

# **Title: Diabetic retinopathy screening guidelines for Physicians in India: Position statement by RSSDI (Research Society for the Study of Diabetes in India) and Vitreoretinal Society of India-2023**

## **I. Abstract**

Diabetic retinopathy (DR) is a leading cause of blindness among working-age adults worldwide. India is the diabetes capital of the world and with the increase in diabetes there is an increasing burden of diabetic retinopathy (DR). This is a position statement jointly developed by RSSDI (**Research Society for the Study of Diabetes in India**) and VRSI (Vitreoretinal Society of India) to provide guidelines for Physicians on DR screening in India. These guidelines emphasize the need for regular DR screening of all people with diabetes, identification of high-risk patients, and appropriate timely referral to Ophthalmologists for early detection and management of DR thereby decreasing the burden of preventable blindness secondary to DR.

**Key words:** Diabetic retinopathy, screening guidelines, Physician, India

## **II. Introduction**

India has 101 million people with diabetes and these numbers are predicted to increase to 125 million by 2045. It is estimated that one in five adults will have diabetes in India. Majority are said to have type-2 diabetes

during their working age impacting their work, family and causing an economic burden on the country.

Diabetes being a chronic disease has several associated systemic complications including DR which affects the vision. DR can be asymptomatic in the early stages and If not detected and managed on time, it may progress to vision threatening diabetic retinopathy (VTDR).The prevalence of diabetic retinopathy is 12.5% out of which 4% are said to have VTDR. In order to timely identify patients with VTDR, we are required to actively screen all the people with diabetes. This is a huge task in a low-income country like ours where the resources are limited. Thus, the need of opportunistic screening for DR done at Physician clinics, who are the first point of contact for any patient with diabetes. Therefore Physicians can play an extremely important role in spreading awareness and do an early screening for DR. This manuscript provides guidelines for DR screening by the Physicians. The diagnosis of DR is possible with imaging and thus the various models available to the Physicians to develop the facility of DR screening in their own clinics are also highlighted.

#### **IV. Who are at risk of developing DR and the timing of the first screening for DR**

Individuals with diabetes are at risk of developing diabetic retinopathy (DR). The onset and progression of DR can be influenced by the duration of diabetes. It is important to note that people with type 2 diabetes may not be aware of the exact duration of their condition. Therefore, it is recommended that individuals with type 2 diabetes undergo screening for DR at the time of diagnosis.

In the case of type 1 diabetes, it is generally recommended to start DR screening between 3-5 years after the onset of diabetes. This timeframe allows for the identification of any early signs of retinopathy.

For women with known diabetes who are planning to conceive, it is crucial to assess their risk of developing DR. Therefore, it is recommended that they undergo their first screening for DR prior to conception. Additionally, it is advised for these women to have a follow-up screening during the first trimester of pregnancy to monitor any changes in their retinal health.

## **V. Why should the patients with diabetes be screened for Diabetic Retinopathy**

Patients with diabetes should be screened for diabetic retinopathy (DR) due to several important reasons. The SMART India Study was conducted in ten Indian states and one union territory, involving over 6,000 patients with diabetes aged 40 years and above who had gradable retinal images. The study found that 12.5% of people with Diabetes had any grade of DR, and 4% had VTDR. This translates to approximately 3 million people in India who are at immediate risk of vision loss due to DR.

Unfortunately, the early stages of DR are asymptomatic, and once vision loss occurs, it is usually not completely reversible. Therefore, it is crucial to screen for DR in order to detect it at an early stage and prevent the development of VTDR.

## **IV. Role of Physicians in DR screening**

Physicians have a critical role in the sensitization and screening for DR as they are usually the first healthcare providers that people with diabetes encounter. Physicians can play an extremely important role in creating the awareness of the risk of vision loss due to DR. It needs to be highlighted

that DR being asymptomatic in early stages may progress silently and thus the need of a regular screening for DR.

Patients being asymptomatic are reluctant to go to an Ophthalmologist for a preventive eye check-up when they have good vision and go only when they start losing vision secondary to VTDR. Physician clinics can provide an opportunistic screening for DR, just like how they would do a blood investigation for their diabetic patients. This will be a very important Value Addition to the services offered to the patients. This will ensure that patients having DR will be identified for an early referral and also will avoid unnecessary visit to an Ophthalmologist's when eyes have no evidence for DR. This will also help to reduce the unnecessary overload of patients with no DR being referred to an Ophthalmologist.

