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Exploring the Feasibility of Opportunistic Diabetic Retinopathy Screening with Handheld Fundus Cameras in Primary Care: Insights from Doctors and Nurses

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Abstract: Aims: This study aims to assess the perspective of doctors and nurses regarding the clinical settings and barriers to implementing opportunistic diabetic retinopathy screening with handheld fundus cameras. Design: This study was a cross-sectional, online questionnaire study. Methods: An online survey was distributed to doctors and nurses working in Portuguese primary care units and hospitals between October and November 2021. The survey assessed current fundus observation practices, potential contexts, and barriers to using handheld fundus cameras. Results: We received 299 eligible responses. About 87% of respondents (n = 255) believe in the clinical utility of handheld fundus cameras to increase patients' access to diabetes-related retinopathy screening, and 74% (n = 218) attribute utility to identify other eye or systemic diseases. More than a third of participants (37%, n = 111) envisioned using such devices multiple times per week. The main potential barriers identified included limited time (n = 90), equipment cost (n = 48), or the lack of skills in retinal image acquisition (n = 47). Most respondents (94%, n = 275) expected a follow-up recommendation to accompany the telemedicine diagnosis. Conclusions: Doctors and nurses support the use of handheld fundus cameras. However, to optimize their implementation, some strategies should be considered, including training, telemedicine-based diagnosis, and support for follow-up through accessible, user-friendly, and efficient information systems.

Keywords: diabetic retinopathy; diabetic macular edema; eye fundus camera; techniques of retinal examination; screening; telemedicine

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1. Introduction

Almost 35% of people with diabetes will develop diabetes-related retinopathy (DR), a sight-threatening disease that is avoidable through early diagnosis and treatment [1–3]. Systematic screening for DR is recommended, consisting of yearly eye fundus examinations [4–6]. However, the screening adherence rates are suboptimal, ranging between 61% and 89% [7,8].

2. Background

Recent research, including a study by our research group [9–15], suggests that doctors and nurses caring for people with diabetes in primary care, or endocrinology/diabetology/internal medicine departments may use handheld fundus cameras during routine appointment visits to reach people who miss traditional DR screenings. This would benefit 11% to 39% of individuals with diabetes [7], increasing their access to this potentially sight-saving exam [5]. The majority of people with diabetes are followed in primary care [16], suggesting this setting is the most adequate to perform opportunistic screenings, potentially increasing the coverage rate of the DR screening, as has been the case in other population screenings. For example, opportunistic breast and cervical cancer screenings are employed in parallel with organized screenings, contributing to an increase of 11% and 25% in screening coverage, respectively [17,18].

Handheld fundus cameras are emerging technologies for point-of-care retinal imaging [19]. These devices have been successfully used in low-resource countries for DR screening, in which nurses, general practitioners, and eye technicians are allocated to retinal image acquisition in community settings [12–15]. Handheld fundus cameras can be integrated into telemedicine platforms, allowing digital images to be sent electronically to ophthalmologists for remote image reading and classification, reducing the need for in-person patient visits to the hospital [15].

With a handheld fundus camera available at the clinic, doctors and nurses who are not specialists in ophthalmology might have the additional advantage of supporting the assessment of other eye conditions, e.g., cataracts and glaucoma, and screening for dementia and cardiovascular risk [9–12]. Traditional fundus ophthalmoscopy is underused by community-based doctors, internists, and neurology or emergency doctors [9,20]; thus, eye fundus examination is not performed in many cases where it would have provided important diagnostic information. The difficulty in using traditional direct ophthalmoscopes is the main reason for their limited use [10,21]. Handheld fundus cameras offer an alternative to ophthalmoscopes, as they are easier to use [9,10,20,21].

Despite the potential to improve healthcare by making eye assessments more easily and more frequently performed, to our knowledge, handheld fundus cameras are not yet implemented in routine clinical care, and no study has assessed whether doctors and nurses have considered their implementation feasible. According to implementation frameworks for innovative interventions in healthcare, operationalization factors and the perceived need for a new medical device highly influence its integration into clinical care [22–24]. Hence, understanding doctors' and nurses' perspectives is paramount in defining strategies that may support implementing eye fundus cameras in primary care.

3. The Study

Aim and Objective

The objective of the present study is to ascertain the perceived need for handheld fundus cameras for opportunistic DR screening, the adequate clinical context, and the potential operationalization factors, from the doctors' and nurses' perspectives. The results aim to help define future implementation strategies.

4. Methods

4.1. Design

This was a cross-sectional observational study applying an online survey.

4.2. Setting and Sampling

The inclusion criteria required respondents to be doctors or nurses (excluding ophthalmology specialists) who are currently or have previously been employed by the Portuguese National Health Service. We emailed all primary care units (family health units), and all health units of the Portuguese autonomous regional administration of Madeira and Azores, asking them to distribute the survey among doctors and nurses. We contacted special interest groups and professional associations focused on diabetes with the same request (Supplementary File S1), and CUF Infant Santo Hospital (currently named CUF Tejo Hospital) distributed the survey internally to all their endocrinology and internal medicine doctors. We also distributed the survey to personal contacts that fit the inclusion criteria. Given the typically low response rates from doctors and nurses due to their demanding schedules, limited time, and frequent survey requests [25,26], we also employed a snowball sampling technique to increase the expected participation of this hard-to-reach population in a time-efficient and cost-effective manner [27]. We thus requested survey respondents to disseminate the survey to others who met the inclusion criteria, through email or social media posts. Survey responses were collected between 15 October and 15 November 2021.

