PREVENTION OF BLINDNESS FROM DIABETES MELLITUS

World Health Organization

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Report of a WHO consultation in Geneva, Switzerland, 9–11 November 2005

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EXECUTIVE SUMMARY

Global prevalence of diabetes mellitus and diabetic retinopathy

Diabetes mellitus currently affects more than 170 million persons worldwide and will affect an estimated 366 million by 2030, with the most rapid growth in low and middle-income countries, among populations of working age. More than 75% of patients who have had diabetes mellitus for more than 20 years will have some form of diabetic retinopathy.

Diabetic retinopathy is a microvascular complication of both type 1 and type 2 diabetes mellitus. The condition is a leading cause of new-onset blindness in many industrialized countries and is an increasingly more frequent cause of blindness elsewhere. WHO has estimated that diabetic retinopathy is responsible for 4.8% of the 37 million cases of blindness throughout the world.

Evidence-based treatment is available to reduce significantly the risks for blindness and for moderate vision loss. Clinical studies spanning more than 30 years have shown that appropriate treatment can reduce the risks by more than 90%.

Delivery of eye care for patients with diabetes

Despite clearly defined clinical guidelines for evaluating and treating diabetic retinopathy in a cost-effective manner, effective interventions, such as laser treatment, are underused, for a variety of reasons. While the available resources and methods differ from country to country, certain basic components of care should be present.

Patients should know that they have diabetes mellitus and that the condition requires care. General population screening for diabetes mellitus with existing methods is considered neither appropriate nor beneficial, although use of such methods to reach subpopulations with a very high prevalence of diabetes mellitus might be both appropriate and feasible for some Member States.

Patients should receive adequate care for diabetes mellitus. The only means of preventing diabetic retinopathy is regulating blood sugar, blood pressure and other risk factors that can be controlled by patients, under the guidance of their care provider. Often, however, physicians do not care for diabetes patients in the manner indicated by the results of randomized controlled trials.

Patients should undergo periodic eye examinations. Professional organizations advocate annual eye examinations for patients with diabetes and prompt treatment when indicated. Nevertheless, many patients with diabetes are not evaluated or treated adequately to prevent unnecessary blindness and visual loss.

Patients should receive adequate treatment for diabetic retinopathy. The prevention of vision loss from diabetic retinopathy should be an integral part of the management of diabetes mellitus. Specific treatment for sight-threatening stages of retinopathy should follow established guidelines.

Patients should be sufficiently aware and motivated to undergo not only an initial eye examination but also regular follow-up examinations. Understanding the difficulties and barriers to regular eye examinations is one step in addressing the prevention of blindness from diabetic retinopathy. It is not enough to provide information that patients can understand; a 'marketing' approach should be used, to 'sell' the patient the idea of the importance of regular eye examinations.

Principles for organizing an eye health system for the care of diabetic retinopathy

The consultation sought to address care for diabetic retinopathy from a perspective that would be applicable across diverse settings, such that the insights and lessons acquired in one area or context could be shared to make current and future initiatives more effective. The decisions made by each country are adapted to that country's resources, social expectations and available health care infrastructure. There is always a trade-off between technical performance and costs, and no country can escape this dilemma in making programme decisions. To assist countries in making informed decisions, the consultation considered the accuracy of the various methods for detecting the presence or severity of diabetic retinopathy, the locations that best serve patient needs and the interval between eye screenings or examinations.

Accuracy of examination results: If diabetic retinopathy is suspected after screening, a decision must be made about the overall management for a given level of diabetic retinopathy. In many developing countries, there are too few persons to provide even basic eye care to the population, let alone specialized eye care for patients with diabetes and related blindness prevention. Involving non-ophthalmic health care providers in various aspects of eye care for patients with diabetes is a viable alternative.

Use of specific photographic systems with expert interpretation could increase the ability of primary care providers to detect diabetic retinopathy, and it has been shown that the evaluations of trained readers of photographs can match or exceed those of physicians and optometrists. The advent of digital photography and high-speed internet connections has made use of electronic images feasible, although issues associated with image compression are yet to be resolved.

Locations for detection and treatment of diabetic retinopathy: Diabetes mellitus and diabetic retinopathy are usually detected and treated at health care facilities ranging from private offices to hospital-based facilities. Alternative sites for providing care might be mobile health vans or health care services, which move to or take up fixed locations near patients' homes. Another alternative is mass community examinations or screening, in which large numbers of patients are seen in a coordinated fashion by teams of providers and associated personnel.

Appropriate follow-up intervals: Significant problems have been encountered in ensuring regular follow-up of patients with diabetic retinopathy. High rates of follow-up have, however, been reported with the use of vans and trained photographic readers using reference standard photographs to provide immediate feedback to patients. By directly addressing patient convenience, access and feedback, this system might serve as a model for a 'marketing' approach for patient-centred detection of eye disease associated with diabetes.

Evaluation and improvement of eye care for patients with diabetes mellitus

In assessing approaches to improving the care system, it is important to: (i) determine the purpose of the proposed system, for example, to screen for a threshold referral level of retinopathy or to provide guidance in management; (ii) assess the performance of the system relative to that of the gold standard, in order to identify trade-offs; (iii) assess the success and actual performance of different eye care systems in various settings; and (iv) understand how patients perceive the benefits of the system. From the perspective of health policy, it should be shown that a traditional or non-traditional proposal for care offers significant benefits over the existing system, sufficient to justify any additional costs.

The performance of systems for eye care for patients with diabetes, even in developed countries, leaves much to be desired. Application of a systems approach to the current systems indicates that alternatives should be explored to improve performance in every area of eye care for patients with diabetes in countries throughout the world.

RECOMMENDATIONS

For Member States

A uniform classification system should be adopted.

It is recommended that the International Clinical Classification of Diabetic Retinopathy (See Annex 3.), which provides a sound scientific basis for a uniform grading system, be used as an acceptable minimum standard for assessing diabetic retinopathy in programmes for prevention of blindness. This system provides a simplified but sound scientific basis for uniform grading by general ophthalmologists who have a basic understanding of diabetic retinopathy and skills in evaluating the retina. It has been adopted by the International Council of Ophthalmology and by many member societies.

The threshold for referral for eye care can vary but should include sight-threatening retinopathy.

It is recommended that the International Clinical Classification of Diabetic Retinopathy be used for determining the threshold for referral to treatment centres. The consultation did not recommend a threshold for referral, other than referral and treatment for sight-threatening diabetic retinopathy (proliferative retinopathy or macular oedema). Member States might decide to use a lower threshold for treatment, such as moderate-to-severe nonproliferative retinopathy.

Member States should choose the most appropriate method for detecting or screening for diabetic retinopathy.

It is recommended that the following performance characteristics be considered in assessing reliability in detecting and grading the severity of retinopathy:

■ A seven-field photographic standard or a dilated indirect ophthalmoscopic and stereoscopic macular examination by a retina specialist experienced in diabetic retinopathy are the two gold standards. Nevertheless, specific photographic systems have been validated against these standards, with high agreement at similar levels.

■ Use of specific photographic systems and protocols (three-field photographs read at a reading centre or specific two-field images graded against a photographic standard by a trained photographer) or an indirect ophthalmoscopic examination though a dilated pupil by an experienced ophthalmologist offer results that are comparable to those of the gold standards.

■ The performance of examinations through a dilated pupil by indirect ophthalmoscopy and stereo-bio-microscopic examination of the macula by an ophthalmologist or an optometrists is 50–70% that of the gold standards.

■ The performance of other photographic systems, with one or two fields and different equipment parameters, is similar to or better than eye examinations by general ophthalmologists and optometrists.

■ Without special and continuing education, the performance of primary health care providers in conducting eye examinations is less than 50% that of the gold standards.

■ There is currently insufficient direct evidence about the performance of non-health care professionals using other systems of detection for diabetic retinopathy (e.g. health care workers in villages using a direct ophthalmoscope and a standardized reference grading card); however, available evidence in other areas of eye care suggests that performance levels comparable to those of general ophthalmologists

and optometrists are achievable.

Member States should choose the most appropriate interval between examinations.

Because diabetic retinopathy is usually a progressive condition, long intervals between screenings might preclude timely detection of sight-threatening disease. Therefore, annual eye examinations are recommended for patients with diabetes (and every other year for persons with excellent glycaemic control and no retinopathy at the previous examination in certain contexts). In all cases in which treatment is indicated, it should be prompt. The choice of interval is up to each Member State on the basis of its assessment of the trade-off between costs and incremental vision loss associated with longer intervals.

Member States should choose the most appropriate personnel and locations for detection of diabetic retinopathy.

It is recommended that each society and culture accommodate its own social and economic needs in providing care. The screening location is closely linked to the availability of appropriately trained personnel. Using non-professional workers is more economical and results in wider geographic coverage. Use of community screening might be appropriate in certain settings. A variety of methods and locations can be used to reach patients where they live or work, rather than requiring them to see a health care provider in a medical office or hospital.

Education about eye health among patients with diabetes should be patient-centred.

Public awareness about diabetes mellitus and diabetic retinopathy is lacking in all societies. It is recommended that health education about these conditions be intensified, and education material and campaigns be oriented to address issues from the patient perspective and not solely that of the provider. Providers and organizations should therefore reassess their educational campaigns and change them into marketing campaigns. Health education must involve local populations and health care workers, customize the messages to fit the needs and expectations of the target audience and use various means of communication.

