World Health Organization
REGIONAL OFFICE FOR Europe

Diabetic retinopathy screening: a short guide

Increase effectiveness, maximize benefits and minimize harm

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Abstract

This guide is designed for policy-makers, public health leaders and senior clinicians involved in planning, designing and implementing diabetic retinopathy screening programmes in the WHO European Region. The purpose of screening is to identify people with diabetes who are at higher risk of developing sight-threatening diabetic retinopathy so that early treatment or intervention can be offered to reduce the incidence of vision impairment or blindness. It demonstrates how the Wilson & Jungner principles apply to diabetic retinopathy screening, describes the pathway to follow and explains how to initiate new programmes or improve the effectiveness of those already existing. The guide forms part of WHO's efforts to increase the effectiveness of screening programmes within the Region, maximizing benefits and minimizing harm.

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CORRIGENDUM

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Subtitle of the publication has been added on the cover page and in suggested citation: Increase effectiveness, maximize benefits and minimize harm.

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Foreword

Diabetic retinopathy is a leading cause of preventable blindness and vision impairment. This guide comes at an important time in the WHO European Region, as trends for diabetes continue to rise and gaps in quality care persist.

The guide aims to capture the challenges policy-makers may face in implementing effective diabetic retinopathy screening and lays out the important steps that should be considered for developing more systematic and quality-assured approaches.

The guide is an output of a cross-programmatic initiative of the WHO Regional Office for Europe that aims to improve screening practices through the life-course and thereby increase effectiveness, maximize benefits and minimize harm. Diabetic retinopathy screening is one of the effective measures recommended by WHO for the prevention and control of noncommunicable diseases, and the prevention of vision impairment and blindness. Combining efforts for better diabetes care and eye care requires ministries of health and public health leaders to work with different stakeholders across professional groups and with patients and at different levels of government. This approach is central to the vision of WHO's European Programme of Work 2020–2025 "United Action for Better Health" for meeting citizens' expectations for health.

We look forward to working with countries to improve the quality of this screening programme, and ultimately improve the quality of life of people with diabetes. We hope this guide proves to be useful in this endeavour.

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Acronyms

ETDRS	Early Treatment Diabetic Retinopathy Study
ICO	International Council of Ophthalmology
NPDR	nonproliferative diabetic retinopathy
OCT	optical coherence tomography
PDR	proliferative diabetic retinopathy
TADDS	Tool for the assessment of diabetic retinopathy and diabetes management systems
VEGF	vascular endothelial growth factor

Executive summary

Diabetic retinopathy is a leading cause of preventable vision impairment and blindness in the WHO European Region (Flaxman et al., 2017). It occurs in about a third of people with diabetes and its damaging effects on vision can be prevented by early detection and treatment through screening (Lee et al., 2015; Thomas et al., 2019; Williams et al., 2004). Vision impairment and blindness have major economic consequences in terms of use of health and social care resources and impact on economic productivity (WHO, 2019).

Although many countries in the WHO European Region have some form of eye checks in place for people with diabetes, these are often not adequately resourced or organized systematically as a screening pathway. Many people with diabetes are living with preventable vision impairment and blindness.

Diabetic retinopathy mainly is caused by the effect of raised blood glucose on the blood vessels in the retina. It can be prevented, and its progression slowed, by control of blood glucose, blood pressure and elevated lipids. If it progresses to an advanced form, treatment with laser and, if available, intraocular drug injections can prevent vision impairment and blindness.

Diabetic retinopathy screening can identify early changes in the retina so treatment can be given before vision impairment or blindness occurs.

The focus of this guide is to show how countries can improve their approach to diabetic retinopathy screening by understanding how to design an effective systematic screening programme.

The guide demonstrates how the principles of screening laid out by Wilson & Jungner (1968) can be applied to screening for diabetic retinopathy. It describes the epidemiology of diabetic retinopathy, how diabetic retinopathy is classified, and considers some of the important design features of a systematic diabetic retinopathy screening programme.

The guide moves on to describe the steps of the screening pathway: identifying the population eligible for screening; invitation and information; testing; referral of screen positives and reporting of screen-negative results; diagnosis; intervention, treatment and follow-up; and reporting of outcomes. It shows that for diabetic retinopathy screening to be most effective, a screening pathway encompassing all these steps should be in place.

The chapters in the guide illustrate how countries can improve the effectiveness of their screening. They provide a framework for undertaking a situational analysis that looks at four domains: ***resources and infrastructure,*** a ***pathway*** for screening, ***quality*** of screening, and ***equity*** in access to high-quality screening. The framework is used to look at how to improve each of these domains with some country examples about how this might work in practice, recognizing that some countries will move forward in a stepwise manner according to their available resources. Some brief examples of good practice from countries are also provided throughout the text.

The penultimate chapter considers important workstreams, such as governance, personnel, information systems and financing, that policy-makers may need to consider in improving or redesigning a diabetic retinopathy screening programme.

Countries in the WHO European Region face common problems in screening for diabetic retinopathy and the guide provides case studies of countries that have tackled these problems. Four important messages are delivered.

- Many low- and middle-income countries do not have enough laser capacity. The guide proposes a stepwise improvement strategy, starting with increasing laser capacity then expanding screening using available technology.
- Many countries cannot identify everyone who has a diagnosis of diabetes. Without a list of all people with a diagnosis of diabetes, some may not be invited for screening and be checked for diabetic retinopathy. Developing accurate and comprehensive lists (either nationally, regionally or locally) is another important step in improving the effectiveness of screening. For countries that do not yet have a comprehensive list(s), other steps can be taken to improve attendance, such as public awareness campaigns.
- Digital retinal photography is considered to be the most effective diabetic retinopathy screening method, but many countries cannot afford to buy cameras to screen everyone who has diabetes. This does not need to stop a screening programme developing, and while slowly increasing digital retinal camera use as resources become available, it is possible for trained and competent practitioners to screen patients using slit-lamp biomicroscopy or direct ophthalmoscopy (if slit-lamp biomicroscopy is not available).
- Many high-income countries have excellent diagnostic and treatment services, but screening pathways often are not in place for all the eligible population. Fragmented systems across family doctor, endocrinology/diabetology, ophthalmology and hospital care may mean that not everyone with diabetes regularly gets invited for screening and receives the same quality of care. A focus on pathway and quality, using integrated e-health information systems, can create a high-quality, equitable and systematic screening service for everyone with diabetes in these countries.

The guide supports policy-makers, public health leaders and senior clinicians to examine critically their current approach to diabetic retinopathy screening and challenges them, whatever their current position, to take steps to improve their approach and make diabetic retinopathy screening systematic, more effective and ultimately equitable for all people with diabetes.

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[1] All weblinks accessed 19 October 2020.

1 Introduction

Diabetic retinopathy is a common complication of diabetes and is a major cause of vision impairment and blindness worldwide (WHO, 2019a) (Box 1). It is estimated that 950 000 people in the WHO European Region have vision impairment or blindness because of diabetic retinopathy (Flaxman et al., 2017).

Box 1. What is diabetic retinopathy?

It is a condition caused by diabetes that affects the retina. Blood vessels in the retina are damaged and become leaky or blocked.

Abnormal blood vessels can grow from the retina, which can bleed or cause scarring of the retina and result in permanent vision impairment or blindness.

Vision impairment most commonly occurs due to thickening in the central part of the retina (diabetic macular oedema), which can lead to irreversible vision impairment.

WHO's *Global report on diabetes* (WHO, 2016) and the *World report on vision* (WHO, 2019a) have highlighted the importance of diabetic retinopathy screening as a means of preventing blindness and vision impairment, and it is one of WHO's recommended effective interventions for noncommunicable diseases (WHO, 2017). Diabetic retinopathy screening is not carried out systematically in many countries in Europe, however, and opportunities to prevent people from developing vision impairment and blindness are being missed.

This guide is part of an initiative by the WHO Regional Office for Europe to improve the effectiveness of screening, maximize benefits and minimize harm. It is an operational guide and is not a clinical guideline. It is built on the approach to screening that has been described in the preceding documents in the series, *Screening programmes: a short guide* (WHO Regional Office for Europe, 2020a) and *Screening: when is it appropriate and how can we get it right?* (Sagan et al., 2020). Readers are encouraged to refer to these documents for further information on terminology, design, implementation and operation of screening programmes.

A note on terms used in this guide

The term ***diabetic retinopathy screening*** is used in this guide. In some countries, it is called diabetic eye screening.

Diabetic maculopathy is a particular kind of diabetic retinopathy. Screening for diabetic retinopathy always includes screening for diabetic maculopathy.

Diabetic macular oedema is a type of ***diabetic maculopathy.*** Both terms are used to indicate damage to the macula (central part of the retina).

2 Purpose of this guide

This guide is designed for policy-makers, public health leaders and senior clinicians involved in planning, designing and implementing services for people with diabetes and/or screening programmes in the WHO European Region.

Most countries of the WHO European Region have some screening or checking for diabetic retinopathy taking place. The focus of this guide therefore is on how to ***increase the effectiveness*** of a country's approach by moving from an unorganized towards a more systematic screening programme.

Each country's health-care system is different, and there is no single way to operate a diabetic retinopathy screening programme. The guide recognizes that countries work under different constraints, such as availability of cadres of clinicians and equipment, access to health facilities, finance to pay for new initiatives and competing health-care priorities. For this reason, the guide is designed to help policy-makers consider options and understand the advantages and disadvantages of different approaches to setting up and operating a programme. The options considered are evidence-based, feasible and achievable, if not for all countries, then for many.

Diabetic retinopathy screening is different to population screening programmes because it targets people who are already known to have a condition. Checking the eyes of a person with diabetes and offering appropriate treatment is an evidence-based intervention that reduces the risk of vision impairment and blindness and should be part of routine care for people with diabetes (WHO Regional Office for Europe & International Diabetes Federation, 1997).

The guide will help policy-makers review their current system of checking or screening for diabetic retinopathy and consider steps to increase its effectiveness through implementing a more systematic approach (Box 2).

Box 2. Taking an integrated approach for people with diabetes

The focus of this guide is diabetic retinopathy screening, but it does not stand alone. Rather, diabetic retinopathy screening takes place within the context of good care for people with diabetes.

Prevention and slowing the progress of diabetic retinopathy depends on good diabetes management. Providing patient education, supporting self-care, and facilitating the control of blood sugar, blood pressure and blood lipids through healthy lifestyles and appropriate treatment can help achieve good health outcomes and quality of life, as outlined in WHO guidance.

Health-care workers and care systems should not operate in silos. Relevant information about diabetes and eye status should be shared with the person with diabetes and across the system to facilitate integrated care. Results of eye screening should be shared with those responsible for diabetes care, and any incidental findings during eye screening, such as cataract or glaucoma, should be referred appropriately to eye-care services (WHO, 2020).

An explanation of technical terms used in the guide is provided in Annex 1.

United Kingdom (England): moving from opportunistic to an effective systematic screening programme

During the 1990s, some local areas in England carried out diabetic retinopathy screening for people with diabetes using 35 mm film, polaroid photography or slit-lamp biomicroscopy. Many areas, however, did not have a complete list of people with diabetes, different retinopathy and referral thresholds were in use, and the quality of screening varied considerably across England.

Screening programmes using digital retinal photography commenced in 1998. A review was carried out by the National Screening Committee in 2003 and a national systematic diabetic retinopathy screening programme was recommended. The national programme was established in 2004 and, as of April 2020, 57 local services across England provide standardized quality-assured diabetic retinopathy screening.

All individuals with diabetes aged 12 years and over are invited for a diabetic eye screening appointment at least annually. Those considered to be at higher risk of progression of retinopathy (including pregnant women with diabetes) can be invited for screening more regularly in digital surveillance clinics as part of the screening programme. The English programme is in the process of extending the screening interval for those at least risk of retinopathy from 12 to 24 months based on evidence of the progression of retinopathy in low-risk individuals.

Since the programme was established, each local area has had a list of people with diabetes that is checked and updated regularly. Screening is performed by qualified screeners who carry out two-field retinal photography. Images are then digitally transferred to a centralized location for retinal grading by qualified individuals. A comprehensive quality-assurance system is in place, which includes regular auditing of grading carried out by individuals grading within the English screening programme.

The diabetic retinopathy screening programme in England screened 2 847 149 people with diabetes in 2018/2019 (83% coverage). Following seven years of screening for treatable diabetic retinopathy, a review of the causes of blindness in England revealed that after five decades, the condition was no longer the most common cause of blindness in the working-age population (Liew at al., 2014). This provides compelling evidence that systematic diabetic retinopathy screening, coupled with timely treatment of sight-threatening disease, can reduce vision impairment and blindness.

3 Principles of screening

Screening programmes: a short guide (WHO Regional Office for Europe, 2020a) describes the principles of screening set out by Wilson & Jungner (1968) (Box 3). These principles or criteria must be met if screening for a condition is to be an effective intervention.

Box 3. Wilson & Jungner's principles of screening

1. The condition should be an important health problem.
2. There should be an accepted treatment for patients with recognized disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognizable latent or early symptomatic phase.
5. There should be a suitable test or examination.
6. The test should be acceptable to the population.
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood.
8. There should be an agreed policy on whom to treat as patients.
9. The cost of case-finding (including a diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
10. Case-finding should be a continuous process and not a "once and for all" project.

Source: Wilson & Jungner (1968).

The next two chapters demonstrate how diabetic retinopathy screening complies with Wilson & Jungner's principles of screening.

3.1. Aim of diabetic retinopathy screening

The aim of systematic diabetic retinopathy screening is to reduce the risk of **vision impairment and blindness** among asymptomatic[1] people with diabetes through the prompt identification and effective treatment of sight-threatening diabetic retinopathy.

People who develop new symptoms of vision impairment should seek care and be managed in existing eye services as normal, not through a screening programme.

[1] Asymptomatic refers to a person with no perceived vision impairment due to diabetic retinopathy.

4

Background information: diabetic retinopathy screening

This chapter considers important background information about diabetic retinopathy screening, inlcuding the epidemiology of the disease, its natural history and classification, thresholds for referral and treatment, and prevention and treatment of retinopathy.

4.1. Epidemiology

About 64 million people in the European Region have diabetes (NCD Risk Factor Collaboration, 2016), or about 7% of the population of the Region. It is estimated that 950 000 people in the WHO European Region have vision impairment or blindness because of diabetic retinopathy (Flaxman et al., 2017).

Diabetic retinopathy is a leading cause of preventable vision impairment and blindness in the working-age population (Cheung et al., 2010; Ding et al., 2012; Leasher et al., 2016). The economic burden of vision impairment and blindness due to diabetic retinopathy in Europe is considerable (Happich et al., 2008; Heintz et al., 2010).

A global study in 2017 found that of the leading causes of vision impairment and blindness, the crude global prevalence (all ages) of diabetic retinopathy as a cause increased between 1990 and 2015, while all other causes of vision impairment and blindness decreased markedly (Flaxman et al., 2017).

The prevalence of diabetic retinopathy in people with diabetes varies according to the type of diabetes, how long they have had the condition, and by region. Which test is chosen to measure prevalence and what is measured can also affect the amount of disease reported. This means that ranges of values for prevalence of diabetic retinopathy reported can differ significantly between studies. In Europe, it is estimated that between 20% and 35% of people with diabetes will have any form of diabetic retinopathy and approximately 2% will have proliferative diabetic retinopathy; for macular oedema among people with type 2 diabetes, the estimates vary widely between 1% and 13%, depending on how it is measured (Williams et al., 2004; Lee et al., 2015; Thomas et al., 2019).

Diabetic retinopathy is an important health problem

Wilson & Jungner's 1st principle

4.2. How diabetes causes diabetic retinopathy

Fig. 1 shows the structure of the eye. The retina is the area at the back of the eye that receives light, transforming it to nervous impulses. The macula is the central part of the retina that allows us to see fine detail and colours.

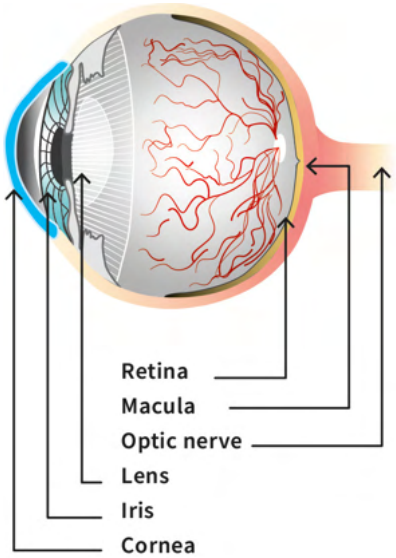
Diabetic retinopathy is a direct consequence of raised glucose levels on the small blood vessels of the retina. Other important risk factors for diabetic retinopathy are raised blood pressure and elevated serum lipids, both of which are common in people with diabetes.

People with diabetic retinopathy may not have any symptoms of vision impairment (asymptomatic).

When a person has the most advanced form of diabetic retinopathy, they can ***suddenly*** develop severe vision impairment or blindness because of bleeding from abnormal retinal vessels into the eye or damage to the retina from a retinal detachment.

As diabetic macular oedema increases in severity, the thickening of the retina affects the central part of the macula. This damage can occur more slowly than in proliferative diabetic retinopathy, leading to ***progressive*** vision impairment.

Fig. 1. The eye



Source: adapted from WHO (2019a).

4.3. Natural history and classification of diabetic retinopathy

The natural history of diabetic retinopathy was described in a pivotal study called the Early Treatment Diabetic Retinopathy Study (ETDRS) carried out in the 1980s (Early Treatment Diabetic Retinopathy Study Research Group, 1991). The description of disease progression in the ETDRS is still used today as the basis for classification systems for diabetic retinopathy.

Classification and grading systems ***classify*** findings on examination using agreed nomenclature and then ***grade*** them according to severity.

