



SUMMARY

SCREENING FOR DIABETIC RETINOPATHY IN QUÉBEC

Diabetes is a recognized public health priority, and its prevalence is reaching pandemic proportions. According to the World Health Organization (WHO), more than 360 million people will be affected by this disease in 2030. In Canada, 1.8 million people have diabetes, or roughly 7.1% of those aged 20 years and older and 18% of those aged 60 years and older. Moreover, diabetes has become epidemic in Aboriginal communities, where its prevalence is at least three times greater than in the general public. According to data from the Institut national de santé publique du Québec (INSPQ), in 2003–2004, diabetes affected nearly 376,000 people, or 6.4% of Québec's population aged 20 and older.

Of the many eye complications caused by diabetes, **diabetic retinopathy** is the most severe. Almost all people with diabetes are affected by it at some point in their lives. Diabetic retinopathy (DR), which is the main cause of blindness in the working population in industrialized countries, is often totally asymptomatic until the onset of complications. Vision loss, which may be gradual or sudden, generally appears only in the final stage of the disease.

The Association des médecins ophtalmologistes du Québec (AMOQ) asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to assess the advisability of screening for diabetic retinopathy and the feasibility of a screening program in Québec. Two specific points were mentioned in the request: to examine the effectiveness of the new generation of digital non-mydratric retinal cameras (without pupil dilation), and to analyze diabetic retinopathy screening programs in other countries.

This report is a systematic literature review on that topic. Assessing the advisability of screening for diabetic retinopathy aims to answer questions about the availability of an effective treatment, the performance of diagnostic screening methods,

the clinical effectiveness and cost effectiveness of screening programs, and the ethical, social, economic and organizational issues surrounding this type of program. The report also includes 1) a description of screening programs in other countries (Great Britain, Germany and France) and Canadian provinces; 2) an analysis of their applicability to Québec; 3) a description of the current situation of DR screening in Québec; 4) an assessment of the feasibility of a systematic screening program in Québec; and 5) possible scenarios to consider in light of issues specific to Québec.

Methodology

Various search strategies were used to query the Medline, Cochrane Library, EMBASE and INAHTA databases to retrieve existing systematic reviews, health technology assessment (HTA) reports and primary studies. For information on ethical and psychosocial aspects, the PsycINFO and PASCAL databases were also queried. The search for primary studies was based on four key areas: diabetic retinopathy; diagnostic screening methods; treatments; and study designs according to the aspect under investigation and outcomes of interest: safety, effectiveness, costs, economic, organizational, ethical and psychosocial issues, etc.

Contextual analysis methods (semi-structured interviews with key informants and analysis of their abstracts) were used to describe current care for people with diabetes in Québec and the ethical and organizational aspects of a potential screening program. Québec data and recommendations from programs in place elsewhere helped prepare possible scenarios for a systematic screening program adapted to Québec.

Effectiveness of diabetic retinopathy treatment

Laser treatments are used to prevent vision loss associated with diabetic retinopathy, primarily pan-retinal photocoagulation (PRP) and focal retinal photocoagulation (FRP). The benefit of laser treatment was established in two large randomized studies: Diabetic Retinopathy Study (DRS), published in 1978 and 1981, and Early Treatment Diabetic Retinopathy Study (ETDRS), published in 1991. The adverse effects of laser treatments most commonly reported in randomized clinical trials were : 1) pain during the procedure; 2) reduced visual field, which has impacts on daily living activities such as the inability to drive a car; 3) loss of night vision and changes in colour vision; and 4) loss of visual acuity immediately after PRP treatments. Other less frequent but serious complications have also been reported, such as accidental laser burns to the retinal fovea potentially causing blindness. However, no study has reported on the incidence of these complications.

The effectiveness of this treatment warranted the implementation of DR screening programs in European countries. Although this treatment is effective, its adverse effects mean that it is crucial to limit it strictly to the cases that would benefit from it.

