61, 85–117. https://doi.org/10.1016/j.neunet.2014.09.003

Schulz, C., Moore, J., Hassan, D., Tamsett, E., Smith, C.F., 2016. Addressing the 'forgotten art of fundoscopy': evaluation of a novel teaching ophthalmoscope. Eye 30, 375–384. https://doi.org/10.1038/eye.2015.238

Screening programmes: a short guide. Increase effectiveness, maximize benefits and minimize harm., 2020.

Selvan, H., Pujari, A., 2019. In Reply: Smartphone Disc Photography Versus Standard Stereoscopic Disc Photography as a Teaching Tool. J Glaucoma 28, e174–e175. https://doi.org/10.1097/IJG.0000000000001384

Sengupta, S., Sindal, M.D., Baskaran, P., Pan, U., Venkatesh, R., 2019. Sensitivity and Specificity of Smartphone-Based Retinal Imaging for Diabetic Retinopathy: A Comparative Study. Ophthalmol Retina 3, 146–153. https://doi.org/10.1016/j.oret.2018.09.016

Senthil, S., Rao, D.P., Savoy, F.M., Negiloni, K., Bhandary, S., Chary, R., Chandrashekar, G., 2025. Evaluating real-world performance of an automated offline glaucoma AI on a smartphone fundus camera across glaucoma severity stages. PLOS ONE 20. https://doi.org/10.1371/journal.pone.0324883

Shah, P., Yauney, G., Gupta, O., Patalano, V., Mohit, M., Merchant, R., Subramanian, S., 2018. Technology-enabled examinations of cardiac rhythm, optic nerve, oral health, tympanic membrane, gait and coordination evaluated jointly with routine health screenings: an observational study at the 2015 Kumbh Mela in India. BMJ OPEN 8. https://doi.org/10.1136/bmjopen-2017-018774

Shanmugam, M., Mishra, D., Madhukumar, R., Ramanjulu, R., Reddy, S., Rodrigues, G., 2014. Fundus imaging with a mobile phone: A review of techniques. Indian J Ophthalmol 62, 960. https://doi.org/10.4103/0301-4738.143949

Sharma, A., Bilong, Y., Patil, J., Katte, J.-C., Ahmad Khaqan, H., Kumar Gupta, N., Patel, A., Sundaramoorthy, S.K., Madhusudan, R.J., Vidhya, N., Lekha, T., Shah, P.K., Saravanan, V.R., Dharwadkar, S.S., Rishi, P., Franco, M.F.E., Chelo, D., Kagmeni, G., Assumpta Bella, L., Kuppermann, B.D., 2020. MIIRetCam (Make In India Retina Camera) assisted retinal imaging in paediatric patients: Useful, artefacts, learning curve. Journal Français d'Ophtalmologie 43, e35–e38. https://doi.org/10.1016/j.jfo.2019.09.003

Sharma, A., Goyal, A., Bilong, Y., Shah, P., Banker, A., Kumar, N., Sharma, R., Kuppermann, B.D., Bandello, F., 2019. Comparison of a Smartphone-Based Photography Method with Indirect Ophthalmoscopic Assessment in Referable Retinopathy of Prematurity: A Smart Retinopathy of Prematurity Model Pilot Study. Ophthalmol Retina 3, 911–912. https://doi.org/10.1016/j.oret.2019.06.006

Sharma, A., Subramaniam, S.D., Ramachandran, K.I., Lakshmikanthan, C., Krishna, S., Sundaramoorthy, S.K., 2016. Smartphone-based fundus camera device (MII Ret Cam) and technique with ability to image peripheral retina. Eur J Ophthalmol 26, 142–144. https://doi.org/10.5301/ejo.5000663

Shen, S.Y., Wong, T.Y., Foster, P.J., Loo, J.-L., Rosman, M., Loon, S.-C., Wong, W.L., Saw, S.-M., Aung, T., 2008. The Prevalence and Types of Glaucoma in Malay People: The Singapore Malay Eye Study. Invest. Ophthalmol. Vis. Sci. 49, 3846. https://doi.org/10.1167/iovs.08-1759

Shetty, A., Nelson, P., Htay, T., 2021. THE EVOLUTION OF OPHTHALMOSCOPY: USING A SMARTPHONE FOR TEACHING THE FUNDOSCOPIC EXAM. JOURNAL OF GENERAL INTERNAL MEDICINE 36, S459–S460.

