DIABETIC RETINOPATHY SCREENING PROGRAM

IN THE WIELKOPOLSKA VOIVODESHIP

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INTRODUCTION

Diabetes mellitus (DM) has been one of the major global public health issue for many decades and the prevalence of DM is expected to increase continuously in all regions of the world in the coming decades. (1) The International Diabetes Federation (IDF) projected approximately 700 million patients with diabetes worldwide by 2045. (2) Diabetic retinopathy (DR), one of the most common microvascular complications of DM, is one of the leading causes of preventable blindness, particularly in the working-age population, and is expected to remain a growing burden on health systems worldwide. (3)

Along with the increase in global prevalence of DM and DR, the global prevalence of vision-threatening DR (VTDR), which includes diabetic macular edema (DME), severe non-proliferative DR (NPDR) and proliferative DR (PDR), is also projected to grow. The global number of VTDR cases was estimated to increase by 57.0%, from approximately 28.5 million in 2020 to approximately 44.8 million in 2045. (4) Screening to detect early sight-threatening lesions of DR for timely monitoring and treatment is a strategy to reduce the burden of vision loss and blindness due to DR. (5, 6)

The burden of DR disproportionately affects countries worldwide. (1, 3) Low to middle income countries (LMICs) tend to have higher prevalence of DM and DR due to their less developed healthcare resources as compared to high income countries. National screening programs for DR, in which all patients with DM in a country are targets, have proven to be an effective public health intervention to sufficiently reduce vision loss from DR. (7–9) Nevertheless, most of the screening programs worldwide are opportunistic, rather than national or systematic. Every year, these screening programs require more intensive manual labor and extensive resources to accommodate the increasing number of patients with DM. Attempts have been made to lower the screening burden while at the same time increase the screening rates. They include teleretinal imaging programs, which turn out to be cost-effective. (9, 10)

Artificial intelligence (AI) algorithms have recently been shown as effective tools for autonomous or assistive screening of DR. (11–13) These algorithms can potentially lower the burden imposed on human personnel and improve access to care for patients. Many retrospective studies found robust performance in terms of diagnostic accuracy of AI for detecting referable DR (rDR) or VTDR. There were much fewer published studies on prospective validation of AI algorithms for DR screening. The results of these studies still supported the high performances of AI for DR screening, although their performances were generally lower, but still acceptable, compared with the results from retrospective validation studies. Real-world studies on AI for DR

screening, however, were rarely found in the literature.

It is generally widely accepted, based on results from many prospective studies in various countries, that AI is an effective tool for DR screening, with a high accuracy in detecting both rDR and VTDR for implementation in primary care settings. However, real-world implementation of AI for screening may rest not on its accuracy alone, but rather on its acceptability by personnel and patients, including their view on the integration of AI screening into existing clinical screening systems as an improvement step [14]. The indicators demonstrating that AI can improve healthcare systems can include the improvement in screening attendance rate, which is the proportion of patients with DM screened for DR [15], and the improvement in referral adherence, which is the proportion of patients detected as referrals by AI who receive eye care at referral centers. One study demonstrated that point-of-care delivery of screening results by AI may improve this adherence rate [16]. Finally, the indicator of reducing the rate of visual loss should be the goal for DR screening, regardless of whether AI is to be deployed or not.

The deployment of AI, as either an autonomous or semi-autonomous screening, may affect the cost of DR screening. The cost-saving from AI may differ from one country to another, depending on the healthcare resources. A study by the NHS DESP found that both the ML algorithms EyeArt and Retmarker were cost saving compared to human grading when they were deployed as semi-autonomous screening [17]. A threshold analysis testing demonstrated that the highest cost of the ML models per patient, before which they became more expensive than human grading, was GBP 3.82 per patient for Retmarker and GBP 2.71 per patient for EyeArt [17]. A cost-minimization analysis from Singapore also found the semi-autonomous model to be more cost-saving than autonomous screening. In this study, the cost of human grading was USD 77 per patient per year, whereas the autonomous screening was USD 66 per patient per year, and the semi-autonomous was UDS 62 per patient per year [18].

