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Teleophthalmology for preventable blindness screening in semi-urban primary care: a cost-effectiveness study from Brazil

Lucas Estéfano Cyrillo Leardini
lucascyrillo.edu@gmail.com

Universidade do Estado do Rio de Janeiro

Denizar Vianna Araújo
Universidade do Estado do Rio de Janeiro

Alexandre Chater Taleb
Universidade Federal de Goiás

Rafael Scherer
University of Miami

Alexandre Antônio Marques Rosa
Universidade Federal do Pará

Leandra Basília de Freitas
Universidade Federal de Goiás

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Abstract

Background

Visual impairment from preventable causes remains a critical public health challenge in Brazil, where over 34% of the population has never undergone ophthalmic examination and specialist access is severely maldistributed. Diabetic retinopathy, glaucoma, age-related macular degeneration, and cataract are leading causes of preventable blindness, yet systematic screening in primary care remains rare in semi-urban municipalities. This study evaluated the cost-effectiveness of a teleophthalmology-based active screening pathway versus the standard Brazilian Unified Health System (SUS) passive referral pathway, assessed acceptability among professionals and patients, and estimated quality-adjusted life years (QALYs) gained through early detection.

Methods

A multicenter cross-sectional study was conducted across eight Primary Health Care Units in a semi-urban municipality in Rio de Janeiro state, Brazil (October 2025–March 2026). A total of 1,290 patients aged 50 years or older and/or with type 2 diabetes mellitus (T2DM) were screened using a portable non-mydriatic fundus camera with remote specialist reporting assisted by artificial intelligence (AI)-based segmentation. A two-arm decision tree compared intervention costs (bottom-up micro-costing) against standard pathway costs (SIGTAP 2024/SISREG 2024) from the public payer perspective. The primary effectiveness measure was time to diagnosis. A QALY scenario analysis was performed using Brazilian-validated utility coefficients. Acceptability was assessed using the System Usability Scale (SUScale; n = 13 professionals) and the Telehealth Usability Questionnaire – Brazil (TUQ-Brazil; n = 99 patients).

Results

Of 1,290 patients, 41.79% had abnormal findings and 2.32% had ungradable images. Mean time to diagnosis was 1.26 days versus 83 days via standard referral. Cost per detected case was R$50.64 versus R$70.82, a reduction of 28.5%. Teleophthalmology was absolutely dominant across all sensitivity scenarios. A QALY analysis (n = 376) yielded an incremental cost-effectiveness ratio (ICER) of –R$4,330/QALY, well below the SUS threshold (~ R$132,000/QALY). Professionals rated the platform 90.96 ± 5.91 (SUScale; “Excellent”). Patients reported a mean TUQ-Brazil score of 6.61 ± 0.32 out of 7.00, with 93.9% willing to reuse the service.

Conclusions

Teleophthalmology demonstrated absolute dominance over standard SUS referral in both cost-effectiveness and QALY analyses, delivering earlier diagnosis at lower cost. High bilateral acceptability

supports scalability within the SUS, and these findings offer actionable evidence for policymakers considering portable fundus camera integration into semi-urban primary care networks.

Background

Preventable blindness remains a major public health burden globally, with an estimated 43 million people blind and over 295 million living with moderate to severe visual impairment worldwide.[1] In Brazil, ophthalmology specialist access is severely maldistributed: half of all ophthalmologists are concentrated in 14 cities, and over 34% of the population has never undergone ophthalmic examination.[2] Diabetic retinopathy (DR), glaucoma, age-related macular degeneration (AMD), and cataract account for the majority of preventable cases, yet most are asymptomatic in early stages, making passive referral-based care structurally inadequate for early detection.[3] Despite Ministry of Health guidelines recommending annual fundus examination for all patients with type 2 diabetes mellitus (T2DM), approximately 50% of this high-risk group does not undergo the procedure.[4]

Teleophthalmology using portable fundus cameras has emerged as a promising strategy to extend ophthalmic screening reach within primary health care, enabling image capture by non-physician health workers with remote diagnosis by specialist ophthalmologists.[5] International evidence suggests cost reductions of up to 40% and coverage increases of approximately 14 percentage points compared to conventional referral pathways, with studies from Canada, Spain, South Africa, and China demonstrating cost-effectiveness across diverse settings.[6, 7, 8, 9] In Brazil, a cost-utility analysis by Ben et al. found systematic teleophthalmology-based screening to be very cost-effective compared to opportunistic referral from the perspective of the SUS.[10] More recently, Meira et al. demonstrated the feasibility and diagnostic yield of teleophthalmology-based retinal screening in a Brazilian primary care context.[11]

The Brazilian context presents a structural particularity that makes access gaps especially difficult to address through conventional means: optometry is not formally recognised as an autonomous health profession in primary care, and its regulatory framework remains contested and underdeveloped. Unlike Canada, the United Kingdom, and Spain, where optometrists play an established role in community-based ophthalmic screening, Brazil lacks this intermediate workforce layer. The practical consequence is that ophthalmic screening in primary care must be performed either by physicians or by other trained health workers operating within clearly defined protocols.