## **V. DR Screening guidelines for a Physician**

It is important for the Physicians to be aware of the screening guidelines for DR. Any patient with diabetes should undergo at least one eye exam every year.<sup>81</sup> The DR screening guidelines depends on the type of diabetes and the stage of DR at the time of screening (Table-1). This is based on the International clinical DR and diabetic macular edema (DME) severity scale.<sup>82</sup> However, the screening interval should be individualized based on the patient's systemic status including glycaemic control, blood pressure, lipid levels and other comorbidities.(Table-1)

**Table-1: Diabetic retinopathy screening guidelines for a Physician**

Type 1 diabetes mellitus	Initial eye examination recommended 5 years following diagnosis of type 1 diabetes mellitus
Type 2 diabetes mellitus	Initial eye examination recommended at time of diagnosis of type 2 diabetes mellitus
Pregnancy in patient with diabetes mellitus	<ul style="list-style-type: none"><li>• Eye examination prior to conception and early during 1<sup>st</sup> trimester</li><li>• Follow up should be individualised based on severity and recent changes in retinopathy</li></ul>
<b>Diabetic Retinopathy Severity</b>	
No Apparent DR	Annual fundus photo screening at Physician clinic
Any evidence of DR or DME	Immediate referral to an Ophthalmologist

DR : Diabetic Retinopathy; DME : Diabetic Macular Edema

## **VI. DR Screening Models for Physician clinics**

Developing a DR screening model at a Physician's clinic has become easy and economical. DR diagnosis can be achieved through image analysis or AI-based algorithms which requires basic resources such as a fundus camera, a trained technician to capture high-quality retinal images, and an internet connection.

In India, options are available to enhance your skill in fundus examination and fundus photography through certified courses on DR. eg, course offered by the Public Health Foundation of India (PHFI).website: <https://ihope2020.org/diabetic-retinopathy>

The various options available to a Physician for screening a diabetic patient for DR are as follows:

1. **Direct ophthalmoscopy** – Physicians trained in using direct ophthalmoscope can do this easily. This is the simplest and the most cost effective method for the Physicians.
2. **Tele-screening for DR** – A retinal fundus photograph can be taken by any technician in the Physician's office and sent to a Retina Specialist or a grading center using internet and receive a report after the image is graded. The report will give the grade of DR and also will suggest on referral or no referral.
3. **Tele-screening for DR using Artificial Intelligence(AI) algorithms** – in the recent times AI is playing a major role in grading the Retinal images and is able to suggest Referral or No Referral for DR. The results are received almost instantaneously as soon as the fundus images are captured. The requirement for a retina specialist or a trained grader is not need here.

#### **A) Screening models for Diabetic Clinics where there is no facility for screening to be done by an Ophthalmologist**

##### **1.Direct Ophthalmoscopy by the Physicians**

Physicians and primary health care providers may use direct Ophthalmoscope (DO) for DR screening. Most of the Doctors are trained in this technique during their undergraduate training.

##### **2. Tele-screening using Portable or non-portable Fundus Cameras**

A retinal fundus camera is used to take the photo of the retina through an undilated (Non-mydratic) pupil can be used to capture retinal images at the Physician clinics. Details of the different types of fundus cameras available in the market utilized for DR screening is provided in

Table-2. With a simple training, any clinic assistant can capture the Retinal images using these fundus cameras. These images can be stored and forwarded online to an remote Ophthalmologists or trained Graders(today very few are available). The retina specialist will review the images, grade them for DR severity and generate a report to be sent back to the physician's office. This whole process may take few hours to a few days depending on the resources available.(Fig-1)

