WHO-EM/CPB/005/E

Report on the

# Regional workshop on planning for the control and prevention of blindness due to diabetic retinopathy

Cairo, Egypt 20–24 November 2006



Regional Office for the Eastern Mediterranean

WHO-EM/CPB/005/E

Report on the

# Regional workshop on planning for the control and prevention of blindness due to diabetic retinopathy

Cairo, Egypt 20–24 November 2006



Regional Office for the Eastern Mediterranean

#### © World Health Organization 2007 All rights reserved.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

The World Health Organization does not warrant that the information contained in this publication is complete and correct and shall not be liable for any damages incurred as a result of its use.

Publications of the World Health Organization can be obtained from Distribution and Sales, World Health Organization, Regional Office for the Eastern Mediterranean, PO Box 7608, Nasr City, Cairo 11371, Egypt (tel: +202 2670 2535, fax: +202 2670 2492; email: DSA@emro.who.int). Requests for permission to reproduce WHO EMRO publications, in part or in whole, or to translate them – whether for sale or for noncommercial distribution – should be addressed to the Regional Adviser, Health and Biomedical Information, at the above address (fax: +202 2276 5400; email HBI@emro.who.int).

Document WHO-EM/CPB/005/E/11.07/75

#### CONTENTS

EXE	CUTI	VE SUMMARY1	
1.	INTI	RODUCTION	
2.	TECHNICAL PRESENTATIONS		
	2.1	Global overview of diabetic retinopathy as a cause of blindness	
	2.2	The burden of diabetes and its complications in Eastern Mediterranean Member	
		States	
	2.3	Clinical practice guidelines for diabetes and the complications of diabetic retinopathy	
	2.4	Issues of eye care among diabetics	
	2.5	Early detection and efficient screening of diabetic retinopathy	
	2.6	Basic considerations for the prevention of blindness in diabetes care and education8	
	2.7	Diabetic retinopathy treatment modalities	
	2.8	Integration of diabetes management within primary health care	
	2.9	Diabetic retinopathy: a model experience in Saudi Arabia	
	2.10	Piloting strategies for the control and prevention of diabetes-related blindness11	
	2.11	Technological issues in screening	
	2.12	Disease severity scale and International Council of Ophthalmology (ICO) clinical	
		guidelines for diabetic retinopathy12	
	2.13	Planning issues for the prevention of blindness from diabetic retinopathy13	
	2.14	GCC Sub Regional diabetic retinopathy meeting report14	
	2.15	Summary of the SWOT (Strength, Weaknesses, Opportunities and Threats) exercise	
3	COU	INTRY PRESENTATIONS 16	
5.	31	Rahrain 16	
	3.2	Egypt 16	
	3.3	Islamic Republic of Iran 16	
	3.4	Iraq	
	3.5	Jordan	
	3.6	Kuwait	
	3.7	Lebanon	
	3.8	Libyan Arab Jamahiriya	
	3.9	Saudi Arabia	
	3.10	Morocco	
	3.11	Somalia19	
	3.12	Tunisia	
	3.13	Yemen	
4.	GRC	UP WORK	
	4.1	Group Work 1: Screening of diabetic retinopathy	
	4.2	Group Work 2: Management of diabetic retinopathy	

5.	CONCLUSIONS	
6.	RECOMMENDATIONS	

#### Annexes

AGENDA	
PROGRAMME	
LIST OF PARTICIPANTS	

#### WHO-EM/CPB/005/E

#### **EXECUTIVE SUMMARY**

Recent evidence suggests that diabetes mellitus is rapidly becoming a major public health problem in the Eastern Mediterranean Region. Epidemiological studies have demonstrated that the prevalence of diabetes is higher than 10% in several countries of the Region and there is every indication that the prevalence is increasing annually.

There is also evidence of rising trends in other risk factors, particularly obesity, hypertension, smoking, dyslipidemias and changing lifestyles with sedentary living and inactivity that are contributing to the burgeoning problem of diabetes. Gulf countries are especially affected with a rise in the complications of diabetes mellitus, including cardiovascular, neuropathy, retinopathy and nephropathy, further compounded by a lowering in quality of life.

Diabetes and its complications require a holistic, comprehensive and integrated approach for prevention; health protection and promotion; curative care and rehabilitation. In most countries of the Region, the main focus is on tertiary treatment, however, the main emphasis of any control strategy should be on primary prevention. Alternate strategies for screening are available, such as mobile units, telemedical approaches, etc. However, the feasibility and utilization of these different approaches will vary according to the circumstances in any particular country.

There are several well-established models for the delivery of diabetes care which effectively address the management of diabetic retinopathy, for example, the Diabetic Centre at King Abdulaziz University Hospital in Riyadh, Saudi Arabia.

Global data indicate that diabetic retinopathy accounts for approximately 5% of all blindness and is rapidly becoming a significant cause of blindness and vision impairment in the Region. In most countries of the Region, reliable epidemiological data on diabetic retinopathy is lacking. Information on community lifestyle and dietary habits, barriers, knowledge, attitude and practices about diabetes and its complications are also unavailable. The lack of adequately trained health practitioners is another major constraint in implementing country programmes for the control of DR.

#### 1. INTRODUCTION

A regional workshop on planning for the control and prevention of blindness due to diabetic retinopathy was organized by the WHO Regional Office for the Eastern Mediterranean (EMRO) in collaboration with IMPACT/EMR and the International Agency for Prevention of Blindness (IAPB). The meeting took place in Cairo, Egypt, from 20 to 22 November 2006. The objectives of the workshop were to:

- review the current situation and increasing prevalence of diabetes and the burden of blindness arising from diabetes mellitus and its resultant complications in Member States of the Eastern Mediterranean Region;
- review eye care issues related to diabetes, including current practices and progress achieved by some Member States, and discuss the constraints faced by countries in the field of management of eye care in diabetes (based on country reports and data collection);
- establish the concept of teamwork and partnerships at all levels for the primary prevention and management of diabetes and its complications, and for patient and public education;
- establish technical cooperation between Member States in the field of training and the management of diabetic retinopathy and operational research; and
- review evidence-based practice guidelines for the management of diabetic retinopathy and recommendations arising out of the last global and Gulf Cooperation Council (GCC) meetings and consider possible implementation in all Member States in the Region.

The workshop was attended by national coordinators from Bahrain, Egypt, Islamic Republic of Iran, Iraq, Jordan, Lebanon, Libyan Arab Jamahiriya, Morocco, Pakistan, Saudi Arabia, Somalia, Tunisia and Yemen. Other participants included WHO Temporary Advisers from Egypt, India, Islamic Republic of Iran, Kuwait, Pakistan and Saudi Arabia, staff from WHO Regional Office for the Eastern Mediterranean and WHO headquarters, and representatives from nongovernmental organizations and professional bodies.

The three main expected outcomes of the meeting were to: compile recommendations outlining strategies for the prevention of blindness due to diabetic retinopathy (DR) in all Member States of the Region; identify priority areas of action as appropriate to existing resources at different levels; identify opportunities and approaches to improving interaction and collaboration between eye-care providers, other members of the diabetes management team and other health-related programmes.

In his opening address Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean, said that non communicable diseases, such as diabetes mellitus, were a major public health problem worldwide. Diabetes affected more than 230 million people and was expected to affect 350 million by 2025. In 2003, four of the five countries with the highest diabetes prevalence among the adult population were from the Eastern Mediterranean Region.

#### WHO-EM/CPB/005/E

Page 3

Diabetic retinopathy was the most common complication of diabetes and a leading cause of visual loss among working populations. Diabetic retinopathy was a multisystem disease, often asymptomatic until its later stages when it led to blindness. It had been estimated that at any given time, 33% of the total diabetic population would suffer from some form of diabetic retinopathy, and that one third of these would have sight-threatening complications.

Many randomized clinical trials had shown the efficiency of laser photocoagulation of the retina when proliferative diabetic retinopathy was present. Prevention of visual loss from diabetic retinopathy by laser photocoagulation was both feasible and cost effective. Unfortunately, a lack of technology and trained human resources had remained a barrier to implementation in developing countries. Lack of awareness among diabetics about the potential for sight-threatening eye complications and poor compliance with periodic eye examinations also hampered early detection and treatment. Thus, the prevention of visual disability from diabetic retinopathy had to go beyond the purely clinical domain to include patient education and early detection, including screening of target populations.

Dr Gezairy emphasized that WHO and the International Diabetes Federation (IDF) were working together for a reduction of blindness due to diabetic retinopathy worldwide. Detailed clinical practice guidelines for the diagnosis, treatment and follow-up evaluation of diabetic retinopathy were available.