Shi, C., Lee, J., Wang, G., Dou, X., Yuan, F., Zee, B., 2022. Assessment of image quality on color fundus retinal images using the automatic retinal image analysis. Sci Rep 12, 10455. https://doi.org/10.1038/s41598-022-13919-2

Shikino, K., Suzuki, S., Hirota, Y., Kikukawa, M., Ikusaka, M., 2019. Effect of the iExaminer Teaching Method on Fundus Examination Skills: A Randomized Clinical Trial. JAMA Netw Open 2, e1911891. https://doi.org/10.1001/jamanetworkopen.2019.11891

Shuai, Z., Wu, C., Tang, Z., Restrepo, D., Morley, M., Nakayama, L.F., 2025. Enhancing AI-based diabetic retinopathy screening in low-and middle-income countries with

synthetic data. JOURNAL OF BIOMEDICAL INFORMATICS 172. https://doi.org/10.1016/j.jbi.2025.104938

Sivaraman, A., Nagarajan, S., Vadivel, S., Dutt, S., Tiwari, P., Narayana, S., Rao, D.P., 2021. A Novel, Smartphone-Based, Teleophthalmology-Enabled, Widefield Fundus Imaging Device With an Autocapture Algorithm. Transl Vis Sci Technol 10, 21. https://doi.org/10.1167/tvst.10.12.21

Smith, A., Negretti, G., Mascaro, A., Bokre, D., Baker, H., Dhalla, K., Murdoch, I., 2018. Glaucoma Control Strategies in Sub-Saharan Africa: A Review of the Clinical and Health Economic Evidence. OPHTHALMIC EPIDEMIOLOGY 25, 419–435. https://doi.org/10.1080/09286586.2018.1501499

Solyman, O., Eldib, A.A., Elborgy, E.S., Abushanab, M.M., 2022. A smartphone-based portable fundus camera for retinal photography in infants with suspected nonaccidental trauma. J AAPOS 26, 214–216. https://doi.org/10.1016/j.jaapos.2022.04.011

Solyman, O.M., Hamdy, O., Abdelkawi, S.A., Hassan, A.A., 2022. Investigating the light emitting diode (LED) flashlight characteristics of a sample of smartphones for its safety in indirect retinal photography. Pan Afr Med J 43, 15. https://doi.org/10.11604/pamj.2022.43.15.32963

Sosale, B., Aravind, S., Murthy, H., Narayana, S., Sharma, U., Gowda, S., Naveenam, M., 2020a. Simple, Mobile-based Artificial Intelligence Algorithm in the detection of Diabetic Retinopathy (SMART) study. BMJ OPEN DIABETES RESEARCH & CARE 8. https://doi.org/10.1136/bmjdrc-2019-000892

Sosale, B., Sosale, A.R., Murthy, H., Sengupta, S., Naveenam, M., 2020b. Medios- An offline, smartphone-based artificial intelligence algorithm for the diagnosis of diabetic retinopathy. Indian J Ophthalmol 68, 391–395. https://doi.org/10.4103/ijo.IJO_1203_19

Staniszewski, B., Atukunda, I., Kousha, O., Kitema, G.F., Blaikie, A., 2024. A new technique for teaching the fundal reflex test and fundoscopy: “screen casting” with the Arclight direct ophthalmoscope attached to the camera of a mobile phone. Eye (Lond) 38, 74–75. https://doi.org/10.1038/s41433-023-02858-5

