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# DIABETIC RETINOPATHY AND DIABETIC MACULAR EDEMA – SCREENING

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## SUMMARY

Diabetic retinopathy (DR) and diabetic macular edema (DME) are leading causes of severe visual loss in the working population. Therefore, both DR and DME have a significant socioeconomic and health impact, which taking into account the epidemiologic predictions is expected to increase. A crucial role in the management of DR and DME (not only for individuals, but also for the population) is played by an adequate screening program. This is based on the structure and organization of the healthcare system, the latest scientific developments in diagnostics (imaging) as well as technological advancements in computing (artificial intelligence, telemedicine) and their practical use. The recommendation presented by World Health Organization is also important. This paper evaluates all these factors, including evidence-based medicine reports and experience from existing DR and DME screening programs in comparable countries. Based on an evaluation of these parameters, recommended guidelines have been formulated for screening for DR and DME in the Czech Republic, including linkage to the Czech National Screening Center and the organization of the healthcare system.
**Key words:** diabetic retinopathy, diabetic macular edema, recommended guidelines, screening

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## INTRODUCTION

Diabetic retinopathy (DR) and diabetic macular edema (DME) are the main causes of morbidity in diabetes mellitus (DM) [1–3]. Most patients in whom DR is present have no complaints until the advanced stages of the disease develop [4,5]. Treatment of DR and DME (laser photocoagulation of the retina, pharmacological intraocular therapy, surgical treatment or a combination of these methods) is more effective in the sense of preventing loss of sight than as a method for restoring visual functions in the advanced stages of the pathology. As a result, it is important to ensure good organization of DR screening and the identification of patients in the early stages of the disease. For this reason, it is the aim of professional ophthalmological societies in the Czech Republic (CZ) to improve the screening program for identifying DR and DME.

Screening serves to identify patients in the population group with a high risk of illness, for the purpose of providing timely treatment or intervention in such a manner as to reduce the incidence and/or mortality of the disease in question within the given population [6]. The aim of screening is to increase effectiveness, maximize benefit and minimize risks. Worldwide, in Europe and CZ there are numerous examples of screening examinations, but in many cases unequivocal

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"evidence based" data on their effectiveness is unavailable. In general screening should be characterized by the breadth of its scope, its targeting at specific risk groups, speed of performance, and not by its complexity [1,6].

The prevalence of diabetes is increasing with industrialization and globalization, and a further increase in the prevalence and incidence of DR is expected in future [2,7,8]. Only 60% of patients with diabetes in CZ undergo regular examinations by an ophthalmologist [9].

A comprehensive ophthalmological examination incorporates examination of visual acuity (VA) with optimal correction, detailed examination including biomicroscopy of the fundus, examination of the visual field and examination of the retina by wide-field imaging system (photography, optical coherence tomography – OCT). However, it is very uneconomical and unsustainable to conduct such a detailed assessment of the finding in ordinary conditions, even in countries with a large number of ophthalmologists (e.g. CZ) [10].

As a consequence, it is of key importance to establish a functioning fast screening system which can identify the maximum number of risk patients in the target population, and refer them in a timely manner to an ophthalmologist, in contrast with those for whom a screening check is sufficient [1].

The organization of screening depends on the level of healthcare and the volume of financial resources designated for prevention in individual countries. It involves the work of general practitioners, internal medicine specialists, diabetologists and ophthalmologists. There are various different methods of identifying and subsequently referring diabetic patients with suspected presence of one of the forms of DR.

Classification may be performed on the basis of VA, the degree of compensation of diabetes, though optimally on the basis of a biomicroscopic examination of the ocular fundus by an eye specialist (ophthalmologist), or with the aid of obtaining photographic documentation and subsequent assessment of the image [10].

In some countries screening programs exist in different preparation phases, which are deployed in the assessment of images by "reading centers" equipped with medical or non-medical staff, sometimes using automated algorithms functioning upon a background of neural networks (artificial intelligence – AI) [11–13].