H.R.H Prince Abdulaziz Ahmed Al-Saud, Chair of the Eastern Mediterranean Region, IAPB, and the chairman of IMPACT/EMR, stated that 314 million individuals globally were visually impaired, of whom 153 million had refractive errors, 124 million had low vision and 37 million were blind. A staggering 85% of blindness was avoidable through using established and affordable technologies, which were among the most cost effective of all health interventions. H.R.H pointed out that studies had shown diabetic retinopathy represented 4.8% of the global causes of blindness. Effective management of diabetic retinopathy lay within early diagnosis in order to preserve visual acuity before the condition worsened. He indicated that it was necessary to establish strategies for screening and early detection of the disease in order to treat it and prevent its complications.

The chairmanship was shared on a rotating basis. The agenda, programme and list of participants are included as Annexes 1, 2 and 3, respectively. Annex 4 contains the International clinical diabetic retinopathy disease severity scale.

#### 2. TECHNICAL PRESENTATIONS

#### **2.1** Global overview of diabetic retinopathy as a cause of blindness Dr R. Pararajasegaram, WHO Temporary Adviser

Currently, diabetes mellitus affects more than 170 million people worldwide. This number is projected to increase to 366 million by 2030. The most rapid growth is in low and middle-income countries among working age populations. Over 75% of patients who have

had diabetes mellitus for more than 20 years have some degree of diabetic retinopathy. Diabetic retinopathy is a micro-vascular complication of both type 1 and 2 diabetes mellitus. It is the most important cause of blindness among those of working age in industrialized countries and an increasing cause of blindness elsewhere. Diabetic retinopathy accounts for 4.8% of the 37 million blind people globally.

Diabetes mellitus is a metabolic disorder that has multiple organ involvement. The management of diabetes requires a holistic approach and not merely one that addresses the main metabolic sign—blood sugar levels. Ophthalmologists need to be conscious of this when dealing with diabetic retinopathy. A multidisciplinary team approach is essential.

There is increasing evidence that lifestyle changes among high-risk populations can eliminate, or at least delay, the onset of diabetes mellitus. Evidence-based interventions are available to reduce the risks of blindness and vision loss among those with diabetes. Studies conducted over the last 30 years indicate that 90% of the risk of blindness can be controlled.

However, there is a gap between available knowledge and technology and their application. Clearly defined guidelines exist for cost-effective interventions (laser treatment represents a good example), but there are many barriers, including lack of awareness, limited availability, poor accessibility and unaffordability of services.

The basic components of eye care include: patient awareness of diabetes and complications; adequate care of diabetes and associated risk factors (which would involve multidisciplinary teams); and patient motivation for periodic eye examinations.

Member States need to agree on a uniform classification system; the most appropriate method for screening or detecting diabetes; the most appropriate intervals between examinations; the most appropriate personnel and locations; and the development of patient-centred eye health education. The choice of method will be dependent on a country's resources. The principles of health promotion, prevention, treatment and rehabilitation are all relevant in the management of diabetes mellitus and its complications, including vision loss.

#### **2.2** The burden of diabetes and its complications in Member States of the Region Dr Oussama Khatib, Regional Adviser, Non communicable Diseases, WHO/EMRO

The Eastern Mediterranean Region is a classic example of a region in the midst of an epidemiological transition. There are increasing rates of obesity, accompanied by a growing prevalence of hypertension and diabetes, high prevalence of smoking and elevated rates of consanguineous marriages (associated with a high risk of genetic disorders).

Diabetes is reaching a pandemic. Prevalence ranges from between 7% and 25% in the Region (it is highest at between 16% and 25% in member countries of the Gulf Cooperation Council (GCC)). Based on recent epidemiological data, the WHO Regional Office estimates that diabetes prevalence will increase by between 0.5% and 1% each year. Many countries in the Region are now reporting the onset of type 2 diabetes at an increasingly young age:

among adults in their teens and twenties, and in some countries in the Region, particularly in the GCC, among children.

Achievements to date have included the development of three sets of regional guidelines aimed at standardizing the management and care of diabetes. National initiatives are now needed to ensure implementation of the guidelines.

Recent estimates from WHO show that in 2002, at least 50 million people were diagnosed with diabetic retinopathy and this number is projected to double by 2025 if no major control activities are developed. It is estimated that more than 2.5 million people experience vision loss due to diabetic retinopathy, and approximately 2% of all people who have had diabetes for 15 years become blind, while about 10% develop severe visual impairment.

Approximately 26% of patients with type 1 diabetes and 36% of those with type 2 diabetes mellitus have never had their eyes examined (the regional percentage is much higher). 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. When examined, almost 61% of these patients are found to have diabetic retinopathy, cataract, glaucoma or another ocular manifestation of diabetes mellitus.

The financial costs associated with visual impairment or blindness, both to the patient and to the health care and benefits system, are very high. In contrast, the cost of screening and preventing diabetic retinopathy is a fraction of that cost; approximately 1.2% of total health care costs for a person with diabetes. The initial key steps would be to build a national plan of action for screening, and then establish the infrastructure and capacity to implement the plan of action for the screening and management of diabetic retinopathy.

## 2.3 Clinical practice guidelines for diabetes and the complications of diabetic retinopathy

Dr Monira Al Arouj, WHO Temporary Adviser

Over 3 million deaths are attributable to diabetes and its complications each year. There is extensive evidence on the optimal management of diabetes in reducing these complications and improving quality of life. But optimal diabetes management is not reaching many, perhaps the majority of, people with diabetes. This reflects the size and complexity of the evidence base, and the complexity of diabetes care itself. The consequences are diverse standards of clinical practice and a lack of proven cost-effective resources for diabetes care.

Textbook management guidelines represent the effort of one author and do not provide reasons for the proposed advice. Clinical practice guidelines exist to overcome this problem. They aim to provide recommendations for the treatment and care of people by health professionals. They can be used in the education and training of health professionals and to develop standards to assess the clinical practice skills of individual health professionals. They can also assist patients in making informed decisions and improving communication between the patient and health professional.

The development of global guidelines on diabetes has offered a unique challenge. The aim was to promote the implementation of diabetes care in a way that was cost effective, evidence-based and applicable in all settings, whatever the resources available. The first global evidence-based guidelines were based on published national evidence-based reviews and guidelines from the previous 5 years. The development process involved health care professionals from diverse disciplines, people with diabetes and staff from nongovernmental organizations. There was input from countries with very different stages of economic development from all regions of the International Diabetes Federation (IDF).

Evidence was given a specific grade according to what kind of study it came from. Evidence from meta-analysis of randomized controlled trials was given the highest grading of IA, while evidence from expert committee reports or opinions and/or clinical experience of respected authorities received the lowest grading of IV. Recommendations, in turn, were graded from A to D depending on the level of evidence on which they were based.

#### 2.3 Issues of eye care among diabetics

Dr Tayyab Afghani, Al Shifa Trust Eye Hospital

The duration of pre-clinical disease (i.e. the window for starting treatment) in diabetes is estimated to be 12 years. Screening the general population for diabetes has not proved to be cost effective, but screening for diabetic retinopathy among the diabetic population, is highly cost effective.

Primary eye care for diabetics has three components: timely and accurate identification; prompt and appropriate referral; and health education, awareness and motivation. Barriers to timely and accurate identification include lack of finances (cited by patients); lack of patient education (cited by physicians); and long waiting times (cited by both).

Identification of diabetic retinopathy may occur as a result of a visit with a primary care physician, or via screening using seven-field fundus photography (considered to be the gold standard), or tele-ophthalmology. If diabetic retinopathy identification is the responsibility of the primary care physician, then short-term training will considerably improve detection and referral rates. Physicians' awareness of screening guidelines has been shown to be low, and busy physicians may not be implementing the guidelines. In developing countries equipment is often insufficient; most physicians do not have ophthalmoscopes or the facilities to carry out the dilated fundus examination.

For seven-field fundus photography, the requirements are: a trained fundus photography technician, equipment, infrastructure and reading by ophthalmologists. Tele-ophthalmology requires an image capture and relay facility and an image receipt and reading facility.

Health education, awareness and motivation should involve the patient, the public, policy-makers and professionals. An effective diabetic health education programme at local, district and national level needs the availability of all essential structures, community participation and integration of government and private sectors. Studies have shown that younger age, shorter duration of diabetes, male gender, low education and rural background

were factors adversely affecting compliance by patients. These groups need special targeting when designing health education programmes.

For advanced eye care, short- and long-term training should be provided for ophthalmologists and laser technicians. Lasers should be active, available and accessible, and biomedical services should be prompt.

#### 2.4 Early detection and efficient screening of diabetic retinopathy

Dr R. Kim, WHO Temporary Adviser

Diabetic retinopathy is present among 30% of diabetics after 3 to 4 years, and among 80% of diabetics after 15 years. Proliferative diabetic retinopathy is present among 2% after less than 5 years, and among 15% after 15 years. Visual loss is a late symptom of diabetic retinopathy. Currently, the disease is often detected too late for effective laser surgery. According to a study published in 2005, the prevalence of retinopathy among urban south Indians was 17.6%. By extrapolation, there are 31.7 million diabetics in India, 5.6 million of whom have diabetic retinopathy.