4.3. Data Collection

An original survey was designed to assess doctors' and nurses' perceptions of using a handheld fundus camera for DR screening in their practice and other potential uses of the camera. We chose EyeFundusScope (Fraunhofer AICOS, Porto, Portugal) [28] as an example of a handheld fundus camera, used in conjunction with screening software. The survey was reviewed by three researchers and two practicing doctors, leading to adjustments in the wording of the questions and survey flow. A preliminary survey was pilot-tested with three doctors and two nurses, who provided general feedback about the survey language and content. The final survey (Supplementary File S2) was hosted online on the SoSci Survey® platform and had 22 questions, which were grouped into five sections: (1) introduction; (2) sociodemographic and professional characteristics; (3) observation of the fundus of the eye; (4) contexts of use of EyeFundusScope; and (5) potential impact and barriers.

4.4. Sample Size and Data Analysis

The sample size (n = 377) was calculated based on a population size of 20.660 doctors and nurses working in primary care units, internal medicine, or endocrinology [29,30], a confidence level of 95%, and a margin of error of 5% using the Survey System sample size calculator [31]. A Microsoft Excel® file with the data was exported from the SoSci Survey® and uploaded into the Statistical Package for the Social Sciences software® (SPSS® version 28.0, IBM Corp., Armonk, NY, USA), which was used for statistical analysis. Incomplete survey responses were excluded from the study. Responses to closed or multiple-choice questions were presented as frequencies. Responses to open questions were analyzed using thematic analysis [32] by two researchers who independently assigned responses to themes, with disagreements discussed and resolved through consensus.

4.5. Ethical Considerations

This study was approved by the Ethics Committee of Hospital CUF Infante Santo (currently named Hospital CUF Tejo) in Portugal on 21 December 2019. Participation in this study was voluntary. Before responding to the online questionnaire, participants were asked for electronic informed consent, and it was only possible for participants to proceed with the online questionnaire after providing informed consent. Survey responses were anonymized. The study was performed in accordance with the ethical principles of the Declaration of Helsinki. Participants' data were collected, processed, and analyzed according to the recommendations of the European General Data Protection Regulation (GDPR), ensuring proper privacy and protection of personal data.

5. Results

5.1. Sociodemographic and Professional Characteristics

A total of 299 complete survey responses were received (Table 1). The response rate was not computed due to the use of snowball sampling.

Table 1. Sociodemographic and professional characteristics.

	Complete Sample (*n* = 299)
	***n* (%)**
Gender	
Female	230 (77%)
Male	69 (23%)
Nonbinary	0 (0%)
Age	
20–30	30 (10%)
31–40	114 (38%)
41–50	90 (30%)
51–60	30 (10%)
61–70	35 (12%)
Profession	
Doctor	158 (53%)
Nurse	141 (47%)
Professional experience in years	
<5	31 (10%)
5–10	55 (19%)
11–20	103 (34%)
21–30	60 (20%)
>30	50 (17%)
Specialty	
No	100 (33%)
Yes	199 (67%)
Medical Specialty *	
Endocrinology	3 (2%)
General and Family Medicine	96 (48%)
General Surgery	1 (0%)
Immunohematology	1 (0%)
Intensive Care	1 (0%)
Internal Medicine	18 (9%)
Obstetrics/gynecology	2 (1%)
Occupational Health	1 (0%)
Pediatrics	6 (3%)
Physical Medicine and Rehabilitation	1 (0%)
Public Health	7 (4%)
Rheumatology	1 (0%)
Not specified	3 (2%)
Nurse Specialty	
Child Health	5 (2%)
Family Health	1 (0%)
Medical/Surgical	5 (2%)

Table 1. *Cont.*

	Complete Sample (*n* = 299)
	n (%)
Mental Health and Psychiatry	4 (2%)
Obstetrics	11 (6%)
Public Health	20 (10%)
Rehabilitation	8 (4%)
Not specified	4 (2%)
Workplace	
Public sector clinic	281 (94%)
Private sector clinic	29 (10%)
Social sector clinic	5 (2%)
Other	4 (1%)
Distance to the nearby hospital with an ophthalmology clinic (Km) **	
P25	5
Median	12
P75	24

*: *n* = 199; **: *n* = 268.

5.2. Observation of the Fundus of the Eye

Practices of observation of the fundus of the eye are summarized in Table 2. In sum, 70% (n = 209) considered eye fundus examination an essential part of the physical examination, yet 82% (n = 244) never performed it in their practice. More doctors than nurses considered eye fundus observation important (p = 0.041). There were no significant differences between nurses and doctors in eye fundus observation (p = 0.457) or doubts in retinal image interpretation (p = 0.182). For these analyses, the categories were dichotomized: for frequency of eye fundus observation, multiple times a week and multiple times a day in one category, and once or twice a week/month/semester/year and never in another category; for doubts in retinal image, never have doubts and doubts in about once in 4 examinations in one category, and 2/3 in 4 examinations, always and not perform fundus examination in another category.