## PRESENT STATUS IN CZ

At present the task of screening is shared by internal medicine specialists and diabetologists, who refer patients to an ophthalmologist for examination of the ocular fundus at intervals in accordance with the last review of the Recommended Guidelines for the diagnosis and treatment of diabetic retinopathy issued in 2016 by the Czech Diabetes Society (CDS), the Czech Ophthalmology Society (COS) and the Czech Vitreoretinal Society (CVRS) [5,14]. The examination itself, the evaluation of the finding and above all the professional care are conducted by ophthalmologists.

In 2022, the General Health Insurance Company (VZP) introduced reimbursement codes for examining diabetic retinopathy with the aid of computer analysis of digital images of the retina in diabetes centers [15]. According to the results of the examination, patients are to be referred for an ophthalmological examination, the breadth of which is fully at the discretion of the ophthalmologist. Photographic documentation of the ocular fundus is used for this purpose, though it is not the regular standard even for ophthalmologists to be equipped with cameras for examination of the ocular fundus, and the use of neural networks is not supported in the recommended guidelines.

No specific "reading centers" have been designated, and the present network of ophthalmologists is not prepared to deal immediately with the potential increase of referred patients. At the same time, there are no processes of automation and use of electronic healthcare (eHealth) – automatic referral of patients between units of the screening network.

Screening frequently takes place in an uncoordinated manner – on the basis of an agreement between individual doctors or between diabetologists and ophthalmological centers (Fig. 1). As a result, regional differences are manifested.

## PRESENT STATUS IN EUROPE

Several EU countries have national DR screening programs based on pre-existing national population diabetes registers (Finland, Sweden, Denmark, Ireland).

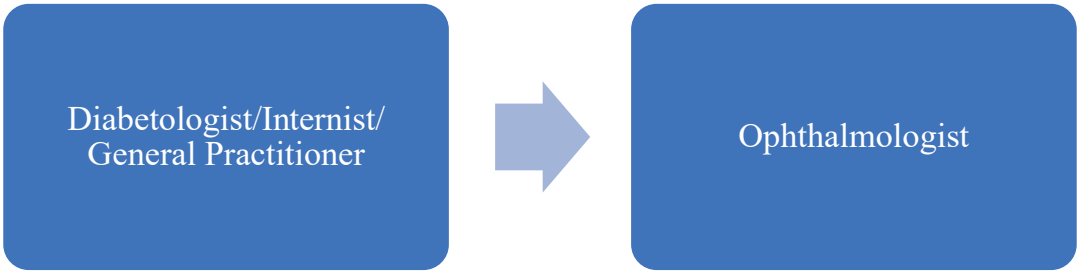



**Figure 1.** Subjects of diabetic retinopathy and diabetic macular edema screening in the Czech Republic

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Patient consent is not always required for inclusion in the register, the programs work with an ophthalmological examination (including examination of VA), and exceptionally with assessment of retinal photographs (Denmark). In other countries regional screening programs exist, using acquisition of retinal photographs from diabetes patients, as a rule using a non-mydriatic camera, and the images are then sent by non-medical staff to a scanning center for assessment and if necessary intervention (France, Italy, Poland) [12,13,16].

A highly sophisticated system exists in Great Britain, where national screening has been in operation since 2003 for all patients with DM from the age of 12 years upwards. As soon as a patient is diagnosed with diabetes, they automatically receive an invitation to attend a screening examination – with an ophthalmologist or optometrist, in a mobile screening center. VA is examined and a photograph of the ocular fundus is obtained (often by non-medical staff), and is assessed remotely by a scanning center [17].