The objective of the Lions Aravind Diabetic Retinopathy Project was to create awareness of the eye complications of diabetes among diabetic patients in the community, and to provide early detection and follow-up treatment for the management of diabetic retinopathy. Diabetic retinopathy screening camps were set up in 34 general eye camps. 16 894 people were screened: 1975 (12%) were found to be diabetic, and 493 (25%) were found to have diabetic retinopathy. A further 137 exclusively diabetic retinopathy screening camps were set up and 47 486 people were screened: 16 584 (35%) were found to be diabetic, and 2971 (18%) had diabetic retinopathy.

The diabetic retinopathy screening mobile van screened 2901 diabetics, diabetic retinopathy was found among 28% of these individuals. Telescreening can be carried out from fixed locations, using ISDN or broadband DSL. It obviates the need for retina specialists, only technicians and trained graders are needed.

An awareness-raising campaign targeted diabetic patients, people prone to diabetes, health workers, laboratory and pharmacy staff, medical shops and students. Strategies included the development and distribution of information, education and communication (IEC) materials; seminars and workshops for physicians; health education training; and guest lectures at clubs and other organizations. General ophthalmologists received short courses in laser training, and technicians received training in fundus fluorescein angiography (FFA) and ultrasonography (USG).

Currently, there is increased awareness, but there is a continuing problem of indifference, and patients are still seeking medical attention at late stages of the disease. Many people still lack information. Multiple approaches are needed for the huge numbers of diabetic retinopathy patients who are receiving no help. Ophthalmologists and physicians have a major role to play in this regard.

#### **2.5 Basic considerations for the prevention of blindness in diabetes care and education** *Professor Morsi Arab, WHO Temporary Adviser*

WHO identifies diabetic retinopathy as the leading cause of preventable blindness and visual disabilities among working populations in economically-developed societies. Diabetic retinopathy takes a long time to become manifest and cannot be arrested after the establishment of normoglycaemia.

The prevalence of diabetic retinopathy is highly correlated with the duration of diabetes. With type 1 diabetes, 10% of individuals develop diabetic retinopathy after 5 years, and 100% after 25 years. With type 2, 25% develop diabetic retinopathy after 5 years and almost 85% after 25 years.

The results of the Diabetes Control and Complications Trial (1995–2000) showed that intensified treatment reduced the progression of diabetic retinopathy by 76% in primary prevention, and by 54% in secondary prevention. In a cohort study, 47% progress to severe nonproliferative diabetic retinopathy, and 56% need laser treatment. The results show the significance of both duration and glucose exposure (hyperglycaemia) for the development of diabetic retinopathy.

Most studies show a causal connection between hypertension and diabetic retinopathy. The United Kingdom (UK) Prospective Diabetes Study showed that tight control of blood pressure halted 34% of the progress of diabetic retinopathy, and 47% of moderate loss of visual acuity.

A number of other correlations have been shown. There is evidence that the severity of diabetic retinopathy is influenced by familial, and possibly a genetic factor. An association has been found between more severe diabetic retinopathy and total cholesterol but not with triglycerides. Although smoking is a risk factor in albuminuria and nephropathy, its effect on diabetic retinopathy is not clear. The use of aspirin failed to prevent the development of diabetic retinopathy.

The basic considerations for the prevention of diabetic retinopathy are: knowledge of the risk factors; control of glycaemic level; control of hypertension; close observation in pregnancy; screening, follow-up, and early intervention; control of serum lipids; discouragement of smoking; no restriction on aspirin (if required for cardiac).

#### 2.6 Diabetic retinopathy treatment modalities

Dr Manal Buhaimed, WHO Temporary Adviser

Currently, available modalities of treatment for diabetic retinopathy are laser photocoagulation, intravitreal medication and surgery. Vision loss from diabetic retinopathy is usually preventable. Improved glycaemic, lipid and blood pressure control are achievable through medication and educational programmes. Studies have shown that for patients diagnosed before the age of 50, reducing haemoglobin A1c (HbA1c) from 9% to 7% would

decrease the lifetime risk for blindness due to retinopathy from 2.6% to 0.3%. For onset of type 2 diabetes after the age of 65, the risk would be reduced from 0.5% to < 0.1%.

A number of studies have examined diabetic retinopathy treatment strategies. The Early Treatment Diabetic Retinopathy Study (1985–1992) showed a reduction in moderate vision loss when patients with diabetic macular edema received photocoagulation. There are some caveats; only 17% of patients with reduced vision at baseline who received photocoagulation had improved visual acuity.

The Diabetic Control and Complications Trial demonstrated that intensive insulin therapy effectively delayed the onset and slowed the progression of diabetic retinopathy. The UK Prospective Diabetes Study showed that tight control of blood pressure also slowed progression.

For proliferative diabetic retinopathy, laser photocoagulation is recommended. The procedure is safe and relatively effective at maintaining a patient's visual acuity, although it does not consistently improve it. In Kuwait, screening has improved but needs to be balanced with treatment services and training. The PixEyes Simulator is a new training methodology which allows trainees to learn with virtual reality patients. Users can practice repeatedly and achieve a satisfactory level of proficiency before real treatment. It is safe and ethical. New treatment modalities include intravitreal steroids. Future therapeutic modalities include anti-VGF approaches, and the EYESI system: a surgical virtual reality.

#### 2.7 Integration of diabetes management within primary health care Dr Mohammad Saleh Memon, WHO Temporary Adviser

Pakistan has five levels of primary health care: basic health centres (covering a population of 10 000), rural health centres (covering a population of 100 000), *tahseel* headquarter centres (covering a population of 1 million), district headquarter centres (covering a population of 3–5 million), and tertiary centres (covering a population of 10 million).

Integration of diabetes management (including complications such as blindness) within primary health care would ideally start at the basic health centres, but functionally would begin at the rural health centre where laboratory facilities are available and an ophthalmologist can be appointed and can visit periodically.

Integration will involve making use of the available physical infrastructure and human resources, partly through education or training. Existing human resources include lady health workers and visitors; laboratory assistants; paramedics who will need orientation in primary eye care in relation to diabetes; a medical technologist who will be involved in checking blood sugar, urine and blood pressure; the ophthalmic assistant to check visual acuity and maintain referral records; and medical officers to advise and make referrals.

An eye care component would consist of screening for diabetes and diabetic retinopathy at the rural health centre, laser facilities at district headquarters level and vitreoctomy surgery at the tertiary level.

The first step should be motivation of three initial stakeholders: (the ophthalmologist, diabetologist and physician). This can be done at district headquarters level (secondary level). The second stage would be to conduct operational research and an educational programme which would involve sociologists, educationists, psychiatrists and nutritionists. The third stage would be the involvement of the community (community-based organizations, school teachers, religious leaders and politicians).

Therapeutic education (teaching that results in a person being willing and able to manage their disease using health care professionals as their resource) is an essential part of the clinical care of diabetes. Constraints to implemention include the fact that professionals conceive medicine as clinical rather than social and are not easily involved in community programmes, and politicians respond more to the demands of affluence than to the real need of the community.

#### 2.8 Diabetic retinopathy: a model experience in Saudi Arabia

Dr Khaled Al Rubeean, WHO Temporary Adviser

The major risk factors for retinopathy among diabetic patients in Saudi Arabia are: the existence of diabetes for 10 or more years; the presence of nephropathy; an age of 60 years and older; poor diabetes control; and the use of insulin.

A major problem in the treatment of diabetic retinopathy has been a lack of coordination between eye care and diabetes specialists: 31% of patients had retinopathy, but only 20% were referred; 43% of ophthalmologist patients had diabetes, but only 7% were referred. Only 11% of patients are seen by both eye care and diabetes specialists.

The National Diabetes Registry was established to track patients and their treatment and to provide data for health planning. Information is collected at hospitals, primary care centres and the private sector from medical records and by direct interview. Data is collected online at www.diabetes.org.sa and stored in a central server, where a data management team cleans and verifies it. Three levels of security prevent misuse. Information includes biographic data, drug use and the existence of complications or associated diseases.

Data are used for patient medical files, health system vital statistics (annual and periodic reports, mortality and morbidity statistics), health planning (mapping disease patterns, costing, citing of new services and monitoring), and geographical reports (mapping disease distribution, availability of services and environmental factors).

The data have shown that age is a key factor in diabetic retinopathy: there are no significant effects before 25 years, the disease peaks after 60 years and decreases after 65 years. 50% of males and 65% of females fail to be diagnosed with diabetic retinopathy.

Geographical mapping data show a higher prevalence of diabetic retinopathy in urban areas and cities.