Table 2. Eye fundus examination practice and clinical contexts for the use of EyeFundusScope.

Eye Fundus Observation	Nurses (*n* = 141)	Doctors (*n* = 158)	Complete Sample (*n* = 299)	*p*
			n (%)	
Do you consider it important in your clinical practice to be able to perform eye fundus observation as part of the physical examination of your patients?				0.041 *
Yes (e.g., diabetic retinopathy, glaucoma, cardiovascular risk, hypertensive retinopathy, retinal venous occlusion, macular degeneration, dementia)	90 (64%)	119 (75%)	209 (70%)	
No	27 (19%)	26 (17%)	53 (18%)	
			n (%)	
I do not know	24 (17%)	12 (8%)	37 (12%)	
Before the pandemic, how often did you observe eye fundus in your clinical practice?				0.457 **

Table 2. *Cont.*

Eye Fundus Observation	Nurses (*n* = 141)	Doctors (*n* = 158)	Complete Sample (*n* = 299)	*p*
			***n* (%)**	
Never	136 (97%)	108 (68%)	244 (82%)	
Once or twice a year	1 (1%)	25 (16%)	26 (9%)	
Once or twice a semester	0 (0%)	11 (7%)	11 (4%)	
Once or twice a month	2 (1%)	8(5%)	10 (3%)	
Once or twice a week	0 (0%)	5 (3%)	5 (2%)	
Multiple times a week	1 (1%)	0 (0%)	1 (0%)	
Multiple times a day	1 (1%)	1 (1%)	2 (1%)	
How often do you doubt how to interpret the images you see from the retina?				0.182 **
Not applicable because I have never performed a fundus examination	121 (86%)	82 (52%)	203 (68%)	
I never have doubts	0 (0%)	0 (0%)	0 (0%)	
I have doubts about 1 out of 4 examinations	2 (1%)	6 (4%)	8 (3%)	
I have doubts about 2 out of 4 examinations	2 (1%)	8 (5%)	10 (3%)	
I have doubts in 3 out of 4 examinations	0 (0%)	10 (6%)	10 (3%)	
I always have doubts	16 (11%)	52 (33%)	68 (23%)	

*: Pearson's chi-square test; **: Fisher's exact test; *p*: level of significance = 0.05.

5.3. Clinical Context for the Use of EyeFundusScope

Participants considered doctors the most qualified healthcare professionals to use handheld fundus cameras (69%, $n = 206$) and suggested integrating eye fundus acquisition tasks into their workflow (62%, $n = 184$), as shown in Figure 1.

Figure 1. Healthcare professionals who would be better qualified to integrate EyeFundusScope into clinical workflow.

If EyeFundusScope was available today, 60% ($n = 180$) of participants say they would use it regularly at their offices (Table 3). However, 11% ($n = 33$) indicated they would rarely use EyeFundusScope (once or twice a semester or month), and 15% ($n = 46$) would never use it. A comparative analysis was conducted between nurses and doctors; significant differences were found in the frequency of use of EyeFundusScope ($p < 0.001$).

Table 3. Frequency and clinical contexts for the use of EyeFundusScope.

Use of EyeFundusScope	Nurses (n = 141)	Doctors (n = 158)	Complete Sample (n = 299)	p
			n (%)	
If EyeFundusScope were available starting today in your office(s), how many visits would you use it for to observe the fundus of the eye?				<0.001 *
Never	27 (19%)	19 (12%)	46 (15%)	
Once or twice a semester	10 (7%)	4 (3%)	14 (5%)	
Once or twice a month	4 (3%)	15 (10%)	19 (6%)	
Once or twice a week	13 (9%)	28 (18%)	41 (14%)	
Multiple times a week	44 (31%)	67 (42%)	111 (37%)	
Multiple times a day	16 (11%)	12 (8%)	28 (9%)	
In your opinion, in what type of clinical appointment or service could EyeFundusScope be used to increase the reach of screening for diabetic retinopathy?				
Follow-up visits unrelated to diabetes with doctors and nurses at primary care units (e.g., health check-ups, family planning appointments, etc.)	46 (33%)	38 (24%)	84 (28%)	0.100 *
Diabetes follow-up visits with **a family doctor, family nurse, or equivalent**	99 (70%)	119 (75%)	218 (73%)	0.322 *
Diabetes follow-up visits with internists, endocrinologists or diabetologists	61 (43%)	77 (49%)	138 (46%)	0.343 *
No context	3 (2%)	6 (4%)	9 (3%)	0.310 **
Another context	3 (2%)	14 (9%)	17 (6%)	0.012 *

*: Pearson's chi-square test; **: Fisher's exact test; p: level of significance = 0.05.

For the majority of participants (73%, n = 218), visits to the medical doctor and nurse in primary care units related to diabetes follow-up were ideal for opportunistic screening. A small number of participants (n = 17) also mentioned other clinical contexts: appointments with a dedicated professional, such as an orthoptist or orthoptic technician (n = 3), or another professional dedicated to this task (n = 1); within DR screening programs in the primary care units as an alternative to traditional desktop fundus cameras, by ophthalmologists (n = 2); and hypertensive crises or sudden vision changes (n = 2) and follow-up appointments for arterial hypertension (n = 1). No significant differences between nurses and doctors were found in the type of clinical appointments to use EyeFundusScope to increase the reach of screening for DR (p > 0.05). Significant differences were found only for another context for using EyeFundusScope (p = 0.012).