Evidence from semi-urban municipalities, defined by the Brazilian Institute of Geography and Statistics (IBGE) as intermediate urban agglomerations that lack full metropolitan infrastructure yet exceed rural service capacity, remains absent from the literature. This study aimed to evaluate the cost-effectiveness of a teleophthalmology-based active screening pathway versus the standard SUS passive ophthalmology referral pathway in a semi-urban primary care setting, to assess its acceptability among healthcare professionals and patients, and to estimate QALYs gained through early detection.

Methods

Study design and setting

A multicenter cross-sectional observational study was conducted across eight Primary Health Care Units (UBS) in Arraial do Cabo, a municipality classified by IBGE as intermediate urban, located in Rio de Janeiro state, Brazil, between October 2025 and March 2026. The study was approved by the institutional ethics committee (CAAE: 92229925.1.0000.5282, Opinion No. 7.924.608) and all participants provided written informed consent.

Participants

Patients aged 50 years or older and/or with a confirmed diagnosis of T2DM were consecutively enrolled regardless of ophthalmic complaints. Patients unable to cooperate with image capture were excluded. A total of 1,290 patients were included.

Intervention

Ophthalmic screening was performed using the Phelcom Eyer portable non-mydriatic fundus camera without pharmacological mydriasis, operated by trained non-physician health workers at the UBS following a standardised image acquisition protocol. The protocol consisted of six retinal photographs per patient: two images per eye centred on the macula and on the optic nerve respectively, plus one external photograph per eye to evaluate the anterior segment. Operators received a structured four-hour training session prior to data collection. Retinal images were transmitted securely to the RedCheck teleophthalmology platform, where specialist ophthalmologists issued remote diagnostic reports assisted by an integrated AI algorithm. The AI component performed automated image quality pre-screening, case prioritisation, and segmentation of retinal lesions, including exudates, haemorrhages, and microhaemorrhages, to support specialist detection of subtle findings (Fig. 2). Diagnostic decisions were made exclusively by human specialists. Results were communicated to patients and referring clinicians at the UBS.

Comparator

The comparator was the standard SUS ophthalmology referral pathway, comprising: initial clinical consultation at the UBS triggered by symptomatic presentation or chronic disease follow-up, referral entry into the SISREG regulatory queue, specialist ophthalmology consultation at secondary care, and, where indicated, additional diagnostic procedures and further regulatory steps for treatment access. This pathway is fundamentally passive in structure and does not systematically reach asymptomatic patients at risk. The present study therefore compares two distinct models of care organisation — active population-based screening versus passive symptomatic referral — rather than two equivalent diagnostic pathways. This comparator was selected because it represents the realistic alternative for the study population in the absence of the teleophthalmology programme.

Economic model

A two-arm decision tree model was constructed from the public payer perspective, comparing the teleophthalmology pathway with the standard SUS referral pathway (Figs. 1a and 1b). Probability parameters were derived from primary study data (n = 1,290) and public secondary sources (SIA/DATASUS 2024 and SISREG/MS 2024). Intervention costs were estimated using bottom-up micro-costing, incorporating equipment depreciation, remote reporting fees, consumables, and health worker time. Comparator costs were estimated top-down using the SIGTAP 2024 procedure table, applying diagnostic equivalence criteria: a SUS ophthalmology consultation delivering equivalent diagnostic output requires a specialist consultation plus bilateral fundus mapping plus biomicroscopy. To ensure comparability of denominators, cost per detected case in the teleophthalmology arm was calculated by dividing total screening cost by the abnormal finding rate (41.79%). All costs are expressed in Brazilian Reais (R$), base year 2026; no discounting was applied given the short time horizon.

Effectiveness measure

The primary effectiveness measure was time to diagnosis, defined as the interval in days from first patient contact at the UBS to receipt of a qualified ophthalmic diagnostic report. This is a process outcome measure capturing care timeliness, which is clinically relevant for progressive conditions such as DR, glaucoma, and AMD, where delayed diagnosis is directly associated with worse visual outcomes.[3] Time to treatment initiation was not measured for two reasons: a substantial proportion of patients had not yet initiated treatment within the study window; and treatment for most conditions is delivered at reference centres outside the municipality, precluding access to treatment records. For the teleophthalmology arm, time to diagnosis was measured directly from primary data. For the standard SUS pathway, this was estimated from SISREG/MS 2024 national regulatory wait-time data for ophthalmology consultations.