For the international community of eye care and diabetes mellitus professionals and organizations devoted to care of patients with diabetes mellitus and diabetic retinopathy.

The consultation recommended that the following activities be pursued and completed within the next 5 years. These activities are complementary to the above recommendations. They are designed to create the rationale and means for expanding systems for preventing blindness from diabetic retinopathy through early detection and treatment, particularly in developing countries.

Create and continually update tables of performance characteristics of alternative approaches to the detection of diabetic retinopathy.

Because trade-offs between cost and performance appropriate to each culture and society are at the foundation of these recommendations, WHO should assist in collecting and disseminating information on the performance of the various approaches for detecting degrees of severity of retinopathy, on the basis of standard evaluation criteria. As new knowledge and methods appear, the information should be updated, so that policy-makers have appropriate, accurate information on which to base their decisions.

Evaluate use by health care workers of standardized reference photographs and direct ophthalmoscopy as a low-cost alternative to photographic approaches.

As noted in section 5, this approach, involving general health care workers, probably offers an acceptable level of performance, as observed in other areas of eye care delivery (e.g. trachoma). Demonstrating that this is the case will be essential to its widespread adoption and acceptance by the societies and populations that might benefit most from such services. This information will also be necessary to provide the basis for informed decisions about trade-offs between cost and performance.

Provide 'seed' support for designing lower-cost, socially appropriate techniques for better detection and treatment.

The use in China and India of low-cost, locally or regionally produced techniques for a variety of medical and other uses offers a compelling model for reducing the costs of photographic systems for detection and laser systems for treatment of diabetic retinopathy. Further, collaboration and changes within and external to such societies will provide new global models that may improve care and cost-effectiveness throughout the world, including in developed countries. Another promising innovation might be use of 'prediction rules' or 'models' to strengthen a suspicion of diabetic retinopathy (or even diabetes mellitus) without an examination.

Conduct international research into systemic deficiencies in health and eye care that contribute to blindness from diabetic retinopathy.

Improvements to increase the cost-effectiveness of eye care for diabetes patients are a global necessity. Blindness due to diabetic retinopathy occurs in part because factors important to both patients and health care providers have not been recognized or incorporated into current diabetes education, screening and treatment programmes. Systems analyses are needed in various cultures to understand better why patients with diabetic retinopathy go blind, particularly when the technical knowledge and services to prevent the condition exist. Operations research is needed for comprehensive, evidence-based characterization of the contributions of significant factors and their interactions to blindness among patients with diabetic retinopathy. Within a standardized protocol, focus group methods can give detailed insight about blind and non-blind patients with retinopathy, members of their families or social support systems and diabetes and eye care providers, including information on the actual care provided and received.

Formulate and use a uniform system for evaluating diabetic retinopathy screening and care programmes.

Uniform evaluation criteria should be formulated and applied in any research or implementation programme for diabetic retinopathy care in order to assess the value of, e.g., community versus patient programmes. Without information on the successes and failures of programmes, progress will be more difficult and slower. Further, an evaluation system would improve collaborations among different projects and countries by providing a common measure for assessment and discussion. The evaluation will require additional collaboration and pilot testing of systems for feasibility and practicality.

1. BACKGROUND

Purpose of the consultation

Diabetes mellitus is an important public health problem worldwide, and more than 75% of patients who have had diabetes mellitus for more than 20 years will have some form of retinopathy. Diabetic retinopathy correlates with the duration of diabetes; thus, with increasing life expectancy, diabetic retinopathy and the ensuing blindness will tend to increase.

In view of the increasing prevalence of diabetes mellitus and diabetic retinopathy throughout most of the world, a consultation on prevention of blindness from diabetes mellitus was convened by the WHO unit of Prevention of Blindness and Deafness to review the current status of diabetic retinopathy care and to define approaches for screening, early detection and management in populations in different settings. (See agenda in Annex 1.) The consultation was held within the context of a contractual agreement between the programme for Prevention of Blindness and Deafness, WHO, and the National Eye Institute of the National Institutes of Health, Bethesda, Maryland, United States of America. The participants were drawn from all the WHO regions and represented experts in both general diabetes care and ophthalmology. (See Annex 2.) During the consultation, the participants sought to build on prior international collaboration and previous successful work of WHO, Member States, the International Diabetes Federation and the International Council of Ophthalmology.

Randomized clinical trials have shown the efficacy of laser photocoagulation of the retina for treating proliferative diabetic retinopathy. Prevention of visual loss from diabetic retinopathy is therefore feasible and achievable with the present state of knowledge, and treatment with laser photocoagulation has been shown to be cost-effective. The Saint Vincent Declaration (1) on diabetes care, formulated under the aegis of WHO and the International Diabetes Federation, listed among its goals the reduction of blindness from diabetic retinopathy within specified dates. Although the Declaration targeted primarily the countries of the European Region there is general consensus that the primary goals should be extended worldwide.

Detailed clinical practice guidelines for the diagnosis, treatment and evaluation of diabetic retinopathy are available from the International Council of Ophthalmology. Use of these guidelines should be extended to the developing parts of the world, with appropriate adaptations for the available technology and human resources, taking into account their stage of health care system development.

The consultation considered evidence from around the world to determine a unified approach to preventing unnecessary blindness. Consensus was reached on global approaches to screening for diabetic retinopathy and treatment by eye care professionals, in an approach that can be integrated into routine diabetes care in each setting. While the work of the International Diabetes Federation formed the basis of this approach, several alternatives were identified for ensuring high-quality decisions about referral for eye care. The approach also builds on the work of the International Council of Ophthalmology and ensures a uniform approach to diabetic retinopathy care based on the best available evidence.

WHO in conjunction with the National Eye Institute and WHO collaborating centres will support Member States in assessing the resources needed for eye care for patients with diabetes. The consultation drew up a framework for making decisions about trade-offs between cost and performance in the screening and treatment of diabetes-related eye disease, and WHO and its partners will further support Member States in validating the models of eye care that they choose to implement.

2. GLOBAL PREVALENCE OF DIABETES MELLITUS AND ITS COMPLICATIONS

2.1 Current burden and trends

Diabetes mellitus is among the leading causes of death, disability and economic loss throughout the world (2,3). WHO has estimated that there were 171 million people worldwide with diabetes mellitus in 2000 and predicted that 366 million people will have diabetes mellitus by 2030 (4). The increase will be due mainly to increases in low- and middle-income countries (Figure 1). The International Diabetes Federation has estimated that another 314 million persons have impaired glucose tolerance, and that number will increase to 472 million by 2030 (5). In the United States of America, for example, as much as 6.3% of the population had diabetes mellitus in 2002, and the prevalence and incidence are increasing (6). The United States Centers for Disease Control and Prevention have estimated that 13 million persons in the United States have diagnosed diabetes mellitus and an additional 5.2 million have the disease but it has not yet been diagnosed (7).

The prevalences in other countries are comparable, even in those with newly developing economies, such as India and China. It was estimated that 26 million people in China had diabetes mellitus in 2001, and the prevalence has increased markedly recently due to population ageing and a rapid increase in incidence (8). Further, while persons with diabetes mellitus in developed countries are mostly elderly, most of those in developing countries are younger (45–64 years), this increasing the impact of diabetes mellitus on those populations and societies (4).

Number of persons with diabetes in the year 2000 and projected increase in 2030

2.2 Prevention of diabetes mellitus

The two main etiological types of diabetes are type 1 and type 2 (9). Type 1 involves β-cell destruction, which may lead to diabetes mellitus, in which insulin is required for survival. Type 2 is the commonest form of diabetes and is characterized by disorders of insulin resistance and insulin secretion, either of which may be the predominant feature. Several trials have shown that type 2 diabetes mellitus can generally be prevented with diet and physical activity, while persons at high risk (with impaired glucose tolerance) can be treated with drugs (10–15). Prevention of type 2 diabetes mellitus would eliminate a large proportion of the risk for visual loss from diabetic retinopathy. To date, no positive results have been obtained in trials for the prevention of type 1 diabetes mellitus.

2.3 Diabetic retinopathy

Diabetic retinopathy is a microvascular complication of both type 1 and type 2 diabetes mellitus. It develops in nearly all persons with type 1 diabetes and in more than 77% of those with type 2 who survive over 20 years with the disease (16). Diabetic retinopathy is a leading cause of new-onset blindness in industrialized countries and a more and more frequent cause of blindness in middle-income countries (18). WHO has estimated that diabetic retinopathy is responsible for 4.8% of the 37 million cases of blindness throughout the world (18).

In the Wisconsin Epidemiologic Study of Diabetic Retinopathy, 13% of the study population who had had diabetes mellitus for fewer than 5 years and 90% of those who had been afflicted for 10–15 years had some degree of diabetic retinopathy when diabetes had been diagnosed when they were less than 30 years of age (presumed to have type 1) (16). Of those with an onset at 30 years or more (presumed to have type 2), 40% who were taking insulin and 24% who were not had some degree of diabetic retinopathy when the duration of diabetes mellitus was fewer than 5 years (17), and 84% taking insulin and 53% not taking insulin had some degree of diabetic retinopathy when the duration of diabetes mellitus was 15–20 years (19).