#### **2.9 Piloting strategies for the control and prevention of diabetes-related blindness** *Dr Mohammad Saleh Memon, WHO Temporary Adviser*

In line with Pakistan's strategic plan for the establishment of diabetic retinopathy services, a number of pilot strategies for the control and prevention of diabetic retinopathy have been established. A pilot project was carried out in Gadaap Town. The first stage included conducting awareness and education activities targeting lady health workers, family physicians, elders, social workers, community-based organizations workers, religious leaders and diabetic patients through lectures, discussions, television and newsletters.

The second stage of the pilot project involved establishing services to provide screening for people aged 30 years and older at primary eye care centres, and laser and vitreoretinal surgery at tertiary centres. There was a low turnout for screening and follow-up treatment. It was found that the prevalence of diabetes was close to 7.7%, rather than the predicted figure of 10%. Diabetic retinopathy incidence was low (10.8% rather than the predicted 25%). Referral follow-up attendance was low (63.6%).

A study of dietary habits of diabetics found that there was no uniform dietary pattern and no relationship between the prevalence of diabetes and calorific intake. It was found that 54% of the population consume more than 1500 calories/day and they may be at risk of developing diabetes in future.

A study of community attitudes looked at the utilization of services and selfmanagement of diabetes in a suburban village. Of a population of 50 000, 500 were registered diabetics. Free screening was offered in the rural health centre of the village and 249 individuals turned up for screening: diabetic retinopathy was detected among 90 individuals (36%), intervention was needed for 31 individuals (36.7%) and follow-up was advised for 59 individuals (63.3%). However, only 4 individuals (6.6%) attended the tertiary centre, 4 km away, for free treatment.

In a study at the tertiary centre conducted between January and December 2004, 363 diabetics were seen. Follow-up was advised for 90 (25%), and intervention for 273 (75%). 289 (80%) had initially attended the retina clinic. Only 86 out of 363 patients really made use of the (almost free) service when referral was within the same hospital. These studies show that while availability and accessibility may be important, attitude is crucial. Awareness and education are crucial factors in people utilizing follow-up/referral services.

#### 2.10 Technological issues in screening

Dr R. Kim, WHO Temporary Adviser

Internal constraints to diabetic retinopathy screening include the lack of availability of trained staff, equipment, technology and standard protocols. External constraints include awareness among the community and health workers. Even if services are available they may

not be accessed due to lack of awareness, indifference, fear or unaffordability. The current scenario is that 55% of individuals eligible for laser treatment do not receive it.

Creating awareness can be achieved through informational and educational materials, health education through voluntary organizations, seminars and workshops for the target audience and guest lectures.

Screening for diabetic retinopathy should include clinic-based practice, outreach and telemedicine. Screening should be carried out at the primary, secondary and tertiary levels. Vision centres, at the primary level, should be adequately equipped with direct ophthalmoscope and slit lamp biomicroscopy.

Screening can be carried out by a trained paramedic at a vision centre through video conferencing with an ophthalmologist from the base hospital. This system allows the patient to be treated close to their home, addresses the human resources issue and saves on time and cost. Mobile units are an effective way to reach otherwise inaccessible patients. At the Aravind Eye Hospital in India a mobile screening van accesses remote areas. Fundus images are recorded using specialized software and are transmitted to the reading and grading centre at the base hospital for diagnosis.

Ophthalmoscopy is the most common screening tool used. Digital fundus photography has made screening easier. Though seven-field fundus photography is the gold standard, it is not practical for screening. Single-field fundus photography can be used for detecting sightthreatening retinopathy, as there is level I evidence that it can serve as a screening tool, although it is not a substitute for a comprehensive ophthalmic examination. While mydriasis is time-consuming and uncomfortable, it improves the quality and sensitivity of screening and is recommended by the National Health Service in the UK and the American Diabetes Association in the USA.

Primary care physicians and ophthalmologists should work hand-in-hand for effective screening and the timely treatment of the diabetic population.

### 2.11 Disease severity scale and International Council of Ophthalmology (ICO) clinical guidelines for diabetic retinopathy

Professor Hassan A. Mortada, WHO Temporary Adviser

The spectrum of diabetic retinopathy ranges from nonproliferative diabetic retinopathy (NPDR), in which pathology is confined within the retina (intraretinal), to preproliferative to proliferative diabetic retinopathy (PDR). NPDR is characterized by microaneurysms, altered retinal vascular permeability, haemorrhages and hard exudates, with or without macular oedema. Microaneurysms are the hallmark of NPDR. They are the earliest lesion visible with an ophthalmoscope, appearing as deep red dots, 15–60 micron in diameter. They require no treatment unless they cause macular oedema.

NPDR ranges from moderate to very severe. In mild NPDR only microaneurysms are present. In moderate NPDR other abnormalities appear, but fewer than in severe NPDR. In

severe NPDR any of the following can be present: (a) severe intraretinal haemorrhages and microaneurysms in all four quadrants of the fundus; (b) venous beading in two or more quadrants; and (c) intraretinal microvascular abnormalities (IRMA) (tortuous hypercellular vessels adjacent to areas of capillary non-perfusion) in at least one quadrant. Very severe NPDR is characterized by any two of the above features.

PDR is characterized by cotton wool spots (fluffy white opacification of inner retinal layers); capillary closure; IRMA; venous changes (beading, looping or duplication); and arteriolar abnormalities (severe narrowing or obliteration of the retinal arteriolar lumen). The Diabetic Retinopathy Study found that 50% of eyes with at least three preproliferative features progress to proliferative retinopathy within 2 years. PDR is characterized by neovascularization; capillary nonperfusion neovascularization of the disc (NVD); neovascularization elsewhere in the retina (NVE); neovascularization of the iris and angle (rubeosis iridis and NVG); and fibrous tissue proliferation. Diabetic macular oedema (DME) is a leading cause of legal blindness. It is treated by focal laser photocoagulation.

#### 2.12 Planning issues for the prevention of blindness from diabetic retinopathy

Dr R. Pararajasegaram, WHO Temporary Adviser

Diabetic retinopathy management requires an integrated approach and must be carried out in settings that permit joint management involving multidisciplinary personnel. Factors determining the site for managing diabetic retinopathy should include: its convenience for patients; quality; cost; the availability of trained personnel and equipment; and a referral system.

Screening and detection should take place in community settings, places of work, primary, secondary and tertiary health centres, and through mobile units. The availability of mobile units allows screening to be provided at sites that are more convenient for the patient. Unfortunately, up to 14% of retinal photographs are ungradeable and these individuals must undergo an alternative form of retinal visualization at a specialized centre. Laser treatment should be carried out at the secondary and tertiary levels, and vitreoretinal surgery at the tertiary level. Patient education and counselling should also be carried out at all levels.

Screening should include measurement of visual acuity and visualization of the fundus. Local availability and human resources will be factors in the choice of the screening tool. Retinal photography and slit lamp indirect ophthalmoscopy, in the hands of properly trained operators, are more sensitive screening tools than dilated direct ophthalmoscopy. In general, retinal photography is a more practical means of screening for retinopathy than slit lamp ophthalmoscopy.

Diabetic retinopathy management requires staff that are appropriately trained and supported. The availability and distribution of personnel competent to carry out the required tasks (e.g. health education, counselling, screening, detection, referral, treatment and rehabilitation) will determine the effectiveness and efficiency of the system to deal with diabetic retinopathy.

Training should be part of comprehensive eye care training and should be taskorientated. Post-training mentoring and continuing medical education should be provided, and if feasible, joint training for those who will be working as a team. Ophthalmologists should receive subspecialty training on VR surgery, medical retina and low vision care. Concepts of community-orientated eye care and principles should be emphasized in addition to the need for monitoring and evaluating the quality of care (including patient satisfaction).

#### 2.13 GCC subregional diabetic retinopathy meeting report

Dr Khaled Al Rubeean, WHO Temporary Adviser

A GCC expert meeting on diabetic retinopathy was held from 5 to 7 June 2006, and resulted in a number of significant conclusions and recommendations. In member countries of the GCC the prevalence of type 2 diabetes ranges from 15% to 25%. Due to genetic and environmental factors and the ageing population, diabetes is increasing at a rate of 1% annually. Diabetic retinopathy affects more than a third of the total diabetic population. Risk factors for retinopathy include duration of diabetes of more than 10 years, presence of nephropathy and presence of hypertension and poor diabetes control.

The costs of diabetes mellitus are now placing a huge burden on Gulf State economies: for example, in Saudi Arabia the estimated direct cost of diabetes is approximately 5 billion Saudi Riyals (SAR), while 4 hundred million SAR are spent on retinopathy annually.

The need to screen for diabetic retinopathy is uncontroversial and screening programmes sensitive to local circumstances should be available to all diabetic patients. Certain "trade-offs" will have to be made, but at a minimum, patients with diabetes should be identified and screened for complications in line with WHO guidelines. Any person with impaired fasting glucose or diabetes discovered to be positive in any screening test should be subject to a retinal examination.

