THE EMERGING EPIDEMIC OF DIABETIC RETINOPATHY IN INDIA

Report of a situation analysis and evaluation of existing programmes for screening and treatment of diabetic retinopathy

KNOWLEDGE TO ACTION
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PUBLIC HEALTH FOUNDATION OF INDIA

THE QUEEN ELIZABETH DIAMOND JUBILEE TRUST

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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Report of a Situation Analysis and Evaluation of Existing Programmes for Screening and Treatment for Diabetic Retinopathy

Foreword

This report provides crucial guidance on how best to tackle what is fast becoming a leading cause of blindness in the Commonwealth and around the world.

Diabetes, which has now reached epidemic levels, brings with it the devastating threat of vision loss and irreversible blindness. Of the estimated 385 million people diagnosed with diabetes globally, over 65 million are in India. This landmark research report details the provisions currently available in India to screen and treat people for diabetic retinopathy, and highlights where improvements are still very much needed.

Research was conducted across 11 major cities in India, in over 80 eye hospitals or departments, 73 diabetic clinics, and interviews conducted with 650 people with diabetes and diabetic retinopathy.

The research gathered from this study has been used to inform The Queen Elizabeth Diamond Jubilee Trust's (the Trust) five-year Initiative to tackle blindness caused by diabetes in India. The report's alarming finding that almost half of all people with diabetes had already lost vision by the time retinopathy was diagnosed shows that intervention is needed, and quickly.

The Trust's Diabetic Retinopathy Initiative is committed to ensuring that there is a reduction in blindness caused by diabetes. It will do this by improving the control of diabetes, ensuring earlier detection and treatment of sight-threatening retinopathy with high quality, affordable methods, and increasing general awareness of the condition and its risks. With early detection and treatment of diabetic retinopathy we can reduce the risk of blindness by 90%.

To guarantee sustainability, it is hoped that the models established through this Initiative will be integrated into India's national and State level health systems, and we are grateful to the close involvement of the Ministry of Health and Family Welfare, Government of India and their shared commitment to control this growing burden. The Trust also aims to replicate this work across a number of other Commonwealth countries in South Asia, the Caribbean and the Pacific over the next five years.

The Trust is proud to be working with two leading experts to deliver our Diabetic Retinopathy Initiative in India; The International Centre for Eye Health, which is based at the London School of Hygiene and Tropical Medicine, and the Public Health Foundation of India, a prominent body strengthening health systems across the country. We are extremely grateful to the hard work of all those involved in the production of this report.

The Queen Elizabeth Diamond Jubilee Trust was established with the mission to enrich the lives of citizens across the Commonwealth, to leave a lasting legacy in honour of Her Majesty The Queen. By working in alliance with our partners to tackle this growing issue, we hope to improve the lives of individuals, their families and communities across the Commonwealth by ensuring that they are no longer at risk of losing their sight.

Dr. Astrid Bonfield CBE

Chief Executive, The Queen Elizabeth Diamond Jubilee Trust

Acknowledgements

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This effort would not have been possible without the unstinted and active involvement of healthcare institutions and eye care hospitals, for providing invaluable perspectives of the field reality. For paucity of space the list is attached in Annexure 2. We thank all the hospital managements, ophthalmologists, physicians and clients attending the respective clinics, who answered all our questions patiently and passionately. We gratefully acknowledge the cooperation and heartfelt efforts made by members of the health workforce and persons living with diabetes and their care-givers for their active participation and contributions.

We are especially grateful to Dr. D Bachani, Deputy Commissioner (Non Communicable Diseases), Ministry of Health and Family Welfare, Government of India (MoHFW, GoI) and Dr. N K Agarwal, Deputy Director General (Ophthalmology), MoHFW, GoI for their vision and commitment to understand the importance of this initiative in order to strengthen national plans. The initiative owes much of its direction to the encouragement, inputs and guidance from Professor Clare Gilbert, Co-Director, International Centre of Eye Health, London School of Hygiene and Tropical Medicine.

Dr. Nikhil Tandon, Professor, Endocrinology, All India Institute of Medical Sciences (AIIMS), Dr. Rajvardhan Azad, former Chief, Dr. RP Centre for Ophthalmic Sciences, AIIMS and Dr. Praveen Vashist, Additional Professor, Community Ophthalmology, AIIMS and his team have been a pillar of strength in executing all activities and in providing thoughtful feedback at all stages. The expert input of participants at the stakeholder's consultation, who volunteered their time, was insightful, especially with regard to the study design and survey instruments (Participant list in Annexure 2). We acknowledge the support of Col. M. Deshpande and the team at HV Desai Eye Hospital, Pune in facilitating data collection in Maharashtra, and Dr. Praveen Vashist, Dr. RP Centre, AIIMS for data collection in Delhi and Jaipur.

South Asia Centre for Disability Inclusive Development & Research,
IIPH, PHFI, Hyderabad

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List of Abbreviations

AECS	Aravind Eye Care System
AIIMS	All India Institute of Medical Sciences, Delhi
AIOS	All India Ophthalmological Society
DM	Diabetes Mellitus
DR	Diabetic Retinopathy
EMR	Electronic Medical Records
FFA	Fluorescein Fundus Angiography
GoI	Government of India
HIC	High income country
HbA1c	Glycated Haemoglobin
IAPB	International Agency for the Prevention of Blindness
ICEH	International Centre for Eye Health
ICMR	Indian Council for Medical Research
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
IIPH	Indian Institute of Public Health
INDIAB	Indian Diabetes Study
INGO	International non-government organization
LCIF	Lions Club International Foundation
LMIC	Low and middle income country
LSHTM	London School of Hygiene and Tropical Medicine
LVPEI	L V Prasad Eye Institute
ME	Macular Edema
MoHFW	Ministry of Health and Family Welfare

NCD	Non Communicable Diseases
NGO	Non-government organization
NHM	National Health Mission, Ministry of Health
NPCB	National Programme for Control of Blindness
NPPCDS	National Programme for Prevention and Control of Cardiovascular disease, Diabetes and Stroke
NPDR	Non proliferative Diabetic Retinopathy
OCT	Optical Coherence Tomography
OPD	Out Patient Departments
PDR	Proliferative Diabetic Retinopathy
PHFI	Public Health Foundation of India
PMOA	Para Medical Ophthalmic Assistant
PODIS	Prevalence of Diabetes in India Study
RIO	Regional Institutes of Ophthalmology
RPC	Dr. R. P. Centre for Ophthalmic Sciences
SACDIR	South Asia Centre for Disability Inclusive Development & Research
STDR	Sight Threatening Diabetic Retinopathy
SMS	Short Messaging Service
SN	Sankara Netralaya
UN	United Nations
VR	Vitreo Retina
WDF	World Diabetes Foundation
WHO	World Health Organization

Executive Summary

Non communicable diseases (NCDs) i.e. cardiovascular disease, cancer and diabetes are recognized as increasingly important causes of death and disability globally, including among rural populations in low income countries. Diabetic retinopathy (DR) is a complication of diabetes which can lead to irreversible visual loss and blindness. However, good control of diabetes reduces the risk of sight threatening diabetic retinopathy (STDR), and it has been estimated that early detection and treatment can reduce the risk of blindness from DR by 90%. Diabetic retinopathy is likely to become a leading cause of blindness over the next 20 years and will affect the poorest people most, as 80% of people with diabetes live in low-middle income countries (LMIC).

India is home to 65million diabetics and it is estimated that this number will rise to 109 million by 2035. One out of every five people with diabetes in India has some degree of DR and an estimated 6 million have the severe, sight threatening form (STDR) which requires treatment.

Services for diabetes and diabetic retinopathy in India

In India, services for people with diabetes and for blindness control are provided by the public health system as well as private practitioners and the not for profit sector. The Ministry of Health and Family Welfare has a program for control of NCDs (the National Programme for Prevention and Control of Cardiovascular disease, Diabetes and Stroke) and for blindness (the National Blindness Control Programme). Little information is currently available concerning the services being provided and whether there are major gaps in relation to the prevention of DR or treatment of people identified with STDR.

A range of different approaches are being used by the government and not-for-profit sector in India to detect and treat DR. However, it is not known which of these approaches is most effective, sustainable, and efficient, or which approach could readily be taken to scale to meet the emerging challenge of blindness from DR.

Aim

The purpose of this study was to assess current service delivery for the management of diabetes and for the treatment of DR in government and private facilities in 11 of the major cities in India. Another purpose was to evaluate different approaches being employed by 14 leading eye care providers in India, to detect and treat DR in relation to efficiency, effectiveness, sustainability and scalability.