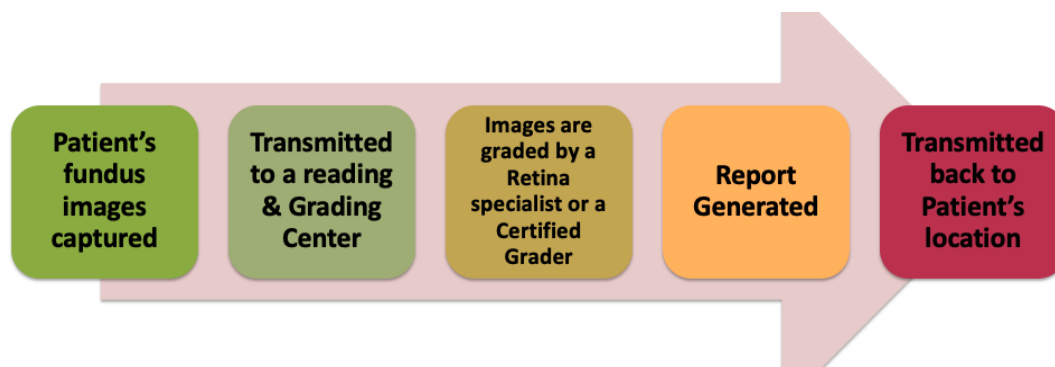


Fig-1 DR screening using Teleophthalmology

### 3. Tele-screening using Portable or non-portable Fundus Cameras using AI

Artificial Intelligence(AI) is playing a major role in DR screening. AI is able to grade the retinal images equivalent to a retina specialist and can identify referable DR and not referable DR. More importantly it can grade and generate a report almost instantaneously. The patient will be able to get his eye report within few minutes and the physician can advise the patient accordingly. (Fig-2)

The sensitivity and specificity of few commercial automated DR grading softwares is given in Table -3.



The report is provided to the patient along with a disclaimer that it is a screening test with a specific sensitivity and specificity, and cannot be used for any medicolegal purpose. The main purpose of the screening test and the automated report is to alert the patients in case any evidence of DR is found so that he or she can be timely referred for a detailed evaluation and further management by an Ophthalmologist. This may ensure a better compliance for DR screening and reducing the risk of vision loss due to DR.

## **B) Where a facility for Ophthalmology referral is present within the Physician clinics**

Physician clinics with an ophthalmology referral facility can ensure timely diagnosis and management of DR

### **1. DR screening as a part of diabetes care**

- Incorporation of DR screening as a standard of care for diabetes with regular referral to an Ophthalmologist for DR screening.

The second option being that instead of sending every patient to the Ophthalmologist for DR screening, a tele-screening facility with or without AI can be setup.

if the patient has a referral DR, then is sent for further evaluation and management to the inhouse Ophthalmologist.

## **C. Community based DR screening**

### **1. DR screening during diabetes screening**

Non-Governmental Organizations (NGOs), diabetic clinics and corporate offices conduct annual health check-up programs or diabetes screening programs annually. DR screening can be included as a part of the package. These days corporate screening programs are also

implemented in offices where a sedentary lifestyle and work stress increases the risk of diabetes and DR at a younger age and these camps can help in opportunistic screening for DR.

## 2. Risk based DR screening

Risk based screening (age, duration of diabetes, blood sugar levels, cholesterol levels, blood pressure levels) would be feasible, cost effective, safe and also the screening can be individualized based on the risk score. The All India Ophthalmological Society (AIOS) task force committee and Vitreo Retinal Society India (VRSI) recommends diabetic retinopathy (DR) screening for individuals with known diabetes who are receiving treatment and have a random blood sugar (RBS) level of  $\geq 200\text{mg/dl}$  ( $\geq 11.1\text{ mmol/l}$ ), or have glycated haemoglobin (HbA1C) levels of  $>6.5\%$  ( $48\text{ mmol/l}$ ). The screening is also necessary for individuals with gestational diabetes when they first report to a healthcare provider.