One example of a classification system based on the ETDRS can be found in the International Council of Ophthalmology (ICO) guidelines for diabetes eye care (International Council of Ophthalmology, 2017; Wong et al., 2018).

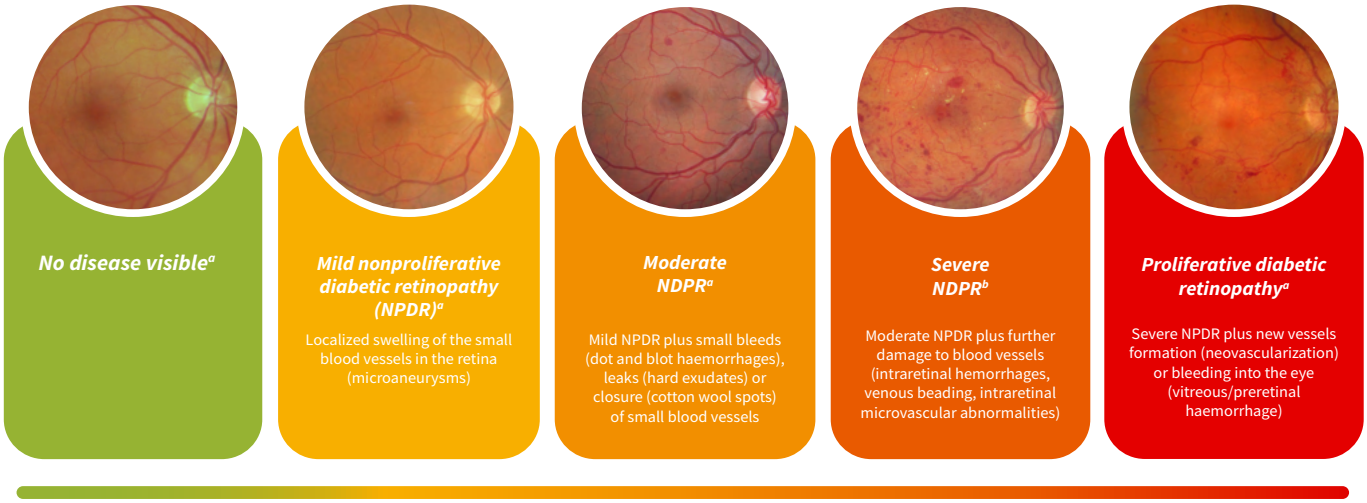
The classification distinguishes between retinopathy and maculopathy because they can progress at different rates and changes in the macula can occur at all grades of severity of diabetic retinopathy.

A simplified version of this classification system is given in Fig. 2a and 2b. The full version of the ICO classification can be found in Annex 2.

The natural history of diabetic retinopathy is adequately understood and there is a recognizable latent or early symptomatic phase

Wilson & Jungner's 4th and 7th principles

Fig. 2a. Diabetic retinopathy classification

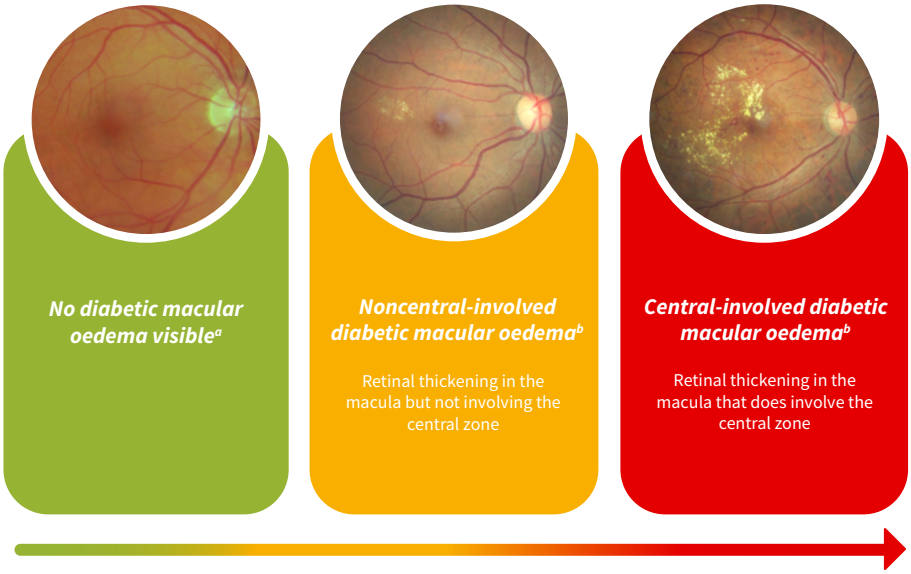


Note: the description of each grade is simplified. For full descriptions, see Annex 2.

[a] Photograph © Simon Harding.
[b] Photograph © Vittorio Silvestre.

Source: International Council of Ophthalmology (2017).

Fig. 2b. Diabetic macular oedema classification



Note: the description of each grade is simplified. For full descriptions, see Annex 2.

[a] Photograph © Simon Harding.
[b] Photograph © Vittorio Silvestre.

Source: International Council of Ophthalmology (2017).

The diabetic retinopathy severity classification (grade) indicates the risk of a person developing the most advanced form of sight-threatening diabetic retinopathy.

Policy-makers should work with clinicians to discuss which detailed classification and grading system is in use in their country and if any amendment or change is required.

4.4. Prevention and treatment of diabetic retinopathy

Good blood glucose control and control of blood pressure and elevated lipids reduces the risk of new-onset diabetic retinopathy and slows progression of existing diabetic retinopathy (Diabetes Control and Complications Trial Research Group, 1993; Turner et al., 1998; Yau et al., 2012). This approach should underpin the prevention and treatment of diabetic retinopathy in all people with diabetes.

Laser treatment is the mainstay of treatment for proliferative diabetic retinopathy and can also be used for the treatment of diabetic macular oedema (Wong et al., 2018).

Anti-VEGF (vascular endothelial growth factor) agents and steroids injected into the eye can reduce the progression of the disease and preserve visual function in diabetic macular oedema (Wong et al., 2018). There are several anti-VEGF agents, and bevacizumab is included in the WHO Model List of Essential Medicines (WHO, 2019b).

Vitrectomy can restore useful vision in eyes with non-resolving vitreous haemorrhage and traction retinal detachment of the macula.

There are agreed policies on whom to treat as patients and accepted evidence-based treatments for patients with diabetic retinopathy

Wilson & Jungner's 2nd and 8th principles

Policy-makers are referred to the ICO guidelines on diabetic eye care (International Council of Ophthalmology, 2017) for further evidence-based recommendations on the treatment of diabetic retinopathy and maculopathy based on resource settings (Wong et al., 2018).

5

Designing an effective diabetic retinopathy screening programme

This chapter looks at some of the important design aspects of a screening programme, including:

- which test or tests should be used to screen for diabetic retinopathy
- how frequently people with diabetes should be screened
- using a pathway to increase effectiveness
- deciding on a referral threshold.

It also considers emerging technology and how this might be used in the future design of a diabetic retinopathy screening programme.

5.1. The screening test

Several tests are used for diabetic retinopathy screening. The sensitivity (the ability of the test to detect disease, if it is present) and specificity (the ability of the test to find there is nothing wrong, if there is no disease) are important factors in choosing a test, but policy-makers need to be aware that information on test performance for diabetic retinopathy is not straightforward to interpret, because:

- researchers use different outcomes to measure sensitivity, such as the ability of a test to pick up ***any*** retinopathy compared to ***sight-threatening*** diabetic retinopathy; and
- some tests are better than others for detecting diabetic macular oedema compared to the different grades of diabetic retinopathy.

Test performance will need to be considered against other factors, such as cost and ease of use. These are looked at in more detail in Table 1. Where cost is not a barrier, the preferred method for screening is digital retinal photography, which provides quality images and an ability to store and audit images.

Sensitivity of different tests can vary according to who does the examination and how well they are trained, which is important for tests such as direct ophthalmoscopy. A systematic review that compared sensitivity of test by operator found the sensitivity of direct ophthalmoscopy by general practitioners (family doctors) varied between 25% and 66% compared to 43% and 79% for ophthalmologists (Hutchinson et al., 2000).

Table 1. Available instruments for screening: their advantages and disadvantages

Technique	Comments
Direct ophthalmoscopy  **© Vittorio Silvestre.**	Advantages • Mobile • Relatively inexpensive • Does not require any special facilities to use Disadvantages • Requires pupil dilation • Only a small field of retina can be examined • Low sensitivity: even with a trained practitioner, small microvascular abnormalities may be difficult to detect • Less effective than slit-lamp biomicroscopy through dilated pupils • No ability to audit retrospectively

Table 1 contd

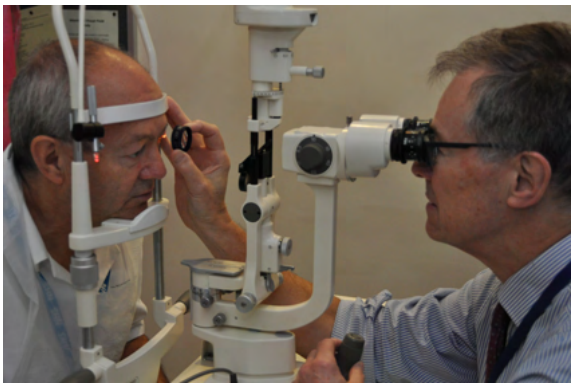
Technique	Comments
Indirect ophthalmoscopy  **© Vittorio Silvestre.**	Advantages • Mobile • Large field of retina can be examined • Relatively inexpensive Disadvantages • Requires pupil dilation • Even with a trained practitioner, small microvascular abnormalities will be difficult to detect • Less effective than slit-lamp biomicroscopy through dilated pupils • No ability to audit retrospectively
Slit-lamp biomicroscopy  **© Simon Harding.**	Advantages • Large field of retina can be examined • Gold standard for training health professionals in retinal examination • Mobile table-top versions are available Disadvantages • Relatively expensive • Most types are desk-based • Requires pupil dilation • Requires special lenses • Usually unable to retrospectively audit results, although it is possible to photograph findings
Optical coherence tomography (OCT)  **© Simon Harding.**	Advantages • One of the best ways to assess macular oedema (retinal thickening and intraretinal oedema) Disadvantages • Needs to be used alongside other screening tests such as slit-lamp or retinal photography to detect diabetic retinopathy • Relatively expensive

Table 1 contd

Technique	Comments
Retinal photography (mydriatic and nonmydriatic)  **© Simon Harding.**	Advantages • Adequate field of retina available for examination • Can be used by trained technicians (non-doctors) • Some are portable – can be transported to the community in mobile units • Can be linked to computers and images can be stored for the long term • Allows objective comparison of the same person, or between different groups of people, examined at different times or by different professionals • Can be used as a patient education tool, giving immediacy and personal relevance • Readily recalled for evaluation of screener performance and audit of grading • Auditable Disadvantages • Relatively expensive • In people with opacities in the lens, such as cataracts, it might not be possible to take an image; this is the main source of failure in diabetic retinopathy screening, and people will need to be rescreened using other methods, such as slit-lamp biomicroscopy Mydriatic versus nonmydriatic cameras • Nonmydriatic cameras require no dilation in 80–90% of cases, although some clinicians will dilate the pupil to reduce the number of images that are not possible to grade; mydriatic cameras require everyone to have pupil dilation • Nonmydriatic cameras require a dark space for maximum pupil dilation • Pupil dilatation can last for several hours[a] and can cause blurred vision; patients are advised not to drive after having their pupils dilated [a] The exact time will depend on which type of eye drops are used and can be between two and 24 hours.

Source: International Council of Ophthalmology (2017). Reproduced by permission.

There is a suitable test and the tests used for screening for diabetic retinopathy are acceptable to the population

Wilson & Jungner's 5th and 6th principles

5.2. How often should people with diabetes be screened?

Several studies have looked at the optimal time between screening tests, sometimes called the screening interval (Tcheugui et al., 2013; Taylor-Phillips et al., 2016). Most studies conclude that the screening interval or frequency of rescreening should be between one and two years.

Some studies have looked at individualizing the length of time between screens, adjusting the screening interval according to the person's glycaemic control and retinopathy or by the severity of the retinopathy alone (Younis et al., 2001; Leese et al., 2015; Scanlon et al., 2015; Byrne et al., 2020). The optimal interval will balance the risks for individual patients and the cost–effectiveness and affordability of the screening programme.

5.3. Using a screening pathway to increase effectiveness

Unorganized but regular eye examinations for people with diabetes are effective if individuals managed in this way receive them regularly and are followed up and referred into treatment services when necessary. The lack of a systematic approach can mean, however, that some people with diabetes do not always receive the eye care they need in a timely manner and opportunities to prevent vision impairment and blindness are missed.

Effective diabetic retinopathy screening requires a screening pathway, and not just a screening test, to be in place.

Fig. 3 provides an example of a standard pathway for all screening programmes. The importance of each step for a successful screening programme is shown below.

Screening for diabetic retinopathy is a pathway (a continuous process)

Wilson & Jungner's 10th principle

Using a pathway can help systematize unorganized eye checks. In studies comparing how screening is organized, systematic screening appears to be more cost–effective than unorganized[2] screening (James et al., 2000; Jones & Edwards, 2010) in reducing the risk of vision impairment and blindness.

Systematic diabetic retinopathy screening (including a diagnosis and treatment of patients diagnosed) is cost–effective (it is economically balanced in relation to possible expenditure on medical care as a whole)

Wilson & Jungner's 9th principle

[2] In concordance with *Screening programmes: a short guide* (WHO Regional Office for Europe, 2020a), this document uses the term *unorganized* rather than *opportunistic* screening to indicate screening that is not organized or systematic.

Fig. 3. Steps in a screening pathway

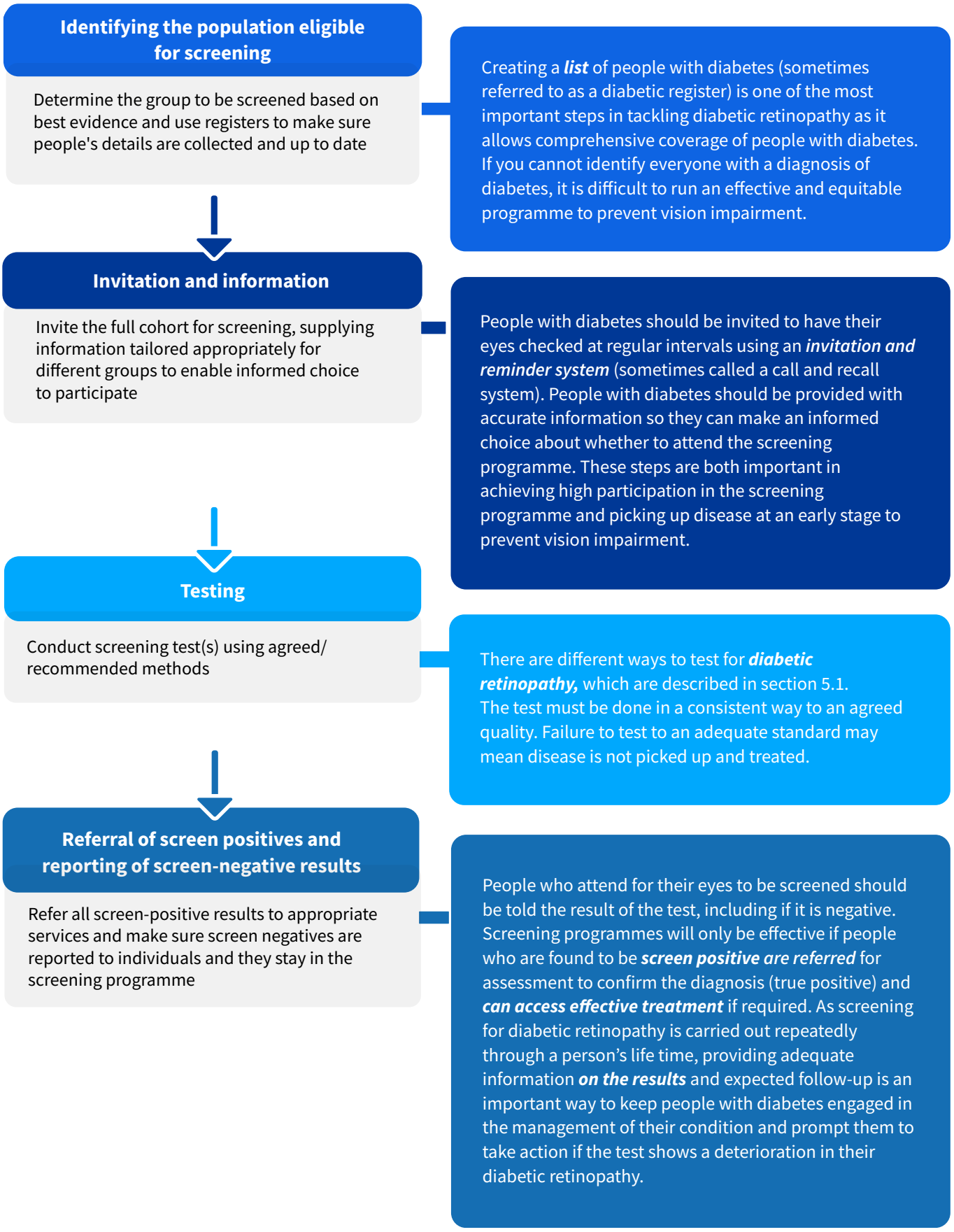
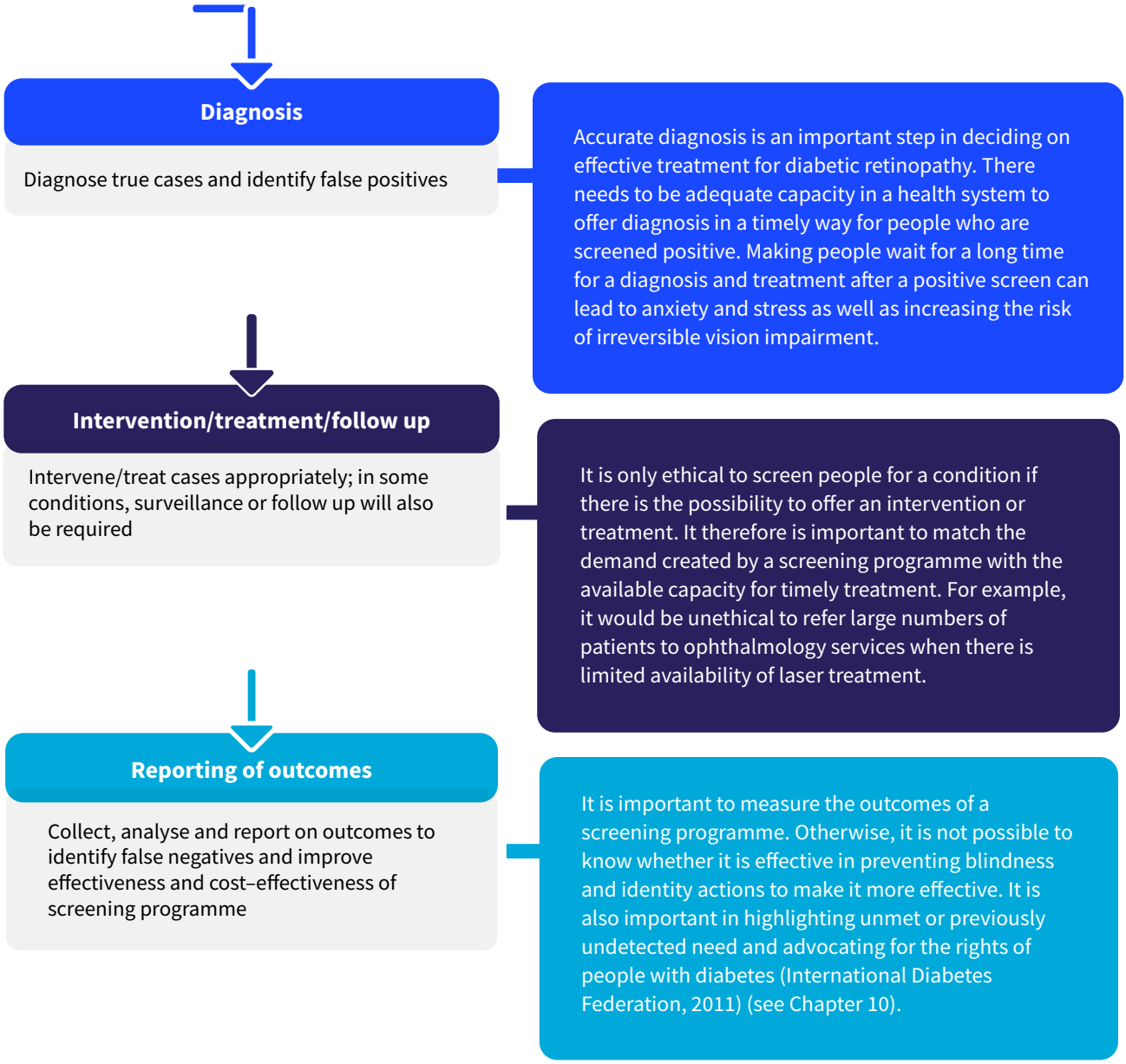