Methods

A. Assessment of eye care services for diabetics and diabetic retinopathy

Quantitative and qualitative techniques were used. Semi structured interviews were conducted with staff and patients in diabetic clinics and in eye clinics. An observational checklist was used to assess all aspects of the health system e.g. staffing levels, infrastructure, technology and equipment, presence of protocols and information for patients. Cities and clinics to be visited were selected focusing on geographical distribution and size. In each city government and private clinics for diabetes and eye care were selected and visited by the research team. The 11 cities were Mumbai, Ahmedabad, Bengaluru, Bhubaneshwar, Chennai, Delhi, Hyderabad, Jaipur, Kolkatta, Pune and Surat.

B. Evaluation of programmes for the detection and treatment of diabetic retinopathy:

Service providers were identified who run programmes outside the eye hospitals to detect and treat STDR. Fourteen eye providers were visited and interviewed to obtain information on the processes involved and to assess efficiency, effectiveness sustainability and scalability of each programme.

Five teams, each led by a senior public health expert with trained investigators, collected the data.

Results

73 diabetic clinics and 86 eye clinics were visited. 288 persons with diabetes and 376 persons with DR, attending eye clinics were interviewed. Fourteen hospitals undertaking screening for the detection and treatment of DR were identified across the country, 12 of which were in the not-for-profit sector.

Key finding

Almost half (45%) of the persons with diabetes attending eye units had already lost vision before the condition was diagnosed. This shows that there is considerable delay in patients seeking eye assessment in diabetes.

Services for diabetics

Not all clinics were staffed by qualified physicians.There were an inadequate number of trained counsellors, dieticians, and laboratory technicians and dedicated clinics for diabetics were not always in place. None of the diabetic clinics had a routine system for checking the eyes of diabetics although patients were often referred to eye clinics. There was a lack of protocols and clinical guidelines for managing factors known to increase the risk of DR i.e. control of blood glucose and lipids, and blood pressure. There was minimal collaboration between physicians and ophthalmologists. 60% of physicians did not know about the government's programme for the control of NCDs. 29% of diabetic patients have never had a retinal examination and they lacked knowledge of risk factors for DR. Two-thirds of patients did not monitor their blood glucose at home and many found changing their diet very difficult.

Services for diabetic retinopathy

Equipment for diagnosing and treating DR was lacking in 70% of government eye clinics and in 43% of private clinics. 25% had a waiting list for laser treatment. 50% of eye clinics identified a training need in medical retina, one-third had a trained retinal photographer and only half employed trained counsellors. Protocols and clinical guidelines for detecting and treating DR were generally lacking and only a few centres had electronic health management information systems which limited the ability to follow up and monitor patients. Most persons with DR knew that diabetes can cause blindness. 40% of patients in public and 13% in private facilities were given no information about diabetes and its complications and two thirds had received no health education. There was lack of knowledge that poor control of blood glucose increases the risk of DR.

Evaluation of programmes for the detection and treatment of diabetic retinopathy

Only two of the 14 service providers had recently started screening for DR in physician clinics: all the other providers used different methods to examine either known diabetics or by identifying diabetics first e.g. house to house visits or camps for diabetics, none of which were integrated into the health system. There was a heavy reliance on optometrists and ophthalmologists for screening and many providers referred all patients to the base hospital for assessment regardless of the severity of the DR. Written protocols concerning criteria for referral, clinical assessment, and for subsequent treatment were generally lacking. Over half had no systematic process for annual screening and over half reported that less than 50% of those referred attend for examination. Over half the providers thought their programmes to be responsive and accessible but most thought their programmes were not sustainable.

Recommendations

Close partnerships need to be developed between national programmes for the control of NCDs and of blindness, with close collaboration between physicians and eye care providers at all levels of the health system so that programmes for the detection of DR are integrated into the health system.

There is an urgent need to strengthen and build the capacity of services for diabetes and for DR, particularly in the government sector. Integrated models for the management of diabetes and its complications need to be developed and implemented at all levels. There is a need for clinical guidelines and written protocols for many aspects of care, together with improved information and counselling for patients. Electronic patient records and management information systems would help to improve follow up and monitoring of patients.

Background

Global estimates of diabetes

There is a global epidemic of diabetes largely due to increasing urbanization with associated dietary and lifestyle changes, which includes a reduction in physical activity. About 382 million people live with diabetes (8.3% of the world's adult population in 2013) and by 2035 this will have increased by 55% to 592 million. Although the main increase in diabetes has been in urban populations, there is compelling evidence that there is an increasing prevalence in rural populations also in low and middle income countries.

In many parts of the world a high proportion of people with diabetes are not diagnosed, and so are not being treated. These individuals often present to health services only when they have developed complications e.g. loss of vision, cardiovascular disease, kidney complications or foot ulcers.

The increasing global incidence of diabetes and other non-communicable diseases and their health and economic consequences has led to a global call to action with a Summit at the United Nations in 2012. The meeting was initiated as a result of advocacy by the International Diabetes Federation (IDF). The report of the next, 66th UN General Assembly stated that the response to the growing crisis would require "a whole-of-government and a whole-of-society effort" and committed to health-promoting environments, strengthening national policies and health systems, international cooperation, including collaborative partnerships, research and development, and monitoring and evaluation.

Diabetes increases the risk of a range of systemic and eye diseases, but the main cause of blindness associated with diabetes is DR. This condition is the result of damage to blood vessels in the retina at the back of the eye. It usually affects both eyes and can lead to vision loss if not detected early and treated. Poorly controlled blood sugar levels, high blood pressure and high cholesterol increase the risk. Clinical studies spanning 30 years have shown that treatment, which includes surgery, can reduce the risk of blindness by more than 90% if the DR is detected and treated early. Once vision has been lost it usually cannot be restored. Every person with diabetes is at risk of DR.

People with diabetes are 25 times more likely than those in the general population to become blind. From an individual's perspective, visual loss is one of the most feared potential complications that can develop as a result of poorly controlled diabetes. More than 75% of people who have had diabetes for more than 20 years will have some form of DR and 10% will have retinopathy requiring treatment because it is sight threatening.[5]

Diabetes in India

Diabetes, mainly Type 2, is now of major public health concern in India. Studies in different parts of the country reveal a high and increasing prevalence in both urban and rural areas, with a higher prevalence being reported from urban areas. Most of this evidence comes from south and central India. In South India, the prevalence of diabetes among adults is estimated to be around 20% in urban areas and nearly 10% in rural areas.[6] These figures show a steep increase compared to studies nearly a decade earlier.

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[1] International Diabetes Federation, Diabetes Atlas accessed at www.idf.org/diabetesatlas, Sixth Edition, 2013

[2] World Health Organisation (WHO), Report by the secretariat: Outcomes of the High level meeting of the General Assembly on the Prevention and control of Non communicable Diseases and the First Global Ministerial Conference on Healthy Lifestyles and Non communicable disease control accessed at http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_6-en.pdf, A65/6, 2012

[3] WHO, Prevention of blindness from Diabetes Mellitus: report of a WHO Consultation in Geneva, Switzerland (9-11 November 2005), 2006

[4] Khan S, Wong S et al. Fundamentals in diabetes. Part 2: Diabetic retinopathy Journal of Diabetes Nursing Vol 15 No 8, 2011

[5] Ibid no. 3

[6] Unnikrishnan R et al, Diabetes in South Asians: Is the Phenotype Different? Diabetes 2014;63:53–55 | DOI: 10.2337/db13-1592

The Prevalence of Diabetes in India (PODIS) Study showed that among adults aged 25 years or more, the prevalence of diabetes was 3.3% and an additional 3.6% had pre-diabetes with fasting that were higher than normal blood glucose levels.[7]

Available estimates show that there are 65.1 million people in India with diabetes and that this number will rise to 109 million by 2035. A large study (14,000 participants) undertaken in four Indian states by the ICMR (INDIAB Study), estimated that there were 62.4 million people with diabetes and 77.2 million people with pre-diabetes in India in 2011.

The 'epidemic' of diabetes in India is fueled by a number of factors. Lifestyle changes due to rapid urbanization, low birth weight and genetic predisposition have contributed to this situation. Low birth weight may result in insulin resistance and hyperinsulinemia leading to the 'thin-fat Indian' i.e. where there is a higher proportion of body fat in adult life for any given body mass index than in Europeans. Rates of low birth weight are high (25-40%) in India, and may be contributing to the rapid increase in NCDs given the change in diet and levels of physical activity. Studies have also shown that Asian Indians have a strong genetic predisposition to diabetes as nearly 75% of people with type 2 diabetes in India have a first degree relative with diabetes. These factors coupled with a sedentary lifestyle and a high glycaemic index diet further increase the risk of diabetes.