Performance of potentially useful diagnostic screening tests for diabetic retinopathy

Scientific evidence and the experiences of systematic screening programs in place elsewhere support the use of digital cameras for DR screening. The sensitivity and specificity of mydriatic and non-mydriatic cameras for detecting sight-threatening diabetic retinopathy (requiring patient referral to a retinal specialist for possible treatment) are equivalent. Mydriasis (pupil dilation) has a considerable influence on participation (compliance) in DR screening. The United Kingdom and Scotland recommend the use of a staged mydriasis protocol (mydriasis after an inconclusive non-mydriatic photograph). Currently, in the majority of the programs, digital non-mydriatic retinal photography is considered a

routine test for high-risk DR screening owing to its sensitivity (86–90%), its specificity (77–87%) and its acceptability compared with other diagnostic techniques. The examination, which takes a quarter of an hour or so, can be performed by a technician or a properly trained professional. The retinal images can be transmitted via a telemedicine network, a method adopted in the programs of other countries and in Canadian pilot projects to optimize ophthalmologists' work time.

Screening effectiveness and cost effectiveness

No randomized clinical trial on the effectiveness of a screening program for diabetic retinopathy was located. However, the effectiveness of such a program can be proven indirectly by noting variations in the incidence of the disease after implementation of a screening program. Observational studies carried out in countries with screening programs, especially in Europe, have effectively revealed a reduced incidence of blindness due to diabetic retinopathy.

With respect to the cost effectiveness of a DR screening program, economic analyses have shown that the shift from opportunistic screening to systematic screening is warranted. The non-mydriatic option tends to offer a better cost-effectiveness ratio. The only Canadian economic study identified was conducted in Ontario and showed that, for remote communities, screening with a digital non-mydriatic camera is more cost-effective than by ophthalmoscopy performed by ophthalmologists who travel there.

Screening programs outside Québec

Several DR screening programs are in place in Europe, and pilot projects have been launched in different regions of the United States and Canada (Alberta, Ontario, British Columbia, Northwest Territories). The UK program provides the most detailed information on the technical aspects of a DR screening program and on the elements key to its implementation and quality assurance.

Owing to the wide diversity of health-care systems and human resources involved in eye health, programs in other contexts are not easily transferable to the Québec situation. Although

several pilot projects have been implemented in Canada and their results seem encouraging, most have broader objectives, such as screening for other diseases or general eye health surveillance. These pilot projects nonetheless provide significant information on various aspects defined in the literature as potential difficulties linked to DR screening: acceptability for patients and professionals (mydriasis and preference for non-mydriatic cameras), patient compliance, visual acuity measurement for diagnosing macular edema, technical aspects (uninterpretable photos), ethical issues (screening in Aboriginal communities) and barriers to telemedicine use. Possible solutions noted in HTA reports or observational studies on pilot projects are presented in this report.

Québec context

Québec does not currently have a systematic diabetic retinopathy screening program. Screening is opportunistic and performed by different professionals (ophthalmologists, general practitioners, endocrinologists and optometrists) using a variety of tests (indirect ophthalmoscopy with dilation, direct ophthalmoscopy most often without dilation). According to Canadian guidelines, all people with diabetes should have annual retinopathy screening tests. This recommendation is not followed in practice, especially because of the low compliance of patients, who are not made aware of the importance of screening and who are apprehensive about mydriasis; the limited number of ophthalmologists,² which reduces access to ophthalmology examinations; and the absence of a well-defined screening strategy.

Moreover, the number of people with diabetes aged 20 and older is rising. The Institut national de santé publique du Québec (INSPQ) reports that nearly 376,000 people in Québec (2003–2004) have diabetes. Assuming a 100% participation rate, the approximate volume of annual screening tests to be performed would be at least 376,000 per year. Examination of treatment billing data from the Régie de l'assurance maladie du Québec (RAMQ) compared with the incidence of diabetes and retinopathy led to the estimation that only 25% of

diabetics who potentially have diabetic retinopathy are actually being treated.