Steinmetz, J.D., Bourne, R.R.A., Briant, P.S., Flaxman, S.R., Taylor, H.R.B., Jonas, J.B., Abdoli, A.A., Abrha, W.A., Abualhasan, A., Abu-Gharbieh, E.G., Adal, T.G., Afshin, A., Ahmadieh, H., Alemayehu, W., Alemzadeh, S.A.S., Alfaar, A.S., Alipour, V., Androudi, S., Arabloo, J., Arditi, A.B., Aregawi, B.B., Arrigo, A., Ashbaugh, C., Ashrafi, E.D., Atnafu, D.D., Bagli, E.A., Baig, A.A.W., Bärnighausen, T.W., Battaglia Parodi, M., Beheshti, M.S., Bhagavathula, A.S., Bhardwaj, N., Bhardwaj, P., Bhattacharyya, K., Bijani, A., Bikbov, M., Bottone, M., Braithwaite, T.M., Bron, A.M., Burugina Nagaraja, S.A., Butt, Z.A., Caetano Dos Santos, F.L.L., Carneiro, V.L.J., Casson, R.J., Cheng, C.-Y.J., Choi, J.-Y.J., Chu, D.-T., Cicinelli, M.V.M., Coelho, J.M.G., Congdon, N.G.A., Couto, R.A.A., Cromwell, E.A.M., Dahlawi, S.M., Dai, X., Dana, R., Dandona, L., Dandona, R.A., Del Monte, M.A., Derbew Molla, M., Dervenis, N.A., Desta, A.A.P., Deva, J.P., Diaz, D., Djalalinia, S.E., Ehrlich, J.R., Elayedath, R.R., Elhabashy, H.R.B., Ellwein, L.B., Emamian, M.H., Eskandarieh, S., Farzadfar, F.G., Fernandes, A.G., Fischer, F.S., Friedman, D.S.M., Furtado, J.M., Gaidhane, S., Gazzard, G., Gebremichael, B., George, R., Ghashghaee, A., Gilani, S.A., Golechha, M., Hamidi, S.R., Hammond, B.R.R., Hartnett, M.E.R.K., Hartono, R.K., Hashi, A.I., Hay, S.I., Hayat, K., Heidari, G., Ho, H.C., Holla, R., Househ, M.J., Huang, J.J.E., Ibitoye, S.E.M., Ilic, I.M.D., Ilic, M.D.D., Ingram, A.D.N., Irvani, S.S.N., Islam, S.M.S., Itumalla, R., Jayaram, S.P., Jha, R.P., Kahloun, R., Kalhor, R., Kandel, H., Kasa, A.S., Kavetskyy, T.A., Kayode, G.A.H., Kempen, J.H., Khairallah, M., Khalilov, R.A., Khan, E.A.C., Khanna, R.C., Khatib, M.N.A., Khoja, T.A.E.,

Kim, J.E., Kim, Y.J., Kim, G.R., Kisa, S., Kisa, A., Kosen, S., Koyanagi, A., Kucuk Bicer, B., Kulkarni, V.P., Kurmi, O.P., Landires, I.C., Lansingh, V.C.L., Leasher, J.L.E., LeGrand, K.E., Leveziel, N., Limburg, H., Liu, X., Madhava Kunjathur, S., Maleki, S., Manafi, N., Mansouri, K., McAlinden, C.G., Meles, G.G.M., Mersha, A.M., Michalek, I.M.R., Miller, T.R., Misra, S., Mohammad, Y., Mohammadi, S.F.A., Mohammed, J.A.H., Mokdad, A.H., Moni, M.A.A., Montasir, A.A.R., Morse, A.R.F., Mulaw, G.F.C., Naderi, M., Naderifar, H.S., Naidoo, K.S., Naimzada, M.D., Nangia, V., Narasimha Swamy, S.M., Naveed, D.M., Negash, H.L., Nguyen, H.L., Nunez-Samudio, V.A., Ogbo, F.A., Ogundimu, K.T., Olagunju, A.T.E., Onwujekwe, O.E., Otstavnov, N.O., Owolabi, M.O., Pakshir, K., Panda-Jonas, S., Parekh, U., Park, E.-C., Pasovic, M., Pawar, S., Pesudovs, K., Peto, T.Q., Pham, H.Q., Pinheiro, M., Podder, V., Rahimi-Movaghar, V., Rahman, M.H.U.Y., Ramulu, P.Y., Rathi, P., Rawaf, S.L., Rawaf, D.L., Rawal, L., Reinig, N.M., Renzaho, A.M., Rezapour, A.L., Robin, A.L., Rossetti, L., Sabour, S., Safi, S., Sahebkar, A., Sahraian, M.A.M., Samy, A.M., Sathian, B., Saya, G.K., Saylan, M.A., Shaheen, A.A.A., Shaikh, M.A.T., Shen, T.T., Shibuya, K.S., Shiferaw, W.S., Shigematsu, M., Shin, J.I., Silva, J.C., Silvester, A.A., Singh, J.A., Singhal, D.S., Sitorus, R.S., Skiadaresi, E.Y., Skryabin, V.Y.A., Skryabina, A.A., Soheili, A.B., Sorrie, M.B.A.R.C., Sousa, R.A.R.C.T., Sreeramareddy, C.T., Stambolian, D.G., Tadesse, E.G., Tahhan, N.I., Tareque, M.I., Topouzis, F.X., Tran, B.X., Tsegaye, G.K., Tsilimbaris, M.K., Varma, R., Virgili, G., Vongpradith, A.T., Vu, G.T., Wang, Y.X., Wang, N.H., Weldemariam, A.H.K., West, S.K.G., Wondmeneh, T.G.Y., Wong, T.Y., Yaseri, M., Yonemoto, N., Yu, C.S., Zastrozhin, M.S., Zhang, Z.-J.R., Zimsen, S.R., Resnikoff, S., Vos, T., 2021. Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: the Right to Sight: an analysis for the Global Burden of Disease Study. The Lancet Global Health 9, e144–e160. https://doi.org/10.1016/S2214-109X(20)30489-7