Image quality and diagnostic performance

The ungradable image rate was 2.32%, consistent with published benchmarks for non-mydriatic portable fundus camera protocols operated by non-physician personnel.[12] Ungradable images were referred for repeat capture, with costs proportionally adjusted in the economic model. Sensitivity and specificity of the AI-assisted reporting system against an independent gold standard were not formally assessed, as the platform operates under ANVISA regulatory authorisation and diagnostic decisions were made exclusively by human specialists. This limitation is acknowledged in the Discussion.

QALY scenario analysis

As a complementary scenario analysis, confirmed diagnoses were converted to QALYs gained through early versus delayed detection, applying a 12-month time horizon. Utility coefficients were sourced from

Brazilian-validated studies: for DR, EQ-5D utilities with Brazilian tariffs;[10] for suspected glaucoma, time trade-off values in Brazilian patients;[13] for AMD, utility values from a SUS cost-effectiveness study;[14] and for cataract, visual acuity-based utility values.[15] Patients with confirmed diagnoses of DR (n = 177), suspected glaucoma (n = 137), cataract (n = 46), and AMD (n = 16) were included (total n = 376). Hypertensive retinopathy and other non-specific findings were excluded due to absence of validated utility coefficients. The resulting ICER was calculated against the SUS acceptability threshold of three times Brazilian GDP per capita (approximately R$132,000/QALY in 2024).

Sensitivity analysis

Deterministic univariate sensitivity analysis was performed varying four key parameters across plausible ranges: regulatory wait time (30 to 150 days), equipment unit cost (R$20,000 to R$40,000), remote report fee (R$5.00 to R$24.00), and loss-to-follow-up rate in the standard pathway (6% to 50%). Dominance status was assessed at each extreme.

Acceptability assessment

Acceptability among healthcare professionals was assessed using the Brazilian-validated SUScale, applied by telephone to all 13 professionals involved in image capture across the eight UBS. Patient acceptability was assessed using the TUQ-Brazil,[18] applied to a sample of 99 patients (calculated for n = 1,290, 95% confidence interval, ± 10% margin of error). Eight of the 21 TUQ-Brazil items were applied, covering the domains of utility (items 1–3), ease of use and learnability (item 6), interface quality (item 7), and satisfaction and future use (items 19–21). Full item-level results for both instruments are provided in Additional files 2 and 3. Both instruments were previously published and validated; neither was developed for this study.

Use of artificial intelligence in manuscript preparation

During the preparation of this manuscript, the authors used Claude (Anthropic, claude-sonnet-4-6) to assist with manuscript drafting and structural organisation. All AI-generated content was independently reviewed, verified, and revised by the authors, who accept full responsibility for the accuracy, integrity, and originality of the published content.

Results

Sample characteristics

Of 1,290 patients screened, the mean age was 63.2 years (SD 10.4) and 61.2% were female. Table 1 presents full demographic and clinical characteristics.

Table 1

Clinical and demographic characteristics of patients undergoing ophthalmic screening across eight primary health care units in a semi-urban municipality (n = 1,290). Data are presented as mean ± standard deviation or n (%). Time to diagnosis reflects the interval from image capture to receipt of the remote diagnostic report (teleophthalmology arm only). SD: standard deviation.

Characteristic	Total (N = 1,290)	Normal exams (N = 721; 55.89%)	Abnormal exams (N = 539; 41.79%)	Ungradable (N = 30; 2.32%)
Age (years), mean ± SD	63.17 ± 10.78	61.90 ± 11.05	64.63 ± 10.32	67.33 ± 7.68
Male, n (%)	501 (38.83%)	262 (36.34%)	222 (41.19%)	17 (56.67%)
Female, n (%)	789 (61.17%)	459 (63.66%)	317 (58.81%)	13 (43.33%)
Time to diagnosis (hours), mean ± SD	30.26 ± 23.04	29.79 ± 12.84	30.82 ± 32.09	31.53 ± 19.92

Screening outcomes

Of 1,290 patients, 55.89% had normal findings and were discharged at the UBS level, 41.79% had abnormal findings requiring specialist referral, and 2.32% had ungradable images requiring repeat examination. DR was the most frequent abnormal finding, detected in 177 patients (13.72% of the total screened population), consistent with national prevalence estimates from the Brazilian Diabetes Society. [16] Table 2 presents the full distribution of ophthalmic conditions identified.

Table 2

Prevalence of ophthalmic conditions identified by teleophthalmology screening (n = 1,290). Conditions are reported for the total sample and stratified by sex. Patients may present more than one condition; percentages reflect prevalence relative to the total screened population. DR: diabetic retinopathy; AMD: age-related macular degeneration.