According to the ophthalmologists consulted, 85% of the patients with diabetes referred to them did not need treatment or their expertise. In Québec, systematic screening would lead to a rise in the number of examinations (about double those currently being done) and treatments (from three to four times more for the first few years), but ophthalmologists would have more time to devote to patients requiring their expertise. Standardizing ophthalmology referral criteria (as part of a screening program), combined with implementing health service corridors, would permit much more effective care. A provincial systematic screening program would allow the gradual introduction of services tailored to the needs of the different regions and would open access to care for all the population with diabetes. A continuing evaluation process, along with secure data collection and analysis, would help ensure the effectiveness of the program based on provincial standards, provide for quality control and assess the budget implications of different scenarios. Some key elements emerged from the analysis of possible scenarios for Québec, such as having professionals share screening activities, defining the acts of taking and reading photos, training professionals to ensure quality photographs and organizing DR screening as part of the current general care for people with diabetes in Québec.

The dominant scenario is built on making screening part of standard health care delivery (primary care and secondary care) co-ordinated and managed by the health and social services agencies (agences de la santé et des services sociaux) through a centre of excellence affiliated with each RUIS (network of university teaching hospitals). The effectiveness of the services offered will depend on co-operation between the levels of health care. Central co-ordination is also necessary for purposes of quality control and evaluation. Screening is performed with a digital non-mydriatic camera with the possibility of staged mydriasis when necessary. Photographs are taken by trained or recognized practitioners. Data are transmitted through Québec's health and social services telecommunications network, the Réseau de télécommunications sociosanitaire (RTSS), to the centres of excellence, which are responsible for diagnosis and treatment. Data can

2. Québec has 287 ophthalmologists for a population of 7,597,768 and remote communities are poorly served.

be transmitted asynchronously because the medical act of diagnosis will be performed *a posteriori*. Patients requiring treatment must be referred within a prescribed time.

Conclusion and recommendations

After analyzing the evidence, the experiences of other programs and Québec's current context, AETMIS concludes that it is advisable and feasible to introduce a diabetic retinopathy screening program in Québec. However, some key elements must be defined before realistic scenarios can be established and costs estimated. These elements include organizing screening as part of the current general care for people with diabetes, determining how professionals will share screening activities, defining the acts of taking and reading photos, and training professionals to ensure quality photos.

AETMIS recommends the gradual introduction of a province-wide systematic DR screening program using non-mydratic retinal cameras for people with diabetes aged 12 years and older in Québec. Such gradual implementation will help ensure that organizational methods are better tailored to available resources and population profiles in the target areas, with the aim of offering quality care. More specifically, AETMIS recommends the following:

- 1) The Ministère de la Santé et des Services sociaux (MSSS) should develop, in collaboration with associations and professional orders, a frame of reference based on the scientific evidence analyzed in this report. That frame of reference should determine the target clients and participating professionals, along with their respective roles and required minimum training; establish optimal screening intervals; guide the choice of screening method and its technical specifications; propose standardized evaluation tools; establish quality-assurance measures and program evaluation parameters; and define the necessary technical and organizational infrastructures, and legislative oversight.
- 2) The Collège des médecins du Québec and the Ordre des optométristes du Québec should determine how responsibilities will be shared among eye care professionals, some of which are already clearly established.
- 3) The health and social services agencies, in collaboration with the RUIS and their centres of excellence, should co-ordinate the gradual introduction of screening in their areas of jurisdiction and should give priority to implementing it in remote communities with a high prevalence of diabetes or poorly served in the current context.
- 4) The health and social services agencies, in collaboration with the RUIS, should co-ordinate the organizational aspects of screening (networking with screening centres of each region and quality control) by using the existing integrated health service corridors. If necessary, these agencies could also be entrusted with the activities and technical aspects connected to tele-ophthalmology (secure data transmission through the health and social services telecommunications network [RTSS], expert image interpretation, archival of retinal images in a database or registry).
- 5) The health and social services agencies, in collaboration with the RUIS and their centres of excellence, should ensure that all the patients in their areas receive timely access to treatment according to the severity of the disease.
- 6) The MSSS should provide support to the health and social services agencies affiliated with each RUIS for implementing the different preferred scenarios and should evaluate the outcomes to determine which modalities are the most effective and cost-effective for extending the program's coverage.