Stockslager, S., Pihlblad, M., Mei, C., 2017. iExaminer: a clinically proven fundus imaging system with medical education potential. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 58.

Stratton, S., Luna, J., Roh, S., Shaikh, N., Alwreikat, A., Jiang, Y., Cotran, P., Bhardwa, M., Ramsey, D., 2021. Smartphone-based Fundus Photography for Remote Glaucoma Assessment in a Low-Resource Setting. INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 62.

Strehlow, M.C., Johnston, J.S., Aluri, K.Z., Prober, C.G., Acker, P.C., Patil, A.S., Mahadevan, A., Mahadevan, S.V., 2024. Evaluation of a massive open online course for just-in-time training of healthcare workers. Front. Public Health 12, 1395931. https://doi.org/10.3389/fpubh.2024.1395931

Subramaniam, A., Orge, F., Douglass, M., Can, B., Monteoliva, G., Fried, E., Schbib, V., Saidman, G., Peña, B., Ulacia, S., Acevedo, P., Rollins, A.M., Wilson, D.L., 2023. Image harmonization and deep learning automated classification of plus disease in retinopathy of prematurity. J Med Imaging (Bellingham) 10, 061107. https://doi.org/10.1117/1.JMI.10.6.061107

Sultan, M.A., Miller, E., Tikkanen, R.S., Singh, S., Kullu, A., Cometto, G., Fitzpatrick, S., Ajuebor, O., Gillon, N., Edward, A., Moleman, Y.P., Pandya, S., Park, I., Shen, J.Y., Yu, Y., Perry, H., Scott, K., Closser, S., 2025. Competency-based education and training for Community Health Workers: a scoping review. BMC Health Serv Res 25, 263. https://doi.org/10.1186/s12913-025-12217-7

Sun, H., Saeedi, P., Karuranga, S., Pinkepank, M., Ogurtsova, K., Duncan, B.B., Stein, C., Basit, A., Chan, J.C.N., Claude Mbanya, J., Pavkov, M.E., Ramachandaran, A., Wild, S.H., James, S., Herman, W.H., Zhang, P., Bommer, C., Kuo, S., Boyko, E.J.,

Magliano, D.J., 2023. Erratum to “IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045” [Diabetes Res. Clin. Pract. 183 (2022) 109119]. Diabetes Research and Clinical Practice 204, 110945. https://doi.org/10.1016/j.diabres.2023.110945

Syzdykova, A., Malta, A., Zolfo, M., Diro, E., Oliveira, J.L., 2017. Open-Source Electronic Health Record Systems for Low-Resource Settings: Systematic Review. JMIR Med Inform 5, e44. https://doi.org/10.2196/medinform.8131

Szymkowski, M., Saeed, E., Omieljanowicz, M., Omieljanowicz, A., Saeed, K., Mariak, Z., 2020. A Novelty Approach to Retina Diagnosing Using Biometric Techniques With SVM and Clustering Algorithms. IEEE ACCESS 8, 125849–125862. https://doi.org/10.1109/ACCESS.2020.3007656