Of persons who have had insulin-dependent diabetes mellitus for 20 years or more, 60% will have had proliferative retinopathy (16), while of those who have had the condition for 30 years or more, more than 12% are blind (20). Each year in the United States, over 33 000 new cases of diabetic macular oedema, 86 000 cases of proliferative diabetic retinopathy and 12 000–14 000 new cases of blindness occur (20–22). If all patients with diabetes with proliferative retinopathy were to receive timely evaluation and treatment, the rate of blindness (let alone less severe visual loss) would be reduced from 50% to less than 5% after 5 years, a greater than 90% reduction in blindness from this disease (23).

3. EVIDENCE BASE FOR THE PREVENTION AND TREATMENT OF DIABETIC RETINOPATHY

Evidence-based treatment reported from clinical studies spanning more than 30 years can reduce the risk for severe vision loss and blindness from proliferative diabetic retinopathy by more than 90%. Methods are also available to reduce the risk for legal blindness and moderate vision loss significantly. Five large multicentre clinical trials conducted in the United Kingdom and the United States provide the scientific basis for the clinical management of diabetic retinopathy.

3.1 Diabetic Retinopathy Study

The Diabetic Retinopathy Study (1971–1975) demonstrated conclusively that scatter (pan-retinal) laser photocoagulation reduces the risk for severe vision loss due to proliferative diabetic retinopathy by as much as 60% (24,25). This study also provided the first and still most widely used classification system for grading the severity of diabetic retinopathy and indications for treatment with scatter laser.

3.2 Early Treatment Diabetic Retinopathy Study

The Early Treatment Diabetic Retinopathy Study (1979–1990) demonstrated that scatter (pan-retinal) laser photocoagulation can reduce the risk for severe vision loss (best corrected vision of 5/200 or worse) to less than 2%. It also showed that focal laser photocoagulation can reduce the risk for moderate vision loss (a doubling of the visual angle) from diabetic macular oedema by 50%, with no adverse effect on the progression of diabetic retinopathy or risk for vitreous haemorrhage for patients with diabetes mellitus who take up to 650 mg of aspirin per day (26,27).

3.3 Diabetic Retinopathy Vitrectomy Study

The Diabetic Retinopathy Vitrectomy Study (1977–1987) provided insight into the timing of vitrectomy surgery to restore useful vision in eyes with non-resolving vitreous haemorrhage (28,29). In particular, it highlighted that, in certain situations, early vitrectomy resulted in better vision. It also drew attention to the poor prognosis of eyes that experience vitreous haemorrhage, regardless of the timing of surgery, indicating the desirability of preventing such late complications of diabetic retinopathy.

3.4 Diabetes Control and Complications Trial and Epidemiology of Diabetes Interventions and Complications Trial

In the Diabetes Control and Complications Trial (1983–1993), conventional blood glucose control was compared with intensive blood glucose control in patients with type 1 diabetes mellitus and little or no diabetic retinopathy. The Trial conclusively demonstrated that, for these patients, intensive control of blood glucose as reflected in measurements of glycosylated haemoglobin reduced the risk for progression of diabetic retinopathy. Those with intensive control showed a 54% reduction in the development of a three-step progression of diabetic retinopathy, a 47% reduction in the development of severe nonproliferative or proliferative diabetic retinopathy, a 56% reduction in the rate of laser surgery and a 23% reduction in the risk for diabetic macular oedema (30–35). Seven years after completion of the Diabetes Control and Complications Trial, the Epidemiology of Diabetes Interventions and Complications Trial showed that persons in the intensive control group continued to have a substantially lower risk for progression of retinopathy than the conventional control group, despite near convergence of glycosylated haemoglobin levels (35).

These studies are notable for two additional findings. First, there is no threshold below which diabetic retinopathy does not occur when glycosylated haemoglobin is elevated; rather, there is a linear relationship between achieved glycosylated haemoglobin level and the risk for visual complications of diabetes. Secondly, persons receiving intensive control had a significant rate of hypoglycaemic reactions, which might argue against such aggressive control in every situation. The choice of a 'target' glycosylated haemoglobin level is therefore arbitrary, involving consideration of the benefits and costs for each patient and thus for each society.

3.5 United Kingdom Prospective Diabetes Study

The findings of the United Kingdom Prospective Diabetes Study (1977–1999) were similar to those of the Diabetes Control and Complications Trial for persons with type 2 diabetes mellitus (36,37). In addition, it highlighted the independent role of systemic hypertension (or its control) in potentiating the development and worsening the progression of diabetic retinopathy. Furthermore, like the Diabetes Control and Complications Trial, it demonstrated the negative effects of elevated cholesterol and serum lipid concentrations on the risk for retinal complications in patients with diabetes mellitus.

4. PRINCIPLES IN EYE CARE FOR PATIENTS WITH DIABETES

Diabetic retinopathy remains the leading cause of new-onset blindness in populations of working age, even in the United States (21) and other industrialized countries. Despite clearly defined clinical standards for evaluating and treating diabetic retinopathy cost-effectively, for a variety of reasons (see below), effective treatments such as laser surgery are underused. It has been estimated that 50% of adults with diabetes mellitus in the United States do not receive the recommended annual eye care that would allow diagnosis and treatment of diabetic retinopathy (38–41). Studies have also shown that many persons who require sight-preserving laser surgery do not receive it (42,43).

It has been reported that about 26% of patients with type 1 and 36% of those with type 2 diabetes mellitus have never had their eyes examined (44). These patients tend to be older, less educated and to have had a more recent diagnosis than those receiving regular eye care. They are also likely to live in rural areas and receive health care from a family or general practitioner. Alarmingly, 32% of patients with diabetes mellitus at high risk for vision loss never undergo an eye examination, and less than 40% of those with high-risk characteristics for vision loss receive treatment (43,45). When examined, almost 61% of these patients are found to have diabetic retinopathy, cataract, glaucoma or another ocular manifestation of diabetes mellitus.

These findings have significant implications for the person and for society. It has been estimated that programmes to identify and treat diabetic retinopathy would have saved the United States health care budget nearly US$ 400 million annually in the early 1990s (46), a figure that would probably be substantially higher today. The total annual cost of diabetic eye disease in the United States at that time was almost US$ 2.8 billion, 75% of which was for persons who received treatment that was not proven to be effective (46). Even persons who are older at the onset of non-insulin-dependent diabetes can significantly benefit in years of sight saved by use of mydriatic fundus photography for screening (47).

In order to prevent vision loss due to diabetic retinopathy, health care and eye care delivery systems in every society should be improved. While specific resources and methods differ widely from country to country, certain basic aspects of care must be delivered in all countries. By focusing on the patient and using common principles, a unified approach can be created, with respect for the resources and culture of each society, for best delivering eye care to patients with diabetes mellitus.

4.1 Patients should know that they have diabetes mellitus and that the condition requires care

While the population prevalence of diabetes mellitus is over 6% in many high- and middle-income countries, a diagnostic 'test' with 98% sensitivity and 98% specificity would yield a post-test probability of a true positive (Bayes' theorem) of only 63% even if the prevalence were as high as 8%. Given the significant costs associated with testing every member of society and the costs for caring appropriately for false-positive patients, general population screening for diabetes mellitus with existing methods is considered neither appropriate nor beneficial at present (48). If the prevalence in the population to be screened were significantly higher, however, screening would be appropriate. Once diabetes is diagnosed, screening for the complications of diabetes mellitus, such as diabetic retinopathy, is considered appropriate and cost-effective (49).

4.2 Patients should receive adequate care for diabetes mellitus

The only means of preventing diabetic retinopathy is by regulating blood sugar, blood pressure and other factors under the control of the patient, as guided by their primary care provider or endocrinologist. Studies in the United States have shown, however, that physicians do not care for patients with diabetes in the manner indicated by the results of randomized controlled trials as embodied in guidelines from their professional societies, the Agency for Healthcare Research and Quality and other organizations (38–41). McGlynn et al. (39) found that a typical patient with diabetes mellitus in the United States would receive only about 40% of the recommended care in a given year.

4.3 Patients should undergo eye evaluation for the presence of diabetic retinopathy

All professional eye care organizations advocate annual eye examinations for patients with diabetes and prompt treatment when indicated, in order to achieve the public health goal of minimizing vision loss (50–52). Some organizations recommend examinations every other year for persons under excellent glycaemic control and no retinopathy on a previous examination. The importance of periodic eye examinations is reflected in their inclusion as a quality indicator for health plans used in the United States (38,41).

Nevertheless, studies have shown repeatedly that patients with diabetes are not evaluated or treated in a timely fashion. For example, an analysis of self-reported care by the civilian, non-institutionalized population of the United States revealed that less than 50% of patients with diabetes and only 60% of high-risk patients (with previous retinopathy or long duration of diabetes) had undergone a dilated eye examination in 1989 (38). Other studies have shown that, although screening and blindness prevention programmes can increase the rate of examinations of the dilated eye, many persons still would not have an eye examination (53,54).

In a study of patients with chronic diseases throughout the United States, McGlynn et al. (39) found that the rate of eye examination remained at 50–60% after more than 10 years of concerted effort, and that the rate was as low as 19% if chart documentation of a dilated eye examination was required as the gold standard. In a longitudinal analysis of care over 5 years derived from Medicare administrative claims (and not chart documentation), Lee et al. (55) found that less than half of patients with diagnosed proliferative retinopathy (and less than one-fourth of persons with background retinopathy at the first visit) had undergone at least one examination every 15 months over 5 years, suggesting that the longitudinal pattern of care use is problematic. To the extent that the findings of McGlynn et al. can be extrapolated, this suggests that less than 20% of patients with proliferative retinopathy at the index visit have undergone at least four spaced examinations of the dilated eye over 5 years.