Technical challenges may also have influenced the successful implementation of AI. Integrating an AI model into the camera system is an important technical issue when a screening program requires the use of existing cameras. Integrating AI into DR screening system with an existing hospital management system or electronic health record system is another challenge to ensure sustainability [14].

In the bigger picture, the concept of AI governance should be applied in real-world implementation to ensure equality, privacy, fairness, inclusiveness, safety and security, robustness, transparency, explainability, accountability, and auditability [19]. There has been a proposition for a governance model

for AI in healthcare which outlines four main components: fairness, transparency, trustworthiness, and accountability [20]. For fairness, there should be Data Governance Panels overseeing the collection and use of data; the design of AI models should ensure procedural and distributive justice. For transparency, there should be transparency for AI model decision-making and support for patient and clinician autonomy. For trustworthiness, educating patients and clinicians is important. Informed consent is required from patients and appropriate – and authorized – use of patient data should be applied. For accountability, regulation and accountability at the approval, introduction, and development phases of AI in healthcare should be followed. Real-world implementation of AI for DR screening should undoubtedly follow this concept.

IMPLEMENTATION OF THE PROGRAM

Basic information

The project **"Diabetic Retinopathy Prevention Program in Wielkopolskie Voivodeship"** was implemented on the basis of the health program of the same name, the implementing entity: the Foundation for Supporting the Development of Ophthalmology "Okulistyka21" (in partnership with the Department of Internal Diseases and Diabetology of the K. Marcinkowski Medical University in Poznań) was selected on the basis of the competition announced on 24 September 2018.

The grant agreement for the implementation of the project was signed on 4 July 2019, project implementation started on 1 August 2019.

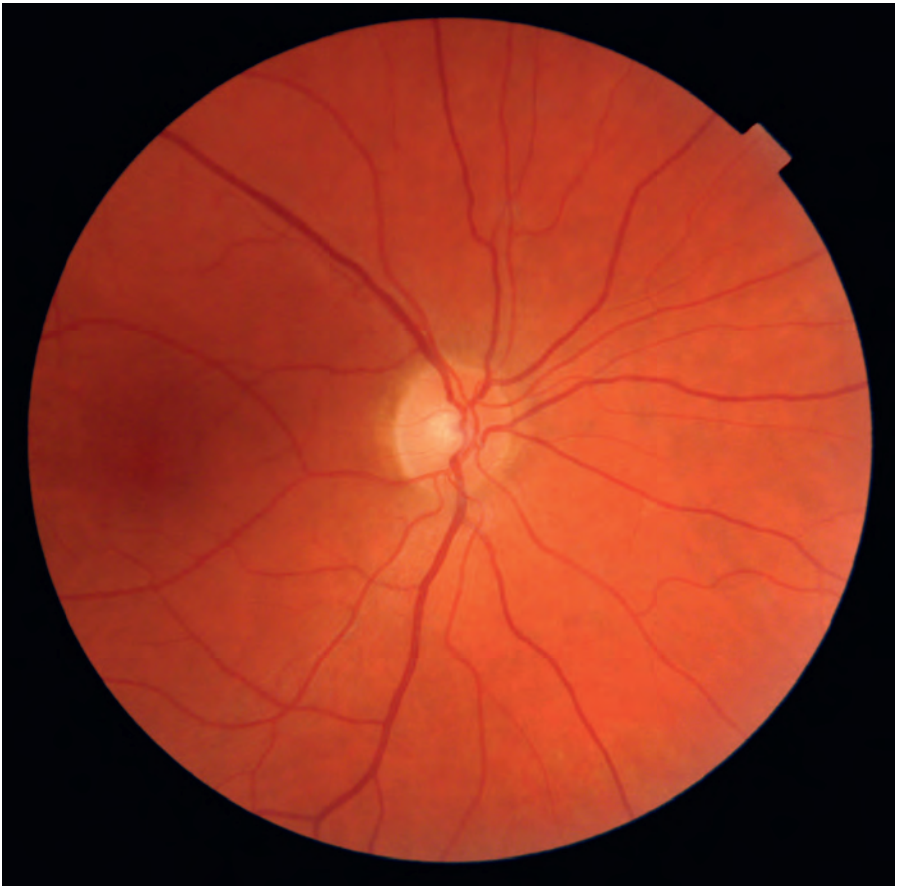
The project according to the original assumptions was to be implemented until 31 July 2022, due to changes made to the project it was extended until 30 June 2023.