Handheld fundus cameras like EyeFundusScope would be a useful clinical tool in the Portuguese national health service (in both primary care units and hospitals), according to 95% of participants (n = 279). Similarly, 86% of respondents (n = 253) indicated that EyeFundusScope would be helpful in the private and social health sectors. Thematic analysis (Supplementary File S3) showed that the main reasons for use, from the respondents' perspective, were (1) increased access to screening and (2) a faster diagnosis. A lack of time and a lack of adequate skills were pointed out as the main reasons for not using EyeFundusScope in the primary care units of the public sector. Respondents also thought that screening should be offered in the public sector and that there are enough practicing ophthalmologists in the private/social sector; therefore, there is no need for alternative screening methods.

The median time considered adequate for the return of the ophthalmologist's response with an assessment of the fundus images was 8 days (P25 = 5 days and P75 = 30 days).

There was a seeming consensus (94%, n = 275) that the telemedicine-based response from the ophthalmologist to the doctor should include recommendations for follow-up care. None of the participants considered this information unnecessary, and 18 participants (6%) were unsure whether this information would be needed.

5.4. The Potential Impact of Using EyeFundusScope in Clinical Practice

The potential impact of using EyeFundusScope in healthcare is presented in Figure 2 and Supplementary File S4. Most respondents (87%, n = 255) agreed or strongly agreed that EyeFundusScope would help screen people with diabetes who fail to attend screening appointments and extend opportunities for screening in remote areas (87%, n = 257), to people with reduced mobility (94%, n = 277), and people living in prisons (85%, n = 249). Most respondents also agreed or strongly agreed (75%, n = 220) that doctors accompanying people with diabetes could use retinal images to discuss the patients' case with an ophthalmologist.

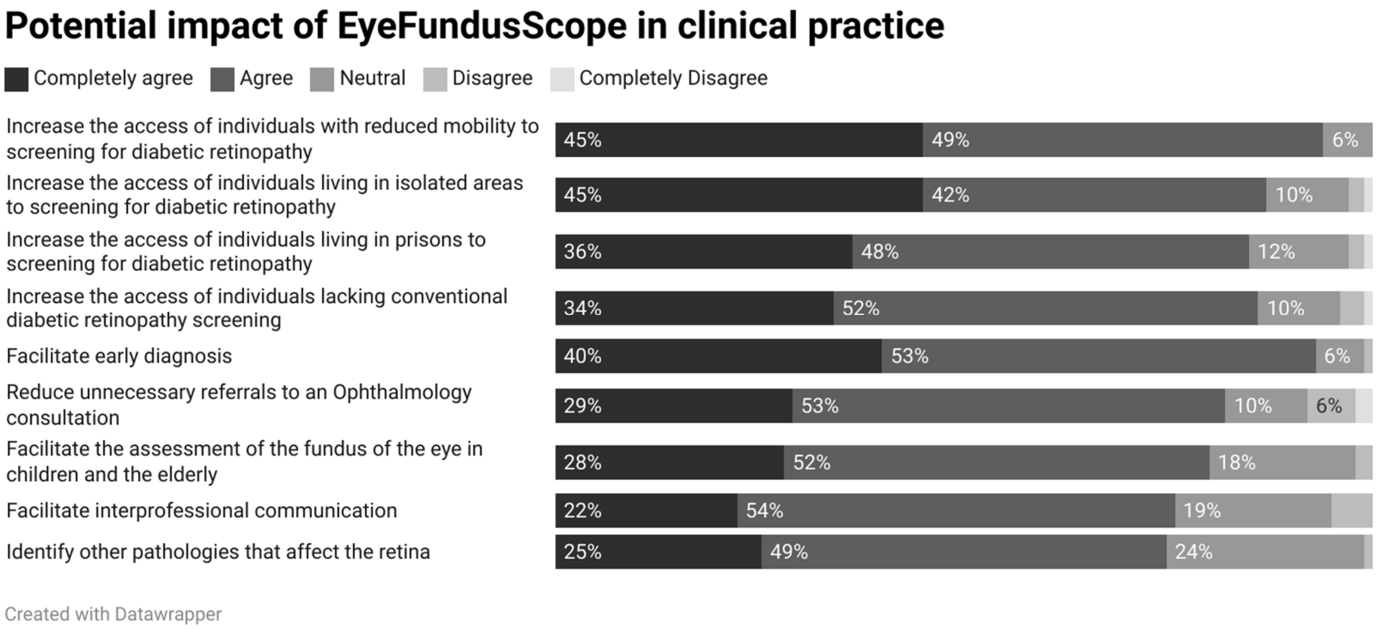

Figure 2. The potential impact of EyeFundusScope in clinical practice.

Most participants (74%, n = 222) also agreed or strongly agreed on the benefit of handheld fundus cameras in identifying other pathologies that affect the retina (e.g., glaucoma, hypertensive retinopathy, cardiovascular risk, or dementia). Making images of the retina with EyeFundusScope at any medical office would facilitate early diagnosis (93%, n = 279, agreed or strongly agreed) and decrease unnecessary referrals to ophthalmology (82%, n = 245, agreed or strongly agreed). Likewise, participants agreed that EyeFundusScope would facilitate the assessment of the fundus of the eye in children and older adults because they do not need to remain still for as long as they do with an ophthalmoscope (80%, n = 238).