Global estimates of diabetic retinopathy

Globally there are approximately 93 million persons living with DR, 17 million with the proliferative type and 21 million with the treatable form of macula oedema (swelling). Approximately 38 million people with diabetes therefore have ST-DR and 1.85 million people are blind from diabetic retinopathy.
Although diabetic retinopathy is currently not a major cause of avoidable blindness in low-middle income countries (LMICs), it has the capacity to become the leading cause over the next 20 years, affecting the poorest people as 80% of people with diabetes live in LMICs. Studies undertaken in the past in industrialized countries demonstrate that people who become blind from DR have a limited life expectancy. This reflects the fact that retinopathy often goes hand in hand with other systemic conditions such as renal failure and cardiovascular disease.

Diabetic retinopathy in India

An estimated 6 million diabetics in India have sight threatening retinopathy. If the proportion of diabetics with STDR remains the same over time, the number will increase to over 10 million by 2035. As the duration of disease is a major risk factor for DR, and the epidemic of diabetes matures in India, the number with sight threatening disease is likely to continue to increase.

The proportion of people with diabetes in India who have diabetic retinopathy lies in the range of 18-26%. A number of small surveys of diabetes have been undertaken in different parts of the country, but data from a nationally representative sample are lacking. There are no estimates of the actual number of people who are blind from diabetic retinopathy in India as most national blindness surveys were undertaken one to two decades ago, and the other surveys were confined to small local areas and the findings are, therefore, not generalizable.

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[7] Sadikot M et al, The burden of diabetes and impaired fasting glucose in India using the ADA 1997 criteria: prevalence of diabetes in India study (PODIS), Diabetes Res Clin Pract. 2004 Dec;66(3):293-300.
[8] Ibid no. 1
[9] Anjana RM, Pradeepa R et al., Prevalence of diabetes and prediabetes (impaired fasting glucose and/or impaired glucose tolerance) in urban and rural India: phase I results of the Indian Council of Medical Research-INdia DIABetes (ICMR-INDIAB) study. Diabetologia. 2011 Dec; 54(12):3022-7. doi: 10.1007/s00125-011-2291-5. Epub 2011 Sep 30.
[10] Yau JWY et al, Global Prevalence and Major Risk Factors of Diabetic Retinopathy, Diabetes Care 35:556–564, 2012
[11] Ibid no. 3

Evidence suggests that early detection and management is the key to control visual loss and blindness due to DR. Although the genetic risk cannot be addressed, many lifestyle factors like obesity, diet and physical activity are eminently modifiable, leading to a reduced risk of DR. For example, a three year prospective study of patients with impaired glucose tolerance in India showed that consistent lifestyle modification prevented progression to diabetes, with rapid progression from impaired glucose tolerance to diabetes in the non-intervention study groups.

Existing strategies and programmes for reducing incidence of diabetic retinopathy

Policy

Diabetic retinopathy is mentioned within comprehensive eye care in the national programme for control of blindness but it is not listed under management of diabetes under non communicable disease programmes in India documents. Advocacy is therefore needed to ensure that control of DR is included in the Ministry of Health policies and operationalized.

Services

Limited information is available concerning the services available for the care of diabetics in India, and whether control of risk factors for DR are being considered or prioritised. Little evidence is available concerning what people with diabetes know about retinopathy or whether they undergo regular retinal examination. Similarly, limited information is available concerning the capabilities and capacity of eye care providers to diagnose and treat DR, this being critical, if programmes for detection and treatment are to be taken to scale. Lastly, although there are several initiatives for the detection and treatment of DR in India, mainly by not-for-profit eye care providers, these programmes have not been formally evaluated for sustainability and their potential to be taken to scale.

To address the growing challenge of visual loss from diabetic retinopathy in India a multi-sectoral approach will be required, and services for the prevention, detection and treatment of DR will be required at all levels of service delivery. Before recommendations can be made on where initiatives should focus, information on gaps in current services as well as optimal approaches for the detection and treatment of diabetic retinopathy is urgently required. This situation analysis was undertaken to assess existing services, the availability of trained, human resources, equipment and other infrastructure for the care of diabetics and of DR, referral mechanisms, health information systems and collaborations. Another purpose was to identify and evaluate different approaches for the detection and treatment of DR to identify which models could potentially be taken to scale, and to learn lessons on 'what works' and how effectively.

The findings will be used to recommend strategies and approaches that can be adopted to strengthen the health system in India to address the growing threat of visual loss from DR.

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[12]International Diabetes Federation, Diabetes Atlas accessed at www.idf.org/diabetesatlas, Fifth Edition, 2011
[13]Ramachandran A et al., Cost-Effectiveness of the Interventions in the Primary Prevention of Diabetes Among Asian Indians: Within-trial results of the Indian Diabetes Prevention Programme (IDPP), Diabetes Care, Volume 30, No 10, October 2007

Aims and Objectives

Aims

- To assess services for the management of people with diabetes and for DR in hospitals and clinics in the largest (most populated) cities in India
- To evaluate existing approaches for the detection and treatment of STDR, and to document best practices in relation to responsiveness, acceptability, efficiency, equity and sustainability

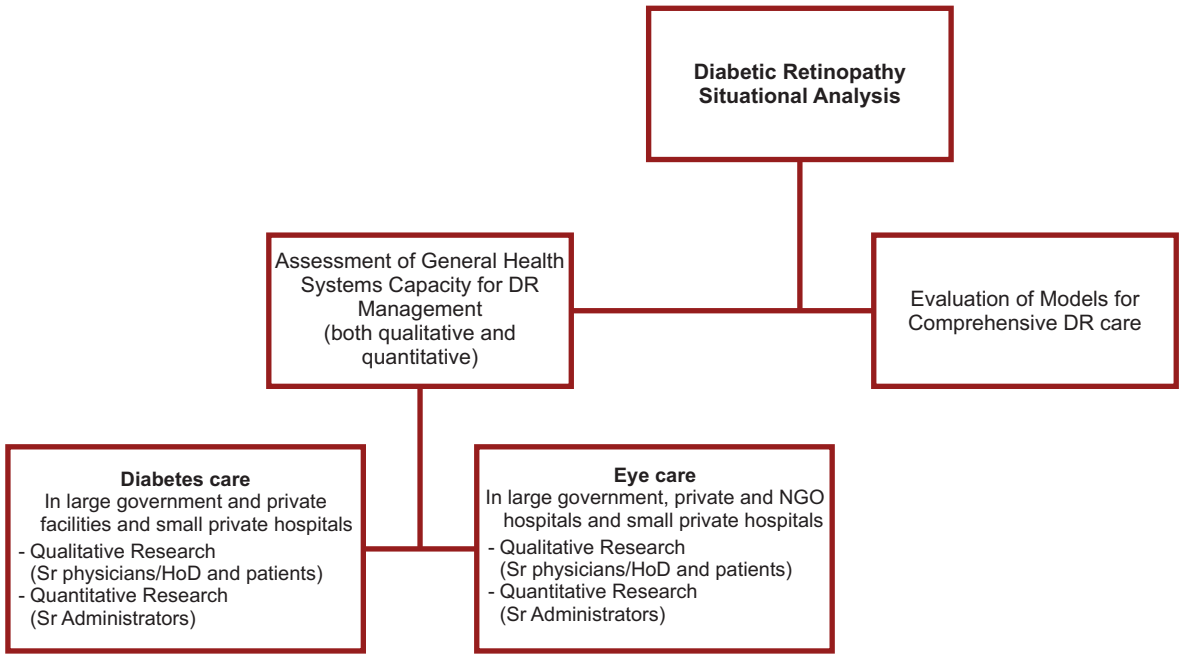
Specific Objectives

1. Review current policies for NCDs, focusing on diabetes, complications and control;
2. Map large public and private sector institutions providing services for diabetics and for diabetic retinopathy (physician and eye care facilities) in the largest cities in India;
3. Ascertain the workload and strategies adopted for diabetic retinopathy and referral pathways;
4. Determine the proportion of diabetics who know about eye complications of diabetes, and the proportion who have had a retinal/eye examination;
5. To assess the capacities of eye care hospitals (both private and public sector) to manage diabetic retinopathy, and whether they are proactive in detecting sight threatening diabetic retinopathy needing treatment;
6. Undertake in-depth evaluation of 6-8 models for detecting sight threatening diabetic retinopathy, which are known to have different approaches (e.g. Telemedicine; eye camps for diabetics; mobile training and treatment); and
7. Identify best practices for screening and management of diabetic retinopathy.

Methodology

Mixed-methods, including quantitative and qualitative techniques were used to assess health services. In order to understand all facets of the health system and capture data with regard to current practices, two broad streams of data were collected (Figure 1).

Figure 1. Sources of data collected during the study



Location of the situation analysis of services and rationale

Assessment of services for diabetics and for diabetic retinopathy

A wide consultative process was adopted to decide where the study should take place and which cities to include. As the prevalence of diabetes is higher in urban than rural areas a decision was made to focus on services in urban areas, recognizing that these would probably represent the best available in India. Many of the services in urban areas are tertiary level referral centres for specialist care for neighbouring districts and smaller towns. If the services in these cities were sub-optimal, it is highly unlikely that services in smaller cities and towns would be better.