The first problem is therefore to ensure that patients who are already known to have diabetes (over 98% of whom visit their primary care physician or endocrinologist at least once a year) receive an examination of their eyes and retinas. Understanding the barriers to receiving examinations is one part of the equation; ultimately, the issues that contribute to preventable blindness among persons with diabetes mellitus must be identified and addressed. Because of the importance of this issue, the consultation addressed approaches that would improve the efficiency and performance of retinal assessment among patients with known diabetes mellitus.

4.4 If retinopathy is detected or if a patient is referred to an eye care provider for an examination, the society must deliver the necessary level of eye care

The question of what management should be provided once a given degree of diabetic retinopathy is detected is up to each society. A critical element of delivering eye care for patients with diabetes is the availability of trained personnel to provide care, ranging from examination to surgical intervention. In developed countries, there is one ophthalmologist per 15 000–50 000 population (56). When optometrists are included, the ratio falls to as low as one per 6000 population (private communication from the American Academy of Ophthalmology). In these countries, therefore, the availability of providers of eye care for patients with diabetes is not an issue. Whether this situation will continue is unclear, given the ageing of the populations of developed countries and the growing use of health care services as economies continue to grow (57). The issue of adequate human resources therefore might not be limited to less developed countries in the future, perhaps providing opportunities to design innovative methods of delivering care.

In developing countries, there are not enough eye care providers to give even basic eye care to their populations, let alone to patients with diabetes. WHO has estimated that even in countries with rapid economic development, such as China and India, the ratio is one provider per 80 000 or more population, although some metropolitan areas (e.g. Hong Kong, Special Administrative Region, People's Republic of China) have ratios similar to those of developed countries.

As the populations of these countries and their economies continue to grow, there will be greater pressure on the available eye care to prevent or treat other causes of visual impairment, such as cataracts (57). The second challenge is thus to find other personnel or other examination techniques that can be used in locations where trained professionals, especially ophthalmologists, are not available or where their skills can be used more productively for resolving other problems, such as reducing blindness due to cataract. Further questions are whether the alternative personnel or techniques should be able to detect a certain degree of diabetic retinopathy (screening) or whether they should be capable of accurate staging or classification in order to determine when and what treatment is needed; and whether the alternative personnel should provide treatment if ophthalmologists are not available.

4.5 Patients should be sufficiently aware and motivated that they not only undergo an eye examination but also return regularly for such examinations

'Patient awareness' or 'patient education' can more usefully be expressed as 'What is the patient buying?' with respect to eye examinations to detect diabetic retinopathy. Diabetes is a chronic disease for which there is currently no cure and which requires constant care and attention. Patients with diabetes can be thought of as 'buying' information about their disease and their eye status well before they 'buy' the treatment necessary for sight-threatening retinopathy. Thus, it is not merely a question of providing enough information in a form that patients can understand—the traditional approach—but of 'marketing' the value of eye care examinations and, if necessary, treatment.

Discussions in focus groups of patients with diabetes mellitus (sighted and blind), their support systems and all types of care providers have raised a number of issues (58,59), apart from the information important for doctor–patient communication. Problems of literacy, numeracy and difficulty in reading were raised in respect of the available educational materials, and the need for culturally appropriate materials and examples was mentioned. A third finding was that patients learn (and doctors communicate) in some ways (e.g. visual, aural, interactive, touch) better than others. These findings emphasize the importance of understanding perceptions in increasing the use of eye care services by patients with diabetes mellitus (60).

Communications destined for patients can have negative or positive messages, and the effect might be different from that intended or anticipated. For example, in some patients, use of the negative message 'You will lose your sight if you don't take care of your diabetes.' only reinforced their fatalistic belief that they were going to go blind, and they concluded that there was nothing they could do. Similarly, patients often behave to their families, friends and doctors in ways that they know are detrimental to their health in order to establish their independence from 'overbearing' control. Another key point was the contrast between the message of the patient's primary care physician ('You will lose your sight if you don't control your sugar.') and that of the ophthalmologist ('You're fine. Come back in a year.') (58). The conclusion of many patients that their eyes were healthy even when they had poor glycaemic and blood pressure control led them to question the skill and knowledge of their primary care provider, thus reducing their confidence.

While there are several beneficial methods of patient education, published studies have demonstrated a lack of persistent behavioural change in patients. Educational materials and campaigns directed to patients with diabetes should therefore be reoriented to address issues from their perspective and not solely that of the provider (60). Direct, one-on-one interactions with tangible feedback are those in which a 'marketing' approach is most likely to be effective. Providers and organizations should thus reassess their educational campaigns and redesign them into marketing campaigns.

The importance of orienting educational messages to each culture and society and to each group within each society is aptly demonstrated in the success of educational and outreach programmes conducted in various countries. Key steps described to the consultation included:

- involvement of local populations in the local health care infrastructure;

- adaptation of the message to fit the needs and expectations of the target audience; and

- use of different modes of communication to reach as many different 'market segments' as possible.

5. PRINCIPLES FOR ORGANIZING EYE HEALTH SYSTEM FOR THE CARE OF DIABETIC RETINOPATHY

Having agreed upon the steps necessary for delivering eye care to prevent blindness and vision loss due to diabetes mellitus, the consultation sought to identify the basic principles of a care system that would be applicable across many settings, so that insights and lessons from different areas could be shared to make individual programmes more effective.

First, each society should determine whether sufficient resources can be devoted to treatment of diabetic retinopathy if it is detected. As treatment requires trained operators and relatively sophisticated equipment and care environments, competing priorities might make treatment unaffordable. If a disease cannot be treated, the benefits of detection are more limited. Thus, those societies and cultures in which treatment of diabetic retinopathy (or even diabetes mellitus) is less cost-effective than other interventions have a more limited rationale for detecting the condition. The rationale would stress the value of educating patients about the presence of non-sight-threatening retinopathy in order to encourage them to adopt better blood pressure and glycaemic control to reduce the progression of retinopathy and other microvascular complications of diabetes mellitus.

Second, if a social decision is made to treat detected diabetic retinopathy, a patient-centred approach within a public health context could yield optimal results. Once a decision is made to detect eye disease in patients with diabetes and to treat it if it is found, the success of the programme will depend on patient-centred marketing, to convince patients to return for regular eye examinations and treatment. By adopting a patient perspective, public health systems and campaigns can be designed that will be more effective in maintaining a desired behaviour over time. At the same time, the public health context will maximize the use of social resources. It will also allow application of effective methods for reaching patients and delivering care that are derived from other, successful programmes, even if they are not based on a western medical model. By broadening ideas for providing eye examinations and appropriate treatment for diabetic retinopathy, many more patients could be served than by relying on care delivered only by ophthalmologists in societies where their time and skills might be better used in other endeavours or programmes.

Third, there is always a trade-off between performance and costs. For example, while seven-field stereo-photographs of the retina read by a trained observer at a dedicated reading centre or examination by an experienced professional specialized in diabetic retinopathy are the ideal 'gold standards', these systems can be very expensive in terms of social resources. In contrast, examination of an undilated eye with a direct ophthalmoscope by

a non-physician health care worker might result in failure to detect a number of cases of diabetic retinopathy, although it is likely to be the least expensive method. No country can escape making trade-offs between resource use and system performance in arriving at key decisions. Even determining the frequency of follow-up screenings for diabetic retinopathy can vary on the basis of what is considered to be an acceptable rate of otherwise preventable vision loss.

Fourth, the decisions made by each country are unique to that country, its resources, its social expectations and the existence of an appropriate health care infrastructure. Giving information on the performance of different techniques for detecting diabetic retinopathy to the responsible entities in each country will allow them to make the decisions and trade-offs that best suit their conditions, albeit in the context of common principles, patient-centred care and public health. Use of standardized definitions of retinopathy, evaluation and the assessment of costs and performance will enable countries to learn from each other's experience.

To assist countries in making informed decisions about whether and how to screen for diabetic retinopathy and how to manage the care of patients who need examination or treatment by trained eye or health care professionals, the consultation highlighted key issues and examined certain issues in depth. A review of the literature indicated that the most important variables were: the accuracy of different methods (and types of observers) for detecting the presence or severity of diabetic retinopathy; the locations can best serve patient needs; and the interval between eye screenings or examinations.

5.1 Accuracy of examination results

5.1.1 Eye care providers

It would seem obvious that accurate assessment of the presence or absence of retinopathy and the degree of severity are vital to prescribing appropriate care to prevent the onset of vision loss and blindness. Yet, two studies in the United States over 20 years ago showed that this was not a safe assumption. Sussman et al. (61) identified variations in the ability of physicians to diagnose eye disease in patients with diabetes accurately. While retina specialists missed no cases of proliferative diabetic retinopathy, internists, diabetologists and medical residents missed 49% of such cases. The overall error rate in classifying severity with the system of the Diabetic Retinopathy Study was 61%, and that of general ophthalmologists was 48%. Kleinstein et al. (62) reported that optometrists could correctly decide if retinopathy was present in 77% of eyes, with correct staging in 57% (error rate, 43%).