5.5. Barriers to Implementation of Eye Fundus Observation with EyeFundusScope

The thematic analysis of the 180 answers (103 from doctors and 77 from nurses) resulted in nine themes corresponding to nine barriers identified (Table 4).

Table 4. Barriers to implementation of retinal imaging in routine care: thematic analysis of participants' quotes.

Main Themes	Sub-Themes	Explanation	Illustrative Quotes
Lack of time (*n* = 90)	Image acquisition	Lack of time for doctors and nurses to perform image acquisition.	"Consumption of more time in appointments, with professionals already overloaded with tasks". "Time constraints in medical and nursing appointments".
	Image classification	Ophthalmologists could not manage this additional task, with some respondents anticipating delays in receiving feedback from the ophthalmologist.	"It would be necessary for some ophthalmologists to be available 100% of the time for this task. Lack of hospital response".
Cost (*n* = 48)		The cost of handheld fundus cameras, including their acquisition, maintenance, and operation.	"Financial barriers, device acquisition, maintenance, and operation costs". "It should be an expensive device".
Need for training (*n* = 47)	Use of handheld fundus cameras and interpretation of images	This included training on the use of mobile fundus cameras and how to interpret retinal images.	"Barriers to learning curves in new technologies, particularly telehealth: generation, export, and electronic delivery of generated files". "There is a need for training in interpreting suspicious fundoscopy images by health professionals not specialising in ophthalmology." "There must be adequate training to enable professionals to use the equipment correctly".
	Software		"Would it be necessary to have the software available on the PCs for the images to pass directly from EyeFundusScope to the PC and directly to Alert [EHR software name]? Or how would the photos be sent to colleagues in ophthalmology?"
	Device storage and maintenance		"(. . .) storage [of the device]".
Number of devices (*n* = 28)	Number of devices available in each healthcare unit	Clinicians expected to need time to get out of the office, find the camera, return to the office, and put the device back in place after acquiring images in scenarios where a device was shared with a group of clinicians from the unit.	"Depending on the number of devices used in each context, it may disrupt workflows". "I foresee a barrier if one of these devices is not assigned to each functional unit. If there is one per ACeS [primary healthcare unit], we are still limited in time for its availability". "If there is one device for each building with several units (as was done with cameras for sending photos for teledermatology appointments), the time to look for the device and return it alone consumes half or more of the appointment time".
	Number of devices at a national level	Enough devices to escalate the initiative at a national level.	"Device availability to reach all regions".
Organization (*n* = 19)		Healthcare units are not adequately prepared with coordination mechanisms between specialities and a clear referral pathway to guide patient follow-up.	"(. . .) the organisation of a circuit between institutions that functions properly". "We need to establish action protocols". "We must create a new care network that integrates every part of the process".

Table 4. *Cont.*

Main Themes	Sub-Themes	Explanation	Illustrative Quotes
Software (*n* = 13)		Having another different platform that is not integrated with existing health information systems.	"Platform or registration in SClinico [healthcare information system in use] of the result so that the information is centralised".
		Manually transferring the images from the camera to the computer and then uploading images to a referral system.	"How are images acquired and sent to services? It may not be a barrier if it does not depend on the professional, but if it depends on it, it will undoubtedly be (e.g., teledermatology)".
		Technical hurdles and need to be more intuitive, easy, and quick software navigation.	"(. . .) network problems in sending the image".
Professionals' non-adherence (*n* = 10)		Professionals' non-adherence—either related to resistance to change or a lack of financial incentives.	"Change of habits and routines is often poorly understood by professionals". "There is no additional financial incentive".
Clinical validation and certification (*n* = 6)		Demonstrate the new medical device's clinical effectiveness, cost–benefit, security, and certification.	"As it is a new technology in the health market, the risks and benefits, costs and results obtained with the new technology and scientific certification must be better evaluated. I think".
Lack of patient cooperation (*n* = 2)		Lack of patient cooperation during image acquisition (e.g., maintaining a sitting position, fixating on the spot, and not moving their eyes).	"Patient cooperation". "Patients' non-adherence".

5.6. Main Barriers

5.6.1. Lack of Time

The most critical barrier (*n* = 90) was the lack of time for professionals to acquire images during routine clinical care and for ophthalmologists to classify the images. Doctors predominantly identified this barrier (*n* = 57 vs. *n* = 33). Our respondents believe that opportunistic screenings would increase the workload of already busy professionals. Doctors and nurses often have tight schedules with no spare time for acquiring fundus images, transferring and sending photos to an ophthalmologist, seeing results, and managing the treatment or referral to the ophthalmologist. Furthermore, respondents suspected that more images to be analyzed by ophthalmologists could delay the diagnosis.

5.6.2. Cost

In the view of 48 respondents (28 nurses and 20 doctors), mobile eye fundus cameras can be costly to the healthcare system. According to them, the cameras' acquisition value and operation and maintenance costs may be a significant barrier.