## GUIDELINES FOR SCREENING OF DR AND DME AND LINKAGE TO OPHTHALMOLOGICAL CARE

**Requirements for components of screening examination for DR** – if met, screening may be performed also by a professional who is not an ophthalmologist

- Examination of visual acuity before application of mydriatic eye drops
  - o Ophthalmologist – best corrected VA
  - o Non-ophthalmologist – corrected VA
- Examination of retina enabling classification of DR
  - o Ophthalmoscopy in artificial mydriasis (performed by ophthalmologist)
  - o Biomicroscopic examination of ocular fundus in artificial mydriasis (performed by ophthalmologist)
  - o Color photography of ocular fundus
  - ■ Minimally 30 degrees of visual field
  - ■ Evaluation by ophthalmologist
    - With or without deployment of AI
  - ■ Evaluation by certified facility FI class IIa according to EU Medical Device Regulation [18,19]

**Requirements for referral of patient to ophthalmologist** (if screening is performed by a professional who is not an ophthalmologist)

- Visual acuity 6/12 and worse and/or
- Deterioration of vision and/or
- Presence of DR and determination of its classification as DR 2–4 (according to classification of International Council of Ophthalmology – ICO) [20] and/or
- Impossibility of examining VA and/or retina

**Minimal components of ophthalmological examination**

- Evaluation of visual complaints
- VA
- Intraocular pressure, gonioscopy according to local finding
- Biomicroscopy of ocular fundus in artificial mydriasis
- Assessment of glycemic index (level of glycated hemoglobin – HbA1c), general condition (pregnancy, blood pressure, serum lipid profile, renal functions)

**Screening – frequency of visits (and recommendation for referral to ophthalmologist) – according to ICO classification [4,20]**

A basic schema of screening visits according to classification of DR and DME is illustrated in Table 1.

**Extraordinary examination appointments**

- Pregnancy – first examination after confirmation of pregnancy
- If first screening without presence of DR, next at 28 weeks
- If first screening with presence of DR, next after 16–20 weeks
- Upon significant change of condition of health, compensation of diabetes, general treatment

**Table 1.** Recommended screening follow-up visits according to the DR and DME classification. Adapted from ICO classification [4,20]

| Classification | Next follow-up | Ophthalmologist visit |
|---|---|---|
| DR 0, mild NPDR (1), DME 0 | 1–2 years | Not necessary |
| Mild NPDR (1) | 6–12 months | Not necessary |
| Moderate NPDR (2) | 3–6 months | Necessary |
| Severe NPDR (3) | < 3 months | Necessary |
| PDR (4) | < 1 month | Necessary |
| Non-CIDME | < 3 months | Necessary |
| CIDME | < 1 month | Necessary |
| DM 1. newly diagnosed | < 5 years | Not necessary |
| DM 2. newly diagnosed | < 1 month | Not necessary |

*DM – diabetes mellitus, DR – diabetic retinopathy, DME – diabetic macular edema, NPDR – nonproliferative DR, PDR – proliferative DR, non-CIDME – non center involved DME, CIDME – center involved DME*