Fig. 3 contd



5.4. Threshold for referral

The intention in diabetic retinopathy screening is to refer patients for treatment ***before*** they have proliferative diabetic retinopathy (PDR) or advanced diabetic macular oedema so that treatment can be started before vision impairment might occur.

The grade at which patients are referred in a screening programme is called the ***referral threshold.*** Patients who are screened and are found to have the referral grade or a more severe grade are called ***screen positive.*** Patients who do not have this severity of disease are called ***screen negative.***

The rate of progression from mild to advanced disease can vary between patients, so screen-positive patients whose diagnosis is confirmed are often kept under ***surveillance*** with an ophthalmologist assessing them at three- or six-monthly intervals before deciding to use laser treatment, anti-VEGF or other treatment

The grade of severity that is set for the referral threshold may differ between countries. Setting a “low” referral threshold (such as mild nonproliferative diabetic retinopathy (NDPR)) could lead to many patients being under ophthalmology surveillance, raising the risk of services being overwhelmed. A “high” referral threshold (such as

severe NDPR) may mean fewer patients under surveillance but risk delaying detection of people with advanced disease. The impact of changing the referral threshold is explored further in Annex 3.

Policy-makers will need to balance these risks. They should refer to evidence-based guidelines and work with clinicians to agree appropriate referral thresholds.

5.5. Emerging technologies in diabetic retinopathy screening

Diabetic retinopathy is a rapidly developing field. Policy-makers will need to ensure they are referring to the most up-to-date evidence and are planning a programme that can respond to changing evidence and new technology.

New types of technologies, such as automated image-grading systems and hand-held cameras, are being developed alongside diabetic retinopathy screening techniques and may offer new methods for screening in the future.

Diabetic retinopathy screening is also likely to benefit from further developments in artificial intelligence-based technologies for image capture and analysis, offering opportunities to improve the quality of imaging and grading.

In addition to currently used diabetic retinopathy grading criteria, analysing retinal vessels might provide an enhanced understanding of cardiovascular/cerebrovascular risk for developing complications.

Linking the retinopathy screening results to other diabetes-related risk factors, such as HbA1c and blood pressure, can support a risk-based approach to setting the next interval for screening. This personalized variable interval approach for diabetic retinopathy screening and screening for other complications is likely to be implemented in coming years.

Policy-makers should work with clinicians and academics to review the evidence base of these emerging technologies and assess their cost–effectiveness and affordability.

United Kingdom (Scotland): using technology to safely manage increased demand for screening

Scotland has had a centralized diabetic retinopathy screening programme since 2003. The programme has evolved as new technologies and evidence have become available. It has a single health information management system that stores digital retinal images, patients' demographic details, patients' results (grade at screening) and invites, and also tracks patients through the screening pathway.

Like many countries, Scotland has faced an increase in the number of people with diabetes, and this has placed pressure on services. Scotland introduced an automated system to read all images, called the Autograder, in 2012. The Autograder accurately identifies patients with the lowest risk (approximately 40% of patients), who can be recalled routinely without further analysis. Images from the remaining patients are then manually graded. This reduces the burden of grading while allowing quality to be maintained, making the screening programme more cost–effective and sustainable for the future. Autograder results are quality assessed as part of ongoing internal (continuous) and external (biannual) quality-assurance processes.

Scotland has now embarked on an initiative to introduce more sophisticated grading capability using the latest artificial intelligence technologies. The aim is to further reduce manual grading and enhance the quality and management of clinical risk (Styles, 2019).

6 Developing an improvement strategy for diabetic retinopathy screening

This chapter looks at how policy-makers can develop a strategy to introduce a new diabetic retinopathy screening programme or revisit and improve the existing approach in their country. It emphasizes the importance of leadership and coordination throughout the system in designing and implementing a major new programme or approach to diabetic retinopathy screening.

The chapter introduces a framework for conducting a situational analysis to assess the strengths and weaknesses of a country's current approach and design an improvement strategy. It recognizes the importance of the pace of change and how some countries may need to take a stepwise approach to their improvement strategies.

The chapters that follow return to the domains of the framework, looking at how to design and plan an improvement strategy that addresses weakness and builds on the strengths of existing approaches.

At the end of the guide, country examples are used to illustrate how this framework can be used to practically develop an improvement strategy.

6.1. Leadership, coordination and management

Any complex change process requires leadership and coordination at all levels of the health system.

6.1.1. National or subnational project team

Policy-makers will need support from a range of stakeholders to develop and implement an improvement strategy. By drawing up a list of stakeholders and noting their areas of expertise and interest, policy-makers can create a team with the right skills, expertise and influence.

The team could include clinical leaders such as ophthalmologists, endocrinologists/diabetologists, family doctors, optometrists (if national regulations include this professional category) and representatives of their professional associations. It can also include service users and civil society, and experts in epidemiology, workforce, information management, financing, purchasing, commissioning and project management. The team should be responsible for designing the strategy and setting up and managing the different workstreams required for its operationalization. As tasks change over time, policy-makers may need to amend membership of the group to ensure it has the right skills and expertise.

Sweden: engaging the main professional groups involved in diabetic retinopathy screening

The National Board of Health and Welfare is a government agency under the Swedish Ministry of Health and Social Affairs that produces regulations and national guidelines for health and medical care. Diabetic retinopathy screening is not considered a national screening programme in Sweden, so the regulations fall under regional administrations. To engage relevant stakeholders, Sweden has established a collaborative working group that includes representatives from the Swedish Retina Society (Medicinska retinaklubben), the Swedish Society for Diabetology and the National Diabetes Register, thereby bringing together the main professional groups involved in diabetic retinopathy screening: ophthalmologists, endocrinologists, internists, general practitioners and diabetes nurses. This collaboration provides the opportunity to discuss and decide evidence-based practices by all relevant actors. The 21 self-governing regions are then responsible for providing local health care in their region, including diabetic retinopathy screening programmes.

6.1.2. Subgroups

The national or subnational team may set up subgroups to organize different workstreams. For example, a ***clinical advisory group*** may be set up to advise the national or subnational team on clinical guidelines, protocols and quality standards for the programme.

6.1.3. Local service-delivery groups

These are crucial in implementing screening programmes effectively. They can help promote multidisciplinary working across ophthalmology, endocrinology/diabetology and family doctor services. Once a screening programme is established, these local groups may continue to oversee day-to-day operation of the local programme.

Clear lines of communication directly from the national or subnational group to local service-delivery groups are necessary, explaining what is expected of the local groups in relation to implementing or changing the programme. The membership of local service-delivery groups will depend on the organization of the health system locally and the chosen model for screening.

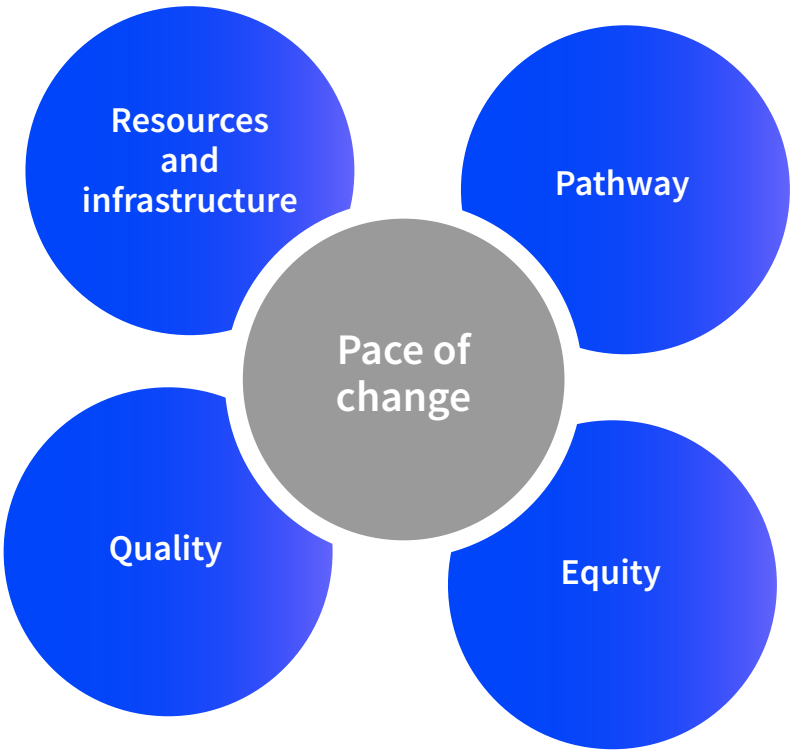
6.2. A framework to guide an improvement strategy

The framework, illustrated in Fig. 4, comprises four domains: resources and infrastructure, pathway, quality, and equity.

Each domain is important in improving the effectiveness of a programme; focusing on one domain exclusively will not achieve maximum improvement for a given set of resources. Investing in equipment without considering the pathway of how people with diabetes might be identified or referred if necessary, for example, will be ineffective.

The framework also considers the appropriate pace of change for a country and how to take a stepwise approach to improvement.

Fig. 4. The four domains of an improvement strategy for diabetic retinopathy screening



6.3. Using the framework to undertake a situational analysis

The framework can be used to undertake a situational analysis. WHO's *Tool for the assessment of diabetic retinopathy and diabetes management systems* (TADDS) (WHO, 2015) is also a useful resource.

The information collected from TADDS and other sources can be analysed according to the four domains to consider the strengths and weaknesses of a country approach to checking or screening for diabetic retinopathy.

6.3.1. Resources and infrastructure

In this domain, policy-makers will bring together information from the situational analysis that allows them to form a picture of the physical and human resources available to the screening programme and how these are used for screening, diagnosis and treatment. This should cover the following issues.

- What equipment is currently used to ***test*** for diabetic retinopathy? The inventory of ophthalmic equipment across all hospitals and other health facilities, as suggested by WHO TADDS, may be helpful in collecting this information.
- What equipment is available for diagnosis and treatment of diabetic retinopathy? WHO TADDS suggests, for example, compiling a list of the number and distribution of public (government) and private hospitals and any information regarding their capacity to provide eye care, with lists of equipment they hold.
- Which ***staff*** are available and trained to screen, diagnose and treat diabetic retinopathy, and where are these staff situated? For this, WHO TADDS suggests compiling the estimated number and distribution of registered ophthalmologists (including vitreoretinal surgeons and medical retinal specialists, optometrists (if national regulations include this professional category) and other relevant clinicians).
- What is the ***current capacity*** for laser and intraocular drug injections, expressed as the number of patients who can be treated in different settings over a defined time frame?
- What type of ***health information management*** technologies (either paper-based, software or a combination) are used (if any) for managing lists of people with diabetes and invitation and reminder systems?
- What kind of software (if any) is used for storing images taken from retinal cameras?

Bringing this information together allows policy-makers to form a view on current capacity, existing gaps and implications for future scenarios. This analysis can then shape the design of a new model for diabetic retinopathy screening, as discussed in Chapter 7, and a health information system, discussed in section 11.5.

6.3.2. Pathway

This domain brings together information on whether there is a pathway in place from identification of the eligible cohort through to referral for diagnosis and treatment.

Policy-makers should find out whether the following are in place:

- processes to enable a list of everyone who has a diagnosis of diabetes to be compiled;
- classification and grading systems with a referral process for screen-positive patients;
- guidelines, protocols and standard operating procedures;
- methods for capturing data flows, including processes to track patients through the pathway; and
- a process for ensuring information on results is transmitted and reported to stakeholders (such as people with diabetes, family doctors, ophthalmologists, leaders, and coordination and management teams).

Policy-makers may attempt to map out the current pathway (see section 12.3, Table 2 for an illustration of how this may be done) to understand where the weaknesses in a pathway, such as inability to identify the eligible cohort for screening, and the strengths, like existing national guidelines, lie.

This analysis can be used to create a new operational pathway; this is discussed in Chapter 8 and section 11.2.

6.3.3. Quality

This domain focuses on the quality of existing services and how this is measured and assessed.

Policy-makers should form a picture of:

- who leads, or is responsible for, screening at local and/or provincial levels;
- what training is available for diabetic retinopathy screening staff, including refresher courses, and whether there are competency tests;
- what indicators, standards or information on the quality of screening or checking for diabetic retinopathy are collected and whether this forms part of a quality-assurance or performance-management system;
- what audits or quality visits are carried out to assess the quality of screening;
- what regular monitoring and evaluation is carried out; and
- whether the screening process is accredited in a quality programme.

Bringing this information together, policy-makers can form a view of:

- whether it is possible to report on the quality of screening
- what, if any, concerns exist about the quality of the current system
- what is currently being done to improve the quality of screening.

This analysis can be used to develop a plan to improve the quality of screening, as discussed in Chapter 9 and sections 11.1, 11.2 and 11.3.

6.3.4. Equity

This domain should capture any inequities in the current system.

- What proportion of people with diabetes currently are having regular check-ups or attend diabetic retinopathy screening? What is happening to other people with diabetes? WHO TADDS suggests using locally or nationally aggregated data on use of diabetes and eye-care services to help with this analysis.
- Is access to screening, diagnosis or treatment influenced by a patient's ability to pay or a country's financing system? WHO TADDS suggests finding out the coverage of the population with government health insurance and the list of items/services that can be claimed under it for diabetes and eye care.
- Is access to high-quality screening, diagnosis or treatment influenced by structural factors in the way it is delivered? These factors include:
    - where a patient lives, such as rural versus urban populations;
    - who manages the diabetes, with some care led by an endocrinologist/diabetologist in a hospital clinic and other by a family doctor in a family medical clinic; and
    - different care being offered to patients with type 1 and type 2 diabetes – WHO TADDS suggests collecting details from locally or nationally aggregated data on use of diabetes and eye-care services based on, for example, diagnosis or type of service.
- Are there inequalities because of patients' characteristics, such as gender, age, disability, ethnicity and disadvantage?

Bringing this information together, policy-makers can form a view on:

- whether a financing system or ability to pay is leading to inequity in access
- structural factors that are leading to inequality in access to services
- other factors that may need to be addressed to tackle any inequity in the system.

Hungary: undertaking a situation analysis to better address the needs of people with diabetes

Hungary carried out a blindness survey in 2014/2015 which identified that diabetes-related vision loss disproportionately affected the population, and that the existing unorganized screening programme was not reaching all who needed services. It also showed that even though Hungary has an electronic medical record system and sufficient ophthalmologists to attend those with diabetes, an exclusive focus on eye status was not adequately addressing the population's needs, and that general public health issues were contributing significantly to the high prevalence of diabetes and diabetic retinopathy (Németh et al., 2018).