Health care providers should receive education regarding the importance of retinal screening and the significance of specific retinal lesions. Diabetic patients, relatives and the general community should be provided with educational materials and programmes regarding diabetes and its complications. All newly diagnosed type 2 and/or established type 1 or type 2 diabetic patients should be referred for a proper fundus examination. The screening personnel and facilities will be dependent on the local infrastructure. Newly diagnosed type 1 diabetic patients aged 12 years or older should be examined within 3–5 years after diagnosis.

Screening for diabetic retinopathy should be conducted by an individual familiar with the manifestations of diabetic retinopathy (ophthalmologist, optometrist, primary care physician, nurse, technician, remote photography, etc.) at the most convenient and appropriate location. A positive fundus examination (abnormal findings) should warrant referral to an ophthalmology clinic. Type 1 and insulin-dependent type 2 patients should be re-screened once yearly at a minimum. Non-insulin-dependent type 2 patients should be re-screened after a period of 1–3 years, according to the situation.

Alternative screening strategies could include mass screenings in communities, eye camps in remote areas and remote telemedical approaches. Options are dependent upon local resources including availability of trained personnel and equipment. The strengths of each country should be considered when attempting to adopt a minimum standard of care.

Treatment of diabetic retinopathy is based upon the severity of the disorder. Retinopathy graded as levels 1–3 (no, mild or moderate non-proliferative retinopathy, respectively) should, in general, be followed up, whereas therapy is usually recommended for levels 4 and 5 (severe non-proliferative and proliferative retinopathy). All cases with diabetic macular oedema should be considered for a thorough evaluation and possible treatment. Patients with DME and retinopathy levels 2–5 should usually be referred to a vitreoretinal specialist.

#### 2.14 Summary of the SWOT exercise

Professor Mohammad Daud Khan, WHO Temporary Adviser

There is adequate knowledge of the disease burden of diabetes including its increasing prevalence. The disease's course, complications and consequences (including blindness, nephropathy, neuropathy and vasculopathy leading to amputations, impotence and stroke) are well known.

Evidence-based treatment and control strategies for the disease and its complications are known and excellent management protocols are freely available. Health delivery systems with primary, secondary and tertiary outlets exist, in addition to human resources, infrastructure and technology. There is global commitment and coordination and some budgetary support.

Diabetes and its complications are preventable through principles of primary, secondary and tertiary prevention. Tremendous technological support is available and is being freely and very effectively used in many centres globally. Innovative approaches for early detection, referral and treatment are also available in some countries.

Weaknesses include low patient, policy-maker and physician awareness of the disease and its complications. Poor advocacy for prioritization has led to poor professional and political commitment. There is also a lack of trained professionals, infrastructure and technology. Management (including planning, implementation, integration, coordination, monitoring and evaluation) is weak. Budgetary allocations are low and financial management is poor. A comprehensive approach (including promotion, prevention, curative intervention and rehabilitation) is lacking. There has been a failure to take up new initiatives and to develop operational research. Collaboration with national, regional and global organizations is lacking.

Individual national programmes must be available and accessible to all segments of society through a defined unit of population. They must be integrated and flexible. National programmes should be appropriate to national resources and a country's culture and environment. At the same time, they should be in accordance with international health systems and open to global collaboration and responsible partnership.

#### 3. COUNTRY PRESENTATIONS

#### 3.1 Bahrain

Diabetes prevalence in Bahrain is between 7% and 25%. The prevalence of severe diabetic retinopathy is between 3% and 10%. Between 340 and 680 diabetics in Bahrain require treatment with an additional 116 new cases per year. A diabetic retinopathy screening programme was started in July 2003 for the early detection and management of diabetic retinopathy. A fully digitized retinopathy screening clinic was established as a pilot project in the Muharraq Region. Digital photography is performed by an ophthalmic technician and is then sent electronically to be diagnosed and graded at the ophthalmology department at the Salmaniya Medical Centre.

Preliminary results from the clinic indicate that all procedures can be handled with a fully digitized system. Fundus photography was as sensitive as ophthalmoscopy in diabetic retinopathy screening. Digital photography may allow a network organization of several screening units around a central ophthalmologic reading centre. Other digital clinics have since been established and are planned throughout Bahrain.

#### 3.2 Egypt

In Egypt, 7.31% of the population have diabetes, a third of whom are undiagnosed; 10% of diabetics have type 1 diabetes and 90% have type 2. Diabetic retinopathy affects 80% of diabetic patients within 15 years or more of the onset of the disease; 90% have NPDR and 10% have PDR.

In line with Vision 2020, in November 2003, the Ministry of Health and Population implemented a plan to control diabetic retinopathy by developing well-equipped ophthalmology hospitals, centres and general hospital departments of all governorates, and an ophthalmic clinic at the Central Diabetic Institute in Cairo. Other Vision 2020 strategies have included: establishing screening programmes; developing examination and treatment protocols; establishing mobile screening and education units; and developing training for ophthalmologists.

Constraints have included low patient awareness of the complications of diabetes and the importance of early treatment, and difficulties of patients in accessing services as a result of a lack of funds or long distances. Strategies to overcome these include a media campaign to promote awareness and increased funding for equipment and staff in rural areas. The new national health insurance will fully cover the management of diabetes.

#### 3.3 Islamic Republic of Iran

Diabetic retinopathy is one of the Vision 2020 priorities. In the Islamic Republic of Iran, organizations involved in the Vision 2020 initiative include the Ministry of Health and Medical Education, the Ministry of Training, the Welfare Organization, medical universities, the Ophthalmology Research Centre and the Iranian Society of Ophthalmology.

Between 3% and 5% of the population are diabetic. There are approximately 200 diabetes clinics nationwide that provide eye care to diabetic patients, although this number is insufficient. Physicians' guidelines on diabetes include eye care.

In a Teheran provincial study on the causes of visual impairment, diabetic retinopathy was found to be the third most common cause (after cataract and vitreoretinal disease). Diabetes was found to be the main cause of visual impairment for 2.43% of those aged 40 and above.

#### 3.4 Iraq

Diabetes prevalence is 10% and diabetic retinopathy prevalence is 25% of type 1 diabetes and 26% of type 2. Diabetes accounts for approximately 10% of all cases of blindness. There is no programme for diabetes-related blindness and no screening of diabetic individuals. There are no guidelines or national plans for the treatment and control of diabetic retinopathy. Nine governmental and three private centres are equipped with a laser but few ophthalmologists are trained in laser treatment or perform vitreoretinal surgery. 2140 cases of diabetic retinopathy cases received laser treatment in 2005.

#### 3.5 Jordan

A 2004–2005 behavioural risk factors survey indicated that 28% of individuals aged 25 years and older in Jordan are diabetic. Data from the survey indicate that 85% of the population are never examined for diabetes mellitus. Blindness, visual impairment and retinopathy are the most common complications of diabetes in Jordan. A 2003 hospital-based survey indicated that 64% of patients had diabetic retinopathy. There are 17 centres that treat and control diabetic retinopathy; four are under the umbrella of the Ministry of Health. National screening and education programmes are weak and a programme for the early detection and prompt treatment of diabetes is needed.

#### 3.6 Kuwait

Diabetes prevalence is increasing in Kuwait. Type 1 diabetes increased from 12.8 per 100 000 in 1994 to 20.1 per 100 000 population in 2002. Type 2 diabetes has increased from 7% between 1970 and 1980 to 15.7% between 1996 and 1998. 60% of the adult population are overweight or obese, and these conditions are increasing among children. In a 2004 study, 46 out of 155 under 18 year olds were diagnosed with type 2 diabetes.

Before the end of 1987, there were no screening activities at any level. In 1987, the Diabetes Fundus Clinic was established at the Amiri Hospital, offering ophthalmoscopy, fundus photography and ophthalmology opinion and referral when needed. In the first year, 1050 patients were screened, and 50.1% were found to have some degree of diabetic retinopathy.

In 1993, a training programme was set up for doctors in diabetes clinics. The national diabetes programme was established in 2002 providing screening services in 34 diabetes

clinics across the country. There is still no structured programme for diabetic retinopathy. However, there are established clinical services for screening in most primary care diabetes clinics and hospitals. A protocol for coordination between screening services and treatment centres is under development and there are plans to establish a teleophthalmology services reading centre.

#### 3.7 Lebanon

Lebanon has a 1.8% prevalence of diabetes type 1. Comparable epidemiological data on type 2 diabetes is lacking, but in the over-40 age group, prevalence is between 10% and 29%. The prevalence of diabetic retinopathy among diabetic patients is almost 17%. There are 300 specialized ophthalmologists in Lebanon, 30% with experience in laser treatment. Ten centres offer laser treatment, 70% of which are located in the Beirut and Mount Lebanon area. In 2005, 10 000 patients were treated in these centres. Future recommendations include campaigns to raise awareness, the development of guidelines to improve patient practice and the provision of free laser treatment.