Selection of cities

All cities in India were ranked in descending order of population size (2011 census) and the 10 most populated cities were selected. As only one city (Kolkatta) was in eastern India another was added – Bhubaneshwar making a total of 11. Sampling was done using a two stage process wherein cities were first stratified based on their population (more than or less than 8 million). The 11 cities were Ahmedabad, Bengaluru, Bhubaneshwar, Chennai, Delhi, Hyderabad, Jaipur, Kolkatta, Mumbai, Pune and Surat.

Selection of services

In each city public and private providers of services for diabetics and eye care providers were identified. Two key variables were chosen to determine the selection of clinics in each city where diabetics are cared for and eye care facilities to ensure a range of size and public and private facilities. Table 1 shows the number of facilities selected by size, sector and number of patients recruited in diabetes and eye facilities.

I. Size of facility

- **Diabetes care facility**
    - Multi-specialty hospital – 100 or more bedded hospital with three or more specialties providing services under one roof
    - Polyclinic – facilities with more than 30 beds with three or more specialties providing services under one roof
    - Stand-alone diabetes clinics – physician/endocrinologist run facilities providing only medical care for diabetes patients
- **Eye care facility**
    - Large dedicated eye hospitals- 20 or more bedded hospital with functioning ophthalmic super-specialty services
    - Hospitals with satellite facilities - eye care hospitals operating from more than one location (offering complete/part services) linked through referral mechanisms
    - Eye care departments in General Hospitals – eye department operating in a multidisciplinary hospital
    - Eye practitioners - individual ophthalmologist practice

II. Service provider i.e. government, not-for-profit or private

Selection of persons living with diabetes and diabetic retinopathy for interview

Patients were randomly sampled at Diabetes and eye care hospital or clinics. Prior permission was taken from the hospital administrators at the clinic/facility. At each diabetic care facility 4-6 diabetes patients were identified among those waiting for doctor's consultation. Care was taken to select equal numbers of males and females. Two patients each, in each of the following age groups (<40 years, 40-50 years, 51-60years and >60 years) were interviewed.

Similar procedures were followed in eye care facilities but here, the patients were only recruited after they were identified as having DR by the ophthalmologist. Since it was very difficult to identify younger patients with DR, in some cities only three age groups (< 50 years; 51-60 years and > 60 years) were recruited. Interviews were conducted by trained interviewers using structured questionnaires.

A. Assessment of services for care of diabetics and of diabetic retinopathy

Semi structured interviews were conducted with physicians/diabetologists and eye care providers. In both types of service each of the six elements of the World Health Organization's framework for health systems were evaluated: i.e. number of staff and their skills; availability of infrastructure, equipment, laboratories and medication; whether clinical guidelines and protocols were available as well as information for patients. In both types of clinics, patients were interviewed to assess their knowledge of diabetes and DR, to assess their health seeking behaviour and the challenges they face in controlling their diabetes and/or in accessing services.

Table 1. Sampling strategy for diabetic and eye care facilities

Diabetic Units<8m	<8m cities	>8m cities	Sampling process
Large government DM/general clinics	2 or 3	4-5	Randomly selected if more
Large private DM clinics	2 or 3	4-5	Randomly selected if more
Small private practitioners	4 to 6		Purposive / snow balling
Total number of clinics:	**10-12**		
Patients with diabetes	5-6/clinic		Purposive: men & women aged ≥40 years
Eye Units providing services for DR	**<8m cities**	**>8m cities**	
Large government eye hospitals/clinics	2 or 3	4-5	Randomly selected if more
Large private eye hospitals/clinics	2 or 3	4-5	Randomly selected if more
Private not for profit eye hospital/clinics	1 or 2		Randomly selected if more
Private for profit eye practitioners	4 to 6		Purposive / snow balling
Total number of clinics:	**10-12**		
Patients with DR	5-6/clinic		Purposive: men & women: 40-59years (x3); >60 years (x3)

Data collection instruments

Personnel managing the programmes were interviewed and data was recorded using pretested data collection instruments. A consultation of key stakeholders was organized to finalize the methodological questions, instruments and scope of the study. The following protocol was followed:

Diabetes care

- Interviews with Senior Administrator/ Heads of Endocrinology Department on diabetes services in relation to DR
- In-depth interviews with Senior Physician/ Heads of Endocrinology/ internal medicine units
- Interviews with Counselors and Dieticians
- Observation at field visits.
- Interviews with patients attending diabetic clinics

Eye care

- Interviews with Senior Administrator/ Heads of Ophthalmology Department on eye care services for DR
- In-depth interviews with Senior Physician/ Heads of Ophthalmology Departments/ eye clinics/ retina units
- Observation at field visits
- Interviews with DR patients attending eye hospitals

Five experienced teams collected data simultaneously after a two-day training at Hyderabad.

B. Evaluation of models for the detection and treatment of diabetic retinopathy

An evaluation of models for detecting sight threatening diabetic retinopathy used by 14 eye providers was conducted to identify best practices for screening and management. The criteria for selecting these models were:

- Different approaches (e.g. telemedicine; eye camps for diabetics; mobile training and treatment)
- Hospitals providing large community-based screening programmes for DR, both Government and private facilities.

After selection of suitable institutions (Annexure 2), a team of senior community eye care physicians developed a framework and protocol for mapping and analyzing services in terms of human resources, protocols, validity of screening procedures, monitoring and follow up of treatment and impact in improving uptake. Information was collected on the processes used in all steps of the programme, from how diabetics were identified for screening through to policies on follow up after treatment.

Multiple approaches were used to assess parameters such as collaboration and partnerships, financial sustainability, comprehensiveness and responsiveness of services; referrals between eye care and diabetic care, and the coverage and cost effectiveness of programmes. First, a range of closed ended questions were administered, drawing on the published literature whenever possible, followed by a detailed observation checklist on service provision, manpower, infrastructure, governance structure, community outreach program, etc. was used to collect information. Finally, service providers were asked to rank their service on a scale of 1 (low) to 100 (high) for each parameter indicated in the enclosed format.

Tools for data collection

Data collection instruments for this component of the study were semi-structured questionnaires and check lists for observation (Appendix 1).

Pre testing data collection instruments

The pre testing of data collection instruments was done in an eye care hospital and a general hospital in Sangareddy District of Andhra Pradesh. Some questions were dropped and others modified, especially those deemed sensitive to answer, based on the pretest. The instruments for patients/ counselors/ dieticians were then translated into regional languages (Marathi, Tamil, Kannada, Oriya, Bengali, Gujarati, Telugu and Hindi languages) using services of a professional agency and back translated to verify accuracy of translation. Patient information sheet and consent forms were also translated into eight regional languages and back translated.

Data management and analysis

The data management and data cleaning procedures included the following steps:

- Development of a database for all relevant questionnaires in MS Access2010
- In depth interviews with counselor at diabetes clinics
- Interview with diabetic patients in diabetic clinics
- Interview with patients with diabetic retinopathy in the eye clinics
- Services for diabetic patients in relation to diabetic retinopathy at physician clinics
- Eye care services for diabetic retinopathy
- Evaluation of programmes for screening and treating diabetic retinopathy.

Features to reduce data entry error were put in place using techniques for:

- Validation
- Skip pattern
- Drop down menu
- Auto calculation, etc.

Data were entered by trained data entry operators. For the purpose of data protection, a login and password was created and copies of the database were stored in three different systems. Data were then cleaned using appropriate steps and transferred into Stata and R software for analysis. Numerous cross classified tables with a focus on the counts/frequencies of various facilities of DR at the different component levels available in context to public and private infrastructure were computed. Bar graphs and pie-charts were also created to visually represent the data.

States, cities, services and patients included in the study

A total of 856 sampling units in 11 cities in 9 States were included in the study over a four month period (Table 3). The cities included in the study represent 7% of India's population.

A total of 73 diabetic clinics (government and private) and 83 eye hospitals (government and private) were visited and data was collected on equipment and service provision. In the diabetes clinics, staff (physicians and counselors/dieticians) and patients (288) were interviewed. In the eye care facilities staff and 376 patients attending the retina service were interviewed.

The cities and the States where they are located, and details of the services visited in each city are shown in Figure 2 and Tables 2 and 3.