In the first implementation period from 1 August to 30 September 2019, the implementer dealt with the organization of research by selecting contractors and suppliers: software, equipment, personnel, educational materials, organization of an educational campaign. In the period from 01 October 2019 to 31 May 2023, tests were carried out in diabetes clinics and patient education was conducted. On the other hand, in the period 1–30 June 2023, a publication summarizing the implemented program was prepared.

Cooperation with diabetes clinics

The implementing entity was obliged to establish cooperation with diabetes clinics contracted by the National Health Fund (NFZ). As part of this cooperation, screening tests for diabetic retinopathy and patient education on prevention were carried out at the clinics.

According to data from the health program, in 2018, there were 53 diabetes outpatient clinics with NFZ con-



Photograph of the fundus of the eye

tracts, while in 2019, there were already 56. Between 2019 and 2022, the number of outpatient clinics dropped to 45, which is 20%. Currently, in 2023, the number is 47 – due to the signing of a new contract by the NFZ in Poznań and the opening of a branch of one of the hospitals in the Poznań agglomeration.

At the same time, it should be noted that among the outpatient clinics that opted out of their NFZ contracts, only one was in Poznań, while the others were located in smaller towns and were often the only NFZ diabetes clinic in the district.

According to the knowledge gained in the outpatient clinics, many clinics are short of specialists, or those available are of retirement age and are planning to stop running clinics under the NFZ. Therefore, a further reduction in the number of diabetes outpatient clinics

with NFZ contracts in the Wielkopolskie Voivodeship can be expected.

To establish cooperation with the clinics, the program implementing entity contacted – in person, by e-mail or by telephone – a total of 50 clinics out of a total of 56. In the case of five clinics, they had terminated their contracts with the NFZ before an attempt to establish cooperation was made, while in the case of one clinic, no contact could be established.

The tests were organized in 30 outpatient clinics in 19 towns in the Wielkopolskie Voivodeship. A total of 53 people were trained in outpatient clinics in the prevention of diabetic retinopathy and the use of fundus cameras and fundus photography.

Many counselling clinics expressed an interest in carrying out the study, but for technical and organizational reasons and staff shortages, they did not cooperate. The most common reasons for non-cooperation included:

- A lack of available space; most of the large health care providers use all the rooms for their purposes or rent them commercially, while the smaller providers that predominate in smaller districts/cities usually occupy one or two rooms and do not have the capacity to provide space for additional examinations;
- Staffing – many facilities did not have the staff they could second to perform examinations if they undertook the examinations themselves, while low interest was found if independent contractors were sought – a situation attributed to shortages of medical staff in the health service;
- too low a rate for the staff involved in the implementation of the research;
- too low, non-market rates for the provision of testing facilities;
- no remuneration for diabetes doctors for their commitment to the program;
- a shortage of specialists and, therefore, an overload of outpatient clinic staff made it impossible to organize additional initiatives for patients at the clinic.

Comparison of the situation before the introduction of the diabetic retinopathy prevention program and the effects of its implementation

According to the health program data, the number of people treated for diabetic retinopathy with NFZ contracts was 5,560 people. This is a counted value from three years (2014–2016). Originally, the program assumed a 10% increase in this value (i.e., 556 people). After changes to the project, the rate was increased to 4,027 people diagnosed with diabetic retinopathy.

During the project period (i.e., 2019–2023), 3,994 cases of diabetic retinopathy were detected in a population of more than 13,000 patients screened in the project. Thus, more than seven times more cases of the disease were detected than originally expected. At the same time, the detection rate of diabetic

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