

Barriers in establishing systematic diabetic retinopathy screening through telemedicine in low- and middle-income countries

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Vision-threatening diabetic retinopathy (VTDR) is one of the leading causes of impaired vision in the working-age population. Early identification, timely diagnosis, and prompt treatment of VTDR have to be tackled simultaneously to reduce the rate of blindness due to this condition. Considerable emphasis has been placed globally on establishing diabetic retinopathy screening (DRS) programs to enable early identification and referral of VTDR for treatment. However, there is an urgent need to shift from the common practice of opportunistic screening to a systematic DRS pathway to ensure that individuals with diabetes are screened at regular intervals and treated appropriately. While systematic DRS programs have been successfully established in countries such as the United Kingdom (UK), it continues to be a challenge to initiate and sustain such programs in low- and middle-income countries (LMIC), home to approximately 80% of people with diabetes. Telemedicine is widely recognized as an ideal DRS screening program. Although it has resulted in an upsurge of opportunistic screening, systematic recall of screened patients remains a challenge. In addition, the link between referred patients from the telemedicine programs to treatment centers is often not established or has failed to deliver; so, there is minimal impact of these telemedicine programs on VTDR blindness at present. This review covers the various barriers of establishing and sustaining systematic telemedicine DRS programs, especially in resource-constrained settings, and the challenges in aligning telemedicine to VTDR treatment pathways to ensure patients with VTDR are treated promptly and effectively.

Key words: Barriers, diabetic retinopathy, screening, telemedicine

The prevalence of diabetes mellitus is growing exponentially with a consequent increase in diabetes-related morbidity and mortality on a global scale.^[1] The International Diabetes Federation estimated in 2019 that there are 463 million adults with diabetes mellitus, and by 2045, it is expected to increase to 700 million.^[1] Approximately one-third of the population with diabetes develop diabetic retinopathy (DR) and 10 percent develop vision-threatening DR (VTDR), a preventable cause of blindness in working-aged people globally.^[2] These complications are mainly diabetic macular edema (DME) and proliferative diabetic retinopathy.

These complications are usually asymptomatic in the initial stages and are therefore best identified by retinal examination or retinal photography. Both these methods of identification of VTDR are not practical for systematic screening of people with diabetes. Retinal examination requires skills. While ophthalmologists and optometrists may be able to share this workload, the ratio of skilled personnel to number of people with diabetes rules this method out as a clinically and cost-effective screening strategy.^[3]

Although retinal photography in ophthalmology departments is more feasible and is more accurately recordable compared to retinal examination, this method of screening is also limited by costs and lack of skill set and is unable to

meet the demands for annual screening for an ever-increasing population of people with diabetes.

Nearly 80% of people with diabetes reside in low- and middle-income countries (LMIC).^[4] In 2010, there were only nine ophthalmologists per million population in LMIC.^[5] Despite 79 ophthalmologists per million in high-income countries during the same period, there is a global shortage of ophthalmologists.^[5] There is therefore an unmet need to identify ways to move DR screening from a service provided within ophthalmology departments in LMIC to a wider program to ensure global coverage. A meta-analysis revealed that outreach screening is an effective alternative to on-site specialist examination as it can increase screening coverage of high-risk patients with DR in remote and resource-poor settings.^[6] Moreover, a public health screening program is best done by the government to ensure economic viability.

Complexities of Current Systematic DRS Program

To illustrate the current standardized National Health System Diabetic Eye Screening Program (NHS DESP), the screening