#### 3.8 Libyan Arab Jamahiriya

Diabetic retinopathy is a major cause of preventable blindness in the Libyan Arab Jamahiriya. Currently, the country has one diabetic centre, located in Tripoli, a number of polyclinics and some diabetes departments in general hospitals. There are 10 fundus cameras and 20 argon lasers in the country, including two non-mydriatic fundus cameras donated by WHO to the Tripoli Diabetic Centre and the Benghazi Eye Centre.

A recent study was carried out to determine the prevalence of diabetic retinopathy. The sample covered 2000 diabetics (864 male and 1136 female), with a mean age of 50, plus or minus 20 years, with a duration of diabetes of 12 years plus or minus 7 years. 760 of the patients were on insulin and 1240 were on oral hypoglycaemic agent. Patients were given a detailed fundus examination with 90 diopters with fully-dilated pupils. It was found that 610 patients (30.5%) did not have diabetic retinopathy; 540 (27.0%) had background diabetic retinopathy; 380 (19.0%) had pre-proliferative diabetic retinopathy; and 470 (23.5%) had proliferative diabetic retinopathy.

#### 3.9 Saudi Arabia

The prevalence of diabetes in Saudi Arabia is between 17% and 23.7%, or 3.5–4 million adults, and the incidence of diabetic retinopathy is 31.3%. Only 40% of diabetic patients have had an eye examination.

Saudi Arabia has an estimated 893 ophthalmologists (239 of whom work within the private sector), and 20 vitreoretinal surgeons. Diabetic retinopathy photoscreening is carried out at 20 diabetic centres in every health region. A photoscreening training programme for optometrists has been established in collaboration with King Khalid Eye Specialist Hospital. The programme is composed of two weeks of lectures focusing on types of diabetic

retinopathy and retinal anatomy, followed by four weeks of practical training on labelling photos with a non-mydriatic camera.

To date, nine optometrists have been trained. Health regions that have the camera and have completed training are Riyadh, Arar, Al-Hassa, Jezan, Assir and Madina AlBaha. The referral of diabetics from primary health care to ophthalmologists has been introduced to the policy and procedures of primary health care work. Type 1 diabetics are referred 5 years after diagnosis, and type 2 soon after diagnosis.

#### 3.10 Morocco

Diabetes prevalence in Morocco is 6% among individuals over 20 years of age; 57% of whom ignore their disease. This has serious repercussions for the quality of life of patients and for the health budget.

In 1995, a national programme for the prevention and control of diabetes was established with the objective of reducing morbidity and mortality related to the degenerative complications of diabetes. Strategies of the national programme include the strict control of diabetes and education about the disease at the primary health care level. Early screening of those at risk of developing diabetic retinopathy has been implemented, including yearly examination of the fundi and angiography, if needed.

In 2005, a national workshop was held in Rabat to discuss the implementation of the global initiative Vision 2020. Recommendations included: a large-scale epidemiological investigation; development of the existing infrastructure; improvements in education on diabetes; generalization of the eye examination to any diabetic at the primary level; equipment of the secondary and tertiary sectors with laser argon and retinal fundus photography; and improvements in monitoring and follow-up.

#### 3.11 Somalia

The prevalence of diabetes in Somalia in 2005 was 2.3% among a population of 10.5 million. It is projected that this figure will rise to 2.9% by 2030. In 2005, the prevalence of diabetic retinopathy was 0.92%, of whom 0.18% have threatened vision.

Services for diabetic retinopathy include health education for diabetic patients to promote control of sugar intake and awareness of the importance of regular ophthalmic checkups. There is a multi-team approach between the physician and the ophthalmologist to follow up for signs of diabetic retinopathy. However, there are no fundus cameras available in the country. The two treatments for diabetic retinopathy, laser and vitrectomy surgery, are also not available, and such cases must be referred to neighbouring countries, such as Kenya and Dubai.

In line with the Vision 2020 initiative, improved services for diabetic retinopathy patients must be established. This would include support for training on laser treatment for a

senior ophthalmologist, and the provision of a fundus camera and laser equipment to start a medical retina unit in Mogadishu to serve as a referral centre for the whole country.

#### 3.12 Tunisia

In Tunisia, diabetes affects 10% of individuals aged over 30. Diabetic retinopathy is one of the main causes of blindness among people under the age of 60. A 2004 study of approximately 150 000 diabetic patients screened by general practitioners in primary health care centres showed that 5.2% of diabetics had diabetic retinopathy. Hospital studies have shown rates ranging from between 37.5% and 74.5%, with 8%–12% with proliferative diabetic retinopathy.

Programme achievements have included screening campaign studies performed in both university centres and in rural areas. The objective was to screen and study the epidemiology and the risk factors of diabetic retinopathy in a teaching centre and to use the data to develop guidelines for a mass screening programme for rural areas appropriate to local conditions. The national programme for prevention of blindness focused on sensitizing patients and health professionals about the necessity of screening for diabetic retinopathy, and risk factors for developing the disease.

The Vision 2020 initiative was launched in Tunisia in October 2001. A new national plan for the prevention of blindness was established (in consultation with WHO) to develop efficient diabetic retinopathy screening and management programmes.

#### 3.13 Yemen

Blindness affects an estimated 1.5% of the population of 22 million, and 4.5% of these individuals have a visual disability. The prevalence of diabetes among the population aged over 20 is male (8%) and female (2%). The Ministry of Public Health and Population has established two national programmes related to diabetes. There are about 20 centres treating diabetes cases. Some clinics are equipped with lasers and fundus cameras. Yemen is in the process of establishing an Institute of Diabetes in Sana'a. Future plans include new services and improved education and training.

#### 4. GROUP WORK

Participants were divided into two groups and were asked to suggest strategies for the prevention and treatment of diabetic retinopathy. Group A was asked to make recommendations on screening procedures for diabetic retinopathy. Group B was asked to make recommendations on diabetic retinopathy management. Both groups were asked to identify indicators for monitoring and evaluation and priority areas of operational research.

#### 4.1 Group work 1: Screening of diabetic retinopathy

Group A suggested that screening should be carried out by a skilled and trained eye care provider, such as a general ophthalmologist, optometrist, diabetologist, internist, general practitioner or technician. For type 1 diabetes, the first screening should take place 5 years after the initial diagnosis; for type 2 diabetes, screening should take place at diagnosis. Equipment would ideally be a digital fundus camera with, or if not available, a stereoscopic biomicroscope with VOLK lens; an indirect ophthalmoscope with tropicamide; or a direct ophthalmoscope under mydriasis with tropicamide. Ideally, a trained medical retina specialist would read the photographs, or alternatively, an appropriately trained general ophthalmologist.

In the public health sector there needs to be improvements in human resources, facilities, programme management, education for health care providers and awareness-raising for the general public. Operational research should take place on piloting different models of screening and comparing efficiency. Other research areas should include constraints on the uptake of services, the impact of training and the impact of health education through knowledge, attitudes and practice studies.

#### 4.2 Group work 2: Management of diabetic retinopathy

Group B recommended that the treatment of diabetic retinopathy should be carried out in secondary eye care centres as soon as possible after diagnosis. Treatment should be given by a general ophthalmologist; an ophthalmologist with a diploma in medical retina (with three to six months' relevant training in country); or a full consultant with one year of additional training in medical retina. The standard guidelines should be followed with minor modifications to meet the requirements of individual patients, institutions and countries. The available human resources (ophthalmologists, ophthalmic nurses and counsellors) and technology should be fully utilized.

Quality control indicators include: informed consent received from the patient, the importance of follow-up and an appointment made for the next session. Patients with diabetic retinopathy need periodic comprehensive check-ups for cataract, glaucoma and refraction, including low vision. The treatment details and response should be documented and shared with the family physician and the diabetologist.

Operational research opportunities included laser treatment (process, outcome and morbidity), patient satisfaction and the cost of treatment. Awareness and education should be targeted at patients and their families, with the involvement of ophthalmologists' nurses, technicians and counsellors.

#### 5. CONCLUSIONS

Diabetes has rapidly become a major public health problem in the Eastern Mediterranean Region, affecting 10%-25% of the population. The prevalence of diabetic

retinopathy among persons with diabetes ranges from between 10% and 50%, and diabetic retinopathy is rapidly becoming a significant cause of blindness and visual impairment in the Region.

Diabetes and its complications require a holistic, comprehensive and integrated approach for prevention, health protection and promotion, curative care and rehabilitation. In most countries of the Region, the main focus of control programmes is on tertiary treatment of diabetes and its complications. However, the main emphasis of any control strategy should be on primary prevention.