Figure 2. Location of cities selected for the study

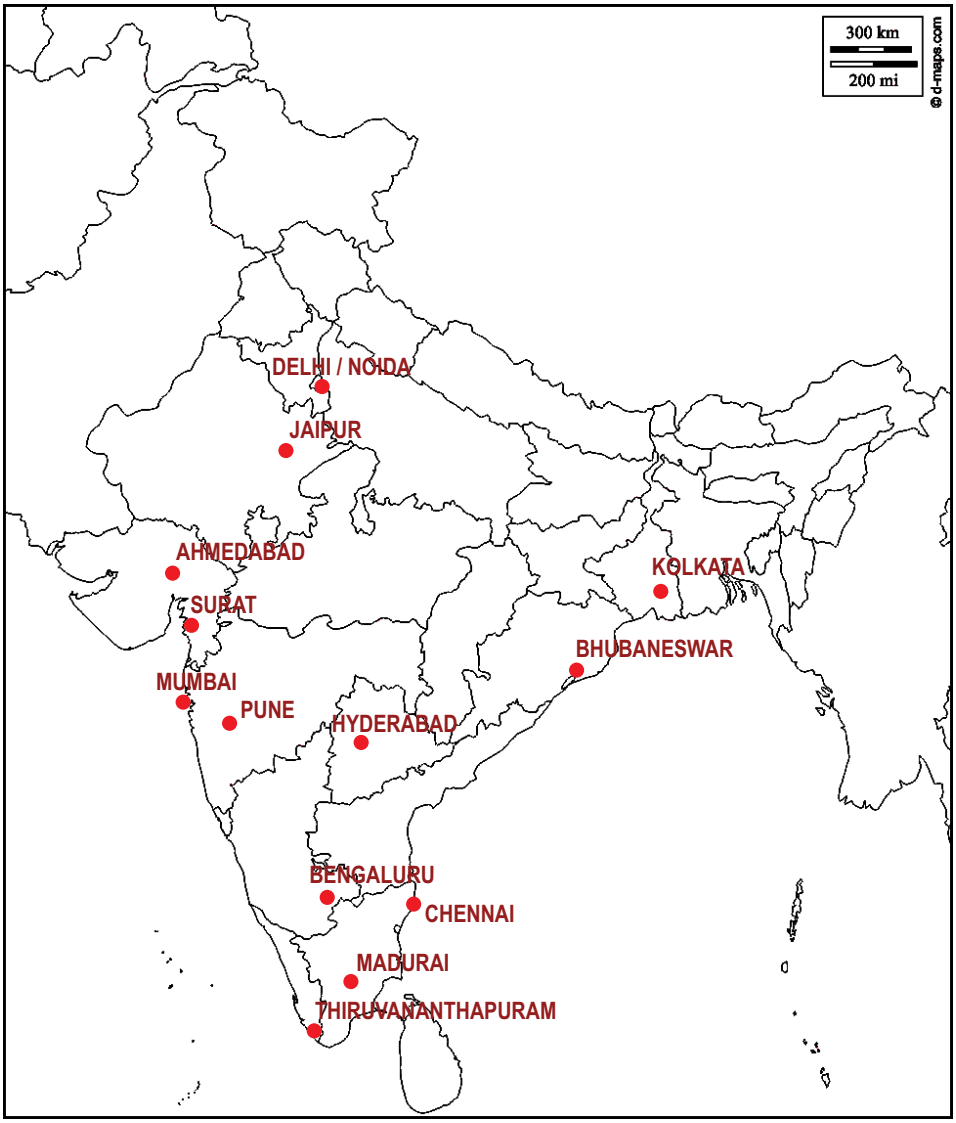


Table 2. Brief description of units and persons included in the sample across India

		Eye Care Units			Diabetic Care Units			
City	Pop. (millions)	Eye Units	Eye patients	DR Models	Diabetic Units	Diabetic patients	Counsellors /dieticians	Total
Mumbai	12.5	8	17	1	10	24	1	61
Delhi	11.0	14	33	2	11	21	4	85
Bengaluru	8.4	9	48	1	6	30	4	98
Hyderabad	6.8	7	57	2	6	40	3	115
Ahmedabad	5.6	9	53	1	9	57	3	132
Chennai	4.7	7	31	2	4	22	2	67
Kolkata	4.5	6	32		2	27		67
Surat	4.5	8	50	1	7	15		81
Pune	3.1	6	21	1	8	15		51
Jaipur	3.1	9	18		8	18	4	57
Bhubaneshwar	0.8	3	16		2	19	1	41
Additional cities where diabetic retinopathy screening programs were visited								
Thiruvanthapuram				1				1
Noida				1				1
Total		**86**	**376**	**14**	**73**	**288**	**22**	**837**

Table 3. Facilities and participants included in the study against targets

Facility / participants	Planned	Included	Achieved (%)
Services for diabetics			
Diabetic clinics	75	73	97
Counselors/ dieticians	26	22	85
Patient interviews in diabetic clinics	300	288	96
Services for eye care	85	83	98
Eye hospital diabetic services	85	83	98
Patient interviews in retina clinics of eye hospitals	375	376	100
Programmes for the detection and treatment of diabetic retinopathy			
Evaluation of diabetic retinopathy models	14	14	100
Total Units	**875**	**856**	**98**

The 14 programmes evaluated were run by eye hospitals/departments in Bengaluru, Delhi, Chennai, Hyderabad, Madurai, Pune, Mumbai, Surat, Ahmedabad and Thiruvanthapuram. Twelve hospitals were in the not-for-profit private sector, and some hospitals ran more than one programme, using different approaches.

Results

The most startling of all findings is that 45% of patients attending eye units with diabetic retinopathy had already lost vision before the condition was diagnosed.

This shows that too little is being done too late.

A. DIABETIC CLINICS - SERVICES FOR DIABETES CARE AND EYE CARE

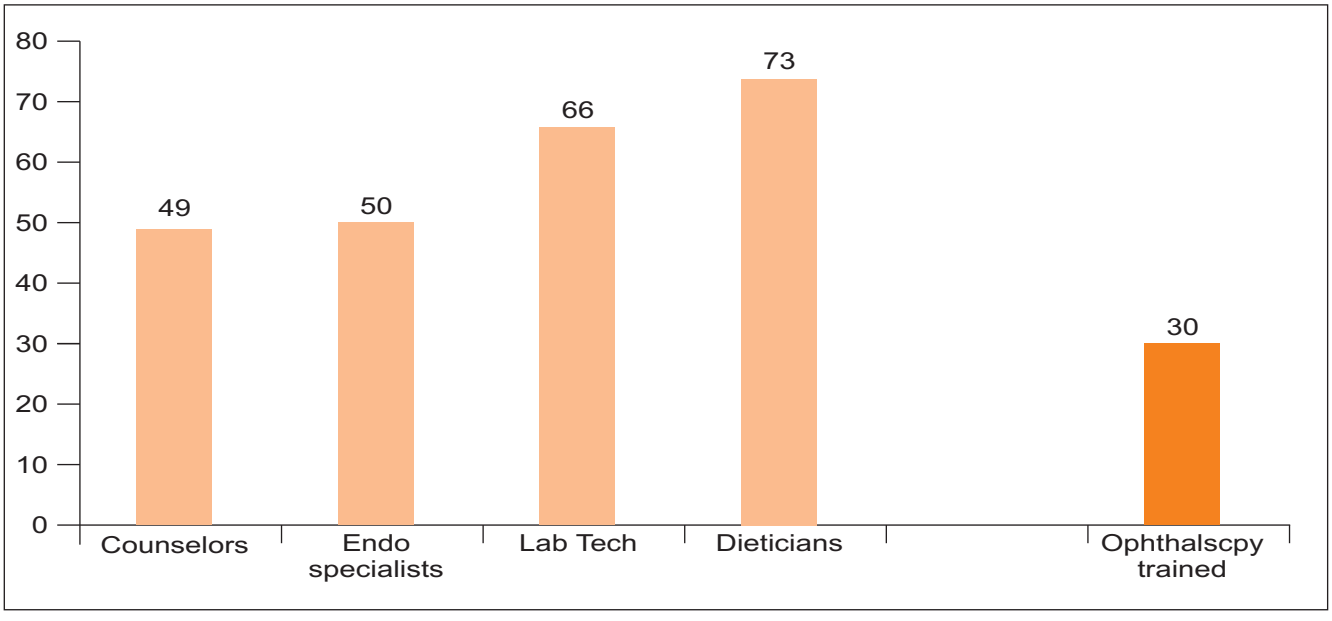
Human Resources

Lack of personnel in relation to numbers, training and orientation was noted in the following areas:

- 49% of clinics did not have a counselor
- 66% of clinics did not have a laboratory technician
- 73% of all facilities had no dietician
- 70% of medical staff were not trained in direct ophthalmoscopy
- 60% of physicians were not aware of the National Programme for Prevention and Control of Diabetes, Cardiovascular Disease and Stroke (NPCDCS).

Interviews with support staff (i.e. dieticians and counsellors) revealed gaps in practice related to detection of diabetic complications, especially regarding eye complications. Only 40% of these personnel knew that diabetes can cause blindness.