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process starts from the primary care physician (PCP) referring everyone with diagnosed diabetes (aged 12 years and over) to the DRS program where a diabetes register is established to ensure each patient is invited for an annual diabetic eye screening appointment.^[7] The DRS also has specifications on the type of acceptable fundus photography, and there are select cameras approved by the NHS DESP ensuring standardization of public health.^[8] For grading of DR, the program developed a diabetic retinopathy grading classification based upon the Early Treatment Diabetic Retinopathy Study (ETDRS) retinopathy severity scale, allocating patients on a scale of R0–R3 and for maculopathy M0 or M1 and evidence of previous laser as P0 and P1. The grading system determines the referral pattern and the follow-up intervals.^[7] Furthermore, to ensure high quality technicians to grade and screen images, they undergo rigorous training by ophthalmologists. All 1500 graders take a monthly test set of 20 image sets, which are then graded against a guide grade.^[7] Those graders who perform poorly on tests to undergo extra training and have all of their work graded again until there is an improvement in performance. As such, it is clear that there are strong controls in place to ensure that it is a high-quality screening program. Overall, NHS DESP is one of the most highly regarded DRS programs established, with strong controls in place to ensure high-quality screens. However, it is a complex system that utilizes a strong healthcare infrastructure, advanced technology, and has adequate funding.

Annual screening using the current methodology of NHS DESP is not cost-effective or sustainable even in the NHS due to the growing prevalence of people with diabetes, increasing costs of the program, and the diminishing healthcare allocations. Therefore, alternative approaches such as OCT-integrated DESP and risk-based screening intervals have been widely researched. In addition, computer-aided grading is also developed to meet this demand.^[9] Automated algorithms using deep learning systems are able to detect referable DR on retinal images with an accuracy of 90%–99%.^[10] The IDx-DR is a US FDA-approved AI system that can detect DR in adults with diabetes without a clinician interpreting it.^[11] This technology has already been studied in LMIC. An AI-based deep learning system in Zambia had a 97%–99% accuracy in detecting referable DR.^[12] Therefore, although the NHS DESP as is currently run is not directly translatable, these innovations when introduced to the NHS DESP are translatable to LMIC if a similar governance structure is in place.

Telemedicine DRS program

A systematic approach will help ensure that all patients at risk are monitored, put on a register, and given an invitation for screening.

In countries where there is a national-based healthcare infrastructure, national screening programs can be implemented on a broad scale compared to the healthcare system where the majority of the population pays for their healthcare expenses from out of their pockets or medical insurance.

Therefore, a set of minimum standards may aid in establishing standardized DRS telemedicine programs.

Minimum standards for systematic DRS telemedicine programs

Establishment of a telemedicine diabetic retinopathy registry

As the primary care infrastructure is underdeveloped, there are

no electronic medical records in most LMIC. However, there is a definite willingness for all nations to develop noncommunicable disease (NCD) registers in an attempt to achieve the sustainable development goals (SDGs). Although most of these registers are not electronic, it is a valuable resource to identify patients who need to be screened. Once such a registry is formed, cooperation from local pharmacies, general practitioners, health workers, diabetologists, ophthalmologists, and other tertiary care physicians who provide care for other complications of diabetes, and most importantly, self-declaration, will rapidly increase the population coverage of the registry. Every attempt should be made to maintain this registry electronically within a database, preferably within an electronic medical record. Furthermore, annual maintenance of a diabetic retinopathy registry would be necessary to successfully implement systematic DRS programs. Maintenance will provide the tracking of DR and be a performance indicator to identify the efficacy of the program.

Technical requirement for retinal image capture

There is a wide assortment of fundus cameras, including traditional fundus cameras, miniature tabletop fundus cameras, integrated adaptor-detector-based handheld ophthalmic cameras, smartphone-based ophthalmic cameras, and ultrawidefield cameras. While some are easy to use and comfortable for patients, these come with a cost of lower quality of images compared to traditional fundus cameras. The risks and benefits have to be balanced after considering local needs. For example, fixed smartphone-based ophthalmic cameras are currently the most cost-effective; however, the patient must have mydriasis for it to be used.^[13,14] Patients prefer nonmydriatic retinal photography. Ultrawidefield fundus photography is another method of telemedicine that has been explored in the United States. Silva *et al.*^[15] compared this method with the traditional nonmydriatic fundus photography in 8,109 patients. The rate of ungradable eyes reduced by 81%, thereby increasing the rate of detection of VTDR. However, this imaging method is most likely to be only feasible in high-resource settings.^[9] Verma *et al.*^[16] suggest incorporating UWF imaging into telemedicine programs in India as their study revealed a lesion distribution of 37% to be predominately peripheral lesions, which could be missed by traditional nonmydriatic fundus photography. This should also be taken into account when designing a telemedicine program for the Indian population. Robust validation of device performance should be included in the quality metrics of a program.