Condition	Total (N = 1,290)	Male (N = 501)	Female (N = 789)
Diabetic retinopathy, n (%)	177 (13.72%)	75 (14.97%)	102 (12.93%)
Hypertensive retinopathy, n (%)	39 (3.02%)	12 (2.39%)	27 (3.42%)
AMD, n (%)	16 (1.24%)	10 (1.99%)	6 (0.76%)
Suspected glaucoma, n (%)	137 (10.62%)	56 (11.17%)	81 (10.27%)
Suspected cataract, n (%)	46 (3.56%)	20 (3.99%)	26 (3.29%)
Other findings, n (%)	124 (9.61%)	49 (9.78%)	75 (9.51%)
— Increased vascular tortuosity	66 (5.12%)	25 (4.99%)	41 (5.19%)
— Retinal pigment epithelium changes	18 (1.40%)	10 (1.99%)	8 (1.02%)
— Myopic fundus	8 (0.62%)	5 (0.99%)	3 (0.38%)
— Chorioretinal scar	6 (0.47%)	4 (0.79%)	2 (0.25%)
— Retinal vein occlusion	5 (0.39%)	1 (0.19%)	4 (0.51%)
— Familial drusen	4 (0.31%)	0 (0%)	4 (0.51%)
— Optic neuropathy	4 (0.31%)	1 (0.19%)	3 (0.38%)
— Retinal lesions	3 (0.23%)	1 (0.19%)	2 (0.25%)
— Choroidal nevus	3 (0.23%)	1 (0.19%)	2 (0.25%)
— Persistent myelinated nerve fibres	3 (0.23%)	1 (0.19%)	2 (0.25%)
— Polypoidal choroidal vasculopathy	1 (0.08%)	0 (0%)	1 (0.13%)

Cost analysis

The estimated cost per screened patient in the teleophthalmology pathway was R$21.16, comprising equipment depreciation (R$4.14), remote report fee (R$12.00), consumables (R$1.50), and health worker time (R$3.00), with proportional adjustment for ungradable image repeat rate. The cost per detected case was R$50.64, calculated by dividing total screening cost by the 41.79% abnormal finding rate. In the standard SUS pathway, applying diagnostic equivalence criteria (specialist consultation R$10.00 + bilateral fundus mapping R$48.48 + biomicroscopy R$12.34), the cost per patient reaching diagnosis was R$70.82. Table 3 presents the consolidated cost-effectiveness results.

Table 3

Cost-effectiveness summary: teleophthalmology versus standard SUS referral pathway. Costs are expressed in Brazilian Reais (R$), base year 2026. Cost per detected case in the teleophthalmology arm was calculated by dividing total screening cost by the abnormal finding rate (41.79%). Standard pathway costs were estimated using diagnostic equivalence criteria based on SIGTAP 2024 procedure values. Dominance status was assessed across all deterministic sensitivity analysis scenarios. ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year; SUS: Brazilian Unified Health System; SIGTAP: SUS Procedure Management System.

Parameter	Teleophthalmology pathway	Standard SUS referral pathway
A. COSTS (R$)		
Equipment depreciation (per exam)	R$4.14	—
Remote report fee (per exam)	R$12.00	—
Consumables (per exam)	R$1.50	—
Health worker time (per exam)	R$3.00	—
Specialist consultation (SIGTAP 0301010072)	—	R$10.00
Bilateral fundus mapping (SIGTAP 0211060127 × 2)	—	R$48.48
Biomicroscopy (SIGTAP 0211060020)	—	R$12.34
Cost per screened patient (R$)	**R$21.16**	—
Cost per detected case (R$)	**R$50.64**	**R$70.82**
Cost reduction	28.5% less costly	
B. EFFECTIVENESS		
Mean time to diagnosis (days)	1.26 days	83 days
Mean time to diagnosis (hours ± SD)	30.26 ± 23.04 h	—
Reduction in time to diagnosis	81.7 days faster	
C. ECONOMIC EVALUATION — PRIMARY ANALYSIS		
ICER (cost per detected case)	Not calculated — absolute dominance	
Dominance status	**Absolute dominance**	
Dominance maintained across all sensitivity scenarios	Yes — all 4 parameters tested	

Parameter	Teleophthalmology pathway	Standard SUS referral pathway
A. COSTS (R$)		
Equipment cost threshold for dominance reversal	R$1,700,000 (64× market price)	
D. QALY SCENARIO ANALYSIS (exploratory)		
Patients included (DR n = 177; glaucoma n = 137; cataract n = 46; AMD n = 16)	376	
Total QALYs gained (early vs. delayed detection)	22.825 QALYs	
Total cost saving for QALY cohort (R$)	R$98,842.88	
ICER (R$/QALY gained)	**–R$4,330/QALY (dominant)**	
SUS acceptability threshold (3× GDP per capita, 2024)	~R$132,000/QALY	
Utility sources	DR: Ben et al. 2020 · Glaucoma: Paletta Guedes et al. 2014 · AMD: Nunes et al. 2020 · Cataract: Brown et al. 1999	