Figure 3. Human resources at diabetic clinics (%)

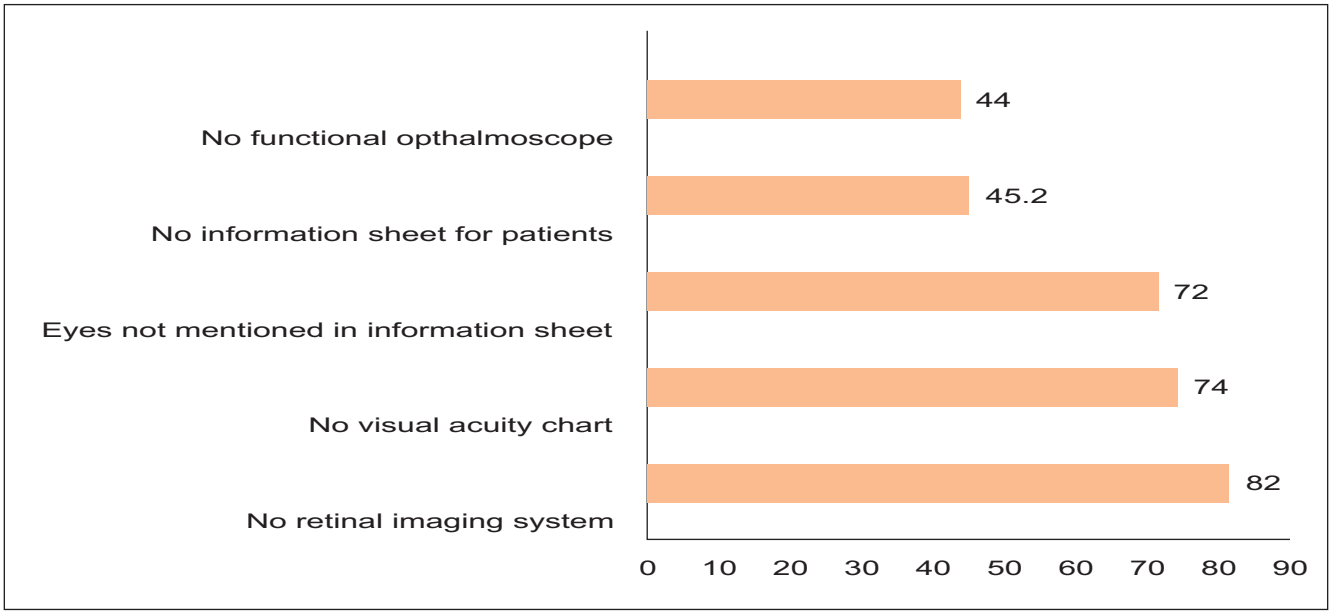


Equipment

Infrastructure and diagnostic equipment

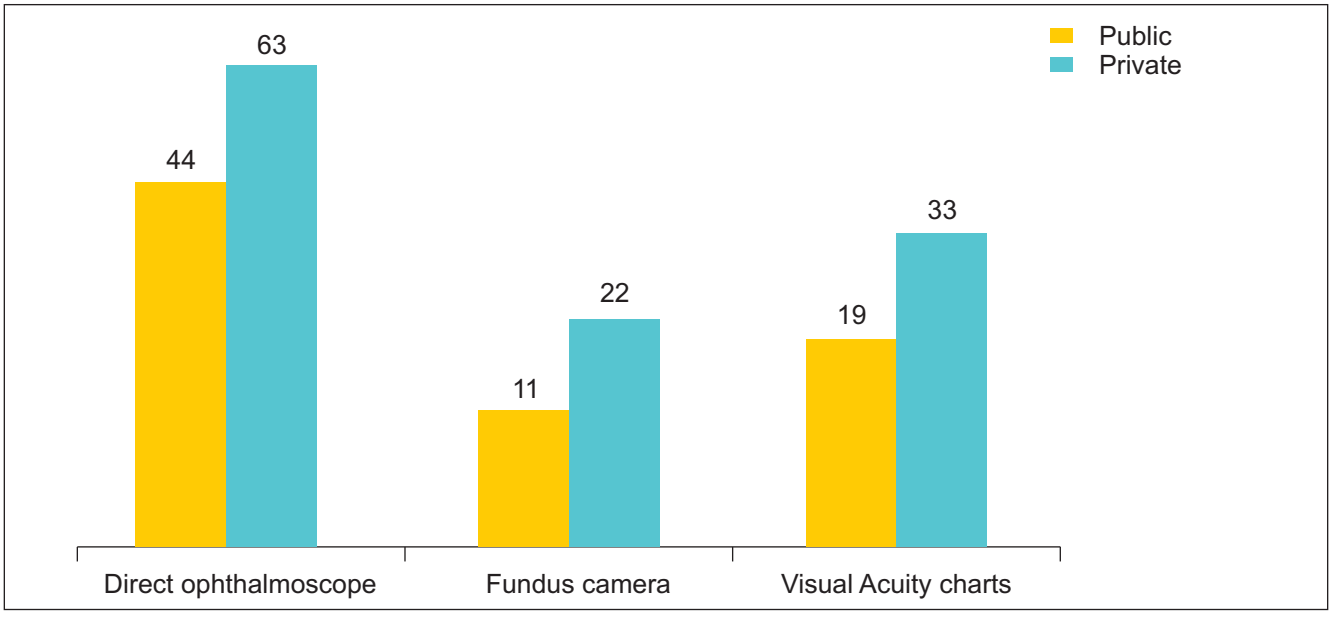
Approximately 74% of all diabetes clinics did not have a vision testing chart, 52% did not have an ophthalmoscope and 88% did not have any mechanism in place for retinal imaging. Information sheets were generally not available(55.8%) and where they were available 72% did not mention the ocular complications of diabetes.

Figure 4. Materials and equipment available at diabetes clinics



Private diabetes clinics were considerably better equipped to detect diabetic retinopathy than clinics in the public sector (Figure 5). Only 63% of private diabetes clinics and 44% of public clinics had a functional direct ophthalmoscope. Nearly double the number of fundus cameras and visual acuity charts were available at private clinics compared to public-funded clinics.

Figure 5. Functional equipment for eye examination at diabetic clinics, by type of provider (%)



Protocols/ Patient Information sheets/ MIS

Screening and treatment protocols

80% of diabetic clinics did not have written protocols on the management of diabetes complications. About 20% of physicians stated that they routinely examined the retina at the first visit. More than half the clinics (59%) did not have facilities in house to measure HbA1C (a better measure than blood glucose) being higher in public (44%) than private facilities (15%).

Health Information Systems

Close to 90% of diabetes clinics used paper medical records. As a consequence only 55% stated that they could access eye data of patients. Approximately 80% of these facilities stated that they would value Electronic Medical Records (EMR), and 57% thought establishing EMR would be feasible in their hospital.

Services provided at Diabetic Clinics, especially for DR

Most hospitals lacked dedicated clinics for diabetics with only 11% of public and 54% of private facilities having dedicated clinics. Three quarters of the medical staff were general physicians. A majority of public funded facilities provide no service for DR. Only a fifth of the physicians examined fundus routinely on the first visit. Information sharing with patients was also cited as lower in public facilities when compared to the private sector. Only 42% of patients were provided any information sheet. Most of the clinics providing information sheets were in the private sector.

Perspectives of physicians, counsellors and dieticians

Physicians' perspectives

Almost all the physicians interviewed acknowledged the importance of screening for diabetic retinopathy. But most felt it was an ophthalmologist's care area and they lacked time, instruments and training support to do the same. About two-thirds of the physicians interviewed were not aware of the National programme, NPCDCS.

Referral between physicians and eye care providers

More than two-thirds of the physicians said they regularly sent patients to an ophthalmologist for an eye examination (73%). Nearly 55% of physicians also stated that they regularly received referrals from ophthalmologists. There was no mechanism for tracking or ensuring whether the referred patients underwent retinal screening once referred. Referral pathways for the management of complications were not clearly defined and feedback from consultations sent to the ophthalmologists was rare.

Excerpts of statements from some physicians

'I first say that this is a silent disease and a silent killer. You don't wait till you get symptoms, if you get symptoms of the eye - you are lost…..if you get symptoms of a heart attack - you are lost, so prevent them.'

'If I ask a patient "Have you gone for an eye exam?" he will say "Yes, I go yearly". But, nobody explains to him that diabetes affects your retina…'

Perceptions of diabetic clinic counsellors / dieticians

Counsellors or dieticians reported that 60% of patients attend the clinically regularly and 41% patients monitor their blood sugar at home. Over three quarters reported that patients found it very difficult to change their diet as a means of controlling their blood glucose levels.