As a result, Hungary designed a diabetic retinopathy screening programme that is part of a broader public health initiative through which an individual's nutrition, general well-being and physical activity status are considered as part of a holistic approach to their diabetes care. Patients are seen in a mobile van equipped with a digital retinal camera so they can be screened at the same time as having a broader assessment of their overall health.

The next steps for the programme are to provide further training on identification of the disease and treatment options. The Government is also taking action on the availability of other relevant treatment modalities.

This analysis can be used to develop a plan to increase equity, as discussed in Chapter 10 and section 11.7.

6.4. Pace of change

Policy-makers should decide early on whether designing and implementing a new systematic screening programme from scratch is an option. The advantages of this approach are that information management systems can be integrated into a single system with digital imaging, and access to effective screening for people with diabetes is achieved more quickly. The resources required to deliver this, however, may be beyond the reach of many countries or regions.

If resources are inadequate to implement a comprehensive new programme in one step or the situational analysis demonstrates that this would be unnecessary or would represent poor use of resources, policy-makers should plan a stepwise improvement process that takes account of available resources to move the screening programme from unorganized to systematic screening at the same time as expanding its coverage.

7

Resources and infrastructure: designing a model

The first domain of the framework identifies the available resources and infrastructure, and any issues in capacity. Policy-makers should use this information to decide how to deploy their resources to produce the most cost-effective and affordable model (see, for instance, Box 4).

Box 4. Making sure there is adequate laser capacity

Some countries may not have adequate laser capacity to meet existing demand and will not be able to meet increased demand once screening is introduced.

In these circumstances, ***increasing laser capacity should be a priority before expanding screening services.***

The Ready Reckoner in Annex 4 provides a method for estimating the likely demand for treatments based on the number of people screened.

In deciding on a model, policy-makers should consider the following.

7.1. Which test(s) should be used?

A decision will be influenced by cost and whether cameras or slit lamps are already in use in the country or new equipment will need to be purchased. A mixed approach might be adopted, using whatever technologies are available in different settings, such as a mix of retinal cameras and slit lamps (see section 5.1) (Box 5).

Box 5. It is possible to conduct diabetic retinopathy screening even if retinal cameras are unaffordable for the whole country

Digital retinal photography is considered to be the most effective diabetic retinopathy screening method, but many countries cannot afford to buy cameras to screen everyone who has diabetes. This does not mean screening-programme development needs to stop; it is possible for trained and competent practitioners to screen patients using slit-lamp biomicroscopy or direct ophthalmoscopy (if slit-lamp biomicroscopy is not available) while slowly increasing digital retinal camera use as resources become available.

7.2. Which staff should conduct the screening?

Options include ophthalmologists, endocrinologists/diabetologists, specialists in internal medicine,[3] optometrists, family doctors, nurses and specially trained technicians. The decision will be influenced by local regulations and whether there are shortages of some staff, and the cost of different staffing grades.

[3] Sometimes referred to as internists or general physicians.

7.3. Where should people with diabetes be screened?

Options could include primary care clinics, multidisciplinary diabetes clinics, ophthalmology clinics, optometrist offices and other accessible locations, such as marketplaces. Mobile testing using vans is also possible. A decision on where to screen will be influenced by ease of access for patients, the test used and available staff. A mixed approach may be required.

Policy-makers may also consider how the following two factors can be altered to deal with ***limited resources or capacity in screening, and diagnostic and treatment services (laser):***

- ***the screening interval:*** options can be between one and two years for people with no retinopathy and can be altered as the programme is established to match capacity; and
- ***the threshold for referral to diagnostic and treatment services:*** different thresholds for referral and treatment within clinically acceptable bounds can be set according to resource settings (this was introduced in section 5.4 (see also Annex 3)).

For example, if screening is carried out by ophthalmologists and there is capacity to see patients more frequently than annually, a threshold of lower-severity diabetic retinopathy might be appropriate. In countries with few ophthalmologists and in which most screening is undertaken by endocrinologists/diabetologists or family doctors, however, policy-makers may decide to preserve ophthalmology expertise for seeing and treating patients with more advanced disease and therefore select a referral threshold of higher-severity diabetic retinopathy.

The impact of different thresholds for referral and screening intervals on demand for eye services and laser treatment should be modelled before starting or expanding the programme to ensure that ophthalmology services do not become overwhelmed with referrals at the outset (Box 6).

Box 6. Choosing an appropriate threshold when expanding screening

In countries that are known to have a significant amount of advanced diabetic retinopathy disease in the population, it is better to start with a high threshold for referral to make sure that people with advanced disease are identified and treated quickly to prevent vision impairment or blindness.

Once those with advanced disease are treated and laser capacity expands, the referral threshold can be lowered and those with less severe disease can be referred.

If a low threshold is used at the outset of a screening programme, there is a risk that eye services can be overwhelmed and those with the most advanced disease will not be identified or treated promptly, leading to disillusionment among patients and clinicians.

Components can be put together in different ways to have an impact on cost–effectiveness, affordability and outcomes. For example, changing the screening interval from one to two years for people with no retinopathy in either eye at the last visit, while at the same time introducing mobile digital retinal cameras, could be compared to keeping a yearly interval and using ophthalmologists to screen patients in private clinics.

Policy-makers may need to work up several models and undertake an option appraisal before deciding on the best approach.

8

Pathway: strengthening the screening pathway

The second domain of the framework is the pathway. Strengthening the screening pathway often requires considerable change management across different organizations. This chapter looks at each part of the screening pathway in detail.

The national project team will need to develop a detailed operational pathway that will then inform all aspects of the operational planning.

8.1. Designing a pathway to fit a health system

An operational pathway is essential for systematic diabetic retinopathy screening. Its design will be influenced by the regulatory framework, funding and organization of the health system (whether health care primarily is funded through insurance, taxation or out of pocket, for example).

Each operational pathway should describe in detail how patients move along the pathway, how they are tested and referred, what fail-safe mechanisms are in place and how performance will be measured will be measured. An example from United Kingdom (England) is shown in Fig. 5.

Availability of resources and staff in a country may lead to a decision to operate several different models with their own operational pathway. In rural areas, for example, the model and pathway is designed so that family doctors are trained to screen patients using an ophthalmoscope and refer for diagnosis, whereas in urban areas, the model and pathway is adapted so that family doctors refer patients to optometrists or ophthalmologists to have their eyes screened.

Many screening programmes fail to be effective because patients are lost along the screening pathway. This can occur when a patient is referred from the organization that does the screening to an ophthalmologist in another organization for treatment. If patients fail to make appointments or do not turn up to be seen, the screening programme will be much less effective in reducing vision impairment. A similar problem can occur when information is not shared between organizations, meaning it is not possible to monitor the quality of the programme.

When designing pathways, policy-makers should pay attention to the transfer of patients or their information between organizations and consider what fail-safe processes can be put in place to track patients between organizations to reduce patients getting lost.

Below, we consider each step in more detail.

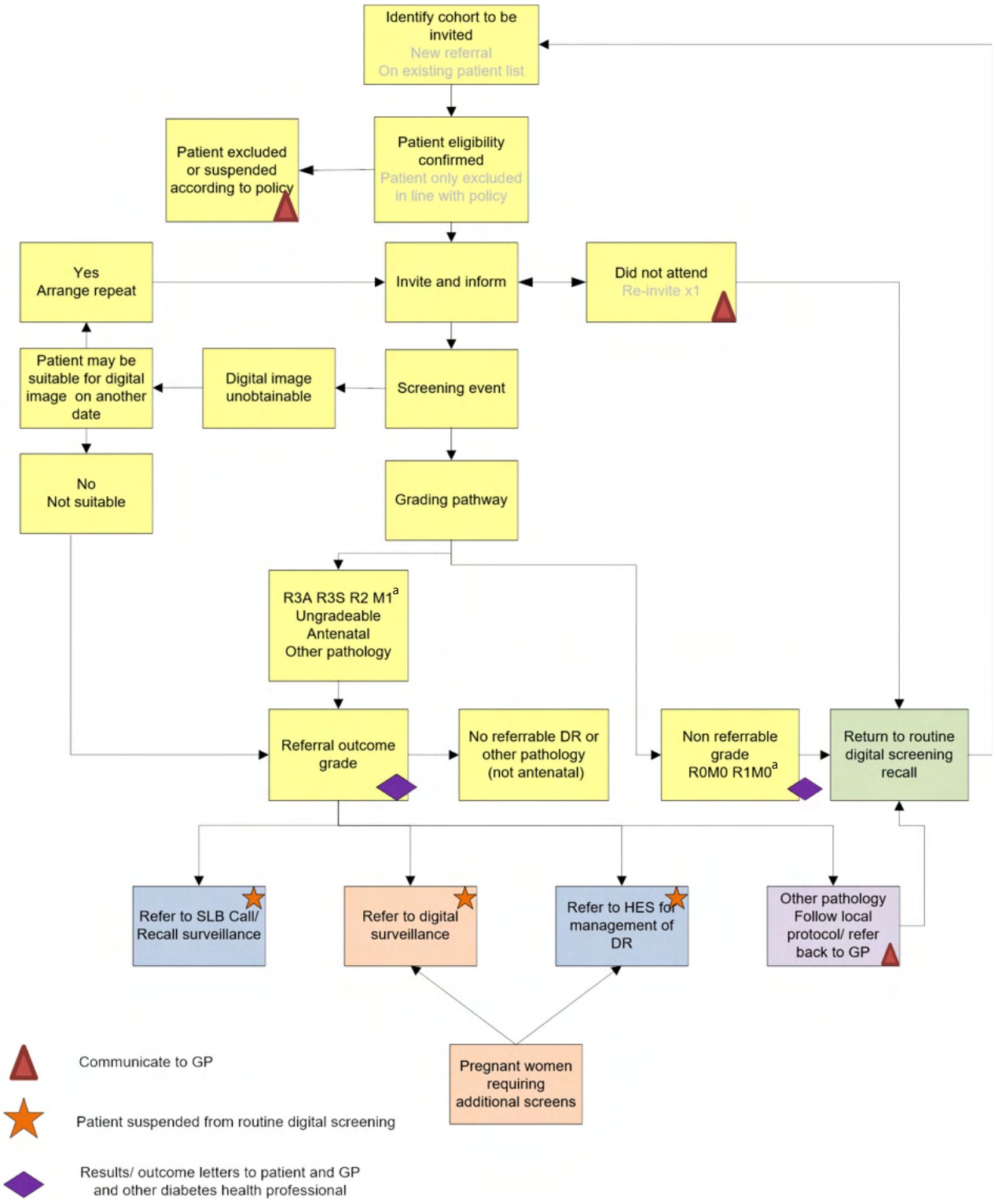
8.2. Identifying the population eligible for screening

A system to identify people with diabetes and invite them for diabetic retinopathy screening is central to a systematic screening approach. This is achieved by creating a list of everyone who has diabetes (Box 7). In some countries, the list may be part of a diabetes register.

Box 7. Identifying the eligible population – a crucial step for effective screening

Many countries cannot identify everyone who has a diagnosis of diabetes. Without such a list, some people with diabetes may not be invited for screening and checking for diabetic retinopathy. Developing accurate and comprehensive lists (either nationally, subnationally or locally) is another important step in improving the effectiveness of screening. For those countries that have not yet got a comprehensive list(s), other steps can be taken to improve attendance, such as public awareness campaigns.

Fig. 5. Country pathway example from United Kingdom (England)



DR: diabetic retinopathy. GP: general practitioner. HES: hospital eye services. SLB: slit-lamp biomicroscopy.

[a] The following are from the grading system used in the NHS Diabetic Eye Screening Programme in United Kingdom (England) (Public Health England, 2017a). R indicates the grade of retinopathy on a scale of no disease (R0) to most severe (R3); M indicates absence (M0) or presence (M1) of maculopathy; S indicates stable disease; A indicates active disease.

Source: Public Health England (2017b). Reproduced by permission.

A list of people with diabetes includes their demographic and contact details. It can also contain up-to-date clinical details and results of previous screening tests and investigations. The list can be held locally (in a clinic, for example), subnationally or nationally.

An electronic list is the preferred option. If the health system already operates an electronic system that contains patient records, it may be possible to automatically generate and update a list of people with diabetes by linking to the health-care patient-record system.

In all cases, the list will only be as good as the accuracy and completeness of the database of people with diabetes.

Well kept paper lists of people with diabetes may offer an alternative if electronic solutions are not available and should not be considered a barrier to developing a more systematic screening programme.

In some countries, lists of people with diabetes are kept by endocrinologists/diabetologists or specialists in internal medicine in diabetes clinics, and in primary care. There may need to be a process of reconciliation or sharing of information to create a single list for screening purposes.

For all systems, policy-makers should check: how people with diabetes are identified; how their information is entered on the list; how it is kept up to date; and what regular quality checks are in place to assess completeness and accuracy of the list. They will need to ensure that steps are taken to address any weaknesses in the system.

Denmark: creating a list of the eligible population

Denmark has a national register for the quality of diabetes care and management (the Danish Diabetes Register) that aims to provide data on all people who have been diagnosed with diabetes in the country. The register includes the Danish Adult Diabetes Registry, a register for children with diabetes (DanDiabKids) and a register for diabetic retinopathy screening (Diabase). The Danish Adult Diabetes Registry was created in 2004 through collecting data from the primary and secondary health-care sectors.

8.3. Invitation and information

The invitation and reminder system (sometimes referred to as a call and recall system) uses the list of people with diabetes to invite people at regular intervals for screening.

Well designed electronic solutions specifically commissioned to identify and invite people for screening will always offer the best option for achieving high uptake and coverage and can also support audit, quality assurance, fail-safe and performance monitoring.

Some countries may be able to operate an invitation and reminder system for diabetic retinopathy screening using existing or upgraded electronic lists of people with diabetes.

It is possible to operate a paper-based invitation and reminder system using index cards and a bring-forward system.[4]

[4] Bring-forward systems are made up of index cards. Each index card has the patient's details and screening history. A filing cabinet is used, with dividers for each month for the next year. When a person is screened, their index card is filed into the month and year they are next due a screen

Invitation and reminder systems, whether electronic or paper-based, require standard operating procedures to record when a person has been invited and whether they attended, and to remind them when they are due for the next screen.

Policy-makers should review existing systems for inviting patients for regular check-ups and decide whether any could be adapted or resources are available to develop an integrated electronic information management system for screening.

Invitations to be screened should be accompanied with patient information that can support informed consent for screening and participation.

Patient information can include:

- what diabetic retinopathy is and why it is important to have diabetic retinopathy screening;
- the importance of controlling blood sugar and blood pressure to reduce the risk of vision impairment;
- where screening will be carried out (for example at the diabetes centre, eye clinic or local optometrist);
- what the patient must do, such as book an appointment;
- what will happen at the screening appointment and advice about use of eyedrops and driving;
- when the result will be available;
- what will happen if the person is found to have diabetic retinopathy that requires further investigation and treatment; and
- information about vision rehabilitation services and how it is possible for people with vision impairment and blindness to maintain an independent and active life.

Fig. 6 shows examples of patient information leaflets.

8.4. Testing

Readers should also refer to section 5.1.

Digital retinal photography is the preferred method for diabetic retinopathy screening but may not be affordable in some health-care systems. The other methods are described in Table 1.

In circumstances where screening is undertaken by an ophthalmologist, ideally it will be done as part of a complete ophthalmic evaluation.

Retinal examination should be done in such a way as to classify and grade retinopathy adequately. In most scenarios this will involve dilation of the pupil. Visual acuity is an important component of assessing vision impairment.

Sometimes, correct imaging of the retina will be obstructed because of coexisting cataracts or other eye conditions. Policy-makers should make sure that guidelines are in place to advise on what should be done if it is not possible to take an image of the retina and on the management of incidental findings (unrelated but significant eye abnormalities) at screening.

Regardless of the system chosen, sensitivity and reliability can be improved by:

- using protocols and guidelines to cover all aspects of screening, including the method for examining the eye, the classification and grading system, a definition of the threshold for referral, and how to record results and refer patients;
- training clinicians or technicians according to the guidelines and making sure they are competent, with regular educational updates undertaken to maintain competence; and
- undertaking audits at regular intervals to pick up any issues with performance.

Fig. 6. Examples of patient information leaflets

Showing leaflets from Italy (front) and Albania (back). Reproduced by permission.

8.5. Referral of screen positives and reporting of screen-negative results

8.5.1. Referral of screen positives

The clinician or technician grading the image obtained through screening should follow clinical guidelines and protocols in deciding whether a patient needs to be referred or screened more frequently.

If the screening is carried out by an ophthalmologist who will also be diagnosing and treating screen-positive patients, policy-makers should ensure careful audits of practice are carried out to ensure the ophthalmologist is operating according to clinical guidelines that have been developed and agreed with national professional societies.

8.5.2. Reporting of screen negatives

Protocols should be in place to describe how screen-negative patients and their doctors are informed of the result of the screen.

For diabetic retinopathy screening, it is important to note that patients can have disease (such as mild NPDR) do not require referral for treatment if the referral threshold is set at a higher level, so they are screen *negative*.

Results of diabetic retinopathy screening are part of the clinical information that informs the overall management of a patient with diabetes. If a patient is found to have mild nonproliferative disease and is classed as screen-negative, the doctor looking after their diabetes should check that the patient's blood glucose, blood pressure and blood lipids are adequately controlled to prevent further deterioration of the diabetic retinopathy.

8.6. Diagnosis

Referral pathways that have been developed with relevant national professional societies should be in place for screen-positive patients.

Screen-positive patients will need to be assessed promptly before a diagnosis can be confirmed. It is important to collect data on the proportion of screen positives that are true positives and those that are false positives, using agreed definitions.