Tan, C.H., Kyaw, B.M., Smith, H., Tan, C.S., Tudor Car, L., 2020. Use of Smartphones to Detect Diabetic Retinopathy: Scoping Review and Meta-Analysis of Diagnostic Test Accuracy Studies. J Med Internet Res 22, e16658. https://doi.org/10.2196/16658

Tan, T., Thirunavukarasu, A., Jin, L., Lim, J., Poh, S., Teo, Z., Ang, M., Chan, R., Ong, J., Turner, A., Karlstrom, J., Wong, T., Stern, J., Ting, D., 2023. Artificial intelligence and digital health in global eye health: opportunities and challenges. LANCET GLOBAL HEALTH 11, 1432–1443. https://doi.org/10.1016/S2214-109X(23)00323-6

Taylor, D.J., Goatman, K.A., Gregory, A., Histed, M., Martin, C.N., Warburton, T.J., Scanlon, P.H., 2009. Image-quality standardization for diabetic retinopathy screening. Expert Review of Ophthalmology 4, 469–476. https://doi.org/10.1586/eop.09.39

Teo, Z.L., Tham, Y.-C., Yu, M., Chee, M.L., Rim, T.H., Cheung, N., Bikbov, M.M., Wang, Y.X., Tang, Y., Lu, Y., Wong, I.Y., Ting, D.S.W., Tan, G.S.W., Jonas, J.B., Sabanayagam, C., Wong, T.Y., Cheng, C.-Y., 2021. Global Prevalence of Diabetic Retinopathy and Projection of Burden through 2045. Ophthalmology 128, 1580–1591. https://doi.org/10.1016/j.ophtha.2021.04.027

Tham, Y.-C., Li, X., Wong, T.Y., Quigley, H.A., Aung, T., Cheng, C.-Y., 2014. Global Prevalence of Glaucoma and Projections of Glaucoma Burden through 2040. Ophthalmology 121, 2081–2090. https://doi.org/10.1016/j.ophtha.2014.05.013

Titoneli, C.C., Filho, M.S., Lencione, D., Vieira, F.P., Stuchi, J.A., Paula, J.S., 2021. Clinical validation of a smartphone-based handheld fundus camera for the evaluation of optic nerve head. Arq Bras Oftalmol 84, 531–537. https://doi.org/10.5935/0004-2749.20210080

Tomic, D., Shaw, J.E., Magliano, D.J., 2022. The burden and risks of emerging complications of diabetes mellitus. Nat Rev Endocrinol 18, 525–539. https://doi.org/10.1038/s41574-022-00690-7

Torous, J., Stern, A.D., Bourgeois, F.T., 2022. Regulatory considerations to keep pace with innovation in digital health products. npj Digit. Med. 5, 121. https://doi.org/10.1038/s41746-022-00668-9

Upadhyaya, S., Rao, D.P., Kavitha, S., Ballae Ganeshrao, S., Negiloni, K., Bhandary, S., Savoy, F.M., Venkatesh, R., 2025. Diagnostic Performance of the Offline Medios Artificial Intelligence for Glaucoma Detection in a Rural Tele-Ophthalmology Setting. Ophthalmology Glaucoma 8, 28–36. https://doi.org/10.1016/j.ogla.2024.09.002

Van Der Zee, C., Chang-Wolf, J., Koopmanschap, M.A., Van Leeuwen, R., Wisse, R.P., 2024. Assessing the Carbon Footprint of Telemedicine: A Systematic Review. Health Serv Insights 17, 11786329241271562. https://doi.org/10.1177/11786329241271562

Varo, R., Postigo, M., Bila, R., Dacal, E., Chiconela, H., García-Villena, J., Cuadrado, D., Vladimirov, A., Díez, N., Vallés-López, R., Sitoe, A., Vitorino, P., Mucasse, C., Beltran-Agullo, L., Pujol, O., García, V., Abdala, M., Sallé, L., Anton, A., Santos, A., Ledesma-Carbayo, M.J., Luengo-Oroz, M., Bassat, Q., 2023. Evaluation of the