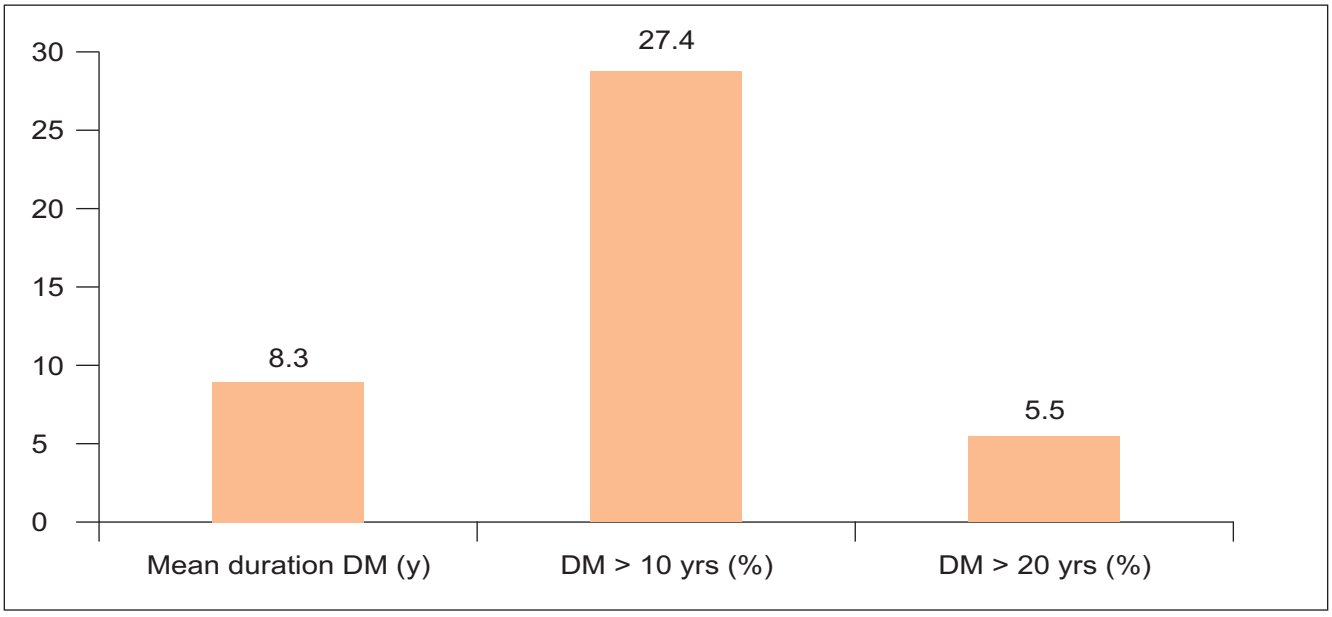
Only 27% of counsellors or dieticians reported talking to their patients about the need for an eye examination, despite knowing that renal and eye complications are the commonest complications.

Patients' perspectives from diabetic clinics

288 diabetic patients were interviewed in diabetes clinics.

The mean duration of diabetes since diagnosis amongst patients interviewed was 8.3 years. About a fourth had been diagnosed as diabetic for over ten years and about 5% had the disease for more than 20 years. 68% reported that they did not have any complications of diabetes, while 15% were under treatment for DR and 17% had other complications.

Figure 6. Characteristics of Clients with Diabetes Mellitus

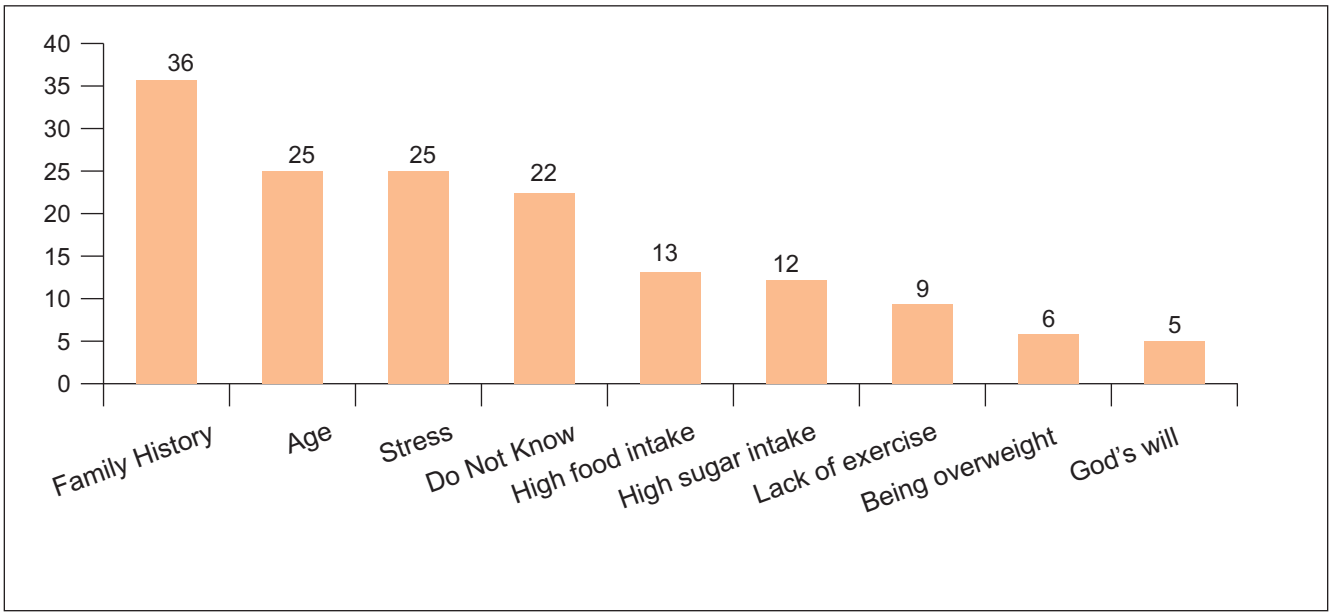


Patient awareness about risk factors for diabetes

Awareness about modifiable risk factor for diabetes was very poor with only one in seven or less being aware of diet, lack of physical activity or being overweight as key risk factors for diabetes (Figure 7). About one in four identified stress and two in five said a family history of diabetes, are important risk factors. 22% of clients were not aware of the cause diabetes. The mention of God's will (5%) is significant as it reflects a fatalistic attitude towards control whether in the form of medication or lifestyle change.

Only 4% of patients had their retina examined at the first attendance and none had annual retinal examinations (clinical examination or photography).

Figure 7. Perceptions on cause of diabetes(%)

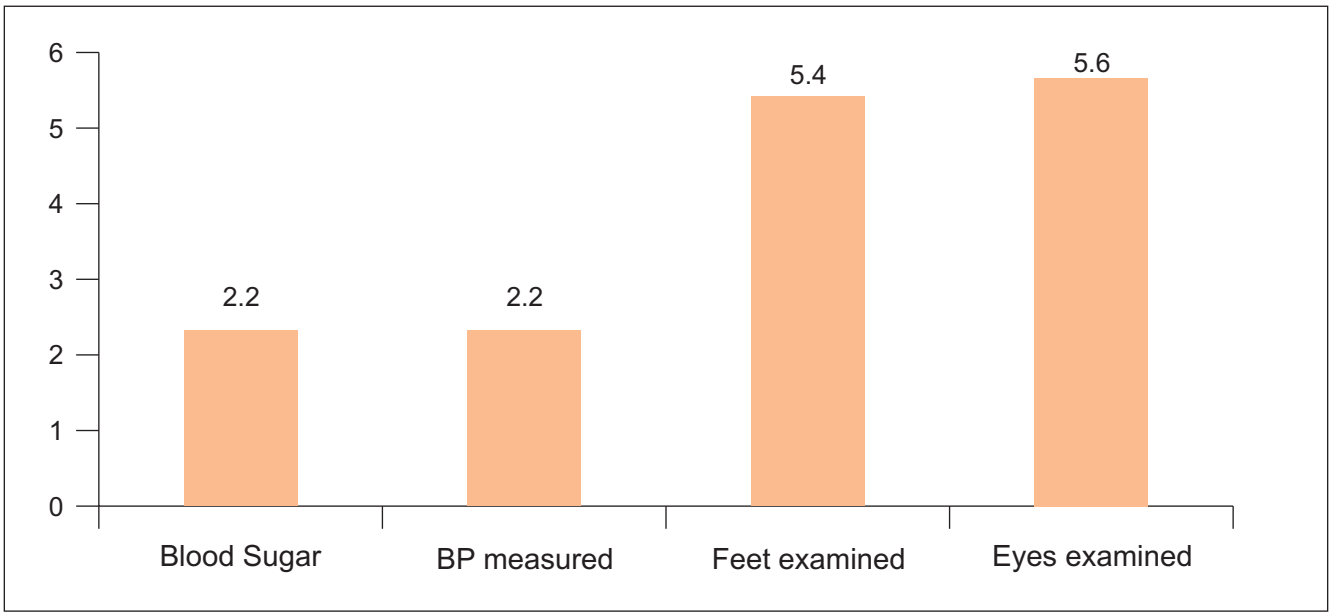


Patient recall of services rendered at diabetic clinics

All patients were asked about when they last visited a diabetic/physician's clinic and what services were provided at that visit.