Professional standards

All DRS programs should be quality assured and the screeners, graders, and ophthalmologists who lead the program need to meet professional standards. As screening is mostly done by non-healthcare workers, it is particularly important for their training to include basic knowledge of the retina and DR.^[17] The graders should be accredited by completing local or web-based training modules. Continuing professional development of all staff should be included in the quality metrics of these telemedicine DRS programs.^[13] Further professional standards recommended by All Indian Ophthalmology Society (AIOS) are to utilize skill-based competence levels for people involved in taking retinal photography in order to provide further professionalization. The graders' knowledge of DR, ability to assess image quality, accuracy of grading, and level of certifications will determine the extent to which the grader can make decisions and follow up.^[18]

Leadership and ownership

Ideally, these programs should be owned by the health department of the government to ensure sustainability. However, in many LMIC, the government priorities have to match their healthcare expenditure and DRS is not a priority. Therefore, nongovernmental organizations, private health providers, and donors can work with their government to achieve a telemedicine system. Governments should invest in infrastructure and technology to assist these programs on a regional and national level.^[9] However, looking at the historical data, and the example of WDF (World Diabetes Foundation), who had initially started 25 projects across the country, after the end of the projects, there is a lack of continuity as the outside involvement stops. This suggests that government intervention will be critical to create sustainable domestic DRS programs that will last.

Infrastructure and secure and safe transfer

Electronic Picture Archiving and Communication System (PACS) is used to transfer images and reports securely between the sender and the recipient. This is made up of four components: imaging instrumentation, a secure network for patient data transmission, workplaces for interpreting and reviewing images, and archives for the storage and retrieval of images and reports. The American Telemedicine Association (ATA) has stated that data communication should be compliant with Digital Imaging and Communications in Medicine (DICOM) standards.^[19]

Mostly, the images are transmitted over the Internet should the area of practice have this facility set up. However, in more rural areas, satellite transmission may be preferred because of the lack of Internet infrastructure in rural areas.^[13] Lack of such infrastructure or reliability of the connectivity is a major obstacle for such programs. However, in most countries, digital literacy far exceeds health literacy; so, there are opportunities to capture images and then upload them by wireless or asynchronously by a store and forward approach.^[9]

Referrals

The aim of any telemedicine DRS program is to identify and treat VTDR. However, the linkage between referral and actually being seen by an ophthalmologist is the single most common cause of concern. The main criteria for referral to an eye care provider were listed by Mansberger *et al.*^[20] The first being patients at risk of VTDR and the second being “unable to determine” results for diabetic retinopathy.^[20] The referrals for VTDR need to be prioritized to enable prompt treatment especially eyes with high-risk proliferative diabetic retinopathy. The rate of referrals and the proportion of ungradable images should be included in the quality metrics of telemedicine programs.

Nonattendance rates

Although efficient telemedicine programs may be set up, if patients do not attend due to any cause, the system needs to be considered a failure. The most common reason for nonattendance for treatment is the lack of public awareness of the risk of blindness due to diabetes in asymptomatic eyes.^[21] A study in the US revealed that approximately 50%–60% attended the recommended annual eye examinations.^[21] Whereas in the UK, the uptake rate is higher reaching up to 82.4% in 2017.^[7] However, this is a national challenge worldwide and perhaps integration of DR screening within primary care checks for other

complications of diabetes may need to be considered. So, a very important standard that needs to be met by any telemedicine program is the number of people who were treated after being referred from the screening program for VTDR.