Performance of a 3D-Printed Smartphone-Based Retinal Imaging Device as a Screening Tool for Retinal Pathology in Mozambique. Am J Trop Med Hyg 109, 1192–1198. https://doi.org/10.4269/ajtmh.23-0378

Varshney, T., Parthasarathy, D.R., Gupta, V., 2021. Artificial intelligence integrated smartphone fundus camera for screening the glaucomatous optic disc. Indian J Ophthalmol 69, 3787–3789. https://doi.org/10.4103/ijo.IJO_1831_21

Vaughan, N., 2024. Review of smartphone funduscopy for diabetic retinopathy screening. Surv Ophthalmol 69, 279–286. https://doi.org/10.1016/j.survophthal.2023.10.006

Vijaya, L., George, R., Paul, P.G., Baskaran, M., Arvind, H., Raju, P., Ramesh, S.V., Kumaramanickavel, G., McCarty, C., 2005. Prevalence of Open-Angle Glaucoma in a Rural South Indian Population. Invest. Ophthalmol. Vis. Sci. 46, 4461. https://doi.org/10.1167/iovs.04-1529

Vishwanath, Swamy, D.T., Gaddi, D.S., 2023. Smartphone for retinal imaging - Case series in resource-limited rural settings. Indian J Ophthalmol 71, 2008–2013. https://doi.org/10.4103/ijo.IJO_2077_22

Wang, H., Liao, X., Zhang, M., Pang, C.P., Chen, H., 2023. Smartphone ophthalmoscope as a tool in teaching direct ophthalmoscopy: a crossover randomized controlled trial. Med Educ Online 28, 2176201. https://doi.org/10.1080/10872981.2023.2176201

Wenting, S., Samin, M., Sanjay, S., Neelam, K., Shibli, K., Chang, S., Cheng, J., 2017. A comparison of undergraduate clinical ophthalmology learning methods: smart phone television display versus slit-lamp teaching telescope. CANADIAN JOURNAL OF OPHTHALMOLOGY-JOURNAL CANADIEN D OPHTALMOLOGIE 52, 385–391. https://doi.org/10.1016/j.jcjo.2016.11.032

Wilson, J.M.G., Jungner, G., 1968. PRINCIPLES AND PRACTICE OF SCREENING FOR DISEASE. WHO.

Wintergerst, M.W.M., Bejan, V., Hartmann, V., Schnorrenberg, M., Bleckwenn, M., Weckbecker, K., Finger, R.P., 2022. Telemedical Diabetic Retinopathy Screening in a Primary Care Setting: Quality of Retinal Photographs and Accuracy of Automated Image Analysis. Ophthalmic Epidemiology 29, 286–295. https://doi.org/10.1080/09286586.2021.1939886

Wintergerst, M.W.M., Brinkmann, C.K., Holz, F.G., Finger, R.P., 2018. Undilated versus dilated monoscopic smartphone-based fundus photography for optic nerve head evaluation. Sci Rep 8, 10228. https://doi.org/10.1038/s41598-018-28585-6

Wintergerst, M.W.M., Jansen, L.G., Holz, F.G., Finger, R.P., 2020a. Smartphone-Based Fundus Imaging-Where Are We Now? Asia Pac J Ophthalmol (Phila) 9, 308–314. https://doi.org/10.1097/APO.0000000000000303

Wintergerst, M.W.M., Jansen, L.G., Holz, F.G., Finger, R.P., 2020b. A Novel Device for Smartphone-Based Fundus Imaging and Documentation in Clinical Practice: Comparative Image Analysis Study. JMIR Mhealth Uhealth 8, e17480. https://doi.org/10.2196/17480

Wintergerst, M.W.M., Mishra, D.K., Hartmann, L., Shah, P., Konana, V.K., Sagar, P., Berger, M., Murali, K., Holz, F.G., Shanmugam, M.P., Finger, R.P., 2020c. Diabetic Retinopathy Screening Using Smartphone-Based Fundus Imaging in India. Ophthalmology 127, 1529–1538. https://doi.org/10.1016/j.ophtha.2020.05.025