8.7. Interventions, treatment and follow up

Patients who are referred to ophthalmology services following diagnosis may require regular surveillance or treatment from an ophthalmologist, depending on a country's clinical guidelines.

Treatment needs to be carried out within a reasonable period following diagnosis, otherwise opportunities to prevent vision impairment and blindness will be lost. The time from referral to treatment should be agreed with national professional societies and be monitored.

Evidence-based guidelines should be used to treat and follow up patients with diabetic retinopathy.

8.8. Reporting of outcomes

Both clinical and programme outcomes should be collected to monitor the performance of the screening programme.

Local, subnational and national data can be used for quality assurance and monitoring the performance of the screening programme to make sure it is achieving the desired results.

Standard operating procedures should be in place to describe what data should be reported locally, subnationally or nationally, which organization is responsible for collecting data and to whom they should send their reports.

Screening pathways can be used to map data flows. If the screening pathway is split across several organizations, policy-makers should decide how to collect the data from different organizations and what steps they can take to ensure data returns are made.

The results of patients' screening tests should be recorded in patients' notes. Outcomes from the screening programme should be recorded in a system that is accessible to health-care providers.

Recording results of individual patients can be used for tracking patients through the screening programme. For example, if an administrator of the invitation and reminder system is informed that a patient is screen-positive but does not have a result back from the ophthalmology appointment, they can check that the patient has been referred and has be seen, and has not been lost.

9

Quality: operating a high-quality diabetic retinopathy screening programme

The third domain of the framework applies to the quality of the whole screening pathway. It is achieved by establishing a quality-assurance system and monitoring and evaluation processes.

Introduction of these systems needs to be proportionate and realistic to the stage of development of a screening programme and the added workload.

Implementation research may be a useful tool for developing and improving the quality of the screening programme over time.

9.1. Quality-assurance system

Quality-assurance systems have various components:

- indicators and standards to measure the performance of the programme
- a system to check that standards are being met
- guidance and operational policies
- mechanisms to ensure the quality of the test
- fail-safe systems
- quality-improvement initiatives to support services to improve their quality.

9.1.1. Indicators and standards

Policy-makers should actively engage clinicians to discuss the value and use of indicators and standards in a quality-assurance system.

Indicators can measure:

- structure – for example, whether screening is carried out using the correct equipment;
- process – such as how many people are screened each month; and
- outcome – the proportion of people with diabetes with sight-threatening diabetic retinopathy and vision impairment or blindness, for instance.

In a screening programme, ***structure and process indicators*** usually are deployed as part of a quality-assurance system. ***Outcome indicators*** usually are utilized as part of a monitoring and evaluation system.

Coverage and uptake are important process indicators for screening programmes:

- coverage is defined as the proportion of the eligible population who have been screened in a defined time period; and
- uptake is defined as the proportion of those invited who attend for a screening test.

Structure and process indicators can also be turned into ***standards*** by attaching a performance measure to the indicator to ensure the quality of the programme. For example, the standard for an indicator measuring coverage in the screening programme may be 80%, meaning all local services should make sure that 80% of people with diabetes have had a screening test in the last year.

In deciding which indicators and standards to measure, policy-makers should consider how they can be measured, who will do the analysis, and how much it will cost to collect and analyse the data.

Agreeing and defining indicators and standards is a complex and technical process. Policy-makers may wish to work with public health specialists, data analysts and clinicians to agree which structures and processes along the screening pathway to measure and how to measure them. It is especially important that indicators and standards are very precisely defined and that policy-makers provide adequate guidance to local services on how to collect the data from either their paper or electronic data-collection system. Failure to do this at an early stage will result in data returns that are not comparable between services and are impossible to use for quality-assurance purposes.

At the outset, a small set of indicators should be monitored. Additional indicators can be added as the programme develops. After collecting data for several years and establishing the performance of screening programmes in a country, an appropriate standard can be attached to the indicator.

Denmark and Israel: measuring indicators to drive up quality

The Danish Adult Diabetes Registry monitors and evaluates the quality of treatment of people with diabetes. One of the indicators measured in this database is the performance of eye examinations within a two-year period in 90% of patients with diabetes and within a four-year period in 95%. Diabase, the register for diabetic retinopathy screening, includes indicators on processes and results related to screening for diabetic retinopathy. From 2018 to 2019, 99% of patients with diabetes had had at least one diabetic retinopathy screening within the previous five years (Jørgensen et al., 2016; Regions Clinical Quality Development Programme, 2020).

Israel has a national performance indicator programme through which indicators and their progress throughout the years can be accessed online. One of the indicators for diabetes is the rate of people with diabetes aged 18–84 who have undergone eye examinations. After diagnosing a patient with diabetes, general practitioners are required to refer them to an ophthalmologist and will be reminded to do so until a result is reported in the system. Monitoring performance in this way has led to high levels of compliance. In 2018, 72.5% of patients diagnosed with diabetes underwent eye screening (National Program for Quality Indicators in Community Healthcare, Israel, undated).

9.1.2. A system to check that standards are being met

Policy-makers should decide early on how they will monitor the quality of the local screening services and who will be responsible. There may be existing regulatory or licensing systems in a country that can be used to check on the quality of the screening service.

Introduction of a quality-assurance scheme should be developed through a participatory strategy with screening services in a stepwise fashion to encourage learning and development and avoid deterring providers from engaging with the quality-assurance system.

The focus in the early phase of the screening programme should be on checking structural indicators, such as staff have received the required training and the correct equipment is being used.

Once these standards are met, the focus should move to other process indicators of quality. A gradual introduction of new standards, alongside support and training for services to enable them to meet the new requirements, can help engage local services with improving quality.

Methods for quality assurance will depend partly on the quality of data returns and existing auditing schemes. Regular internal auditing of the quality of the test and processes is an important mechanisms carried out by local screening providers to imbed quality into a screening programme and may mean less external quality assurance is needed.

The national or subnational designated body for quality assurance of the screening programme may use national audits, inspection visits and performance monitoring using data returns to check on the quality of the screening.

Policy-makers should ensure that guidelines or protocols that describe what action will be taken if a screening service fails to meet expected quality standards are in place.

Ireland: monitoring a quality-assurance standard that has led to an improvement in quality of images

Ireland's diabetic retinopathy screening programme (Diabetic Retina Screen) holds six Quality-assurance Committee meetings annually. One of the functions of the Committee is to review the programme's overall performance against the national Quality Assurance Standards.

The Committee reviewed the standard that measures the quality of the screening test by calculating how many digital retinal photographs cannot be graded because of a poor-quality image (ungradable images). The overall programme standard is that fewer than 6.3% of people screened should have an image that is of poor quality (ungradable).

The programme contracts two private providers to deliver screening in Ireland. An in-depth review of performance across both providers was carried out and concluded that one had a higher rate of ungradable images. The provider was informed of the report and as a result carried out an audit of ungradable images, identifying several issues and proposing a set of remedies. The remedies were approved by the Quality-assurance Committee and corrective action was taken. The review of this standard reduced the ungradable rate from over 14.5% to 6.9%. Further work to reduce the rate is ongoing.

9.1.3. Checking the quality of the screening test

The effectiveness of the screening programme relies on the quality of the screening test.

If digital retinal cameras are used and images are stored, it is possible to put in place a cost-effective, systematic quality-control system in which a proportion of images are double-read (by highly trained retina specialists and/or reading software) and discrepancies are picked up using an arbitration system as a way to improve quality.

It is harder to routinely check the accuracy of a screener if the method is slit-lamp biomicroscopy, as unlike digital retinal photography, images are not taken and stored for later review. In these circumstances, regular audit of screen-positive and a proportion of screen-negative patients can be organized to verify adherence to guidelines and quality of care provided. Peer-to-peer learning can also be used to drive up the quality of the screening test.

Regular training and auditing is very important if direct ophthalmoscopy is used for screening, as the sensitivity is low.

9.1.4. Fail-safe systems

Fail-safe systems are processes and procedures put in place to reduce the chance of error and harm to patients. They are particularly important where patients are referred to another organization or department, such as when a patient is referred from a screening service to an ophthalmologist for diagnosis and treatment.

In diabetic retinopathy screening, fail-safe processes might be in place to check that:

- everyone with a diagnosis of diabetes is on a list;
- people who have been invited to screening have been screened or indicated that they did not want to be screened; and
- screen-positive patients have been seen by an ophthalmologist in a timely manner.

Ideally, fail-safe processes form part of an integrated information management system, but they can be put in place in paper-based systems using index cards and bring-forward systems.

9.2. Monitoring and evaluation of a diabetic retinopathy screening programme

Monitoring and evaluating a diabetic retinopathy screening programme at regular intervals is essential.

Monitoring is the process of regularly measuring the outcomes of the screening programme at national or subnational level to ensure that it is achieving its aims.

Finland: the Finnish register of visual impairment

The Finnish Register of Visual Impairment enables the study and monitoring of the incidence of visual impairment in Finland. The Register serves as a basis for planning for preventive measures, treatment, rehabilitation and other special services for people with visual impairment. It also provides research material on ophthalmological diseases and visual impairment.

Diabetic retinopathy was the principal diagnosis for 4% of people registered in 2018. Of all people registered, 9.2 % had diabetes, and in 2018, 10.2% of new cases had diabetes (National Institute for Health and Welfare, 2018).

Monitoring should occur regularly, such as annually. Policy-makers should choose outcome indicators that can indicate whether the programme is successful. Ideally, these would monitor the proportion of people with diabetes developing vision impairment because of diabetic retinopathy, but obtaining these kinds of data might be difficult in some settings and, as numbers are small, it may prove challenging to monitor year-to-year in some settings.

For this reason, process indicators can be used as a proxy for outcomes. Indicators that might be considered include coverage, uptake and proportion of patients with sight-threatening retinopathy receiving laser treatment timeously. Policy-makers should work with public health and information experts to develop appropriate measures that can reliably be collected and analysed from screening services.

Evaluation is the periodic review of how the screening programme is working in light of new evidence, available resources, changes in technology or changes in the population. For diabetic retinopathy screening, this might mean that a national review is needed if the number of people with diabetes increases because of rising rates of obesity and inadequate capacity for screening or ophthalmology services. Other changes that require an evaluation may include increasing availability of retinal cameras, which allows a country to redesign its programme.

Portugal: professional associations help in improving accountability

Portugal has a population-based diabetic retinopathy screening programme, monitored and evaluated annually by the National Programme for Diabetes of the Directorate General of Health. Portugal measures the proportion of people with diabetes who have attended diabetic retinopathy screening, with increasing numbers being seen over the years.

Portugal contd

The percentage of positive screening tests and number of hospital referrals are also reported, as well as other indicators. It nevertheless is difficult to monitor how many of those screened are followed-up by a specialist, require treatment, complete treatment or develop blindness.

The National Programme for Diabetes is working with information experts to develop new tools to collect and analyse these data.

The Portuguese Diabetes Society, with its Diabetes Observatory, has an important role in diabetic retinopathy screening programmes. A professional association can be helpful in ensuring the follow through and improvement of an already established screening programme by, for example, raising awareness of the importance of the population-based diabetic retinopathy screening programme, taking part in follow up and participating in the review of clinical guidelines (National Diabetes Observatory, 2019).

10

Equity: addressing inequity in diabetic retinopathy screening programmes

Diabetic retinopathy screening will only be successful in reducing risk of vision impairment and blindness if most people with diabetes are ***screened and treated*** for diabetic retinopathy.

Policy-makers should look at financing and structural factors in programme organization that may be leading to inequity in access to high-quality screening or treatment for parts of the population.

Areas with low coverage because of inadequate capacity in the screening service should be identified and any issues addressed. If services across the country or region are adequate, coverage may be low because uptake is low.

Where uptake is low, policy-makers and local services should try to determine why this is the case through disaggregating data to identify specific populations with low uptake and using appropriate research and engagement techniques. They should use evidence-based interventions to increase participation (Lawrenson et al., 2018) and provide people-centred services.

Policy-makers should be aware of how health inequalities may affect the risk of vision impairment from diabetic retinopathy. People from disadvantaged and ethnic minority communities are likely to have higher rates of diabetes and, if they have diabetes, are more likely to have lower uptake rates for diabetic retinopathy screening. The International Diabetes Federation has highlighted the importance of the rights of people with diabetes in this regard (International Diabetes Federation, 2011).

Behavioural and cultural insights for health (WHO Regional Office for Europe, 2020b) may help policy-makers understand how social, cultural, political, psychological or economic factors can affect participation. It refers to knowledge derived from the social sciences and health humanities that can support understanding of the drivers and barriers to participation. These insights are often context dependent and can be used in the design, implementation and evaluation of health policies to ensure they are effective, acceptable and equitable.

A systematic review that looked at barriers to, and enablers of, access to diabetic retinopathy screening in different income settings found that lack of knowledge, attitude, awareness and motivation were perceived as major barriers by people with diabetes. Enablers were fear of blindness, proximity of the screening facility, experiences of vision loss and being concerned about eye complications. From the providers' perspectives, lack of skilled human resources, training programmes, infrastructure for retinal imaging and cost of services were the main barriers (Nishantha Piyasena et al., 2019).

Addressing reasons for low uptake can be considered in relation to ***access*** and ***health literacy.***

10.1. Improving access to diabetic retinopathy screening services

Policy-makers can consider access from the perspective of patient characteristics such as age, disability, gender, religion and culture characteristics that may affect their access to a screening service (Box 8).

Box 8. Achieving equity in access to high-quality diabetic retinopathy screening

Many countries have excellent diagnostic and treatment services, but often screening pathways are not in place for all the eligible population. Fragmented systems across family doctors, endocrinologists/diabetologists, ophthalmologists and hospital care may mean that not everyone with diabetes gets invited regularly for screening and receives the same quality of care.

A focus on pathway and quality, using integrated e-health information systems, can create a high-quality equitable screening service for everyone with diabetes in these countries.

Kyrgyzstan: improving access to diabetic retinopathy screening

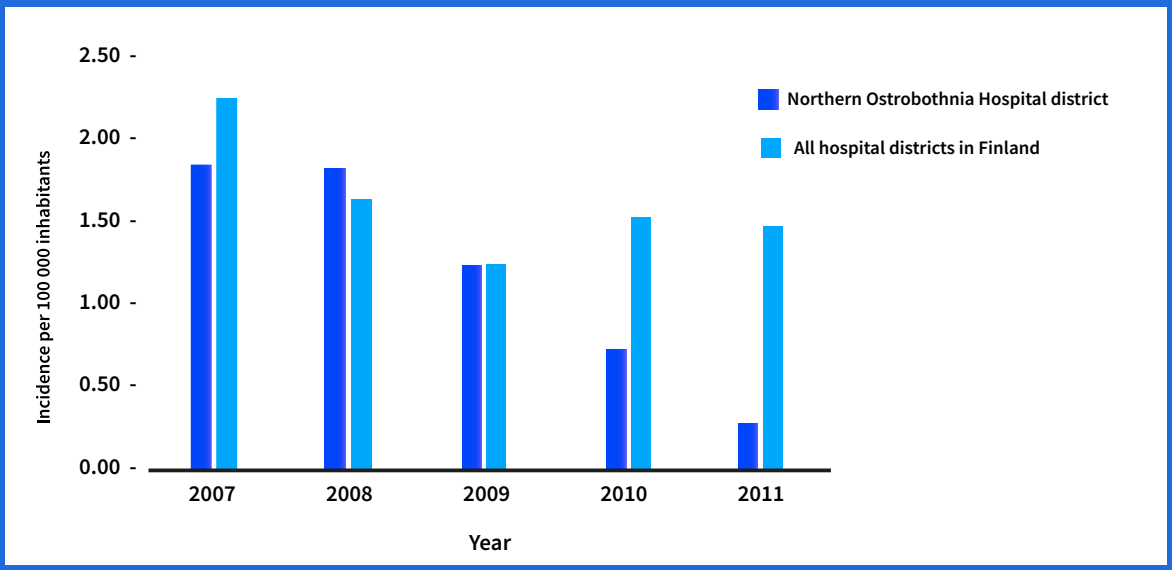
Kyrgyzstan does not have a national diabetic retinopathy screening programme, but uses two ways of promoting diabetic retinopathy screening. First, clinical protocols recommend people with diabetes to get their eyes checked regularly by an ophthalmologist. Second, people with diabetes are encouraged on World Diabetes Day to attend specialized centres where they can get their eyes and blood sugar levels checked. Events are held annually on this day in every major city of Kyrgyzstan: free mass testing of blood sugar levels and opportunities to have a consultation with an endocrinologist are offered in squares and large shopping centres, and people are recommended to have their eyes checked. Special lectures are organized in local centres for people with diabetes in which complications, including retinopathy, are discussed.

Where and when a service is offered and who staffs it can alter the service's accessibility to certain groups of patients. Screening services that are offered only during working hours, for example, may deter working people from attending appointments.

Finland and Norway: using telemedicine to improve access and efficiency

A project was launched in 2007 to tackle the high variations of quality and access to diabetic retinopathy screening in northern Finland. The project used a mobile eye unit in the Northern Ostrobothnia Hospital district. The incidence of visual impairment due to diabetic retinopathy decreased by 86% in the district in the first five years of the project, while a milder decline of 35% was observed in all of Finland. The use of the mobile eye unit allowed a large volume of high-quality screening to be delivered in areas that had observed inequitable access, thereby increasing participation (Hautala et al., 2014) (Fig 7).

Fig. 7. Incidence of visual impairment due to diabetic retinopathy per 100 000 inhabitants: Northern Ostrobothnia Hospital district and all hospital districts in Finland



Source: Hautala et al. (2014).