Re-call

The basic difference between opportunistic screening and a systematic and structured telemedicine program is the ability to recall the screened patients at predefined intervals.^[22] This requires recall facilities and administrative manpower. In Ghana, the ComHIP program exists to allow patients to be aware of nutritional health information, medication adherence, follow-up appointments, and sending daily reminders to patients’ mobile phones. Similar initiatives are possible to establish the recall of screened patients in LMIC.^[23]

Review of Barriers and Potential Remedies

A systematic review of barriers/enablers for DRS programs revealed that these are different in each income setting.^[24] The main barriers that impede the implication of DRS programs, especially in LMIC are funding, legislation, sustainable finance models, country and population-specific hurdles, and quality metrics. Barriers can be effectively divided into those that impede the initial creation of the DRS program and those that stop the DRS program from functioning well. At the beginning of DRS programs, the key barriers that are faced are issues in relation to funding, legislation, sustainable management, governmental involvement, and stakeholder engagement. Crossing these barriers is essential to ensure that the DRS program can be successfully started and maintained throughout the LMIC. After the creation of the DRS programs, barriers that stop it from functioning well are population coverage and awareness, patient perception of telemedicine, and country-specific needs for change. These will all be discussed in further detail below.

Funding the telemedicine program

Firstly, most LMIC do not have adequate funding provided by governmental bodies or ministries of health to set up a quality-assured DRS program. According to the English national screening program, the total cost of the program is approximately 84 million USD or 40 US dollars per person screened.^[7] Moreover, treatment facilities in LMIC are particularly challenging to set up in these regions as the treatment options of VTDR are costly.^[25] Most primary care infrastructure is also rudimentary. Establishing IT infrastructures and the purchase of advanced equipment are further obstacles faced. Furthermore, a study on the cost-utility for telemedicine in the rural Indian setting reveals that a one-off DR telescreening would be cost-effective compared with no screening. It also suggests that increasing the frequency of screening to every 2 years would also be worthwhile; however, the results would be dependent on administrative costs of establishing and maintaining screening.^[26]

Legislations

One of the major challenges of telemedicine projects in countries such as India is the legislation that prevents trained staff in non-eyecare settings to dilate the pupils to capture mydriatic retinal photographs unless supervised by an ophthalmologist. So, only nonmydriatic retinal photography can be performed, beating the purpose of using non-healthcare professionals for this purpose in remote locations. Health Insurance Portability and Accountability Act (HIPAA) compliance of transmitting

retinal images through nonsecure routes is also a major challenge. However, the recent relaxation of this legislation for telehealth in the United States is a major breakthrough. Retinal images may be transmitted with patient details via HIPAA noncompliant routes as long as it is not public-facing. Recent changes to telemedicine legislature in India now state that telemedicine is perfectly legal as long as guidelines are followed. The transmission of retinal images to experts graders and doctors can be done with much more legislative ease.^[27]

Financial sustainability

The initial investment of a telemedicine DR screening is substantial if established to the required standards.^[28] The costs of cameras remain high. Advancing imaging technology is associated with increasing costs. The computing and telecommunications expenses are also prohibitive for LMIC. Although integration with electronic medical records is encouraged, there are very few centers in LMIC that have this facility. So, most do not have records or use handwritten registers or excel sheets to keep their records. For a quality-assured program, the screeners and graders also need to be trained and updated constantly. These costs are usually recovered from payment received for screening episodes. Any telemedicine program will have an initial surge of screening episodes when initiated due to the screening of patients who have already been identified. The program then stabilizes at a steady state. This is a challenge for programs that are initiated on a pay-for-performance scheme.^[29] Another challenge is the inequity in the reimbursement strategy of telescreening and consultation in comparison to a face-to-face ophthalmology consultation. Due to the COVID-19 pandemic, some reimbursement schemes now cover telehealth consultations. The financial sustainability of these programs in LMIC is best achieved if the telemedicine program is backed by a national policy that all patients with diabetes have to be screened for DR. However, this policy should also be extended to include patients. Nonattendance of patients at DR screening programs is a major challenge. Although most research studies on nonattendance have not concentrated on attendance rates in telemedicine DR screening or have reported that attendance in telemedicine programs has been perceived to be better, it remains a challenge. Penalties for nonattendance, increasing insurance premiums for nonattenders, and incentivizing for attendance may be options that need to be explored. However, these can also negatively impact these screening programs.