**Table 2:** Different types of Fundus cameras utilized for the DR screening

<b>Fundus cameras</b>	<b>Advantage</b>	<b>Disadvantage</b>
<b>Mydriatic desktop fundus cameras</b>	30 to 45 deg FOV, can cover upto 75deg FOV with Montage, Stereo images of various fields, excellent resolution, seven field stereo photography, easy to use with training, good image quality, good for hospital usage, Better sensitivity and specificity for detecting DR by ETDRS fundus photograph grading than DO or IDO exam	Requires mydriasis, Expensive, Time taking procedure for training photographers and graders
Commercially available cameras	Carl zeiss FF 450 plus, 3 Nethra-Forus (Model:Flora)	
<b>Non mydriatic Fundus camera</b>	45deg FOV, Autofocus, auto alignment, user interphase software, task automation, storage of images, and export of images to database and facility to share retinal images through network or internet connection.	Ungradable photographs and low sensitivity particularly in Indian eyes with dark iris, in cases of Cataract or small pupil size

Commercially available	Zeiss Ciruss 600, Artelus (Crystal Vue) NFC-700, 3 Nethra-Forus (Model:Classic), Canon CR-2 &AF, Centre Vue DRS, Topcon TRC NW 400, AFC-230,Nidek,gamagori,japan	
<b>Ultra wide field Fundus camera</b>	Very wide field of view up to 200 degree without dilatation, can detect peripheral DR lesions	Very expensive, cannot be used for mass screening unless the cost gets reduced
Commercially available	Optos, Optomap/Daytona Staurenghi lens (Ocular Staurenghi 230 SLO Retina Lens), Ocular Instruments Inc, Bellevue, WA, USA) Pomerantzeff camera, Retcam (Clarity Medical Systems, Inc., Plea santon, CA, USA), ZEISS Clarus 500 (Zeiss, Carl Zeiss Meditech, Inc., Dublin, USA)	
<b>Handheld</b>	Handheld digital cameras are portable, require less space, minimum power consumption and less skills and training	Image quality may be inferior without mydriasis especially for older people with cataract.
Commercially available cameras	Zeiss Visuscout 100 (Carl Zeiss, Jena, Germany), Smartscope Pro (Optomed, Oulu, Finland) Volk Pictor Plus (Volk Optical, Mentor, OH, USA), VersaCam TM DS-10 (Nidek, Gamagori, Japan), Horus DEC 200 (MiiS, Hsinchu, Taiwan), Genesis-D (Kowa, Nagoya, Japan)and Optomed Aurora	
<b>Smart phone based fundus camera</b>	Smartphones are universally available and these smartphone based fundus cameras are cost effective alternative option for traditional fundus camera.	Require mydriasis
Remidio fundus on phone (FOP)(Remidio Innovative Solutions,Bangalore,India)	US FDA- approved validated retinal imaging system, Mydriatic and Non mydriatic and anterior imaging module, 45deg FOV (M) with $\pm 20D$ adjustment with 12x optical magnification, 40 deg FOV (NM) and 10X	

	magnification, Tabletop model or handheld mode and Can also be attached to smartphone	
Make in India Retinal Camera(MII Retcam,India)	Capable of visualising even peripheral regions of retina upto pars plana along with posterior pole, provides video and also still image	<b>Require mydriasis</b>
<b>Other Smart phone based validated fundus cameras available</b>	Peek Retina(Nesta,London,UK), PanOptic+iExaminer(Welch Allyn,skaneateles Falls,NY), D-EYE, padova,Italy	Peek vision device requires mydriasis, PanOptic and D-Eye has limited FOV 25deg and 20 deg

**Table 3:** Sensitivity and Specificity of the commercial automated DR grading algorithms

<b>Few commercial automated DR grading software</b>	<b>Fundus images Involved</b>	<b>Sensitivity and Specificity</b>
IDx-DR with Topcon Fundus camera (US FDA approved AI algorithm, on April 2018)	819 participants fundus images	Sensitivity and specificity of the technology was 87.2% and 90.7% respectively for detecting more than mild DR.
Retmarker	102,856 fundus images	Compared to arbitrated human grading results the Sensitivity for Retmarker in detecting DR were 73.0% for any retinopathy, 85.0% for referable retinopathy and 97.9% for proliferative retinopathy and False positive rate was 47%
EyeArt (Eyenuk Inc., based in Los Angeles, USA), (US FDA approved on 2020)	915 participants fundus images	96% sensitivity and 88% specificity for detecting mild DR and 92% sensitivity and 94% specificity for detecting vision-threatening DR

Google AI (Google Inc.)	Training- 103,634 images Validation -5764 imgaes From both sites	In INDIA two centers dataset was used: Sankara Nethralaya Sensitivity: 92.1% Specificity: 95.2% AUC: 0.980, Aravind Eye Hospital Sensitivity: 88.9% Specificity: 92.2% AUC: 0.963
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## VI. PM-JAY DR guidelines for a Physician

Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) is a Centre and state co-sponsored health insurance/assurance scheme providing health care services as per predefined packages to about 500 million population based on specific eligibility. This scheme is implemented by National health authority (NHA) in partnership with state health agencies through 28,000 empaneled facilities (both government and private) across India except 3 states (Delhi, West Bengal, and Odisha).