Finland and Norway contd

People with diabetes in some remote areas of **Norway** live a long way away from centres that have qualified staff who can grade diabetic retinopathy images. To improve access to diabetic retinopathy screening for people such as these, the Norwegian Health Directorate has developed a model of a programme for diabetic retinopathy screening in which retinal images are taken in local settings (opticians, local medical centres or others with the required equipment). The images are then transferred using telemedicine solutions and grading is performed at a grading unit where graders can interpret 4–5 times more images than when assessments for diabetic retinopathy are carried out as part of a full consultation/eye examination. The programme currently is being implemented, although financial and digital/telemedicine challenges still need to be resolved.

Patients may have difficulty accessing diabetic retinopathy screening services because of the location of the service. Older patients or patients on low incomes, for example, may not be able to attend if they have to travel far to a town to visit an ophthalmologist or optometrist, or female patients may not be willing or able to attend screening without a chaperone.

Policy-makers may consider offering more accessible services to patients for whom distance to a service is proving a barrier to uptake by training family doctors who are situated nearby. Other solutions, if resources allow, include using a mobile retinal camera for more remote communities or a telemedicine solution.

An important consideration is that for some modalities of screening, patients will need drops to dilate the pupil so that the retina can be seen clearly. Eyedrops affect the vision and patients are advised not to drive for several hours (see Table 1) after they have been administered and may be deterred from screening because they cannot drive. Policy-makers should work with services to make sure this does not affect access by, for example, placing screening services close to public transport or popular marketplaces.

10.2. Increasing health literacy

Health literacy is a complex notion that relates to people's knowledge, motivation and competencies in accessing, understanding, appraising and applying health information to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion and maintain or improve quality of life during the life-course. Health literacy can be understood in different ways.

- ***Distributed health literacy*** refers to the way health literacy is dispersed throughout a group, such as in a family or in an individual's social network, and is used as a collective resource to handle health information, make choices and manage health.
- ***Health literacy responsiveness*** describes the way in which services, organizations and systems make health information and resources available and accessible according to the health literacy strengths and limitations of the people they serve (this sometimes is termed organizational health literacy).
- ***Community health literacy*** comprises the assets and capacities within communities, such as cities, neighbourhoods or groups, that promote health for all the community's members. Strong community health literacy diminishes the likelihood of anyone being left behind because of their individual level of health literacy.
- ***Digital health literacy, or e-health literacy,*** refers to individual and social factors and technological constraints that might affect an individual's ability to use digital technologies.

Using this analysis, policy-makers can work with people with diabetes to improve health literacy. For example, if people with diabetes are not attending screening because they do not understand why it is important, perhaps because information materials are not easy to understand or are not available in the patient's language, or

community literacy levels are low, information can be transmitted locally through respected leaders rather than via written materials.

Policy-makers or local services can work with patient groups and service providers to produce information in different formats to increase understanding of diabetic retinopathy screening. These may need to be targeted to different socioeconomic, cultural or demographic groups. Young people with type 1 diabetes, for example, might need different information than older people with type 2 diabetes.

Doctors, nurses and other clinicians who are in regular contact with people with diabetes provide another conduit for transferring accurate information. They can be offered training to explain why diabetic retinopathy screening is important, address any anxieties or concerns of the patient and support patients to participate in screening.

11

Managing the change process

This chapter considers the different workstreams of an overall improvement strategy and how these can be introduced in a stepwise manner.

Each country will have different ways of introducing new or changing programmes in their health system, using, for example, national programme directives, specifications or clinical guidelines.

Different approaches can also be taken to purchasing equipment, and computer and information management systems. Centralized systems may use a national body to purchase or commission equipment, while decentralized systems will leave purchasing of equipment and information systems to local organizations.

If the approach is decentralized, care should be taken to ensure that equipment and information management systems meet national specifications so that comparable data can be collected across a country or subnational area.

11.1. Governance and accountability

A governance and accountability framework should be put in place at an early stage of programme development. The framework will be influenced by a country's regulatory and legal system and may require legal endorsement in some countries.

It will need to address who is responsible and accountable for different aspects of the screening programme, including clinical guidelines, monitoring performance and delivery of the screening service at local level. This will be particularly important where models for delivery include civil society or independent practitioners such as optometrists.

The framework should be linked to the quality-assurance system, which should have processes in place for dealing with errors and false negatives that occur in screening programmes.

11.2. Guidelines, protocols and standard operating procedures

A clinical advisory group can be used to develop or adapt existing evidence-based clinical guidelines such as those defining referral criteria and clinical standards.

Guidelines for diagnosis and treatment should be developed with relevant national professional societies.

Once a pathway has been agreed, protocols and standard operating procedures should be written to cover the different steps in the pathway.

Clinicians and managers working in a pilot site may be well placed to develop and write protocols and standard operating procedures.

11.3. Personnel

The pathway and model for screening will determine which trained staff are needed for the screening programme.

All local screening services should have a ***clinical lead*** who has overall responsibility for the programme at local level. Depending on how the programme is organized, this may be an ophthalmologist, endocrinologist/diabetologist, specialist in internal medicine or a family doctor. The role of the clinical lead is to ensure the quality and coverage of the service. They do this by making sure that everyone working in the screening programme uses the correct clinical guidelines and protocols, are up to date with training and return the required information to the clinical lead. It is usually the responsibility of the clinical lead to compile reports on performance and submit them to a subnational or national lead.

Some large screening services may have a ***manager*** to help the clinical lead carry out their role.

Screening can be carried out by ***family doctors, optometrists, ophthalmologists, endocrinologists/diabetologists, specialists in internal medicine*** or ***technicians.*** Staff carrying out the test should be trained to examine the eye or take an image and grade their findings according to the adopted classification and grading system.

Administrative staff should be trained to use information management systems and carry out fail-safe tasks. Lastly, ***information management specialists*** and/or ***data analysts*** may need to be trained to operate an electronic information management system and produce data reports for the programme.

Policy-makers should work with human resources and training experts to decide how staff should be trained and receive any refresher/update training, and whether they need a special test to demonstrate competency. Any training or competency testing should be in line with regulatory frameworks. Policy-makers may need to take account of turnover of staff working in screening and put in place regular updates and checks on qualifications to ensure staff remain competent.

Spain and Sweden: different staff cadres can be trained to screen and grade digital images

Diabetic retinopathy screening in **Spain** is carried out according to the organizational model of each autonomous region. Most regions have unorganized screening, although some have started to organize screening programmes.

Specially trained staff (technicians, nurses or nursing assistants who have received specific training) take a retinal image using digital retinal cameras. The images are sent electronically to family doctors, trained nurse personnel or endocrinologists, who grade the images. If the result is screen-positive (abnormal) or the grader is uncertain, the image is sent to an ophthalmologist for a definitive diagnosis. Ophthalmologists also carry out internal quality control by reviewing a random selection of screen-negative images.

A training programme and infrastructure for retinal imaging are available to support the development of organized screening.

Sweden provides a wide range of courses to professionals involved in screening. One example is the yearly courses on diabetic retinopathy offered by the Swedish Ophthalmological Society for residents and ophthalmologists. The Karolinska Institute in Stockholm also provides a course in diabetic eye care and retinal photography for nurses who have specialized in ophthalmic care, and the 21 self-governing regions organize courses at local level.

11.4. Equipment

The success of diabetic retinopathy screening depends on careful consideration being given to equipment for every step of the process.

All equipment, including computer systems and monitors to view images, and the vans used to transport equipment, must be fit for purpose and maintained to the appropriate standards, and a replacement plan must be in place (Fig. 8).

In selecting equipment, it is important to ensure image quality comparability (by setting minimum image quality standards) and data compatibility (for uploading in shared repositories or sharing strategies among care providers).

It is vital that all pieces of equipment have a maintenance plan and a valid maintenance contract. In some places, additional protection (such as electricity surge protectors) must also be purchased to protect the kit.

Ophthalmic cameras must be of sufficient quality to enable reliable grading to be undertaken on the images taken. Regular quality-assurance audits of equipment must take place.

Fig 8. Mobile van for taking images

© Simon Harding.

11.5. Information management system

Commissioning an e-information management system is complex, and policy-makers will need expert advice Compatibility with existing software can cause major barriers to implementing new systems.

An information management system can be paper and/or electronic. Both systems should have standard operating procedures so that staff know how to use them correctly.

E-information management systems can track the patient through the screening pathway and generate management and performance data that can be very helpful in monitoring a screening programme.

An e-information management system can also link different aspects of care of people with diabetes, such as diabetic retinopathy screening, renal function, and diabetic and blood pressure control.

11.6. Health system capacity

Policy-makers should work with clinicians to model the impact of introducing a screening programme on existing ophthalmology services and staff.

Planning needs to include the extra demand placed on services because of a first-pass effect. This is where the first round of screening picks up a lot of people with more advanced disease that requires vitreoretinal surgery or laser treatment. The ready reckoner provided in Annex 4 may help policy-makers estimate this effect.

The first round of screening may also detect a large number of cataracts or other eye disease that will need referral for treatment. Policy-makers should consider how they can integrate care for people with these incidental findings into an overall plan for eye services, including developing guidelines for referral of incidental findings to ophthalmology services.

Policy-makers will need to consider both these possible pressures on ophthalmology services and if appropriate might consider having a clinically appropriate higher threshold for referral for diabetic retinopathy at the first round of screening, so reducing some of the pressure on ophthalmology services (see Box 6).

Links should be established between retinal and vision rehabilitation services for those identified late or with diabetic retinopathy sufficiently severe that rapid loss of vision function is expected.

Ophthalmology services may need a long-term increase in capacity to receive referrals from the screening service. This may require investment in additional staff and new equipment for diagnosis and treatment of diabetic retinopathy.

Staffing capacity can also be increased by creating new staffing cadres and subspecialties. For example, if retinal cameras are used in ophthalmology departments, they can be operated by technicians rather than more highly trained ophthalmologists. If laser services are expanded, creating medical retina subspecialists, expert in the use of lasers, may make services more cost–effective.

Any changes to staffing structures or introduction of new staffing cadres will need to be done in consultation with professional national societies and within the legal and professional frameworks operating in a country.

11.7. Financing

Once a screening pathway is agreed, it can be used to map out the financing model. This can be quite complex as there may be several different organizations involved in the screening pathway.

Depending on the financing system in each country, policy-makers may need to decide whether social or private insurance systems should get dedicated funding for operating the screening programme up to the point of referral for screen positives or whether additional funding should include diagnosis and treatment of people with diabetic retinopathy.

Other questions that policy-makers will need to address include whether there will be additional funding for set-up costs for equipment, training, information management systems, quality assurance and management of the programme.

Policy-makers should plan for an expansion in demand for laser and other treatment that occurs at the first screening round and factor in the costs, affordability and feasibility of meeting this extra demand.

11.8. Communication and information for patients and professionals

Policy-makers should consider developing a communication strategy as a discrete workstream. This will have three components.

11.8.1. Communication with key stakeholders

Policy-makers will need to communicate regularly with key stakeholders before the programme starts and when it is fully operational. Development of a stakeholder map may be a useful starting point. This can reflect each stakeholder's interests and the kind of communication they will need. Stakeholders might include patient groups representing the interests of people with diabetes and those who have vision impairment, and associations representing professional groups, such as ophthalmologists and optometrists. It should also include vision rehabilitation services that support people with severe vision impairment and blindness.

11.8.2. Patient information materials

These can be developed centrally or left to local programmes to design. Use of focus groups involving people with diabetes are important in developing good-quality materials (see sections 8.3 and 10.2).

11.8.3. Information materials and communication for those working in the programme

Policy-makers will need to communicate to those working in the programme on a regular basis and may find a regular newsletter for staff a useful way of keeping people up to date. Having regular meetings with clinical leads to discuss how the programme is working and what might be done to improve it is also helpful.

11.9. Using pilots to test a model

Having decided on a particular model and implementation strategy, it is recommended that a pilot or demonstration service be set up to test systems and check whether the model works. It may be worthwhile operating the pilot in two different settings in countries that have mixed health financing systems or different operational challenges in, for example, rural and urban settings, to assess whether modification is required according to a financing model or setting.

11.10. Taking a stepwise approach

If a decision is taken to introduce change in a stepwise manner, this can be done in different ways.

Policy-makers may start a new programme or approach in a few areas where there are enthusiastic clinicians who are trained and competent and slowly extend the coverage of the programme to cover the country or region as more staff become trained.

New technology and training for staff can be introduced to a few sites and then the programme rolled out as more equipment becomes available.

Another approach is to incrementally raise the quality of screening by introducing new clinical guidelines alongside the introduction of a quality-assurance system.

Lastly, introduction of a new information management system can also be used to embed a new screening pathway across a country.

Armenia: taking a stepwise approach to improving diabetic retinopathy screening

It is estimated that approximately 96 000 people in Armenia have diabetes. In 2017, the Armenian Eye Care Project, in cooperation with the Ministry of Health and the World Diabetes Foundation, implemented a project called “Preventing Blindness from Diabetic Retinopathy” (World Diabetes Foundation, 2020). Project activities were integrated with the comprehensive project, “Bringing Sight to Armenian Eyes”. Integration of the projects enabled eye screening for more than 52 000 people.

Three methods were used to identify people who had diabetic retinopathy. First, the population was invited for a general check-up of eye health, including visual acuity, ophthalmoscopy, tonometry and refraction (if appropriate). Those who had symptoms of diabetes were also referred for digital retinal photography. Secondly, family doctors and endocrinologists referred their patients with diabetes, and thirdly, people who were at high risk were identified by a World Bank-supported screening project.

The project started by training around 10 medical staff to screen patients using four retinal fundus cameras in one region of Armenia and then expanding to 100 medical staff in all regions of Armenia, with the use of 10 fundus cameras on a rotational basis.

Armenia contd

The artificial intelligence grading system linked to the digital retinal photographs enabled early detection of diabetic retinopathy. Use of the fundus cameras with connection to artificial intelligence was managed by technical staff and did not require the involvement of ophthalmologists in the field. A data-archiving software system that allows collection and storage of information of patients with diabetic retinopathy, their diagnosis and follow-up options was introduced.

The project trained more than 1200 medical staff and 30 technicians and nurses on the use of portable fundus cameras with artificial intelligence in all 10 regions of Armenia and the capital city of Yerevan.

The project improved access to diabetic retinopathy screening services by:

- providing accessible screening through primary health-care providers and mobile medical teams travelling to villages – detailed assessments and laser treatment were also made more accessible through a mobile eye hospital, regional eye centres and the leading eye hospitals in the capital;
- training professional staff to provide high-quality services and information to people with diabetes – training was provided for ophthalmologists, endocrinologists and family medicine doctors, together which enhanced networking among the professional groups to facilitate a patient centred-approach; and
- raising public awareness of diabetic retinopathy and healthy lifestyles for people with diabetes – various approaches were used, including leaflets, public service announcements, and interactive training materials for family medicine doctors and health-point nurses to further disseminate information and bring about behavioural change among the population.

Challenges were faced in training health-care providers as public educators, as they were not used to acting in this role. The project also highlighted the need for further knowledge and understanding of diabetic retinopathy among people with diabetes, as lack of understanding acted as a barrier to them engaging with the programme.

When the project was completed in 2020, it had screened over 52 000 people for diabetic retinopathy. Of those screened, 16 000 received digital retinal imaging, 8500 were diagnosed with diabetic retinopathy and/or diabetic macular oedema, and 1229 people received laser treatment.

12

Country examples

This chapter presents three examples of common country scenarios in different contexts in the WHO European Region.

The examples show how the framework can be used to undertake a situational analysis using the four domains and how to use this to develop an improvement strategy.

The third example also illustrates an analysis of a pathway that may be done as part of a situational analysis. It shows how a pathway map can help to identify weaknesses in the pathway and illustrates what can be done to strengthen a pathway even where resources are limited.

12.1. A middle-income country with a mixed model of diabetes care

In this example, patients with diabetes are managed in a variety of settings, some by endocrinologists and others by family doctors. Patients may have their eyes checked by family doctors or endocrinologists, or be referred to ophthalmologists. Endocrinologists/diabetologists and ophthalmologists work in either private practice or in the state-funded hospital clinics. ***There are no protocols that govern where patients should receive their diabetes care or have their eyes screened. This is often influenced by a patient's ability to pay for private care.***

Fig. 9 summarizes findings from the situational analysis in the four domains.

A priority for this country will be to ***increase equity of access*** by extending screening to all people with diabetes regardless of their ability to pay. Several models could be looked at, such as encouraging private optometrists and ophthalmologists to participate in a more systematic screening programme, working to agreed guidelines and protocols. An alternative could be to set up a programme based on existing state hospital diabetes clinics extending screening to all people with diabetes in a locality – this could use mobile clinics via vans with retinal cameras or table-top slit lamps.

If there is concern about the capacity of screening or laser treatment services to meet demand, screening can be started with an extended interval of two years for people with no evidence of retinopathy or maculopathy in either eye, rather than screening everyone every year and then decreasing the screening interval as capacity becomes available.

A second priority would be to map out a pathway and develop clinical guidelines and protocols to describe what patients should expect from a screening programme regardless of where they are managed or who screens them.

Creating an e-list of all people diagnosed with diabetes will be particularly important as a way of ***strengthening the pathway.*** The e-list can be used for invitations and reminders, and for tracking patients and checking they are referred for treatment when needed. Further information will be required to decide the best way to do this. Endocrinologists/diabetologists in state hospital diabetes clinics may be important stakeholders in driving forward these lists, as they may already have systems that could be rolled out. An alternative might be to develop a national system or diabetes register possibly linked to payments.

If the choice is to create a more systematic screening programme based on the many individual ophthalmologists and optometrists in private practice, the focus will need to be on how to ensure ***quality*** in the system. Audits can be useful tools but require robust data collection and resources to analyse and feed back results. Data returns can be encouraged by linking to reimbursements.

Appointing a locality clinical lead who can engage with ophthalmologists and optometrists and promote use of clinical guidelines and classification systems, audits and refresher training may also be a way to improve quality. The clinical lead could also be responsible for carrying out quality-assurance visits and auditing clinical records.