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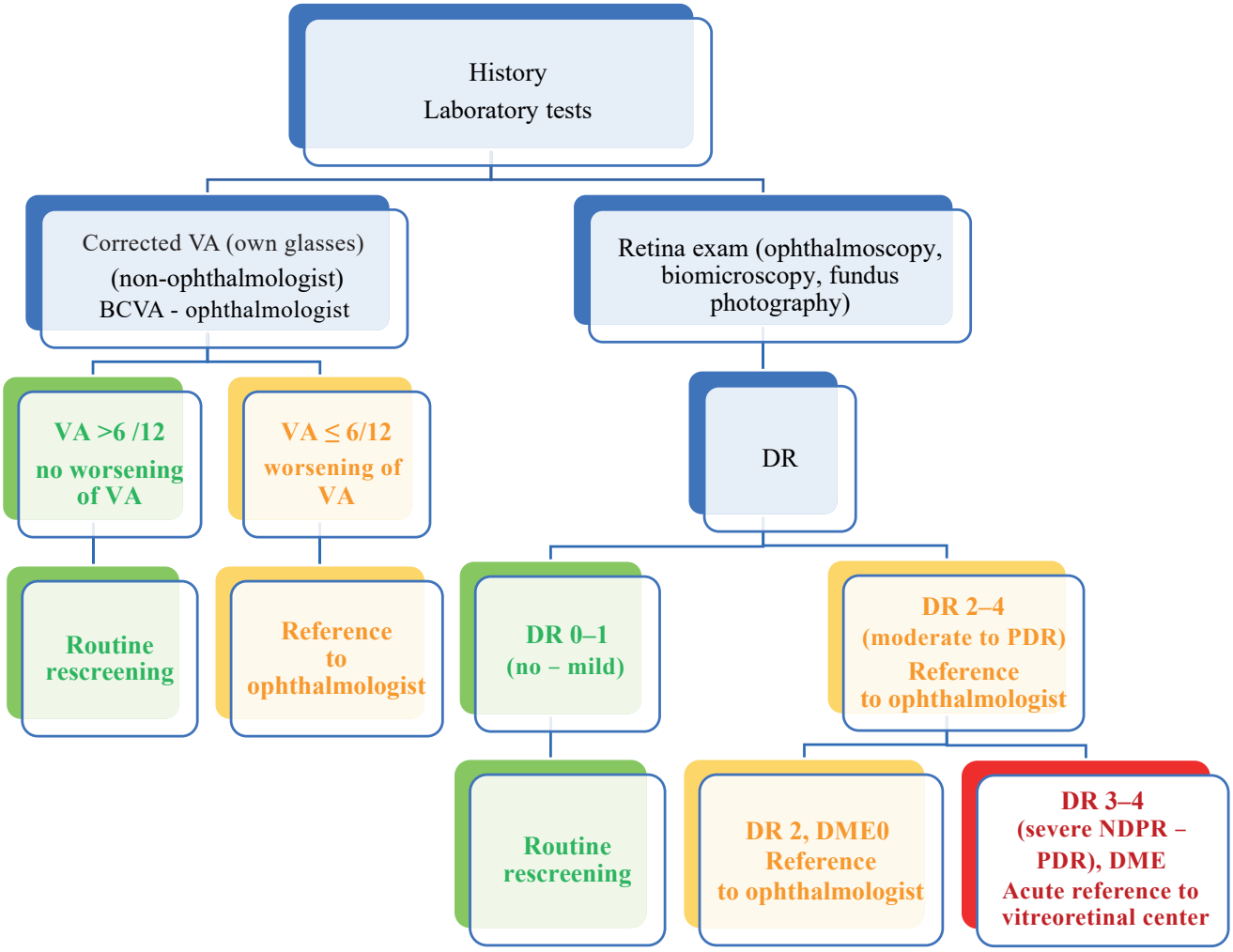



**Figure 2.** Algorithm of basic screening and patient reference to ophthalmology care (green – rescreening, orange – reference to ophthalmologist, red – acute reference to vitreoretinal center)

*VA – visual acuity, BCVA – best corrected VA, DR – diabetic retinopathy, NPDR – nonproliferative DR, PDR – proliferative DR, DME – diabetic macular edema*

- o Commencement of treatment by identified regimen or insulin pump
- o Commencement of peritoneal dialysis or hemodialysis
- o Change of classification of DM
- o Decompensation of hypertension
- o Following transplant of kidney, pancreas, islets of Langerhans

**Algorithm of basic screening and patient reference**

Fig. 2. illustrates the decision-making process for patient reference according to evaluation of VA and examination of the retina.