Wintergerst, M.W.M., Petrak, M., Li, J.Q., Larsen, P.P., Berger, M., Holz, F.G., Finger, R.P., Krohne, T.U., 2019. Non-contact smartphone-based fundus imaging compared to conventional fundus imaging: a low-cost alternative for retinopathy of prematurity screening and documentation. Sci Rep 9, 19711. https://doi.org/10.1038/s41598-019-56155-x

Wong, S., Tsai, J., 2021. Telehealth and Screening Strategies in the Diagnosis and Management of Glaucoma. JOURNAL OF CLINICAL MEDICINE 10. https://doi.org/10.3390/jcm10163452

Wong, T.Y., 2002. Cerebral White Matter Lesions, Retinopathy, and Incident Clinical Stroke. JAMA 288, 67. https://doi.org/10.1001/jama.288.1.67

Wong, T.Y., Tan, T.-E., 2023. The Diabetic Retinopathy "Pandemic" and Evolving Global Strategies: The 2023 Friedenwald Lecture. Invest. Ophthalmol. Vis. Sci. 64, 47. https://doi.org/10.1167/iovs.64.15.47

World Health Organization, 2022. WHO Global Model Regulatory Framework for medical devices including IVDs (GMRF).

World report on vision, 2019. . World health organisation, Geneva.

Wu, A.R., Fouzdar-Jain, S., Suh, D.W., 2018. Comparison Study of Funduscopic Examination Using a Smartphone-Based Digital Ophthalmoscope and the Direct Ophthalmoscope. J Pediatr Ophthalmol Strabismus 55, 201–206. https://doi.org/10.3928/01913913-20180220-01

Yan, W., McGuinness, M., Chakrabarti, R., Fotis, K., Finger, R.P., 2023. Comparison of Photographic Screening Methods for Diabetic Retinopathy – A Meta-analysis. Ophthalmic Epidemiology 30, 221–229. https://doi.org/10.1080/09286586.2022.2065311

Yap, B.P., Kelvin, L.Z., Toh, E.Q., Low, K.Y., Rani, S.K., Goh, E.J.H., Hui, V.Y.C., Ng, B.K., Lim, T.H., 2024. Generalizability of Deep Neural Networks for Vertical Cup-to-Disc Ratio Estimation in Ultra-Widefield and Smartphone-Based Fundus Images. Transl Vis Sci Technol 13, 6. https://doi.org/10.1167/tvst.13.4.6

Yatsuya, H., Folsom, A.R., Wong, T.Y., Klein, R., Klein, B.E.K., Sharrett, A.R., 2010. Retinal Microvascular Abnormalities and Risk of Lacunar Stroke: Atherosclerosis Risk in Communities Study. Stroke 41, 1349–1355. https://doi.org/10.1161/STROKEAHA.110.580837

Young, B.K., Cole, E.D., Shah, P.K., Ostmo, S., Subramaniam, P., Venkatapathy, N., Tsai, A.S.H., Coyner, A.S., Gupta, A., Singh, P., Chiang, M.F., Kalpathy-Cramer, J., Chan, R.V.P., Campbell, J.P., 2023. Efficacy of Smartphone-Based Telescreening for Retinopathy of Prematurity With and Without Artificial Intelligence in India. JAMA Ophthalmol 141, 582–588. https://doi.org/10.1001/jamaophthalmol.2023.1466

Yusuf, A.M., Lusobya, R.C., Mukisa, J., Batte, C., Nakanjako, D., Juliet-Sengeri, O., 2022. Validity of smartphone-based retinal photography (PEEK-retina) compared to the standard ophthalmic fundus camera in diagnosing diabetic retinopathy in Uganda: A cross-sectional study. PLoS One 17, e0273633. https://doi.org/10.1371/journal.pone.0273633

Zimmer-Galler, I.E., Kimura, A.E., Gupta, S., 2015. Diabetic retinopathy screening and the use of telemedicine: Current Opinion in Ophthalmology 26, 167–172. https://doi.org/10.1097/ICU.0000000000000142

- Smartphone-based fundus imaging may expand low-resource retinal screening access
- We review 30 smartphone-based fundus imaging solutions and three key design types
- Reported performance varies by disease, device, protocol, and clinical context
- Implementation depends on workflow, training, AI, governance, and sustainability
- Minimum reporting standards may improve study comparability and evidence synthesis

Declaration of interests

☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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