More recent work indicates that performance levels are not yet adequate. Schmid et al. (63) found that optometrists in Australia detected retinopathy in 94% of eyes, but the severity classification was accurate in only 58%. Prasad et al. (64) found that optometrists in the United Kingdom were able to identify sight-threatening diabetic retinopathy on screening in 76% of cases. In numerous studies of photographic and telemedicine systems, the performance of general ophthalmologists in detecting retinopathy and staging the severity of disease generally fell short of that of camera-based systems (65). It should be noted, however, that in most studies the performance of eye care providers in determining whether retinopathy was present and, to a lesser extent, its grading into sight-threatening or more severe retinopathy was significantly more accurate than that of providers asked to grade severity into four or more classes, as in the Diabetic Retinopathy and Early Treatment Diabetic Retinopathy studies.

5.1.2 Non-ophthalmic health professionals

Use of non-ophthalmic physicians and other health care providers in eye care for patients with diabetes has been suggested by a number of authorities. Ophthalmologists generally constitute no more than 2% of the physician workforce, even in developed countries, and are particularly scarce in some regions of the world. Thus, additional manpower is needed to provide care not only for patients with diabetes but also for those with other eye diseases, such as cataract. Patients with diabetes have identified lack of care coordination as a major barrier to receiving regular eye care:

having to see yet another doctor (an ophthalmologist) presents an additional burden (59). Thus, being able to see just one doctor for comprehensive diabetes care enhances the continuity of care and thus the ability to receive higher quality care. General practitioners are usually best placed to situate the risk for vision loss for each patient as part of the overall care strategy for diabetes, as the known risk factors for retinopathy are among the conditions managed by the general practitioner or endocrinologist.

Awh, Couples & Javitt (66) conducted pre- and post-educational assessments of 10 university-affiliated physicians (five in family practice, three internists and two endodcrinologists), who examined 20 patients. In the pre-test, 80% found that pupil dilatation for direct ophthalmoscopy was both unfamiliar and uncomfortable, and only one physician could name a medication used for dilatation. The mean score on a written examination on eye conditions and diabetes was 49%; 30% were familiar with the schedule for eye examinations, and 43% recommended delayed referrals for patients with retinopathy. The score in the pre-test on a nine-point scale for detecting any retinopathy was 6.6. The performance of these physicians for detecting and referring eyes with pre-proliferative or proliferative retinopathy (sight-threatening) was only 40%.

In a study in Glasgow, Scotland, among junior physicians with no specialized education or training, one-third made appropriate referrals to a diabetic retinopathy clinic, but only 30% gave a 'correct' diagnosis (67). In a pre-test based on photographs among general practitioners in New South Wales, Australia, 44% made a correct diagnosis (68). Endocrinologists were able to identify microaneurysms correctly in 80% of patients, macular oedema in none, neovascularization on the disc in about 50% and neovascularization elsewhere in 30% (69). An important issue for diabetes eye care is the referral period or interval for additional eye care based on the findings of the screening or detection system. In this study of whether appropriate referral periods were determined relative to the results of analysis by the gold standard 7 field photographic system, diabetologists made appropriate referral recommendations 64% of the time, ophthalmologists 56%, and nonmydriatic photographs 69% of the time. Interestingly, the various providers more often recommmended later follow-up than indicated by the 7 field photographs, with rates of 24% for diabetologists, 23% for non-mydriatic photographs, and 41% for ophthalmologists.

Published studies thus indicate that non-eye care professionals who are interested in the eye care of patients with diabetes and who conduct such examinations without additional education or training perform somewhat more poorly than eye care providers. When examinations are not performed, referral patterns vary, with room for improvement in most settings. The overall performance of care for most chronic diseases by primary care providers is less than 50% (39).

Awh and colleagues (66) reported that failure to detect sight-threatening retinopathy fell from 60% to 15% and that for maculopathy fell from 83% to 16%, with improved familiarity and use of dilating drops, after a 4 hours course with post-testing 12 days later. The scores for accuracy of classification of severity of disease rose only slightly, however, from 6.6 to 7.0 (on a nine-point scale). Bibby et al. (67) noted that physicians who received 40–50 h of special instruction and outpatient training in a diabetic retinopathy clinic were subsequently able to make more appropriate referrals (65% versus 33%), fewer incorrect diagnoses (5% versus 25%) and more correct diagnoses (67% versus 30%). Confos, Frith & Mitchell (68) found that the accuracy of interpretation of photographs increased from 44% to 53% 6 weeks after a workshop on diabetic retinopathy, while the reported use of clinical examinations with a direct ophthalmoscope increased from 41% to 69%. Gill et al (70) found that, while education can enhance sensitivity for detecting retinopathy, it can be associated with lower specificity (more referrals).

None of the studies reported on the persistence of the benefits of education in the long term. On the basis of the results of studies in other areas of medicine, it might be expected that practitioners who care regularly for a sizeable number of patients with diabetes and who continue to practice in the way recommended in the educational intervention are likely to continue to practice at a higher level (71). It is less clear, however, how these practitioners would fare if new recommendations for care and use are made on the basis of new findings. As eye care is not the primary activity of general physicians, any significant change in eye care for patients with diabetes will be unlikely to be translated quickly into changed practice, and new educational efforts will be needed to bring general practitioners up to date.

5.1.3 Photographic systems

Performance levels

As for any technique to care for patients with diabetes, the technical parameters of performance must be assessed (72) to determine the accuracy (and sensitivity, specificity and predictive value) of interpretation of images relative to the gold standard being used; the technical standards of image capture resolution, colour depth, image handling and display resolution used; and, perhaps more realistically, how such systems perform in comparison not only with the gold standard but also with community practices in Member States.

While studies on the technical features necessary for best care have been published, no study has provided complete technical specifications for image analysis on the basis of the findings of a large number of observers with appropriate numbers of non-diabetes retinal findings. The practical issues of implementation (73) include the number of photographs needed and deciding whether non-mydriatic photos are sufficient or whether dilatation is needed. Even in the two fields in which there are image standards, radiology and dermatology, the standards were often determined arbitrarily and then tested empirically (74). All publications in telemedicine should, as a matter of course, specify both the technical standards used to capture, process and display the image, the interpretation of the gold standard and the actual methods of fundus image capture. Nevertheless, a recent review suggested that photographic systems are appropriate for use in daily care of patients outside the research environment (75).

The Diabetic Retinopathy Study, the Early Treatment Diabetic Retinopathy Study, the Wisconsin Epidemiologic Study of Diabetic Retinopathy and numerous other studies have shown that the level of agreement between the standard seven-field photographic system and study experts is high but does not reach 100% in most assessments. Classification agreement is reported as 80–90% and agreement on detection of a specific finding (vitreous haemorrhage) as 79–99% (65,76). Agreement on the characteristics of diabetic macular oedema is consistently low (76). These best potential performance rates suggest that there is a ceiling to the level of agreement that can be expected between humans and photographic interpretation by expert readers in reading centres. The choice of gold standard necessarily affects evaluation of the performance of other modes of examination.

Several studies of the performance of non-retina specialists and non-study team experts in comparison with a photographic gold standard have obtained similar results. For example, Pugh et al. (77) reported that off-the-shelf photographic systems performed at least as well as human providers (Table 1).

Table 1 Comparison of techniques for classification of diabetic retinopathy compared to referencee standard photographs (7 - field)

Technique	Sensitivity (%)	Specificity (%)	Misclassified PDR or moderate-severe NPDR as none or mild NPDR	No retinopathy noted when either PDR or moderate-severe NPDR present
Ophthalmologists	33	99	49/73	19/73
Physicians Assistants	14	99	43/51	11/51
One non-mydratic photograph	61	85	29/64	9/64 (10)
Three dilated photos	81	97	14/68	6/68 (3)

PDR, proliferative diabetic retinopathy
Four-stage system used: none, mild NPDR, moderate–severe NPDR, proliferative DR
( ) - Photographs ungradeable

Technical issues in the use of standard photographic images

In view of the interest in photographic systems, much work has been devoted to specific technical issues (72,75), including the number of photographs needed; the fields to be used if the full seven-field set is not used; whether photographs should be taken through dilated pupils; and who should interpret the photographs.

In 2004, the American Academy of Ophthalmology concluded that, in the United States, single-field photography is adequate for screening for the purpose of detecting diabetic retinopathy but not for management (73) What is 'acceptable' necessarily varies from society to society in relation to the acceptable 'error' or 'miss' rates and the associated costs of achieving specific performance levels. Most studies indicate that performance levels with photographic systems are at least as good as or better than those of examinations by physicians and health care providers other than experienced retina specialists (75). Sufficient evidence therefore exists that different societies and countries can adopt different technical performance standards and thus use different techniques. Some will want to do everything possible to avoid misclassification and thus use dilated seven-field photography, while others will adopt the seemingly opposite approach of using a single-field photograph through an undilated pupil. These approaches are not, however, contradictory; rather, they reflect choices based on available resources.

Use of digital images

The original reference studies, the Diabetic Retinopathy and Early Treatment Diabetic Retinopathy studies, were conducted with high-quality photographic film images, which require time and money to process, develop and then ship for interpretation. The advent of digital photography and high-speed internet connections have made the use of electronic images feasible. It is not, however, clear that all electronic images are as accurate or useful in image interpretation as film. Basu et al. (78) noted that compression ratios of only 1:20 to 1:12 (or, by implication, less)

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with file sizes of 66–107 kilobytes were adequate for image interpretation for screening with the JPEG format. In contrast, Baker et al. (79) reported that compression ratios as high as 1:113 did not interfere with the accuracy and reproducibility of electronic images of diabetic retinopathy.