The rising incidence and the lack of awareness among patients and their families about the threat to vision caused by diabetes mellitus is a major cause of the high incidence of visual impairment and blindness from diabetic retinopathy. In most countries of the Region, reliable epidemiological data on diabetic retinopathy are lacking. Furthermore, information on community lifestyles and dietary habits, barriers, knowledge, attitude and practices about diabetes and its complications is unavailable.

Participants reviewed the reports of the WHO consultation on the prevention of blindness due to diabetes mellitus held in Geneva in 2005, the GCC meeting on diabetic retinopathy screening and control held in Qatar in 2006, and the document *Guidelines for the prevention, management and care of diabetes mellitus*. WHO Regional Office for the Eastern Mediterranean technical publication series no. 32, 2006, and endorsed the recommendations in these documents.

Participants recognized the existence of several well-established models for the delivery of diabetes care which effectively address diabetic retinopathy management, such as the Diabetic Center at King Abdulaziz University Hospital, Riyadh, Saudi Arabia. Participants also acknowledged the existence of several well-established models within the Region for the screening and referral of patients with diabetic retinopathy, e.g. Bahrain for digital documentation and telemedicine, and Oman for integration of primary and secondary health care for the eye care of diabetic. Some countries of the Region do not have services for the detection and treatment of diabetic retinopathy. The lack of adequately trained health practitioners is one of the major constraints in implementing country programmes for control of diabetic retinopathy. There is great variation in the availability of human resources and in employment and retention opportunities. Regional and international organizations working to control diabetic retinopathy are vital for generating the support required for this initiative.

#### 6. **RECOMMENDATIONS**

#### Member States

1. Develop strategies for integrated planning for the prevention and control of visual impairment due to diabetic retinopathy.

- 2. Ensure that the management of diabetic retinopathy is an integral part of national diabetes control programmes and primary health care, and is incorporated into national plans for Vision 2020 and the prevention and control of blindness.
- 3. Develop strategies to raise awareness of diabetic retinopathy among diabetic patients and their families and among health care professionals, health planners and policy-makers.
- 4. Use the International Council of Ophthalmology's clinical classification standards and practice guidelines for diabetic retinopathy in national programmes for the prevention of blindness in the Region.
- 5. Choose an appropriate method for screening and detection identified in the report of the WHO consultation on prevention of blindness from diabetes mellitus, held in Geneva in November 2005. Alternative strategies for screening, such as mobile units, telemedical approaches, etc. may be considered by countries according to their feasibility and the circumstances in each country.
- 6. Evaluate successful regional models for the delivery of diabetes care that include screening and referral of patients with diabetic retinopathy and consider for adoption by other countries as appropriate.
- 7. Ensure operational research, including both qualitative and quantitative research, is an integral part of any prevention programme.
- 8. Establish realistic, feasible and practical monitoring indicators for the control of diabetic retinopathy that could be integrated within country-specific health management information systems.
- 9. Train general ophthalmologists in the management of diabetic retinopathy. Strengthen regional and national resource centres to provide such training with decentralization of laser treatment.
- 10. Explore public–private partnerships to enhance the effectiveness and coverage of diabetic retinopathy control programmes.

#### WHO Regional Office

- 11. Give priority to countries that do not have services for the detection and treatment of diabetic retinopathy in order to support the development of these services.
- 12. Constitute a working group on diabetic retinopathy to assist in the development and field testing of a simplified grading scheme card for diabetic retinopathy and to explore the availability of affordable technology in the management of diabetic retinopathy.

13. Convene a follow-up meeting in 2010 to monitor progress in the prevention of blindness due to diabetic retinopathy. Collaboration with IMPACT/EMR and IAPB/EMR should be maintained and extended.

#### Annex 1

#### AGENDA

- 1. Welcome and opening remarks
- 2. Introduction of participants, election of Chairperson and Rapporteur
- 3. Adoption of the agenda
- 4. Objectives and expected outcomes of the meeting
- 5. Country presentations: Bahrain, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Pakistan, Morocco, Saudi Arabia, Somalia, Tunisia and Yemen
- 6. Summary of key points from country presentations
- 7. Global overview of diabetic retinopathy as a cause of blindness
- 8. The burden of diabetes and its complications in Member States of the Eastern Mediterranean Region
- 9. Clinical practice guidelines for diabetes and the complications of diabetic retinopathy
- 10. Issues of eye care among diabetics
- 11. Early detection and efficient screening of diabetic retinopathy
- 12. Basic considerations for the prevention of blindness in diabetes care and education
- 13. Diabetic retinopathy treatment modalities
- 14. Integration of diabetes management within primary health care
- 15. Diabetic retinopathy: a model experience in Saudi Arabia
- 16. Piloting strategies for the control and prevention of diabetes-related blindness
- 17. Technological issues in screening
- 18. Disease severity scale and ICO clinical guidelines for diabetic retinopathy
- 19. Planning issues for the prevention of blindness from diabetic retinopathy

- 20. GCC subregional diabetic retinopathy meeting report
- 21. Summary of the SWOT exercise
- 22. Working sessions in two groups:A: Screening of diabetic retinopathyB: Management of diabetic retinopathy
- 23. Group presentations and plenary discussion
- 24. Conclusions and recommendations
- 25. Closing session

#### WHO-EM/CPB/005/E

Page 27

#### Annex 2

#### PROGRAMME

#### Monday, 20 November 2006

- 08:30–09:00 Registration
- 09:00–10:00 Plenary session
- 09:00–09:20 Opening remarks Dr Haifa Madi, Director of Health Protection and Promotion Introduction of participants
- 09:20–09:25 Election of Chair and Rapporteur Adoption of agenda
- 09:25–09:40 Objectives and expected results of the regional workshop on planning for the control and prevention of blindness due to diabetic retinopathy *Dr A. Choudhury, MO/CPB, WHO/EMRO*
- 09:40–10:00 Burden of diabetes and its complications in Member States of the Region *Dr O. Khatib, RA/NCD, WHO/EMRO*
- 10:30–11:40 Country presentations
  - Bahrain
  - Egypt
  - Islamic Republic of Iran
  - Iraq
  - Jordan
  - Kuwait
  - Lebanon
- 11:40–12:00 Discussions on country presentations
- 13:00–14:20 Country presentations (*continued*)
  - Libyan Arab Jamihiriya
  - Morocco
  - Pakistan
  - Saudi Arabia
  - Somalia
  - Syrian Arab Republic
  - Tunisia
  - Yemen

- 14:20–15:00 Discussions on country presentations Summary of key points from country presentations Dr Haroon Awan, Sight Savers International
- 15:30–17:00 Technical presentations
  - Clinical practice guidelines for diabetes and the complications of diabetic retinopathy
    Dr Munira Al Arouj, WHO Temporary Adviser
  - Issues of eye care in diabetics Dr Tayyab Afghani, Al-Shifa Eye Hospital
  - Early detection and efficient screening of diabetic retinopathy *Dr R. Kim, WHO Temporary Adviser*
  - Issues of patient and public education awareness *Professor Morsi Arab, WHO Temporary Adviser*
  - Diabetic retinopathy treatment modalities Dr Manal BuHaimed, WHO Temporary Adviser
  - Integration of diabetes management within primary health care *Dr Saleh Memon, WHO Temporary Adviser*
- 17:00–17:45 Discussions
- 18:00–19:00 Opening ceremony
  - Address by Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean
  - Address by H.R.H. Prince Abdul Aziz Bin Ahmed Bin Abulaziz Al Saud, Regional Chair, *IAPB*
  - Address by H.E. Dr Hatem Elgabali, Minister of Health and Population, *Egypt*
  - Global burden of diabetes and blindness, by *Dr R*. *Pararajasegaram, WHO Temporary Adviser*
  - Group photograph

19:00–20:00 Reception

#### Tuesday, 21 November 2006

- 09:00–10:00 Technical presentations
  - Diabetic retinopathy a model experience in Saudi Arabia Dr Khaled Al Rubeean, WHO Temporary Adviser
  - Diabetic retinopathy: A community-based model in Pakistan Dr Saleh Memon, WHO Temporary Adviser
  - Technology issues in screening Dr R. Kim, WHO Temporary Adviser
  - Disease severity scale and ICO clinical guideline for diabetic retinopathy *Professor Hassan Mortada, WHO Temporary Adviser*
- 10:00–10:30 Discussions and technical guidelines report
- 11:00–12:20 Technical presentations
  - Planning issues for DR (infrastructure, human resources, equipment, team approach) Dr R. Pararajasegaram, WHO Temporary Adviser
  - GCC subregional diabetic retinopathy meeting report *Dr Khaled Al Rubeean, WHO Temporary Adviser*
  - Global report and implementation at various levels Dr R. Pararajasegaram, WHO Temporary Adviser
  - Summary of the SWOT "Strength, Weaknesses, Opportunities and Threats" exercise