Effectiveness and dominance

Mean time to diagnosis in the teleophthalmology pathway was 1.26 days (30.26 ± 23.04 hours), derived directly from primary data. Estimated time to diagnosis via standard SUS referral was 83 days, based on SISREG/MS 2024 national regulatory wait-time data. Teleophthalmology was simultaneously less costly (R$50.64 vs R$70.82 per detected case) and more timely (1.26 vs 83 days to diagnosis), constituting absolute dominance. The ICER was not calculated, as dominance renders it undefined. Across all sensitivity analysis scenarios, including regulatory wait times as low as 30 days and equipment costs as high as R$40,000, absolute dominance was maintained. For teleophthalmology to cease being less expensive than the standard pathway under diagnostic equivalence, equipment unit cost would need to exceed R$1,700,000, approximately 64 times current market price.

QALY scenario analysis

A total of 376 patients with confirmed diagnoses of DR (n = 177), suspected glaucoma (n = 137), cataract (n = 46), and AMD (n = 16) were included in the QALY analysis. The estimated total QALYs gained through early versus delayed detection was 22.825. Combined with the total cost saving of R$98,842.88 for this cohort, the ICER was –R$4,330 per QALY gained, indicating simultaneous cost savings and health gains. This value falls well below the SUS acceptability threshold of approximately R$132,000/QALY. This

analysis should be interpreted as exploratory, as utility coefficients were derived from published literature rather than prospectively measured in study participants.

Acceptability

Healthcare professionals (n = 13) rated the teleophthalmology platform with a mean SUScale score of 90.96 ± 5.91 (95% CI: 87.39–94.53), classified as “Excellent” per established benchmarks. No professional scored below the acceptability threshold of 70, and 61.5% achieved scores of 90 or above. Items related to ease of use obtained the highest mean scores, while the item addressing need for technical support showed the greatest variability (2.08 ± 1.12), reflecting individual differences in digital familiarity. Patients (n = 99) reported a mean TUQ-Brazil score of 6.61 ± 0.32 out of 7.00 (range 5.50–7.00). The highest-scoring item was item 2, addressing time and travel savings (6.80 ± 0.51), with 97.0% scoring 6 or 7. In the satisfaction and future use domain, 93.9% indicated willingness to reuse the service and 92.9% reported satisfaction with the system. Complete item-level results are provided in Additional files 2 and 3.

Discussion

This study demonstrates that teleophthalmology-based active ophthalmic screening in semi-urban primary care is absolutely dominant over the standard SUS passive referral pathway: it costs less per detected case and delivers diagnosis substantially faster. The 81.7-day reduction in time to diagnosis is clinically meaningful, as all major conditions detected are progressive and time-sensitive, with delayed diagnosis directly associated with worse visual outcomes and higher downstream treatment costs.[3]

A distinctive structural feature of the teleophthalmology model is that 55.89% of screened patients received a normal result and were discharged directly at the UBS, avoiding unnecessary specialist referrals. This triage function is intrinsic to active screening and structurally absent from the passive referral model. The majority of abnormal cases detected were asymptomatic patients, primarily those with early-stage DR, suspected glaucoma, and pre-symptomatic AMD, who would not have spontaneously sought specialist care, representing diagnostic value that the standard referral model cannot generate.

The QALY scenario analysis reinforces this conclusion from a complementary methodological angle. An ICER of –R$4,330 per QALY gained represents simultaneous cost savings and health gains, placing this intervention in a position of absolute dominance also when outcomes are expressed in quality-adjusted life years. This value is approximately 30 times below the SUS acceptability threshold, providing a robust policy basis for adoption even under conservative utility assumptions.

The role of artificial intelligence warrants explicit discussion. The RedCheck platform uses AI for image quality pre-screening, case prioritisation, and automated segmentation of retinal lesions including exudates, haemorrhages, and microhaemorrhages. This segmentation function supports specialist detection of subtle findings that may be missed on unassisted review, a clinically relevant capability

illustrated in Fig. 2. Diagnostic decisions were made exclusively by human specialists. A formal disaggregation of the incremental cost of the AI component was not conducted, as the platform is licensed as an integrated service. Future studies should evaluate the marginal cost-effectiveness of AI-assisted versus non-AI-assisted teleophthalmology models.