Patient perceptions

A major hurdle to telemedicine DR screening is the patient perception of this screening compared to a face-to-face consultation by an eye doctor. This is particularly true in LMIC. In contrast, studies from the US show that patients were satisfied with the option of having their eyes screened closer to home and that they were happy to co-pay for their screening episode.^[30] In contrast, in China, teleconsultation was observed as an inferior option to face-to-face screening, resulting in nonadherence to DR screening appointments.^[31] However, a study in India revealed that 34% of the study participants felt telemedicine as more satisfying than in-person screening due to cost reductions, time-saving, and no travel requirement. Furthermore, in selecting future screening programs, 50% felt it should be through teleophthalmology. In the Indian population, there is still potential to improve patient perceptions and therefore increase updates regarding DRS screening programs.^[32]

Coverage of population

All people with diabetes need to be screened for DR at regular intervals. However, when resources are restricted, some countries may need to decide on defining the high-risk populations for annual DR screening. For example, in the UK, all people aged 12 or above with a diagnosis of diabetes are invited to be screened annually for DR. Although this is ideal for global translation, it is not cost-effective. Also, when balancing resources versus numbers needed to be screened, each country may need to restrict its population coverage to the high-risk group. This in turn may be associated with risks of missing VTDR, or not reaching the hard-to-reach communities. Geographic information system mappings may aid in visualizing geographic access barriers to eye care and identify underserved areas that may benefit from telemedicine.^[33]

Medical liability

Although DR screening is restricted to identifying DR-related events, patients may harbor other vision-threatening diagnoses that may not be picked up by telemedicine programs. The medical liability of such situations may need to be clarified with policymakers and legal departments. This is particularly important in computer-aided grading such as artificial intelligence programs.

Quality metrics

The performance of a telemedicine DR screening program needs to be quality assured. There are several metrics that could be used to monitor a program, including attendance rates, time to grading, quality of grading, number of referrals, proportion of ungradable images, outcome of referred patients, follow-up of screen-positive patients, credentials of graders, quality of retinal images, and validation of the performance of the retinal cameras.^[29,34] However, these metrics are not recorded in most LMIC. Data management is in its infancy and the reliability of connectivity is modest.

Patient and public awareness

Patient and public awareness is a major challenge in most LMIC. Recent qualitative studies on patient experience and perceptions of diabetic retinopathy telemedicine screening suggest that there is a lack of patient awareness of DR-related blindness.^[35] As an asymptomatic disease, patient attitude and health-related behaviors play significant roles in the success of these programs.^[31,36] Education support is required for people to want to access treatment when they are asymptomatic. Communication between the referrer and the patient needs to be improved significantly.^[22] Although telemedicine offers the convenience of healthcare provision close to home and saves time on transport and reduces costs, fear of the outcome, mydriasis, and perception that face-to-face consultation is better are negative perceptions of care that need attention.^[37] In addition, some patients made find it challenging to embrace the advances in technology.^[37,38]

Stakeholder engagement

Diabetic retinopathy screening and treatment is not a health priority for many LMIC. Therefore, it is a challenge to engage policymakers, but their buy-in is essential for the economic viability and sustainability of a telemedicine program. The DR pathway is complex and requires the cooperation of camera manufacturers, telecommunications and data management, diabetologists, primary care doctors and allied health workers, ophthalmologists, and optometry services to

work collaboratively. Therefore, a sound value proposition backed by an evidence-based approach with standardized camera specifications, protocols, and training are required to provide assurance and confidence to clinicians from other specialties to refer patients to the telemedicine program.^[17] DRS in low-resource settings can be improved by teaming up with nongovernmental organizations (NGOs), research foundations, the private sector, and international agencies that can provide screening, equipment, drugs, DR units, treatment, and other care services.^[39] The country's domestic and international stakeholders need to engage with their ministries of health to invest in eye health so that avoidable blindness such as DR can be prevented.^[40,41] High-income countries can also assist in improving research and surveillance of avoidable blindness and share their strategies with LMIC.^[9]