Professor Mohammad Daud Khan, WHO Temporary Adviser

- 12:20–13:00 Discussions and formation of groups
- 14:00–17:30 Group work Group A: Screening. (Human resources, operational research, infrastructure and technology, integration and management) Group B: Management (Human resources, operational research, infrastructure and technology, integration and management)

#### Wednesday, 22 November 2006

- 09:00–10:00 Group (A) presentation and discussion
- 10:00–11:00 Group (B) presentation and discussion
- 11:30–12:30 Conclusions and Recommendations and closing session Dr A. Choudhury, MO/CPB, WHO/EMRO

#### Annex 3

#### LIST OF PARTICIPANTS

#### BAHRAIN

Dr Ebtisam Al Alawi Consultant Ophthalmologist National Coordinator Salmaniya Medical Centre Ministry of Health Manama

#### EGYPT

Dr Khaled Amer Chief of Vitreo Retinal Department National Eye Center Ministry of Health and Population Cairo

#### ISLAMIC REPUBLIC OF IRAN

Dr Afshin Parsikia Vision 2020 Coordinator Centre for Disease Control Programme Manager for Prevention and Control of Blindness Ministry of Health and Medical Education Teheran

#### IRAQ

Dr Ahmed Salih Rasoul Vision 2020 Coordinator Director-General National Programme for Blindness Elimination Ministry of Health Baghdad

#### JORDAN

Dr Bassam Qasem Director of Disease Control Directorate National Coordinator for Blindness Prevention Ministry of Health Amman

#### LEBANON

Dr Samia Haddad Focal Point of Ophthalmology Health Care Department Ministry of Health Beirut

#### LIBYAN ARAB JAMAHIRIYA

Dr Suaad Mohamed F. Fituri President of National Control and Prevention of Blindness Programme and Vision 2020 Coordinator Consultant Ophthalmologist Surgeon Director General Tripoli Eye Hospital Tripoli

Dr Abdrahman Benzaglam Ophthalmologist Eye Hospital Zawia Dhamani General People's Committee for Health and Environment Tripoli

#### MOROCCO

Dr Fatima-Zahra Mouzouni Services of Metabolic and Endocrinology Diseases Director of Epidemiology and Disease Control Ministry of Health Rabat

#### PAKISTAN

Professor Asad Aslam Khan National Coordinator of Blindness Control Director, Punjab Institute of Preventive Ophthalmology King Edward Medical University/ Mayo Hospital Ministry of Health Lahore

#### SAUDI ARABIA

Dr Saad Al Ghamdi Vitreo Retinal Surgeon Head of Ophthalmology Section King Fahd Medical City Ministry of Health Riyadh

#### SOMALIA

Dr Abdirisak Dalmar Focal Point for Vision 2020 Director, PBL programme Ministry of Health Mogadishu

#### TUNISIA

Professor Amal Ouertani Chief of Ophthalmic Department Charles Nicole University Hospital Coordinator, Tunisian National Programme for Prevention of Blindness Ministry of Public Health Tunis

#### YEMEN

Dr Abdullah M. Al Kohlani National Programme Director for Prevention of Blindness/Vision 2020 National Coordinator Ministry of Public Health and Population Sana'a

#### **WHO Temporary Advisers**

Dr Sameh Abdel Shakkour General Director – MD Diabetologist National Institute for Diabetes and Endocrinology Cairo EGYPT

Dr Munira Al Arouj Consultant Diabetologist Amiri Hospital Kuwait **KUWAIT** 

Dr Abdul Aziz Al Rajhi Senior Consultant Ophthalmologist Riyadh SAUDI ARABIA

Dr Khaled Al Rubeean Director, Diabetes Centre Assistant Professor of Medicine and Endocrinology King Abdulaziz University Hospital Riyadh SAUDI ARABIA

Professor Morsi Arab Chair, Eastern Mediterranean and Middle East (EMME) Region International Diabetes Federation Professor of Medicine University of Alexandria Alexandria EGYPT

Dr Manal Bouhaimed Assistant Professor Faculty of Medicine Kuwait University Consultant Vitreo Retina Specialist AlBahar Eye Centre Kuwait **KUWAIT** 

Dr Mohammad Ali Javadi Professor Ophthalmic Research Centre of Shaheed Beheshti University of Medical Sciences Head of Department Director of Eye Bank Iran Teheran **ISLAMIC REPUBLIC OF IRAN** 

Professor M. Daud Khan Rector Khyber Institute of Ophthalmic Medical Sciences/ Pakistan Institute of Community Ophthalmology (PICO) Hayatabad Medical Complex Peshawar PAKISTAN

Dr R. Kim Coordinator Tifac CORE Centre of Excellence in Diabetic Retinopathy Chief of Vitreoretinal Unit Aravind Eye Hospital Madurai INDIA

Dr Saleh Memon Director Al Ibrahim Eye Hospital Karachi **PAKISTAN** 

Professor Hassan Mortada Professor of Ophthalmology Cairo University Cairo **EGYPT** 

Dr R. Pararajasegaram Consultant Ophthalmologist Vision 2020 WHO/HQ Geneva SWITZERLAND

#### **WHO Collaborating Centres**

#### **Al Shifa Trust Eye Hospital** Dr Tayeb Afghani

Director of Projects and Consultant Ophthalmologist Rawalpindi PAKISTAN

#### **King Khaled Eye Specialist Hospital** Dr Saeed Al-Gehedan Consultant Ophthalmologist Riyadh SAUDI ARABIA

#### **Other Organizations**

#### International Agency for the Prevention of Blindness (IAPB)

H.R.H. Prince Abdulaziz Bin Ahmed Bin Abdulaziz Al-Saud Regional Chair for the Eastern Mediterranean Riyadh SAUDI ARABIA

Al Basar International Foundation Dr Syed Shariq Masood Medical Director (BCP) Al Khobar SAUDI ARABIA

#### **Al Basar International Foundation**

Dr Adel Al-Rushood Secretary General Assistant Professor, Department of Ophthalmology King Fahd University Hospital Al Khobar SAUDI ARABIA

#### Al Manhal Charitable Organisation

Dr Mohamoud Ahmed Mohamed Director, Manhal Health Care Hargeisa SOMALIA

#### Federation of Islamic Medical Associations

Professor Hafizur Rahman Director FIMA, Save Vision Islamabad PAKISTAN

#### **The Fred Hollows Foundation**

Dr Rubina Gillani Country Manager Peshawar PAKISTAN

#### Layton Rahmatullah Benovelent Trust (LRBT)

Dr Mirza Khurram Azam Lahore Hospital Lahore PAKISTAN

#### The International Association for Lions Clubs

Dr Mohamed Zidan Governor Cairo EGYPT

#### **Sight Savers International**

Dr Haroon Awan Country Representative Islamabad PAKISTAN

#### **Observers**

Dr Rajiv Khandekar Adviser and Head of Eye and Ear Care Ophthalmologist and Epidemiologist Eye and Ear Health Care Ministry of Health Muscat OMAN

Dr Zeinab Osman Professor of Ophthalmology Research Institute of Ophthalmology Cairo EGYPT

Dr Ihab Saad Assistant Professor of Ophthalmology Cairo University Cairo EGYPT

WHO Secretariat

Dr Hussein A. Gezairy, Regional Director, WHO/EMRO Dr Haifa Madi, Director, Health Protection and Promotion, WHO/EMRO Dr Oussama Khatib, Regional Adviser, Noncommunicable Diseases, WHO/EMRO Dr Abdul Hannan Choudhury, Medical Officer, Control and Prevention of Blindness, WHO/EMRO

Mrs Marianne Orfali, Senior Administrative Clerk, WHO/EMRO

Ms Yasmina Ibrahim, Secretary, WHO/EMRO

#### Annex 4

#### INTERNATIONAL CLINICAL DIABETIC RETINOPATHY DISEASE SEVERITY SCALE

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

#### Table 1. Diabetic retinopathy disease severity scale

# Proposed disease severity levelFindings observable with dilated ophthalmoscopyDiabetic macular oedema apparently absentNo apparent retinal thickening or hard exudates in posterior<br/>poleDiabetic macular oedema apparently presentSome apparent retinal thickening or hard exudates in posterior<br/>pole

#### Table 2. Diabetic macular oedema disease severity scale

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.

#### Table 3. Diabetic retinopathy (initial and follow-up evaluation)

#### Initial examination history

Duration of diabetes [A:I]

Glucose status (haemoglobin A1c) [A:I]

Medications [A:III]

Systemic 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 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]

#### WHO-EM/CPB/005/E

#### Page 41

#### Table 3. Diabetic retinopathy (initial and follow-up evaluation, cont.)

#### 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]

Source: International Council of Ophthalmology (www.icoph.org/guide/guidelist.html).

Ratings: A: Most important, B: Moderately important, C: Relevant but not critical.

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.