Fig 9. An example of a situational analysis in a middle-income country with mixed models of diabetes care

This kind of approach will need engagement with professional associations, as it may require a change in existing clinical practice. A way to start could be to identify a small number of enthusiastic, trained and motivated clinicians who can promote the change in their locality and act as champions of systematic screening.

12.2. A high-income country with an integrated pathway of care for diabetes

In this scenario, most health care in this country is paid through social health insurance. The country has a health information management system and a national diabetes register. People with more complex diabetes are usually cared for in hospital multidisciplinary diabetes clinics led by endocrinologists/diabetologists. Their eyes are screened as part of their annual check-up and they are automatically sent reminders. ***Those patients who are cared for by their family doctor are referred to private ophthalmologists for screening, paid through the social health insurance system.***

Fig. 10 summarizes findings from the situational analysis in the four domains.

In this example, there is noticeable ***inequity in access to effective systematic screening*** between patients who are cared for by family doctors in primary care and those attending hospital multidisciplinary diabetes clinics.

The priority for this country is to strengthen the screening offered to patients who are managed by family doctors.

Several different approaches could be considered, but focusing on creating a ***screening pathway for patients managed by family doctors*** should be a priority. This could be done by the introduction of a ***health information management system*** that manages the patient pathway, automatically sending out invitations, recording the results of screening, referring patients who are screen-positive and generating results letters to go to family doctors. The system could be used by ophthalmologists working in private practice and screening undertaken in multidisciplinary diabetes clinics, and to audit the quality of screening and classification of images and ***drive up quality.***

An alternative approach could be to build on the success of the hospital multidisciplinary diabetes clinics and commission them to deliver locality screening through the use of mobile digital cameras.

A focus on quality will be important in either approach. If ophthalmologists in private practice continue to screen patients, refresher courses might be needed to make sure they are familiar with classification and referral guidelines used in the screening programme and to ensure they communicate their results to the national information system.

A quality-assurance system building on agreed quality standards could be strengthened. This could involve carrying out inspection visits and developing methods to check on the quality of screening and grading, wherever it is carried out, through, for example, auditing retinal images or providing online exemplar retinal images against which clinicians can regularly review and check their performance.

In this example, using information management systems to embed a pathway into clinical practice can make sure all patients with diabetes can have access to a more systematic screening programme.

12.3. A low-middle-income country: strengthening a screening pathway in a rural setting

This example is set in a low-middle-income country where only the capital city and a few large urban centres have relatively good health resources and ophthalmologists. Many patients, however, live in remote rural areas where there are fewer resources and staff.

Most people with diabetes in rural areas are managed by an endocrinologist, specialist in internal medicine or their family doctor in a polyclinic. Some patients with complex type 1 diabetes are managed by specialist endocrinologists in hospital diabetic clinic in towns, but this is unusual.

Most primary care clinics do not have Internet or e-information systems, so they use a paper-based list of people with diabetes. Patients with diabetes are called for regular check-ups for their diabetes at the polyclinic and the doctor looking after their diabetes is also responsible for checking their eyes. Some doctors will examine the patient's eyes using direct ophthalmoscopy.

Fig 10. An example of a situational analysis in a high-income country with an integrated pathway of care for diabetes

Sometimes the doctor will ask ophthalmologists working in the polyclinic to check the patient using indirect ophthalmoscopy or slit-lamp biomicroscopy if available. Results are recorded in their patient records.

Patients needing treatment are referred to the nearest specialist ophthalmologist in regional hospitals.

Fig. 11 summarizes findings from the situational analysis in the four domains and Table 2 shows an example of an analysis of a screening pathway in a low-middle-income country.

Fig. 11. An example of a situational analysis in a low-middle-income country

Table 2. An example of an analysis of a screening pathway in a low-middle-income country

Steps in the screening pathway	How is it done?	What are the weaknesses?	What can be done to improve the system?
Identify the population eligible for screening	Patients who attend primary care and are diagnosed with diabetes have their name, ID, details of their diabetes and contact details entered into a paper list. Some patients with type 1 diabetes are referred to a specialist endocrinologist at the nearest hospital diabetes clinic.	Relies on staff in primary care remembering to enter people with diabetes on the list. Paper-based systems are difficult to search, update and extract data from. Relies on type 1 patients being referred and entered into the screening system at the diabetes clinic. Resource intensive on administrative staff.	Clinic staff can operate fail-safe systems to check that all patients who come for a check-up or request prescriptions for diabetic medicines are on the list. Clinic staff can check with the hospital diabetes clinic that patients with type 1 diabetes have been entered on to the screening system at the clinic.
Invitation and information	All patients with diabetes are given a leaflet informing them about diabetic retinopathy and that they should have their eyes tested at regular intervals. Clinic staff operate a bring-forward card-based filing system to call patients and tell them to come and have their diabetes and eyes tested.	Bring-forward systems are subject to human error when filing individual cards and they need clinic staff to regularly check them to identify people who have not attended.	Clinic staff can carry out audits to check that patients who are invited to come for a check-up have had their eyes tested.
Testing	Family doctors and endocrinologists examine the retina using a direct ophthalmoscope. Guidelines instruct the clinician how frequently to examine the eyes and record their findings using standard systems. Clinic staff record that patients have had their eyes tested on the card filing system and on the patient record.	Family doctors and endocrinologists are not normally trained in performing retinal examination using a direct ophthalmoscope Direct ophthalmoscopy is not overly sensitive and is reliant on the skill of the clinician looking at the patient's eyes. Paper-based systems for recording results may be mislaid. It is difficult to audit results or perform quality assurance.	Regular training or refresher courses for medical staff using direct ophthalmoscopy can improve sensitivity. Provision of reference images on cards for grading helps produce more consistent results. Regular audits and/or visits to the staff performing retinal examination helps motivation and quality improvement. Create capacity for ophthalmologists working in primary care to screen patients for diabetic retinopathy. As resources become available, introduce mobile digital retinal cameras.

Table 2 contd

Steps in the screening pathway	How is it done?	What are the weaknesses?	What can be done to improve the system?
Referral of screen positives	Guidelines describe the threshold of disease that should be used for referral to an ophthalmologist. They also specify the advice that should be given to patients with diabetic retinopathy on how to improve their diabetic control. Patients who are found to have diabetic retinopathy are given a referral letter to make an appointment to see an ophthalmologist. Standard letters are used for referrals, including a request for the ophthalmologist to inform the family doctor of their findings.	It is difficult to collect outcome data from ophthalmologists or to check that patients have been seen and treated within an appropriate time frame.	Clinic staff can use the bring-forward card system to operate a fail safe to check that referred patients are seen within an agreed time frame and to check on outcomes.
Reporting of screen negatives	Patients who are screen negative have their results recorded on their patient record and on their clinic card, which is put back into the bring- forward system at an appropriate time interval for their next eye screen. Patients are told when they should next attend the clinic for their diabetic check-up and have their eyes screened.	This system relies on patients remembering to make an appointment to have their diabetes and eyes checked.	Bring-forward systems can be used as a fail safe to check whether patients have attended for the screening appointment.
Diagnosis	Diagnosis is performed by ophthalmologists using slit-lamp biomicroscopy.	This system relies on consistency between ophthalmologists in the way their report their findings on examination on patients' records.	Standard templates for drawing findings of the retina may improve accuracy of recording of results. Quality-assurance visits from local health authorities can verify that patients' records are accurate and complete.

Table 2 contd

Steps in the screening pathway	How is it done?	What are the weaknesses?	What can be done to improve the system?
Intervention, treatment, and follow up	Treatment and surveillance and follow up is organized by ophthalmologists.	Ophthalmologists might not operate an effective recall system for patients requiring follow up.	Local health authorities can work with ophthalmologists and the local health system to improve cooperation and compliance with organizing follow-up visits.
Reporting of outcomes	Data from the list of people with diabetes, patient records, cards and letters are used to collate data on number of patients seen, referred and treated.	Relies on ophthalmologist writing on the patient's records or a letter to primary care/clinic to inform them of findings. Aggregate data are likely to be inaccurate because of missing data and inaccurate recording of results. Data collation from paper-based system requires a lot of administrative resources.	Concurrent recording of findings in separate paper databases may increase accuracy of data.

In this country, a priority should be to build laser capacity and other treatments outside the capital and make it more widely accessible to the rural population. Having done this, the focus can be placed on improving screening capacity and quality.

Mobile digital retinal photography would be a good strategy to improve screening in remote areas, but resources may not be available for widespread mobile digital retinal screening in the foreseeable future. In the meantime, it may be worthwhile building screening capacity among the existing workforce using slit-lamp biomicroscopy or direct ophthalmoscopy (if this is the only test available). This may require training programmes for ophthalmologists, endocrinologists/diabetologists and family doctors.

People with advanced disease should be identified at an early stage in the programme and offered timely treatment to prevent further vision impairment. A high referral threshold therefore would be appropriate until most people with advanced disease have been identified and treated.

Strengthening the screening pathway can have a rapid benefit, even with paper-based systems. Fail-safe systems can check whether patients have had their eyes checked and that they have been referred and received treatment in a timely manner.

13 Conclusion

This screening guide provides practical information and guidance for policy-makers on how to improve current approaches to diabetic retinopathy screening.

It shows how it is possible to build on existing systems and take a stepwise approach to improving the effectiveness of current approaches so that high-quality systematic diabetic retinopathy screening becomes a universal offer to all people with diabetes.

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Annex 1. Explanation of technical terms used in the guide

Blindness: where the individual has no perception of light in the best eye or light perception measures less than 3/60 in the better eye. (Further information and definitions can be found in the WHO *World report on vision* (WHO, 2019).)

Cataract: a dense, cloudy zone that forms in the lens of the eye. It prevents light travelling through the lens sending clear images to the retina.

Cotton wool spots: an abnormal finding on the retina. They appear as fluffy white patches and are caused by damage to nerve fibres.

Diabetic maculopathy: defined as any involvement of the macula (central part of the retina) by diabetic retinopathy.

Eligible population: a defined population that meets the criteria to be offered screening.

Fail-safe system: a back-up mechanism that ensures that if something goes wrong in a system, action will be taken to ensure a safe outcome.

False negative: a normal test result in a person who does have the condition being tested for.

False positive: an abnormal test result in a person who does not have the condition being tested for.

Guidelines: sets of evidence-based recommendations that aid decision-making about care in specific health systems and resource settings.

Exudates: small white or yellowish white lipid deposits located in the outer layers of the retina. They are caused by leaking of fluid from blood vessels in the retina.

Incidence: number of new cases occurring within a population during a specified time period.

Mydriasis: dilatation of the pupil. In order to examine the retina more reliably, pharmacologically active drops can be put in the eye to dilate the pupil.

Macula: centre of the retina, it is responsible for sharp, detailed and colour vision.

Macular oedema: defined as any thickening of the macula (central part of the retina) detectable on clinical examination or investigation. It can be noncentral-involved or central-involved. It requires observation and may require treatment.

Microaneurysm: a tiny sack protruding from very small blood vessels in the retina. These protrusions may rupture and leak blood.

Neovascularization: new abnormal blood vessels that grow from within the retina into the vitreous towards the centre of the eye.

Prevalence: the number of cases of a condition in a given population at a point in time.

Protocols: agreed frameworks outlining the care that will be provided to patients in a designated area of practice, such as vision health screening for people who have diabetes.

Retina: the innermost layer of the eye. Containing photoreceptor cells and fibres connecting with the brain, it is nourished by a network of blood vessels.

Sensitivity: the ability of the screening test to identify people with the condition as positive (abnormal).

Sight-threatening diabetic retinopathy: defined as a level of retinopathy and/or maculopathy that indicates there is a significant risk of progression to advanced disease. This is a level of retinopathy that is more severe than moderate nonproliferative diabetic retinopathy and noncentral-involving diabetic macular oedema.

Specificity: the ability of the screening test to identify healthy people as negative (normal).

Standard operating procedures: methods used to achieve or comply with the protocols.

Vision impairment: occurs when an eye condition affects the visual system and one or more of its vision functions. It is measured by testing visual acuity in the better eye. It can be graded as mild, moderate, or severe. (Further information and definitions can be found in the *World report on vision* (WHO, 2019).)

Vitreous: the transparent gel-like fluid that fills the globe of the eye.

Vitreous haemorrhage: a bleed that occurs in the vitreous gel in the centre of the eyeball behind the lens, causing sudden vision impairment.

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Annex 2. Classification and grading systems

Table A2.1 shows the International Classification of Diabetic Retinopathy and Diabetic Macular Oedema of the International Council of Ophthalmology.

Table A2.1. International Classification of Diabetic Retinopathy and Diabetic Macular Oedema

Diabetic retinopathy	Findings observable on dilated ophthalmoscopy
No apparent diabetic retinopathy	No abnormalities
Mild nonproliferative diabetic retinopathy	Microaneurysms only
Moderate nonproliferative diabetic retinopathy	Microaneurysms and other signs (such as dot and blot haemorrhages, hard exudates, cotton wool spots), but less than severe nonproliferative diabetic retinopathy
Severe nonproliferative diabetic retinopathy	Moderate nonproliferative diabetic retinopathy with any of the following: • intraretinal haemorrhages (≥ 20 in each quadrant) • definite venous beading (in two quadrants) • intraretinal microvascular abnormalities (in one quadrant) • no signs of proliferative retinopathy
Proliferative diabetic retinopathy	Severe nonproliferative diabetic retinopathy and one or more of the following: • neovascularization • vitreous/preretinal haemorrhage

Diabetic macular oedema	Findings observable on dilated ophthalmoscopy[a]
No diabetic macular oedema	No retinal thickening or hard exudates in the macula
Noncentral-involved diabetic macular oedema	Retinal thickening in the macula that does not involve the central subfield zone that is 1 mm in diameter
Central-involved diabetic macular oedema	Retinal thickening in the macula that does involve the central subfield zone that is 1 mm in diameter

[a] Hard exudates are a sign of current or previous macular oedema. Diabetic macular oedema is defined as retinal thickening, and this requires a three-dimensional assessment that is best performed by a dilated examination using slit-lamp biomicroscopy and/or stereo fundus photography.

Source: International Council of Ophthalmology (2017). Reproduced by permission.

Reference

International Council of Ophthalmology (2017). Updated 2017 ICO guidelines for diabetic eye care. San Francisco (CA): International Council of Ophthalmology:1–33 (http://www.icoph.org/downloads/ICOGuidelinesforDiabeticEyeCare.pdf, accessed 19 October 2020).

Annex 3. Referral thresholds

Fig. A3.1 illustrates the possible impact of using different grades for referral thresholds on ophthalmology services, as discussed in section 5.4 and Chapter 7.

Fig. A3.1. Illustration of impact on ophthalmology services of different referral thresholds for diabetic retinopathy screening

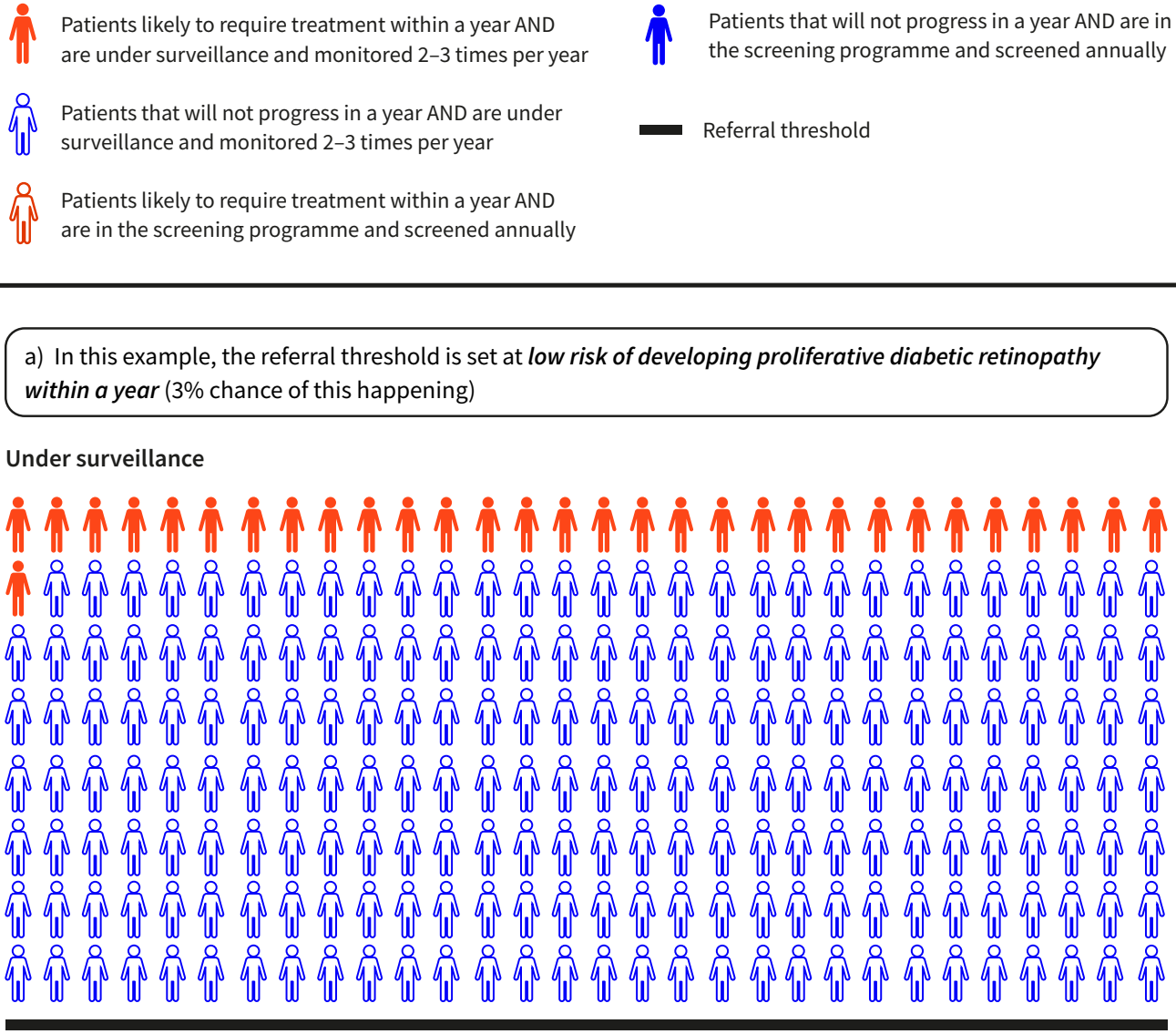
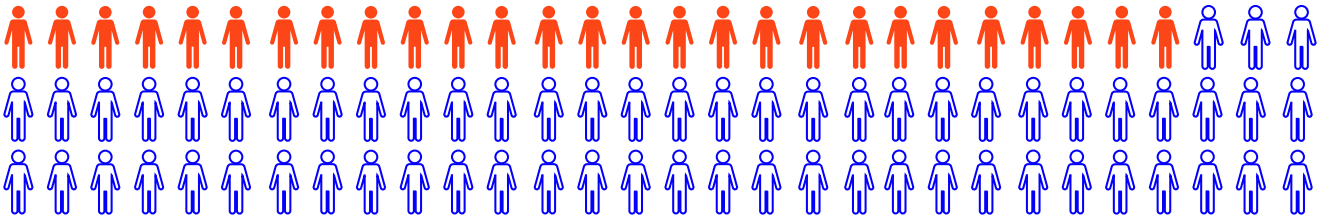