**Further measures**

- Use of register of patients with DM – initially via general practitioners and diabetologists, necessary accordance across disciplines
  - o Stage 1 – record of DM yes/no
  - o Stage 2 – record of DR yes/no
- Notification of diabetes via eHealth
  - o Stage 1 – direct identification – automatic reference/notification for screening examination (SMS/email/post) for patients newly diagnosed with DM
  - o Stage 2 – pregnancy – automatic reference for screening examination
  - o Stage 3 – reference for examination according to classification of DR
- Incorporation and institutionalization of photographic documentation in screening
  - o Stage 1 – new code – AI – specialization of diabetology – already entered
  - o Stage 2 – approval of code for specialization of ophthalmology
  - o Stage 3 – review of code according to guidelines of professional societies (including CVRS and COS) and approval for general practitioners
- Standardization of tertiary centers

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**Table 2.** Recommended additional measures to improvement of DR and DME screening

| Measure | 1. Stage | 2. Stage | 3. Stage |
|---|---|---|---|
| **National Diabetological Register** | DM + patients register and notify | DR + patients register and monitor | |
| **Notification** | Newly diagnosed patients | DM + patients in pregnancy | According to DR classification |
| **Photo documentation** | AI reimbursement code | AI ophthalmology code | AI code for general practitioners |
| **Standardization of ophthalmic centers** | Definition of referential centers | Establishing national network with standardized equipment | |
| **Data management** | Register/Data storage<br>Data transfer physician - register | Ophthalmologists' inclusion | Complex register with data transfer between subjects/ individual electronic health records |

*DM – diabetes mellitus, DR – diabetická retinopatie, AI – umělá inteligence*

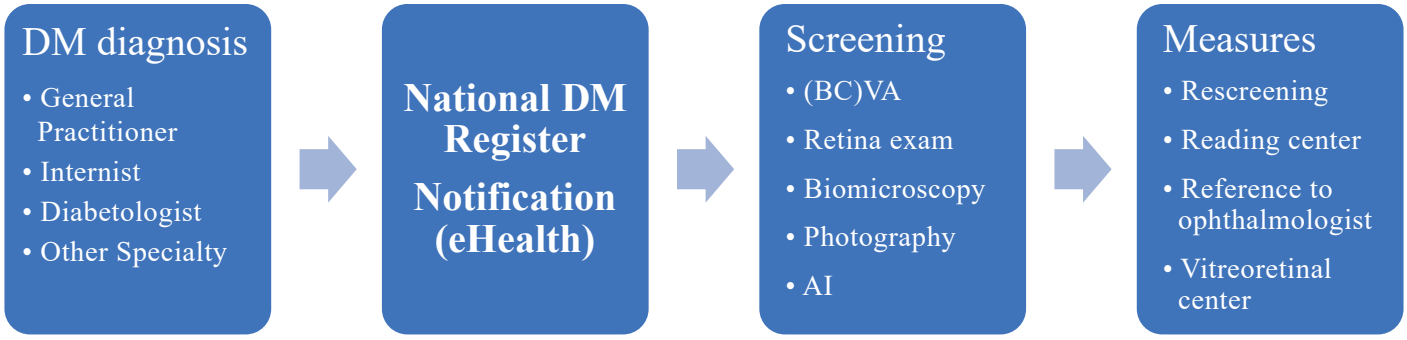



**Figure 3.** Proposal of final status of DR and DME screening in the Czech Republic
*DM – diabetes mellitus, DR – diabetic retinopathy, AI – artificial intelligence, BCVA – best corrected visual acuity*

  - o Stage 1 – referential center for referral of patients with severe DR and/or DME – on framework of existing centers – definition of staff and instrument equipment (fundus camera/s, OCT, laser, vitreoretinal equipment)
  - o Stage 2 – supplementary equipment and establishment of national network
- Creation of data matrix and use of telemedicine
  - o Stage 1 – use of register, anonymization of data, basic notification, local database
  - o Stage 2 – data interface for transfer of images and other data between register, primary screening center/ophthalmologist and tertiary center with patient access to system
- Institutionalization of national screening program
  - o Stage 1 – engagement of diabetologists – already in progress
  - o Stage 2 – coordination of care between diabetologists and ophthalmologists
  - o Stage 3 – engagement of general practitioners and full coordination with payers and other subjects

Further measures are presented in summary in Table 2. The target status of the comprehensive screening program for identifying DR and DME is illustrated in Fig. 3.

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