These findings align with international evidence. Coronado et al. reported teleophthalmology dominance in a Canadian semi-urban pharmacy-based setting,[6] and Ortiz-Toquero et al. demonstrated cost-effectiveness in a rural Spanish primary care model.[7] In the Brazilian context, Ben et al. found systematic teleophthalmology-based DR screening to be very cost-effective,[10] and Meira et al. confirmed operational feasibility in Brazilian primary care.[11] The present study extends this evidence to a multi-disease, semi-urban, non-physician-operated active screening model, a context not previously studied in Brazil and directly relevant to the majority of SUS municipalities.

High bilateral acceptability strengthens the implementation argument. The SUScale score of 90.96 among professionals indicates low operational barriers to adoption. The pattern of item-level variability, technical support need scoring most variably, points to a clear implementation requirement: structured and ongoing training rather than one-time onboarding. The TUQ-Brazil results reveal that the primary value perceived by patients was time and travel savings (item 2, mean 6.80), consistent with the semi-urban context where specialist access requires displacement to reference centres. Professional usability at this level is a known predictor of technology adoption and sustained use in primary care digital health contexts.[17] Patient willingness to reuse the service at 93.9% indicates that the teleophthalmology model does not compromise the care experience.

Several limitations should be noted. The convenience sampling approach may have introduced selection bias, potentially overestimating screening yield relative to a fully population-based programme. The 83-day comparator wait time was derived from national SISREG data and may not reflect local regulatory conditions precisely; a contemporaneous local control group was not available. The analysis covers the detection phase only; downstream treatment costs and long-term clinical outcomes were not captured due to restricted access to patient records, and time to treatment initiation was not directly measured. Sensitivity and specificity of the AI-assisted reporting platform were not independently validated. The QALY scenario analysis relied on literature-derived utility coefficients and should be interpreted as exploratory. The study was conducted in a single municipality, which may limit generalisability. Future research should examine long-term clinical outcomes, incorporate prospective utility and diagnostic accuracy measurement, and test this model in additional semi-urban municipalities.

Conclusions

Teleophthalmology-based active ophthalmic screening in semi-urban primary care demonstrated absolute dominance over the standard SUS passive referral pathway, delivering earlier diagnosis at lower cost per detected case. High bilateral acceptability among both healthcare professionals and patients supports the operational feasibility and scalability of this model within the SUS. These findings provide

actionable evidence for policymakers and health managers considering the integration of portable fundus camera technology and AI-assisted teleophthalmology into primary care networks, particularly in semi-urban Brazilian settings where specialist access gaps are most pronounced.

Abbreviations

AMD
Age-related macular degeneration
AI
Artificial intelligence
ANVISA
Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency)
DATASUS
Departamento de Informática do SUS
DR
Diabetic retinopathy
ICER
Incremental cost-effectiveness ratio
IBGE
Instituto Brasileiro de Geografia e Estatística
QALY
Quality-adjusted life year
SD
Standard deviation
SIA
Sistema de Informações Ambulatoriais
SIGTAP
Sistema de Gerenciamento da Tabela de Procedimentos, Medicamentos e OPM do SUS
SISREG
Sistema Nacional de Regulação
SUScale
System Usability Scale (Brazilian-validated version)
SUS
Sistema Único de Saúde (Brazilian Unified Health System)
T2DM
Type 2 diabetes mellitus
TUQ-Brazil
Telehealth Usability Questionnaire – Brazil
UBS
Unidade Básica de Saúde (Primary Health Care Unit)

Declarations

Ethics approval and consent to participate

This study was approved by the institutional research ethics committee of the Universidade do Estado do Rio de Janeiro (CAAE: 92229925.1.0000.5282, Opinion No. 7.924.608). All procedures were conducted in accordance with the Declaration of Helsinki and Brazilian Resolution CNS 466/2012. Written informed consent was obtained from all individual participants included in the study.

Consent for publication

Written informed consent for the publication of deidentified personal and clinical details was obtained from all individual participants included in the study. Retinal images presented in Fig. 2 were published with specific written consent for image publication, obtained under the study ethics protocol (CAAE: 92229925.1.0000.5282). No directly identifying information is reported.

Competing interests

The teleophthalmology reporting platform (RedCheck) used in this study was provided as part of the service implementation in the participating health units. RedCheck had no role in study design, data collection, data analysis, interpretation of results, or the decision to submit this manuscript for publication. Phelcom Technologies provided equipment access through a loan agreement under the same conditions. No financial compensation was received from either company by any author. L.E.C.L. declares an affiliation with RedCheck and Phelcom Technologies through the service implementation agreement, which is formally disclosed herein. D.V.A., A.C.T., R.S., A.A.M.R., and L.B.F. declare no competing interests.