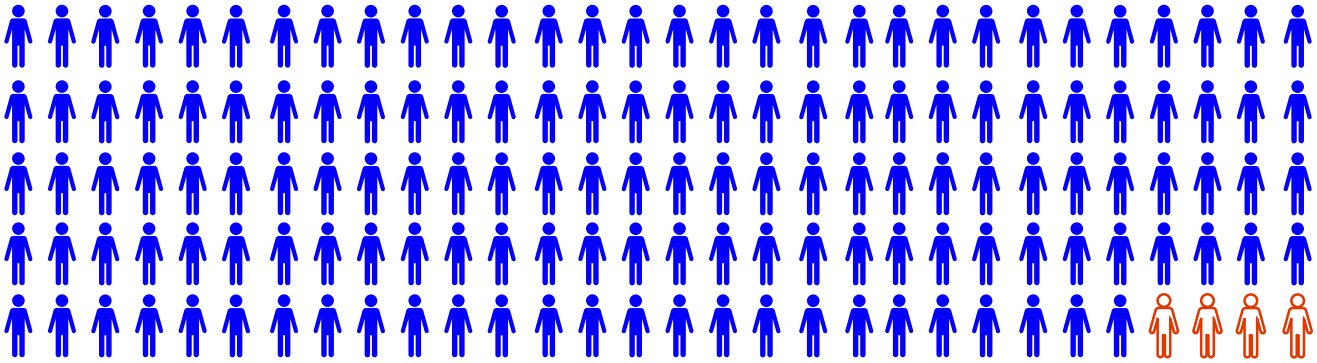
Fig. A3.1 contd

b) In this example, the referral threshold is set at ***moderate risk of developing proliferative diabetic retinopathy in a year*** (11% chance of this happening)

Under surveillance



Routine screening



90 patients will be screen-positive and referred:

- 27 patients requiring treatment will be identified
- **BUT 63** patients not requiring treatment within a year will ALSO be under surveillance

150 patients will be screen-negative and stay in routine screening; of these:

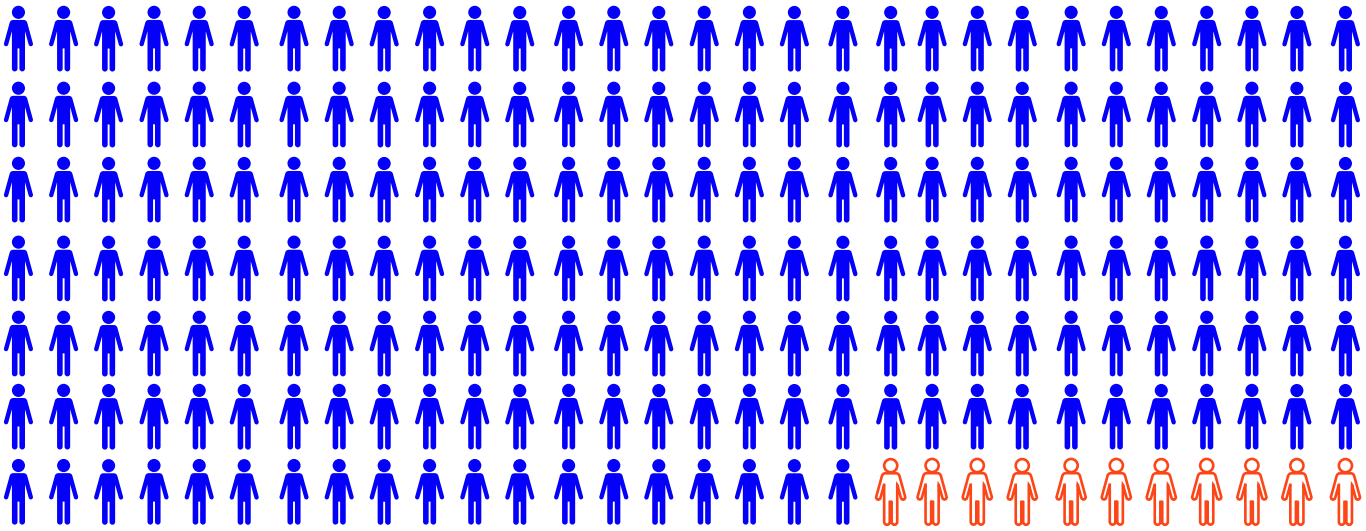
- **146** patients not requiring treatment will be seen annually
- **BUT four** patients who will progress in a year to proliferative diabetic retinopathy **will not** be identified immediately and will be seen annually

Fig. A3.1 contd

c) In this example, the referral threshold is set at ***high risk of developing proliferative diabetic retinopathy in a year*** (50% chance of this happening)

Under surveillance

Routine screening



30 patients will be screen-positive:

- 20 patients requiring treatment will be identified
- **BUT 10** patients not requiring treatment within a year will ALSO be under surveillance

210 patients will be screen-negative and stay in routine screening; of these:

- 199 patients not requiring treatment will be seen annually
- **BUT 11** patients who will progress in a year to proliferative diabetic retinopathy ***will not*** be identified immediately and will be seen annually

Ideally, screening could distinguish exactly which patients are likely to need treatment within a year and should be under surveillance 3–6 monthly, from those who do not need treatment and only need to be screened annually. However, this is not possible as grades of diabetic retinopathy only give a risk of this happening.

The illustration is based on a country with systematic screening and an incidence of any retinopathy of 24% (consisting of: 15% mild nonproliferative diabetic retinopathy (NPDR), 6% moderate NPDR, 2% severe NPDR and 1% proliferative diabetic retinopathy (PDR)).

Rates of progression are estimated based on the Early Treatment Diabetic Retinopathy Study. Data on diabetic macular oedema are not easily interpretable and have not been included in these estimates.

A patient with PDR has an approximately 40% risk of severe vision impairment in two years without treatment. Appropriate treatment halves the risk of severe vision impairment at this stage (Early Treatment Diabetic Retinopathy Study, 1991).

In this example, for every 1000 patients who are screened annually, 240 will have retinopathy. It is assumed that patients who are screen-positive and referred will be under surveillance and seen 2–3 times per year and those staying in routine screening will be reviewed in 12 months. The screen-negative group will have varying risks of progression to PDR, also shown in each panel, and will be detected at subsequent visits (provided they attend).

Reference

Early Treatment Diabetic Retinopathy Study Research Group (1991). Grading diabetic retinopathy from stereoscopic color fundus photographs – an extension of the modified Airlie House classification. Ophthalmology 98:5(Suppl.):786–806. http://www.sciencedirect.com/science/article/pii/S0161642013380129 (accessed 19 October 2020).

Annex 4. Ready Reckoner: estimating service demand for treatment

The tool is designed to illustrate how many people will need treatment when a decision is made to start screening. It is assumed that there will be annual diabetic retinopathy screening with a referral threshold of moderate nonproliferative diabetic retinopathy.

Fig. A4.1 is the tool and Fig. A4.2 a worked example.

Fig. A4.1. Ready Reckoner: estimating the number of people who will require treatment for a diabetic retinopathy screening programme operating an annual screening interval and a threshold set at moderate nonproliferative diabetic retinopathy

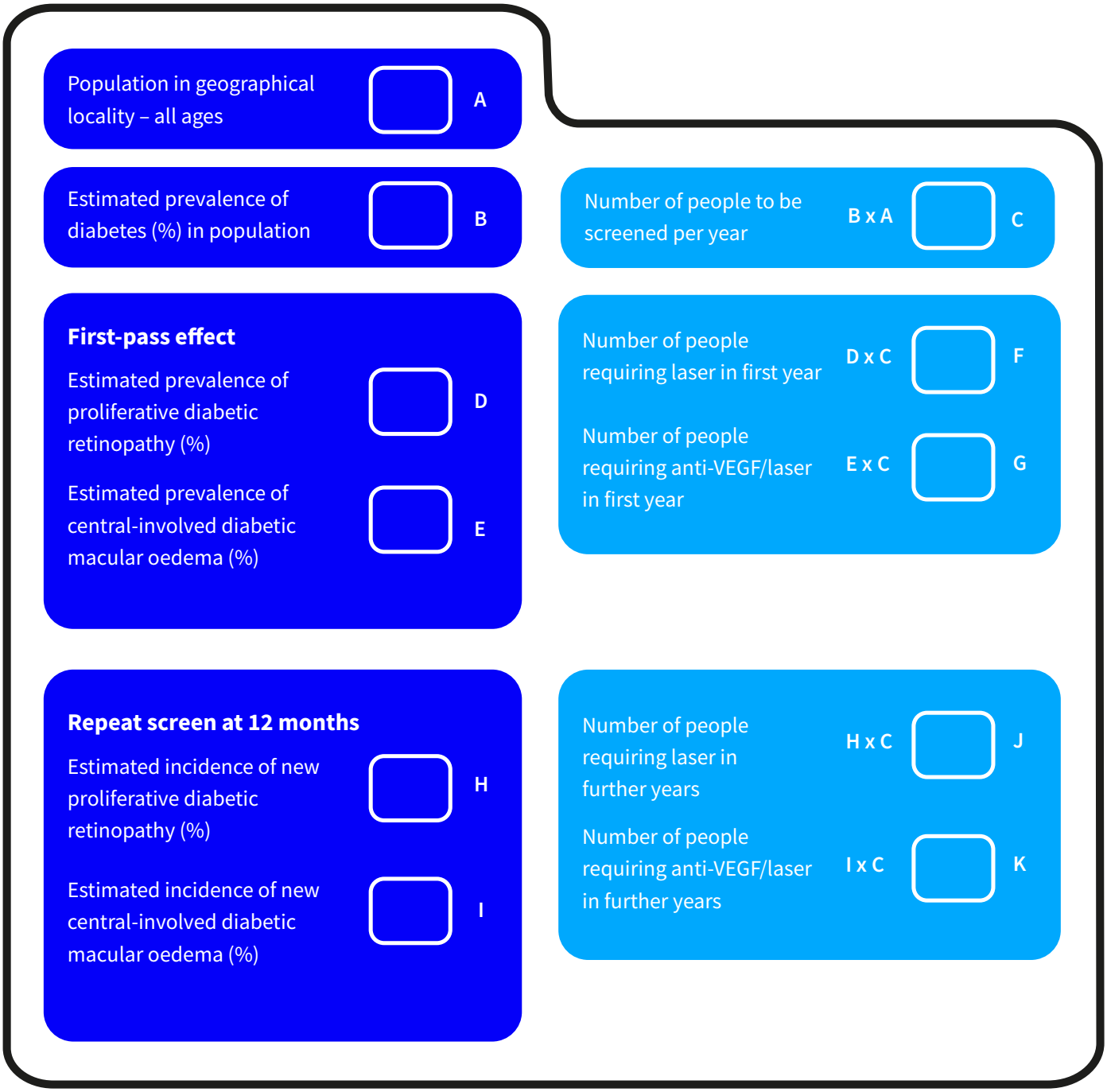
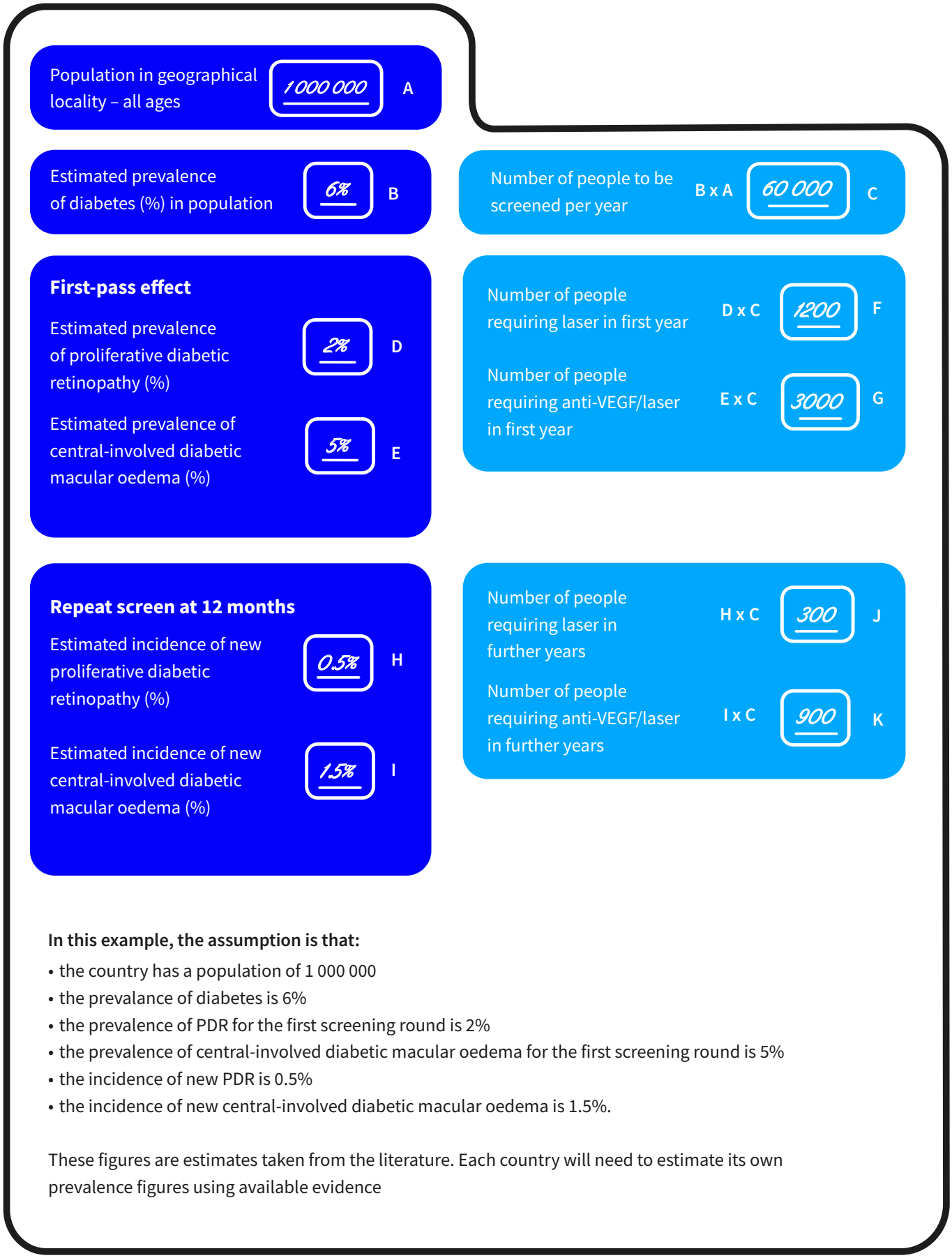


Fig. A4.2. Ready Reckoner: worked example



In this example, the assumption is that:

- the country has a population of 1 000 000
- the prevalance of diabetes is 6%
- the prevalence of PDR for the first screening round is 2%
- the prevalence of central-involved diabetic macular oedema for the first screening round is 5%
- the incidence of new PDR is 0.5%
- the incidence of new central-involved diabetic macular oedema is 1.5%.

These figures are estimates taken from the literature. Each country will need to estimate its own prevalence figures using available evidence

In this example, a population of 1 million (A) has an estimated prevalence of diabetes of 6.0% (B) and the number of people who will need to be screened each year will be 60 000 (C).

In the first year there will be a significant first-pass effect, detecting previously undetected prevalent disease. It is assumed that the local service will expect to treat established proliferative diabetic retinopathy (PDR) and central-involvement diabetic macular oedema (DMO). An estimated prevalence of previously undetected PDR of 2.0% (D) gives 1200 people (F) requiring a course of laser treatment. An estimated prevalence of previously undetected central-involved DMO of 5.0% (E) gives 3000 people (G) requiring a course of anti-vascular endothelial growth factor (VEGF) therapy to be started if available. These numbers mean that a phased introduction might be required if there is not enough laser treatment available.

In subsequent years the numbers requiring treatment will be much lower. Estimated incidences of 0.5% for PDR (H) and 1.5% for central-involved DMO (I) will generate 300 people requiring laser treatment (J) and 900 requiring anti-VEGF or laser treatment (K).

These numbers will be affected by several variables. For example, in countries with higher rates of type 1 diabetes, the numbers of cases with PDR could be significantly higher.

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