Lim et al. (80) compared 35-mm photography with standard slide film images to digital non-mydriatic photos (640 × 480 resolution) and found agreement ranging from 98% for intraretinal microvascular abnormalities, to 95% for venous beading and 63% for micro-aneurysm. The sensitivity, however, ranged from only 25% for neovascularization on the disc to 100% for venous beading; the positive predictive value ranged from 50% for intraretinal microvascular abnormalities to 100% for neovascularization on the disc, while the negative predictive values ranged from 48% for microaneurysms to 100% for intraretinal microvascular abnormalities.

Importantly, validation studies of two vision network systems (81,82,83) reported high agreement rates with the seven-field photographic standards of the Early Treatment Diabetic Retinopathy Study. Thus, the degree of resolution in the images appears to play an important role in the usefulness of digital images. While the issue of image compression remains to be resolved, the published literature indicates that some image resolutions are comparable to photographic standards.

Use of photographic systems by non-physician, non-professional providers

The use of non-physician health care professional examiners for detecting diabetic retinopathy has been coupled with use of photographic systems in the United Kingdom (84,85). The performance of trained photographic readers using a Polaroid camera system has matched or exceeded that of physicians and optometrics. An accuracy of more than 90% in staging retinopathy has been reported with a modified Early Treatment Diabetic Retinopathy Study system that is similar to the International Clinical Diabetic Retinopathy system used by the American Academy of Ophthalmology and the International Council of Ophthalmology.

5.1.4 Use of reference photographs to standardize direct observation

Use by ancillary health care workers (and physicians) of a reference card or set of photographs in grading the severity of disease has been validated in the care of trachoma and other eye diseases, such as with the WHO trachoma grading card and primary eye care chart. The principle has also been used in numerous randomized controlled trials to achieve consistency in grading the presence and severity of other ocular features, such as lens opacities, corneal and conjunctival findings and optic disc damage (86–88). Use of such reference systems, however, requires careful training and regular monitoring, as performance reliability can vary (86).

5.2 Locations for detection and treatment of diabetic retinopathy

Diabetes mellitus and diabetic retinopathy are usually detected and treated at a health care facility, where one or more eye care professionals are available, in developed countries. Ophthalmologists and optometrists (in certain countries) provide most eye care services and can at least diagnose (ophthalmologists and optometrists) and treat (ophthalmologists) diabetic retinopathy, in private offices, public outpatient clinics and hospital facilities.

5.2.1 Health care facilities

Eye care can be given in the offices of primary health care providers or general practitioners, but eye care services for diabetic retinopathy are rarely provided in these settings. A research group at the University of Melbourne, Australia, showed that most of the Australian general practitioners surveyed examined none or less than half of their patients with diabetes mellitus; of those who did examine these patients, two-thirds did not use pupil-dilating drops (89). The level of examination had not changed appreciably after the release of national guidelines for

diabetes care by the National Health and Medical Research Council of Australia (90). Information on self-reported referral patterns showed, however, that most patients were regularly referred for an examination. For example, of those general practitioners who referred patients to an ophthalmologist, 98% referred them for an examination at least every other year. In contrast, in the United States during a similar period, less than half of the primary care providers in Indiana referred all patients with type 1 diabetes mellitus to an eye care specialist annually (91). In the United Kingdom, examination of the fundus appeared to be common in some studies. In a survey of general practitioner practices in Oxfordshire, 83% conducted fundoscopy, but 63% referred patients for screening for diabetic retinopathy, indicating that about one-third were confident in performing their own screening (92).

The detection and treatment of diabetic retinopathy in developed countries is thus done mainly by trained eye care providers and, therefore, in dedicated facilities. This is not surprising, as health care systems in developed countries concentrate their resources in specific locations, to which patients must go. This practice does, however, create a barrier to patient use because of transport, time and convenience factors.

5.2.2 Community-based screening

Alternative means of providing health care might include mobile resources near patients' homes, such as mobile health vans or health care services located in shops, shopping centres, workplaces, residences or schools. These alternatives do not, usually involve experienced physicians, as the number of patients with problems requiring their skills is likely to be small. Instead, other health care providers, such as nurses and technicians, and other techniques, such as photographic systems, are used.

Use of such alternatives is more advanced and more widespread in less developed countries, where transport and access to metropolitan health care facilities are scarce. Throughout Africa, Asia and parts of Latin America, trained local and regional health care workers deliver care to large segments of the population. These workers have the advantage of being known, and thus trusted, locally, and they may have the same culture and share experiences with their potential patients, enhancing the acceptability of the message they seek to spread. Further, such systems are more affordable and cost-effective than systems requiring physicians, who might be scarce in these societies. Thus, in alternative locations, non-physician providers deliver the bulk of the care.

Another widely used alternative is mass community examinations or screening. These have been conducted throughout Asia (93) and Latin America (94). In these programmes, large numbers of patients are seen in a coordinated fashion by teams of providers and associated personnel. The programmes have been widely seen to be successful in reaching many people with diabetes mellitus who would not otherwise have been seen because of various obstacles in obtaining care. In the most successful programmes, detection is coupled with treatment of sight-threatening retinopathy.

The consultation recognized that each society and culture must accommodate its social and economic needs in providing care. Scarce physician resources might best be used to address surgical needs, while less expensively trained workers can undertake detection. Use of non-professional workers is more economical, involves less resistance to the use of standardized methods and results in greater geographic coverage. Community screening might be appropriate in certain settings. A variety of other methods can be used to reach patients where they live or work, rather than requiring them to see a health care provider in a medical office or hospital.

5.3 Appropriate follow-up intervals

Once diabetes mellitus has been diagnosed and patients have had an initial eye assessment, of any kind, they must continue eye care. As there is no cure for diabetes mellitus, prevention of vision loss requires regular examinations. Nevertheless, there are significant problems in ensuring appropriate follow-up. The shortfall in efforts to ensure appropriate follow-up is illustrated by studies showing that only 68–85% of patients referred for treatment start the treatment, and only 85% who start treatment complete it (43–45), indicating that 28–42% of patients who are referred for treatment do not receive the necessary care. The fact that over 40% of patients with diabetes who are referred for treatment do not actually complete it has not been addressed in educational and intervention programmes. Merely concentrating on ensuring that patients are examined (and that those examinations are accurate) is not sufficient.

In 1989, Olsen, Kassoff & Gerber (95) reported the results of a survey of ophthalmologists in New York State, United States, at a time when the results of the Early Treatment Diabetic Retinopathy and the Diabetic Retinopathy Study had demonstrated the benefit of laser treatment for both proliferative retinopathy and macular oedema. The study showed that only 63% 'almost always' recommended laser treatment for proliferative retinopathy, and another 31% 'usually' did so. Laser treatment for macular oedema, even when vision was significantly compromised, was recommended only 73% of the time, and was recommended only 63% of the time when vision was mildly compromised. Khadem, Buzney & Alich (96) found that use of the recommended treatment patterns did improve with time but not statistically significantly. A report by Hall, Albrecht & Lee (97) is unique in the United States, in reporting a high degree of conformity with recommended diabetic retinopathy care. Unlike the other studies, which were based on surveys, these authors relied on reviewing physician documentation of treatments and follow-up intervals.

McCarty and colleagues at the University of Melbourne, Australia, used a series of surveys of optometrists and ophthalmologists to assess the impact of national clinical practice guidelines on clinical practice over time, observing the use of laser photocoagulation and fluorescein angiography and the timing of cataract surgery (98,99). These surveys demonstrated better self-reported conformity over time.

The best reported follow-up rates (higher than 90%) on a recurring basis have come from Newcastle, England (unpublished data), with the use of vans and trained photograph readers, who used standardized reference photos and provided immediate feedback to patients. By directly addressing the issues of convenience, access and feedback, this system might provide a model for a true 'marketing' approach to patient-centred eye disease detection in diabetes.

CONCLUSIONS

6.1 Alternatives in eye care for patients with diabetes mellitus

The consultation strongly recommended that, if a screening and detection programme is implemented, resources be found for necessary laser treatment. From a public health perspective, detecting disease that cannot be treated is a poor use of resources. The participants recognized the importance of finding new methods for providing the resources necessary to deliver care within the changing international intellectual property rights regime. While education regarding the presence of retinopathy that is not sight-threatening might help to reduce the rate of progression to blindness, this has not yet been adequately demonstrated.

All treatment should be consistent with uniform international standards. The International Council of Ophthalmology guidelines for diabetic retinopathy care (52) (See Annex 4.) give detailed information about the expected performance of ophthalmologists who treat diabetic retinopathy.

The consultation came to the following conclusions:

- An adequate level of accuracy in detecting any degree of retinopathy (screening function) is achievable by a variety of health care providers using photographic systems.

- The current level of accuracy of health care providers in classifying the severity of diabetic retinopathy means that many alternative systems can be expected to perform at least as well and thus represent appropriate alternatives.

- Education can improve the performance of health care providers, including non-eye care professionals, although long-term data on persistence are lacking. Use of photographic standards might be an alternative that would also enhance the performance of all systems to detect and follow-up cases of diabetic retinopathy.