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Author Contribution

L.E.C.L. conceived and designed the study, collected primary data across all eight participating health care units, performed the economic modeling and statistical analysis, and wrote the main manuscript text. D.V.A. and A.C.T. supervised the research as principal and co-supervisor respectively, contributed to the conceptual framework of the economic evaluation, and critically reviewed all manuscript versions. R.S. provided scientific consultancy on artificial intelligence applications in ophthalmology, contributed

to data processing methodology, and reviewed the manuscript. A.A.M.R. provided specialist consultancy in retinal disease diagnosis, contributed to the clinical interpretation of screening findings, and reviewed the manuscript. L.B.F. contributed to data acquisition by conducting patient interviews for the acceptability assessment and ensured informed consent was properly obtained and documented across all study participants. All authors read and approved the final manuscript.

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Data Availability

The datasets generated and analysed during the current study are not publicly available due to ethical restrictions protecting participant confidentiality, in accordance with Brazilian Resolution CNS 466/2012 and the General Data Protection Law (Lei Geral de Proteção de Dados, Law No. 13.709/2018). Data were collected under ethics approval (CAAE: 92229925.1.0000.5282) and participant consent was obtained exclusively for research purposes within the approved protocol. Aggregate data supporting the findings of this study are available from the corresponding author upon reasonable request and subject to institutional approval.

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Figures

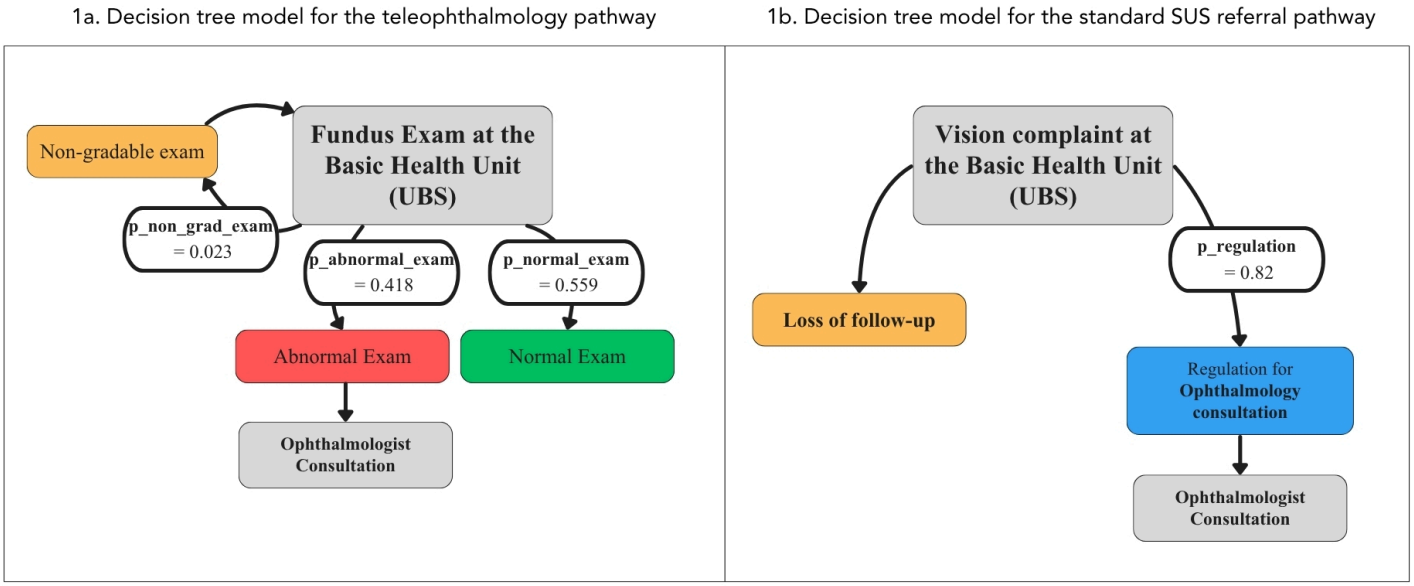


Figure 1

Decision tree models for the teleophthalmology pathway (1a) and the standard SUS referral pathway (1b). In the teleophthalmology arm, patients undergo portable fundus camera examination at the primary health care unit; outcomes are classified as normal (p=0.559), abnormal (p=0.418), or ungradable (p=0.023). In the standard SUS referral arm, patients enter the SISREG regulatory queue following initial clinical consultation; the probability of completing the referral pathway is 0.82, with 0.18 lost to follow-up. UBS: primary health care unit; SUS: Brazilian Unified Health System; SISREG: National Regulatory System.