5.6.3. Lack of Training

The third most mentioned barrier (*n* = 47) was the need for training. Participants (29 doctors and 18 nurses) considered that professionals should receive training in interpreting retinal images and operating a fundus camera, including basic operating instructions to set up the device, acquire images, and store and recharge the device. Another critical aspect to cover is how to use the software, for example, sending the photos to the ophthalmologist.

6. Discussion

6.1. Principal Findings

We found that doctors and nurses consider that handheld fundus cameras used opportunistically in primary care would increase the coverage of DR screening. Diabetes-related follow-up appointments would be the most suitable context to reach more people, and a teleophthalmology service would have to be provided to support doctors and nurses with remote diagnosis and guidance on patient management. However, our respondents expressed concerns about the capacity of the healthcare system to acquire handheld fundus cameras due to their costs. Furthermore, according to them, the added time and the need for more skills in image acquisition would pose significant challenges.

To our knowledge, only one study has investigated the possible barriers to implementing handheld fundus cameras in routine primary care [33]. The identified barriers in that study were similar: time, financial factors, and training, which are also commonly reported in implementing technology at the point of care [34,35].

Successful organizational changes in healthcare are characterized by the professionals' perceived need for the change, including the benefit for the patients; being prepared for the change; and having the opportunity to influence the shift [24]. Our study demonstrates that doctors and nurses perceive the need for opportunistic DR screening in diabetes follow-up appointments with handheld fundus cameras but do not feel prepared. Nevertheless, participants stressed the need for training, the lack of time, and equipment costs.

Training in image acquisition should be provided to address the need for more skills. Also, since the difficulty of non-ophthalmology specialists in interpreting images in fundus observation was expressed by our respondents—and reported in previous studies [36]—handheld fundus cameras must be provided in conjunction with a telemedicine-based service. In a recent survey conducted in Germany, an Artificial Intelligence (AI) diagnosis was proposed in conjunction with a smartphone-based screening of DR [33]. Still, doctors mentioned negative attitudes toward AI in that study [33]. In our context, as AI is already in place in DR screening (Central Regional Health Administration), providing AI-based classification of images acquired with handheld fundus cameras seems feasible.

Additional time spent on examinations is often a significant concern among doctors and nurses in implementing interventions with new medical technologies [33,37]. Nevertheless, doctors have successfully accommodated opportunistic cervical cytology [18] and teledermatology [38,39] in primary care. Eye fundus examination with a handheld fundus camera potentially fits well in the care pathway, as it could be integrated into the regular assessments of people with diabetes, along with blood pressure and blood sugar assessments. The clinical workflow may only be affected by the increased length of a diabetes appointment with an estimated increase in time of $2.5 +/- 1.7$ min [15]. Since not all people with diabetes will need an opportunistic screening, this might not significantly impact the overall schedule for the day. In a future pilot study, the additional time added to the patient's appointment, the number of patients screened each day, and the total number of appointments per day should be collected to assess the impact on schedules. A relevant factor for implementation that has an impact on time is the integration of electronic health records (EHRs), which aligns with the literature [33,40].

The acquisition and maintenance costs of handheld fundus cameras cannot be denied, and in the view of our respondents, would be a significant barrier. However, we need to find out if respondents had the potential cost-effectiveness taken into consideration or if it was considered relevant. The impact of two interventions in healthcare can be better ascertained through the estimation of cost-effectiveness. In this case, we would consider the costs and the clinical outcomes of opportunistic DR screening. We would need information such as the proportion of more advanced DR cases in patients undergoing opportunistic screening and the treatment costs of those patients compared to patients who miss the recommended screening appointments and consequently require treatment for more advanced DR. If handheld fundus cameras replace ophthalmoscopes, more efficient utilization is anticipated.

We found that the availability of handheld fundus cameras in clinical offices can change the practice of medical doctors and nurses, increasing eye fundus examinations from 19% to 84%. The utility of handheld fundus cameras in primary care goes beyond DR screening: our respondents recognized their utility in assessing several systemic conditions and eye diseases other than DR [9,10,20,21]. Several studies have reported that traditional fundus ophthalmoscopy is underperformed by community-based doctors [9,20], which is confirmed by our study. The underuse of the ophthalmoscope can be explained by doctors' difficulty using this device [10,21]. Using a mobile fundus camera can help reduce the number of unnecessary referrals to ophthalmology, reducing costs with hospital appointments and patients' transportation. The fact that our respondents work in healthcare units with a mean distance of 12 km (5–24) from an ophthalmology clinic may have contributed to the perceived value of fundus imaging being performed at their offices in situations other than DR screening. It would allow them to prevent patients from traveling that distance to the hospital.

Despite the potential to replace ophthalmoscopes at primary care offices, handheld fundus cameras were not among the several point-of-care tests reported as helpful in primary care in a landmark study in Australia, Belgium, the Netherlands, the United Kingdom (UK), and the United States of America (USA) [41]. The study was conducted when there was little evidence of the diagnostic accuracy of handheld fundus cameras. Based on our study's results, we believe the response might be different today, encouraging new policy decisions about the need for handheld cameras in conjunction with telemedicine.