In April 2022, NHA released the HBP 2022 which includes the DR screening package including - refraction, fundus photo and optical coherence tomography (OCT). This package has a cross speciality model with reimbursement applicable to screening both by a Physician or an Ophthalmologist.

## VIII. Role of metabolic control in the management of DR

Good metabolic control including blood sugar level, blood pressure and dyslipidemia retards the progression of DR

- Higher the initial levels of HbA1c higher the risk of DR. Intensive glycemic control (HbA1c <7%) especially in the early stages of

onset of diabetes has a profound impact in the progression of DR and reduces the risk of developing DR by 27%.

- Control of high lipids reduced the risk of developing hard exudates and also preserved vision by decreasing the associated vision loss.
- In type-2 there is a decrease in DR by 31% for every 1% decrease in HbA1c and a decrease in vitreous haemorrhage by 11% for every 10 mm decrease in systolic blood pressure.

## **VII. Quality assurance standards for DR screening:**

Quality assurance should be a part of any DR screening program in order to achieve maximum benefit.

1. An informed consent before capturing the retinal images
2. A good quality, affordable, sleek, easy to operate fundus camera, that can provide high resolution images with wide field of view (130-200 degree) would be ideal.
3. Two images of the retina per eye (one macula centred and one optic disc centred image) would be useful to ensure that DR is not missed. An additional image of the anterior segment of the eye would provide additional information regarding media opacity/ cataract.
4. Although non-mydratic fundus cameras are used for screening, mydriasis/ use of dilatation eye drops improves the gradeability of the images and reduces the number of ungradable images.
5. The grading of the retinal images should be done by certified human graders.
7. AI softwares used should be validated and approved for DR detection. A disclaimer should be there with the report that it is a screening test and

not for medicolegal purpose. AI grading of DR can be utilized as an assistive tool, with the final grading of DR to be determined by a doctor.

8. The DR screening reports should be promptly available with the patient when having a follow up check-up with the Physician to ensure a timely referral to an Ophthalmologist in case DR is present

9. Proper backup and storage of the retinal images and DR diagnosis data is essential for follow-up. Preferable if there is an inbuilt alert system in case a patient misses his or her screening visit.

10. There should be a recall system where individuals with diabetes who have been screened the previous year are called back for DR screening/ retinal imaging through a reminder call/ SMS.

## **IX. Creating public awareness for DR**

Every opportunity should be used to spread awareness of blindness due to DR. A Physician should insist on the report of DR screening at the time of consultation. Patient education posters in patient waiting areas, pamphlets with pictures can help spread awareness about DR. DR screening should become a part of standard of care for diabetes.

## **X. Summary of the position statement**

- Any individual with diabetes is susceptible to developing DR.
- The occurrence of DR is influenced by the duration of diabetes, applicable to both type-1 and type-2 diabetes.