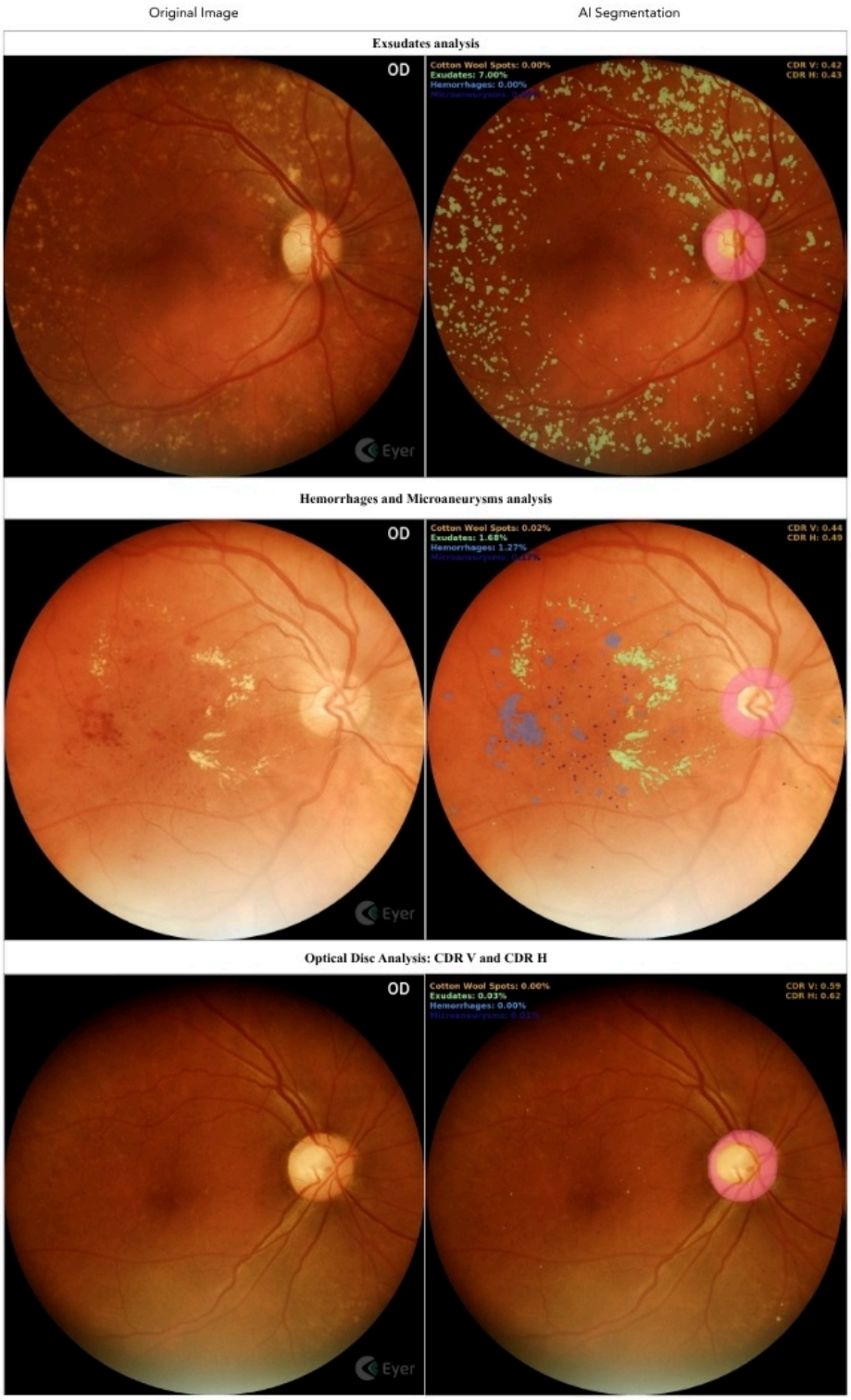


Figure 2

Representative retinal fundus images captured with the Phelcom Eyer portable non-mydriatic fundus camera, shown without (left column) and with (right column) AI-assisted segmentation generated by the RedCheck platform. Row A: exudate analysis showing extensive hard exudates (green overlay) and cup-to-disc ratio measurement (CDR V: 0.42 / H: 0.43). Row B: haemorrhage and microaneurysm analysis showing colour-coded overlays for haemorrhages (light blue) and microaneurysms (dark blue), with

exudates (green). Row C: optical disc analysis showing automated cup-to-disc ratio calculation (CDR V: 0.59 / H: 0.63) to support glaucoma screening. All segmentation maps were reviewed by specialist ophthalmologists prior to issuing the diagnostic report. Images published with patient consent obtained under ethics protocol CAAE: 92229925.1.0000.5282. CDR: cup-to-disc ratio; AI: artificial intelligence.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.jpg
- Table3.jpg
- Table2.jpg
- AdditionalFile2SUScale.docx
- AdditionalFile3TUQBrazil.docx