- The follow-up care intervals remain a problem, both from the perspective of both the provider and the patient. While most patients are told by their provider to return within a specified interval, patients are poorly compliant (55). Further, societies necessarily differ in what they consider to be an acceptable rate of preventable vision loss in relation to the interval between follow-up, based on competing health and social needs.

Thus, the consultation considered that there are several viable alternatives for detecting patients with diabetic retinopathy and for referral for treatment, if the society chooses to provide treatment. The choice depends on individual cultures and societies and is based on both economic and non-economic considerations.

6.2 Principles in assessing methods of care

In assessing approaches to improving the care system, through technological means alone or in support of health care providers, four questions must be answered.

The first concern is to determine the purpose of any proposed system. The necessary performance standards and criteria by which to judge the success of new approaches or approaches other than gold standards, vary according to the goals of the system. For example, a system designed to screen for a threshold referral level of retinopathy would need to distinguish only between normal fundi, fundi with threshold referral findings and fundi with more severe conditions. In contrast, a system designed to provide guidance in the management of diabetic retinopathy would have to be able to distinguish the various stages of retinopathy that might be present. As reported in the published literature, performance has always declined as the requirements of the system increase.

Secondly, for evaluation, the performance of the system relative to that of the gold standard must be known, so that the trade-offs can be identified. In the case of diabetic retinopathy, the practice guidelines of the International Council of Ophthalmology (52) and the American Academy of

Ophthalmology (50) prescribe observation by a trained, experienced observer or a full seven-field photographic interpretation according to the standards of the Wisconsin Reading Center as the gold standard. Thus, any study of the value of a system, such as remote telemedicine care in diabetic retinopathy, must establish its performance and reliability relative to either of these gold standards. Nevertheless, no system is perfect at the outset. If a new approach offers added advantages, such as better access to care, reaching more people with diabetes at a lower unit cost, then a level of technical performance that is at least as good as (or perhaps lower than) current care—even if not up to the gold standard—might be appropriate.

Thirdly, the success and actual performance of different eye care systems for diabetes patients should be evaluated in various settings, as has been done by the Aravind Eye Health System and other groups in India (93). While the design of such systems has been reported, no formal, prospective, structured evaluation of the benefits, costs and trade-offs for eye care has yet been published. For example, reports of the use of telemedicine systems in controlled settings such as prisons (102), while promising, do not include the necessary elements described above, nor do they include a systematic evaluation plan that would be generalizable to the community setting.

Fourthly, integral to the process are efforts to understand how patients perceive the benefits of these systems (101). As patients can access information on the Internet, perhaps telemedicine and other systems offer an opportunity to enhance patient education and understanding. In regions of the world where internet access is unrealistic at present, however, other methods of ensuring adequate understanding of successes and failures should be included in any development and implementation plan.

On the basis of these four general principles, specific non-traditional (and even traditional) care proposals can be placed in a proper context. For example, if a system is designed for assessing the severity of diabetic retinopathy and is to be used to manage follow-up intervals and the timing of laser surgery, it should be able to classify patients or fundi into the categories of the Early Treatment Diabetic Retinopathy Study, the Diabetic Retinopathy Study or the new International Clinical Classification (International Clinical Diabetic Retinopathy) at specified and feasible technical standards acceptable to that society (100). In addition, as over 40% of vision loss from diabetes stems from macular oedema (22,23), the system should also be sufficiently robust to detect this condition. Further, if the system involves use, for example, of three photographs or even only one, its validity relative to a gold standard should also be presented and the performance trade-offs understood (72,75). From the perspective of health policy, it should be shown that the system offers significant benefits over the existing system, which are sufficient to justify any additional costs.

6.3 Systems approach to eye care for patients with diabetes mellitus

Allocation, administratively or through a market operation, of scarce health care resources, particularly physicians, should be made in the context of overall health care and social welfare. Thus, in a systems approach, different responsibilities will be allocated to different entities in different societies and countries. In some societies, easy access to specialist eye care providers (retina specialists) is the norm, while in others a general ophthalmologist is responsible for providing laser treatment for sight-threatening eye disease, with minimal capability to address advanced vitreo-retinal tractional detachment.

Applying a systems approach to the current care systems in developed countries suggests that alternatives should be actively explored as a means of improving performance in every area of eye care for patients with diabetes. As described above, performance leaves much to be desired in every aspect of care, ranging from access, to accuracy of classification, to ensuring adequate treatment. Thus, significant lessons can be drawn from experiences with other systems; currently, the performance of no one system is objectively ideal.

Current alternatives are based on either reference photographs or photographic systems to screen or manage referral to ophthalmologists who treat diabetes-related eye disease, whether by laser or incisional surgery. The systems usually overcome the inconsistent accuracy of interpretation of fundi (live or images) by use of 'reading centres', retina specialists or trained readers. Their task is to assess accurately and quickly the absence or presence of diabetic retinopathy and then to make referrals on the basis of associated decision rules, or to classify the

severity of disease and then to make recommendations for follow-up care intervals with the photographic system until treatment referral is warranted. In order to make such systems as useful as possible (and thus economically feasible), proponents of these alternative image-based systems have gravitated towards their placement in locations accessible to patients, such as mobile vans, or in the offices of primary care or general practitioners, where all diabetes care can be concentrated.

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ANNEXES

1. Agenda, purpose and expected outcome

Agenda

The global burden of diabetes mellitus and complications

Current burden and trends
Diagnosis and classification of complications of diabetes mellitus
Clinical practice guidelines for diabetes and its complications

Issues in eye care in diabetics

Eye care deficiencies contributing to blindness from diabetic retinopathy
Improving integration of eye care within diabetes management

Patient and public education and awareness

Core content of patient and public diabetic retinopathy education Materials

Disease and its complications
Importance of early detection
Efficacy of laser treatment

Production and dissemination of diabetic retinopathy education Materials

Development and publication of materials
Integration with diabetes information
Community distribution
Clinics/provider distribution

Early diabetic retinopathy detection and screening approaches

Training of general practitioners in diabetic retinopathy detection
Detection and referral within diabetes care clinics
Detection within eye care clinics (primary, secondary, tertiary)
Community-based screening models

Purpose

- Review the global burden of diabetes mellitus, its distribution and future trends.

- Identify core diabetic retinopathy related eye health education messages for integration with diabetes patient education materials.

- Review evidence-based practice guidelines for diabetic retinopathy management and identify potential simplifying adaptations for public health application in developing country health care systems.

- Define alternative approaches for screening and early detection of diabetic retinopathy among diabetic populations in different settings.

Expected outcome

- Recommendation regarding the diabetic retinopathy content of diabetic patient education materials.

- Drafts of screening protocols for the early detection of diabetic retinopathy in different health care settings.

- Strategies for prevention of blindness due to diabetes with the public health perspective and as appropriate to existing resources and

different levels of technological application.

■   Identification of opportunities and approaches to improve interaction and collaboration between eye care providers and other members of the diabetes management team.

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3. International clinical diabetic retinopathy and macular edema disease severity scales

DIABETIC RETINOPATHY DISEASE SEVERITY SCALE (REFERENCE 100)

PROPOSED DISEASE SEVERITY LEVEL	FINDINGS OBSERVABLE WITH DILATED OPHTHALMOSCOPY
No apparent retinopathy	No abnormalities
Mild nonproliferative diabetic retinopathy	Microaneurysms only
Moderate nonproliferative diabetic retinopathy	More than microaneurysms but less than severe nonproliferative diabetic retinopathy
Severe nonproliferative diabetic retinopathy	Any of the following: More than 20 intraretinal haemorrhages in each of four quadrants Definite venous beading in two or more quadrants Prominent intraretinal microvascular abnormalities in one or more quadrant And no sign of proliferative retinopathy
Proliferative diabetic retinopathy	One or more of the following: Neovascularization Vitreous or preretinal haemorrhage

DIABETIC MACULAR OEDEMA DISEASE SEVERITY SCALE

PROPOSED DISEASE SEVERITY LEVEL	FINDINGS OBSERVABLE WITH DILATED OPHTHALMOSCOPY
Diabetic macular oedema apparently absent	No apparent retinal thickening or hard exudates in posterior pole
Diabetic macular oedema apparently present	Some apparent retinal thickening or hard exudates in posterior pole

IF DIABETIC MACULAR OEDEMA IS PRESENT, IT CAN BE CATEGORIZED AS FOLLOWS:

PROPOSED DISEASE SEVERITY LEVEL	FINDINGS OBSERVABLE WITH DILATED OPHTHALMOSCOPY*
Diabetic macular oedema present	Mild diabetic macular oedema: some retinal thickening or hard exudates in posterior pole but distant from the centre of the macula Moderate diabetic macular oedema: retinal thickening or hard exudates approaching the centre of the macula but not involving the centre Severe diabetic macular oedema: retinal thickening or hard exudates involving the centre of the macula

* Hard exudates are a sign of current or previous macular oedema. Diabetic macular oedema is defined as retinal thickening and this requires a 3-dimensional assessment that is best performed by a dilated examination using slit-lamp biomicroscopy and/or stereo fundus photography.