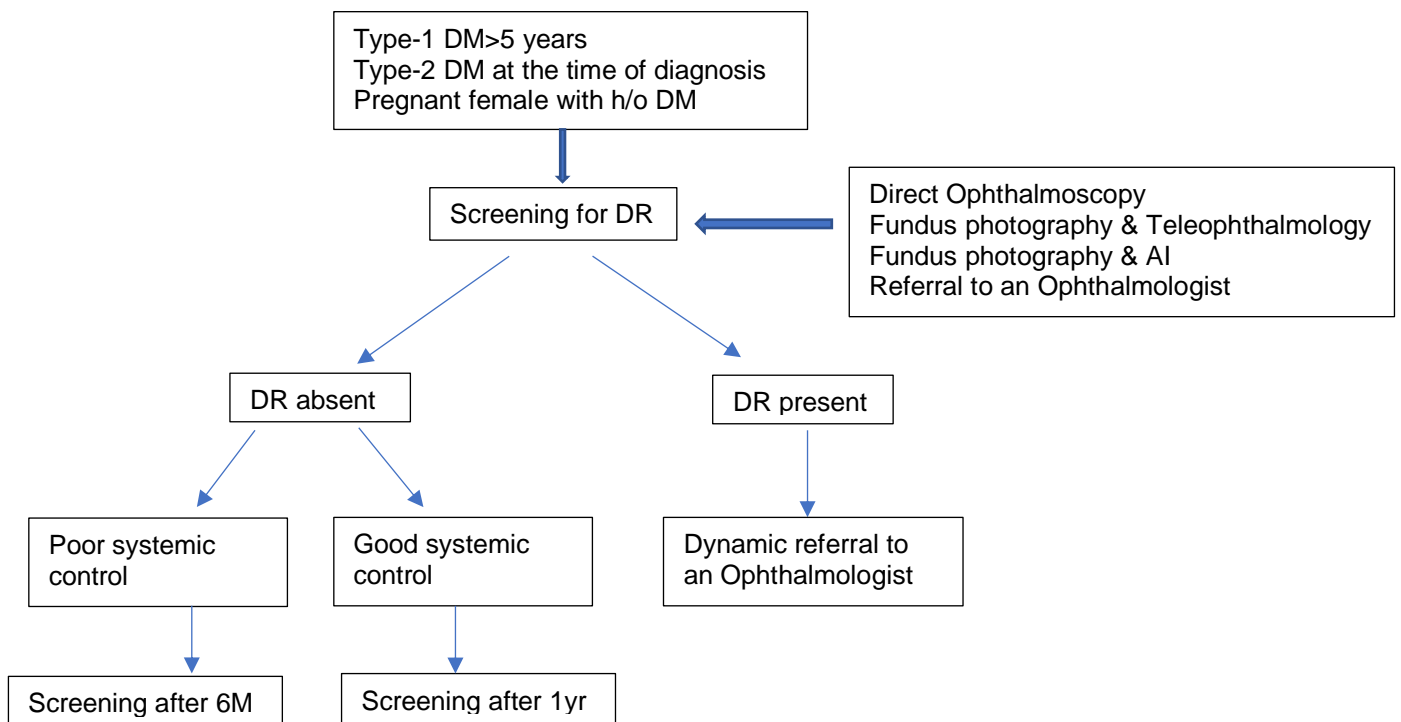
- The initial stages of DR are symptomless, necessitating proactive annual screenings for early detection in all diabetes patients.
- Advanced stages of DR can lead to irreversible vision loss.
- Optimal management of systemic factors like blood sugar, blood pressure, and lipid profile is pivotal in slowing down DR progression.
- Physicians, as the primary healthcare providers for diabetes patients, have a vital role in raising awareness about DR.
- Physicians should establish an effective DR screening program in their clinics, facilitating early detection, timely referrals to Ophthalmologists, and prevention of VTDR.
- Non-mydriatic cameras utilizing AI algorithms in fundus photography can aid in identifying referral or non-referral cases of DR.
- Collaboration between physicians and ophthalmologists is imperative in the screening process for DR in diabetes patients.
- Public awareness campaigns through clinic posters, patient education materials, and media initiatives can enhance understanding of the risks of blindness associated with DR.

## **Conclusion**

India faces a significant burden of diabetes, resulting in a rise in diabetic retinopathy (DR) cases and preventable blindness. Lack of awareness and asymptomatic early stages of DR contribute to patients not seeking eye screenings, leading to the development of vision-threatening DR (VTDR) and permanent vision loss.



In conclusion, the position statement by RSSDI and VRSI serves as a crucial guide for fostering collaboration between physicians and ophthalmologists in India. By working together, they can effectively combat the burden of diabetic retinopathy (DR) and prevent unnecessary blindness. The statement emphasizes the importance of raising awareness, implementing early screening measures, and utilizing cost-effective models to detect and manage DR at its early stages. Through this collaborative effort, we can strive towards a future where preventable blindness due to DR becomes a rarity in India.



**Fig-2 Flow chart for DR screening at a Physician clinic**