The fact that participants considered an 8-day wait for a test result from the ophthalmologist to be adequate suggests that they were not envisioning using handheld fundus cameras to assess potential emergencies. However, future studies might focus on those situations, as ocular fundus examination provides essential diagnostic red flags in vision or life-threatening neurologic diseases [42]. According to the literature, emergency doctors miss 13% of acute life or vision-threatening fundus pathology in direct ophthalmoscopy [43]. As a result, those patients are referred to neurology for stroke or seizure [43]. In contrast, one-third of neurocardiogenic syncope, peripheral vertigo, primary headache, and psychogenic syndromes are misdiagnosed or classified with uncertainty using direct ophthalmoscopy by emergency doctors [44]. In our study, respondents mainly work in primary care units, where many patients with those pathologies are often initially present. It is of concern that doctors reported diagnostic uncertainty in fundus examinations or did not perform fundus examinations in primary care. A mobile fundus camera may enable more rapid clinical decision-making and efficient resource utilization. The use of mobile fundus cameras and real-time telemedicine can be explored in future studies.

From the results of our study, we can expect that doctors will use handheld fundus cameras more often than nurses, as our respondents considered medical doctors to be the most qualified healthcare professionals to perform eye fundus imaging (although there was a balanced distribution between doctors and nurses in our sample). This may be because, in Portugal, an eye fundus examination with an ophthalmoscope is absent in nursing training but is considered a core competence in medical training [45,46]. Yet, our respondents considered diabetes follow-up appointments with nurses a suitable context for DR screening, similar to an Australian study [47]. All in all, we need a definition of the professionals accredited to use handheld fundus cameras. Of note, the training and practice of doctors and nurses vary by country [48,49], and nurses' successful use of handheld fundus cameras has been reported [12–15].

6.2. Future Directions and Considerations for Clinical Implementation

We recommend using this study's results to construct an organizational approach for implementing handheld fundus cameras in primary care. Establishing a training plan for doctors and nurses in each primary care unit that adheres to an opportunistic screening of DR with handheld fundus cameras is of utmost importance. Prior work recommended a four-hour training session for nurses (without previous experience in retinal image acquisition) about image protocol and acquisition procedure, led by a retina specialist, followed by five weeks of non-consecutive days of continuous remote feedback from an ophthalmologist [15]. According to the same study, over 80% of patient images were suitable for clinical decision-making from the 7th day onwards [15]. These results encourage and suggest that doctors and nurses can achieve good image quality with a training program similar to the one described. Furthermore, the potential improvement in DR screening rates may justify the training effort. Moreover, including handheld cameras in the curriculum of medical and nursing schools may decrease future implementation efforts. The same study outlined the training content: the main eye structures, the techniques for acquiring images with a handheld fundus camera—including image alignment, usable field-of-view, and image quality (focus, artifacts, and contrast)—and the use of the operating system, (e.g., storing and forwarding images) [15]. Including handheld fundus cameras in the curriculum of medical and nursing schools may decrease future implementation efforts. For compliance and quality assessment purposes, the log of each training session with trainees' and trainers' names should be recorded. The continuous monitoring of handheld fundus camera usage quality should include evaluating the percentage of images suitable for clinical decision-making and the examination duration per person. A decline in these metrics may indicate the need for personnel retraining.

Further clinical evaluations, namely, a pilot study to generate evidence of an improved patient care learning curve and the accommodation of the increased appointment length will be crucial. The dissemination of the evidence among health professionals and patients is of paramount importance. Future research could explore the cost-effectiveness of handheld fundus cameras. Their cost-effectiveness may improve if they are utilized not only for opportunistic DR screening but also for evaluating other ocular and systemic conditions. Such evidence should guide purchase decisions for handheld fundus cameras in the future.

The adaptive efforts required from healthcare units extend beyond the initial financial investment for handheld fundus cameras and personnel training. They should also encompass incentive payments to encourage the adoption by doctors and nurses; the maintenance of cameras, other hardware, and software; and the training of new staff. Smartphones must be replaced every few years, and batteries should be recharged according to the manufacturer's instructions. Each healthcare unit should establish a protocol that includes a schedule for camera recharging, replacement of smartphones and other hardware components, and software upgrades. Additionally, the protocol should incorporate a plan for training new personnel, which the device company may provide.

Using teleophthalmology and mobile health technology in medical care raises a considerable number of legal and ethical issues, from which we highlight the need to comply with both healthcare regulations and general privacy regulations, such as the GDPR in Europe, the Health Insurance Portability and Accountability Act (HIPAA) in the United States [50–52], and the international standard DICOM—Digital Imaging and Communications Exchange, Storage, and Communication of Digital Medical Images and Other Related Digital Data [53,54]. In addition, best practices in software development should be followed and include verifying safety and cybersecurity and implementing stringent privacy and security measures such as data encryption [55], which is crucial since the software with the EyeFundusScope fundus imaging cameras runs alongside a referring system for seamless integration into the health system's referral system; thus, anonymization is not possible. Informed consent is recommended to be obtained for the collection of clinical data—informing patients of the purpose, method, and duration of information storage—and for telemedicine—informing the person regarding the quality and safety and ensuring that the person can choose between teleophthalmology and an in-person evaluation by an ophthalmologist [55].