4. International Council of Ophthalmology International Clinical Guidelines: Diabetic retinopathy (initial and follow-up evaluation) http://www.icoph.org/guide/guidelist.html

Initial examination history

- symptoms [A:III]
- age at onset of diabetes [A:I]
- duration of diabetes [A:I]
- glucose status (haemoglobin A1c) [A:I]
- medications [A:III]
- medical history [A:II] (e.g. onset of puberty, obesity)
- renal history [A:I]
- systemic hypertension [A:I]
- pregnancy status of women under 50 years of age [A:I]
- serum lipid levels [A:I]
- family history [B:III] social history [A:III] (alcohol, cigarettes)
- social history [A: III] (alcohol, cigarettes)

Initial physical examination

- best-corrected visual acuity [A:I]
- ocular alignment and motility [A:III]
- pupil reactivity and function [A:III]
- measurement of intraocular pressure [A:III] (preferably by aplanation tonometry)
- confrontation visual fields [A:III]
- gonioscopy when indicated (for neovascularization of the iris or increased intraocular pressure) [A:III]
- slit-lamp biomicroscopy (cornea, iris, lens, vitreous) [A:III]
- stereo examination with biomicroscopy of the posterior pole [A:I]
- examination of the peripheral retina, best performed with indirect ophthalmoscopy or with slit-lamp biomicroscopy, combined with a contact lens [A:III]

Diagnosis

- classify both eyes for category and severity of diabetic retinopathy, with presence or absence of clinically significant macular oedema. [A:III]

Follow-up history

- visual symptoms [A:III]
- interval ocular history [A:III]
- glucose control medications and control regimen [A:I]
- glucose status [A:I]
- interval medical history [A:III]
- changes in medications [A:III]

Follow-up physical examination

- best-corrected visual acuity [A:I]
- measurement of intraocular pressure [A:III] (aplanation tonometry)
- gonioscopy when indicated (for neovascularization of the iris or increased intraocular pressure) [A:III]
- slit-lamp biomicroscopy with iris examination [A:II]

- stereo examination with biomicroscopy of the posterior pole [A:I]
- examination of the peripheral retina, best performed with indirect ophthalmoscopy or with slit-lamp biomicroscopy, combined with a contact lens [A:III]

Patient education

- Discuss results of examination and implications. [A:III]
- Educate patients on the importance of reducing blood pressure and serum lipid levels, if they have high blood pressure and increased serum lipid levels. [A:I]
- Educate patients about the importance of maintaining good glucose control and monitoring glycosylated haemoglobin. [A:I]
- Advise patients with new visual symptoms to contact their ophthalmologist in a timely manner. [A:III]
- Communicate with the attending physician, e.g. family physician, internist or endocrinologist regarding eye findings and other significant findings. [A:III]
- Refer for or encourage patients with significant visual impairment or blindness to use appropriate vision rehabilitation and social services. [A:III]

Ancillary tests

- Fundus photography may be valuable at the initial examination if significant disease is present, because it might document the need for more frequent examinations and document significant progression of disease and response to treatment. [B:III]

- Fluorescein angiography is indicated as a guide for treating clinically significant macular oedema, [A:I] as a means of evaluating unexplained decreased visual acuity [A:III] and as an aid in identifying subtle areas of neovascularization or capillary non-perfusion when abundant signs of severe nonproliferative diabetic retinopathy are present. [B:III]

The ratings of importance are divided into three levels:
- Level A, defined as most important
- Level B, defined as moderately important
- Level C, defined as relevant but not critical.

Ratings of the strength of evidence

The "ratings of strength of evidence" also are divided into three levels:

Level I provides strong evidence in support of the statement. The design of the study allowed the issue to be addressed, and the study was performed in the population of interest, executed in such a manner as to produce accurate and reliable data, and analyzed using appropriate statistical methods. The study produced either statistically significant results or showed no difference in results despite a design specified to have high statistical power and/or narrow confidence limits on the parameters of interest.

Level II provides substantial evidence in support of the statement. Although the study has many of the attributes of one that provides Level I support, it lacks one or more of the components of Level I.
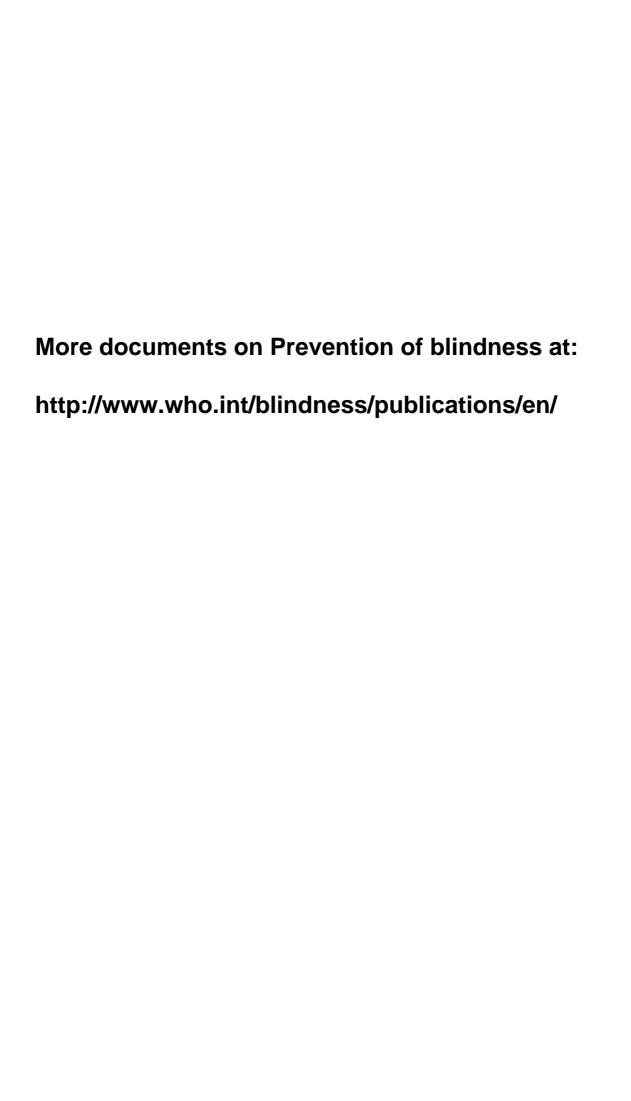
Level III provides a consensus of expert opinion in the absence of evidence that meets Levels I and II.

PREVENTION OF BLINDNESS FROM DIABETES MELLITUS

MANAGEMENT RECOMMENDATIONS FOR THE PATIENTS WITH DIABETES

SEVERITY OF RETINOPATHY	FOLLOW UP (MONTHS)	FOCAL LASER	SCATTER (PANRETINAL) LASER	FLUORESCEIN ANGIOGRAPHY
1. Normal or minimal nonproliferative diabetic retinopathy	12	No	No	No
2. Mild-to-moderate nonproliferative diabetic retinopathy without macular oedema	6–12	No	No	No
3. Mild-to-moderate nonproliferative diabetic retinopathy with macular oedema that is not clinically significant	4–6	No	No	Occasionally
4. Mild-to-moderate nonproliferative diabetic retinopathy with clinically significant macular oedema	2–4	Yes[a,b]	No	Yes
5. Severe or very severe nonproliferative diabetic retinopathy with no macular oedema	3–4	No	Sometimes[c]	Occasionally
6. Severe or very severe nonproliferative diabetic retinopathy with clinically significant macular oedema	2–4	Yes[c]	Sometimes[c]	Yes
7. Non-high-risk proliferative diabetic retinopathy with no macular oedema	2–4[d]	No	Sometimes[c]	Occasionally
8. Non-high-risk proliferative diabetic retinopathy with clinically significant macular oedema	2–4[d]	Yes[e]	Sometimes[c]	Yes
9. High-risk proliferative diabetic retinopathy with no macular oedema	3–4	No	Yes	Occasionally
10. High-risk proliferative diabetic retinopathy with clinically significant macular oedema	3–4	Yes[e]	Yes	Yes
11. High-risk proliferative diabetic retinopathy not amenable to photocoagulation	1–6	Not possible[f]	Not possible[f]	Occasionally
12. Very severe proliferative diabetic retinopathy	3–4	No	Yes[f]	Yes

Adapted from American Academy of Ophthalmology Summary Benchmarks, June 2001 (www.aao.org)

a   Exceptions include: hypertension or fluid retention associated with heart failure, renal failure, pregnancy or any other causes that may aggravate macular oedema. Deferral of photocoagulation for a brief period of medical treatment may be considered in these cases.

b   Consider focal laser treatment. Deferral of clinically significant macular oedema treatment is an option when visual acuity is excellent, close follow-up is possible and the patient understands the risks.

c   Scatter (pan-retinal) photocoagulation surgery may be considered as patients approach high-risk proliferative diabetic retinopathy. The benefit of early scatter photocoagulation at the severe nonproliferative or worse stage of retinopathy is greater in patients with type 2 diabetes than in those with type 1. Treatment should be considered for patients with severe nonproliferative diabetic retinopathy and type 2 diabetes. Presence of other factors, such as poor compliance with follow-up, impending cataract extraction or pregnancy, and consideration of fellow eye will help in determining the timing of the scatter photocoagulation.

d   If scatter photocoagulation is performed, follow-up at 3–4 months; otherwise, follow-up at 2–3 months.

e   It would be preferable to perform the focal laser photocoagulation first prior to scatter photocoagulation.

f   Vitrectomy indicated in selected cases

More documents on Prevention of blindness at:

http://www.who.int/blindness/publications/en/

DIABETES
OFTEN CAUSES
BLINDNESS

YET 90% OF CASES
CAN BE PREVENTED