It would also be advisable to use opportunistic screening programs in regions where there are no national healthcare infrastructure as a stepping stone to systematic screening. At least in this method, DRS will be offered and would triumph over no screening at all.^[6]

Breakdown of the link between telemedicine screening and treatment center

One of the major challenges is the establishment of the link between screeners and graders and the limited supply of ophthalmologists with expertise in the identification and treatment of VTDR.

Lack of treatment facilities and expertise

Significant resources are required to improve capacity and capability to treat VTDR.^[42] The initial outlay is significant for most LMIC compared to the available resources.

Country Specific Need for Change

First, the burden of diabetes mellitus is disproportionately high in some LMIC. For example, in the UK, there are approximately 4 million people with diabetes compared to a corresponding 70 million in India. Therefore, a single national program is not feasible in India and there is an unmet need to identify ways by which DRS programs can be established in each LMIC especially in those with limited resources and fragmented healthcare infrastructure.^[9]

Second, evidence reveals that while tertiary care of VTDR has been the focus of ophthalmologists in LMIC, there needs to be a shift toward more primary and secondary prevention strategies, that is, screening programs.^[9] However, the primary care infrastructure is still in its infancy and considerable investments are required.

Third, while there is an emergence of opportunistic screening for VTDR in LMIC led by hospital-based services, there requires a cultural shift from ad hoc screening to interval-based screening. While annual screening is recommended, this is again not feasible in LMIC with large numbers of people with diabetes. Therefore, local evidence-based risk-based screening has to be established. This requires the need for data linkage and re-call facilities. Many of these challenges may be solved by telemedicine.^[9]

Conclusion

There are barriers and definite global health inequity when reviewing DRS programs on a global scale. The best economies have well-developed healthcare systems in place but much fewer

people with diabetes; in contrast, the weakest economies do not have the healthcare systems in place but have the strongest demands for necessitating these telemedicine screening and treatment pathway to reduce blindness due to VTDR.

Establishing and maintaining DRS programs in LMIC is a much more complex task than providing DRS programs in high-income countries. It requires a multifaceted approach that improves a country's educational level, healthcare provision services, logistical services, and public health policies. These barriers coupled with the lack of public awareness can be overcome by providing the right kind of knowledge and standard practice.

Furthermore, barriers and enablers are different in each income setting. The most consistent barrier pervasive in all countries is the lack of knowledge and awareness of DR.^[24] In LMIC, the lack of functional health literacy and knowledge of eye examinations/clinics are major barriers preventing users from accessing services. Public awareness should also be increased and we recommend a push for higher educational health literacy by implementing more educational interventions.

The main barriers for healthcare providers are the lack of an adequate referral system, financial constraints, and lack of human resources. From our review, it has become clear that solutions to these barriers will be required including program in government health setting priorities, educational advancement, and healthcare restructuring. Better integration of healthcare infrastructure is required to roll out national screening programs. Countries such as India have invested in opportunistic screening to ensure population coverage.^[25] However, it is time to consider systematic telemedicine DRS programs at the state or national level by either following a polyclinic set up in Canada or as a single program. A recent implementation in Peru reveals that it is possible to achieve good results using telemedicine when education, screening, and care are integrated into the general health infrastructure.^[43] Furthermore, the integration of artificial intelligence and other computer-aided diagnosis has the potential to further reduce the current barriers to provide LMIC systematic DRS programs.

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Conflicts of interest

There are no conflicts of interest.

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