Patient satisfaction and acceptability with point-of-care fundus image and evaluation by a telemedicine-based ophthalmologist should be an important part of the assessment of introducing this technology in a primary care setting. The available studies focusing on patient satisfaction, such as the study by [56], reported high satisfaction levels. Studies on patients' perspectives regarding the immediate release of laboratory and imaging test results (excluding DR), such as the survey-based study by [57], found that most patients preferred receiving test results via a patient portal, even if it meant viewing abnormal results before discussing them with a healthcare professional and experiencing increased worry in such situations. Furthermore, a randomized controlled trial by [58] demonstrated higher patient satisfaction and confidence in point-of-care testing in general practice compared to pathology laboratory testing for three chronic conditions. The same study also highlighted that patients felt that point-of-care testing strengthened their relationship with their general practitioners. Based on the available literature, there is no evidence of patients' psychological distress or other psychological distress associated with point-of-care, telemedicine, or immediate test results; however, further research targeting DR is necessary.

6.3. Limitations

Our results may have been affected by three sources of bias: non-response bias, the snowball sampling method, and the perceived ease of use of handheld fundus cameras. Respondents, as opposed to non-respondents, may have had a prior interest in or even a positive attitude toward fundus cameras (or digital technology, in general). Additionally, because snowball sampling relies on referrals from researchers' and participants' networks (and participants are more likely to refer others with similar characteristics and experiences), our sample may not accurately represent the broader population of interest, thus limiting the study's generalizability. To minimize sample bias, we increased sample diversity by initially reaching out to units from all over the country (including the islands), and several national interest groups (Supplementary File S1).

The heterogeneity of hospital medical specialties among our respondents, with a few respondents in each specialty, limits our ability to determine in which hospital settings a handheld fundus camera would be more useful for diagnosing conditions other than diabetes-related retinopathy. Furthermore, the images depicting image acquisition might have influenced the perceived ease of use of EyeFundusScope. However, users' perceptions of the effort required to become proficient with the technology do not necessarily reflect the ease of use each professional will experience when interacting with it [59]. The existing infrastructure in primary care settings and the varying levels of technology acceptance among respondents may have influenced their responses, making them potential confounding factors. With 88% of respondents working in the public sector, their views may have been shaped by tight schedules and limited resources; indeed, time constraints and equipment costs were identified as the two main barriers. Additionally, varying levels of technology adoption, as defined by [60], also apply to medical devices. Thus, doctors and nurses who are late adopters might have focused more on the barriers of handheld fundus cameras. Furthermore, the Technology Acceptance Model (TAM) suggests that the use of technology depends on two variables: how useful the technology is perceived to be and how easily it can be employed [59]. Our study demonstrates a duality of views: while doctors and nurses recognize the value of using handheld fundus cameras for opportunistic DR screening, they also see significant potential challenges to implementing this approach.

Another potential limitation of our study is that we did not achieve the calculated sample size. Post hoc analysis indicated, however, that our sample size was sufficient to establish a margin of error of 6% instead of the 5% initially planned, which we believe will importantly warrant the relevance of our results.

7. Conclusions

Many people live with diabetes and are at risk of DR; however, they fail to attend organized DR screenings, risking vision loss and blindness [1–3]. As research has been suggesting new handheld fundus cameras to reach opportunistically these patients [9–15], it is essential to understand the requirements for its implementation in clinical settings. By surveying doctors and nurses, this study found a general perception of the need for handheld fundus cameras to optimize the coverage of DR screening. It also revealed that such devices may be the new ophthalmoscopes. A successful implementation will rely on organizational and political factors. The first is a strategic definition of the clinical setting. Primary care should be a priority due to the potential to reach many patients with diabetes, both in diabetes follow-up and in the community—at patients' homes, nursing homes, and prisons—and because handheld fundus cameras can aid clinical diagnosis in other eye diseases and systemic conditions in primary care. The second is defining the professionals accredited to use handheld fundus cameras, bearing in mind that nurses can also play an essential role with adequate training. Third, the screening platform should be integrated with EHRs and efficient communication with the ophthalmology department should be ensured.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/diabetology5060041/s1, File S1—Survey Questions; File S2—Survey Invites Sent; File S3—Some Examples of Direct Quotes, File S4—The Potential Impact of Using EyeFundusScope in Clinical Practice.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of CUF Infante Santo Hospital (currently named CUF Tejo Hospital) (approval date: 21 December 2019).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data supporting this study's findings are available from the corresponding author upon reasonable request.

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Conflicts of Interest: The authors declare the following conflicts of interest: Sílvia Rêgo and Francisco Nunes are employees of Fraunhofer Portugal AICOS (Porto, Portugal), and this institution is developing EyeFundusScope, a smartphone-based fundus camera for diabetic retinopathy screening, and a system for diabetic retinopathy screening based on deep learning. Matilde Monteiro-Soares, Marco Dutra-Medeiros, and Cláudia Camila Dias are PhD supervisors of the doctoral student Sílvia Rêgo. Still, they have no financial involvement with Fraunhofer Portugal AICOS. No other relationships or activities could appear to have influenced the submitted work. The funders had no role in the study's design or the manuscript's writing.

Abbreviations

DR	diabetes-related retinopathy
GDPR	General Data Protection Regulation
AI	Artificial Intelligence
EHRs	electronic health records
UK	United Kingdom
USA	United States of America
HIPPA	Health Insurance Portability and Accountability Act
DICOM	Digital Imaging and Communications Exchange, Storage, and Communication of Digital Medical Images and Other Related Digital Data
TAM	Technology Acceptance Model

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