Based on recall, it was observed that the mean time that elapsed since the last examination at a diabetic clinic was about 2 months for Blood sugar and Blood pressure (Figure 8). It was observed that eye examination was done at an average interval of 5.6 months.

Figure 8. Mean duration of different services accessed by patients based on patient recall (months)



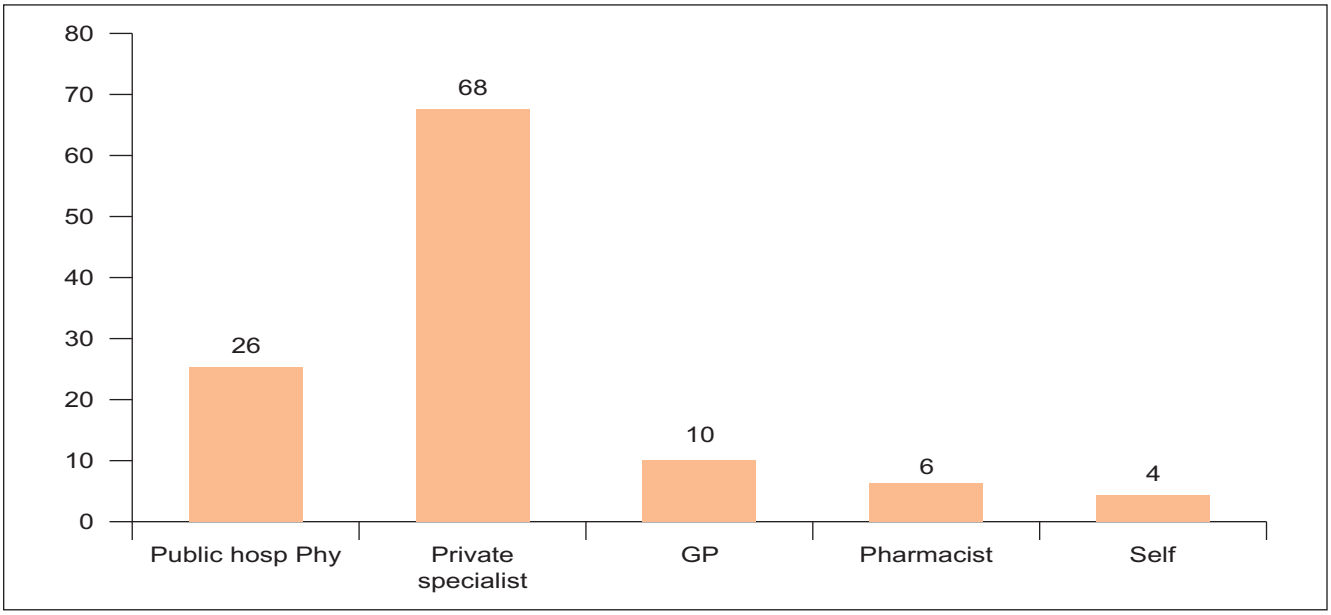
Provider preferences

Private specialists were the most sought after providers with 68% of all clients reaching them for a consultation (Figure 9). Only 26% of all clients interacted with a dietician, 15% met with a counselor and 10% consulted an optometrist/ vision technician at OPD visits. Interactions with pharmacists were also directed towards gathering information regarding DR (6%). About 4% of clients also reported that they relied mostly on information sourced by themselves (4%).

Interactions with providers

Patients were interviewed on how long their consultations lasted to share the average time that they usually spend at the diabetic clinic for a consultation, as a total of the activities including recording case histories, providing treatment-related information or health education. The mean time for a consultation/ interaction was found to be 12.2 minutes.

Figure 9. Providers consulted for Diabetes Management (%)



Challenges in controlling diabetes

Only 45% of patients really understood what controlling their diabetes meant, and 26% thought their diabetes was poorly controlled.

Two-thirds of patients did not monitor their blood glucose at home

70% of patients in public and 40% in private facilities did not know that good control of diabetes meant keeping glucose within certain levels

Table 4. Patient responses regarding controlling diabetes

	Challenges in controlling diabetes	%
Life style factors	Changing diet	45%
	Exercise	18%
Costs	Cost of Investigation	10%
	Cost of Medication	13%
	Loss of wages	6%
Difficulty remembering	Clinic appointment	8%
	Remembering medication	14%
Other reasons	Lack of time	9%
	Distance to the clinic	9%
	Accept being diabetic	4%
	Other	10%

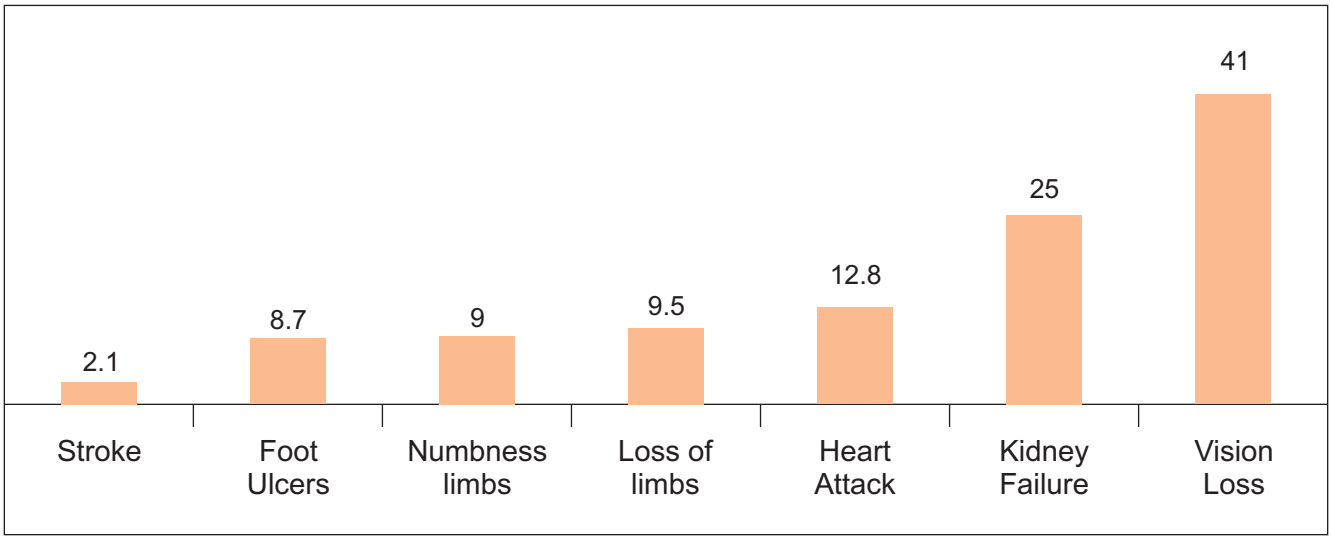
The major problems in managing diabetes for DM patients were in the form of lifestyle modification, i.e. maintaining an appropriate diet and regular exercise (for nearly 45% of all patients) (Table 4). The costs of investigation and medication were the second most prohibitive factor as cited by 26% of DM patients. Distance to the clinic, which would imply transportation costs and loss of wages, was also highlighted. Remembering appointments and medication were the other significant challenges in DM management (26%).

Patient perception of complications

84% of diabetic patients knew about the complications of diabetes and 73% knew about the eye complications with 41% knowing that diabetes can lead to vision loss. Indeed, blindness was the complication patients feared the most (Figure 10).

Vision loss was the complication feared most by the clients interviewed (Figure 10).

Figure 10. Complications of concern to all diabetics (%)



Patient awareness about Risk factors for Diabetes Mellitus

Awareness about modifiable risk factors among diabetic patients was very poor with only one in seven or less being aware of diet, lack of physical activity or being overweight as key risk factors. About one in four identified stress and two in five stated family history as important risk factors.

There was a lack of awareness about risk factors for complications among diabetics: 40% did not know that hypertension was a risk factor and 65% did not know about high cholesterol. In relation to diabetic retinopathy a significant proportion were not taking any steps to detect diabetic retinopathy.

The mention of "God's will" (5%) is significant as it reflects a fatalistic attitude towards treatment, either in the form of medication of lifestyle change. 22% of clients were not aware of the cause of diabetes.

Excerpts from diabetic patient interviews

'Services should be integrated and interlinked so that the poor common man can get facilities very easily in less time'

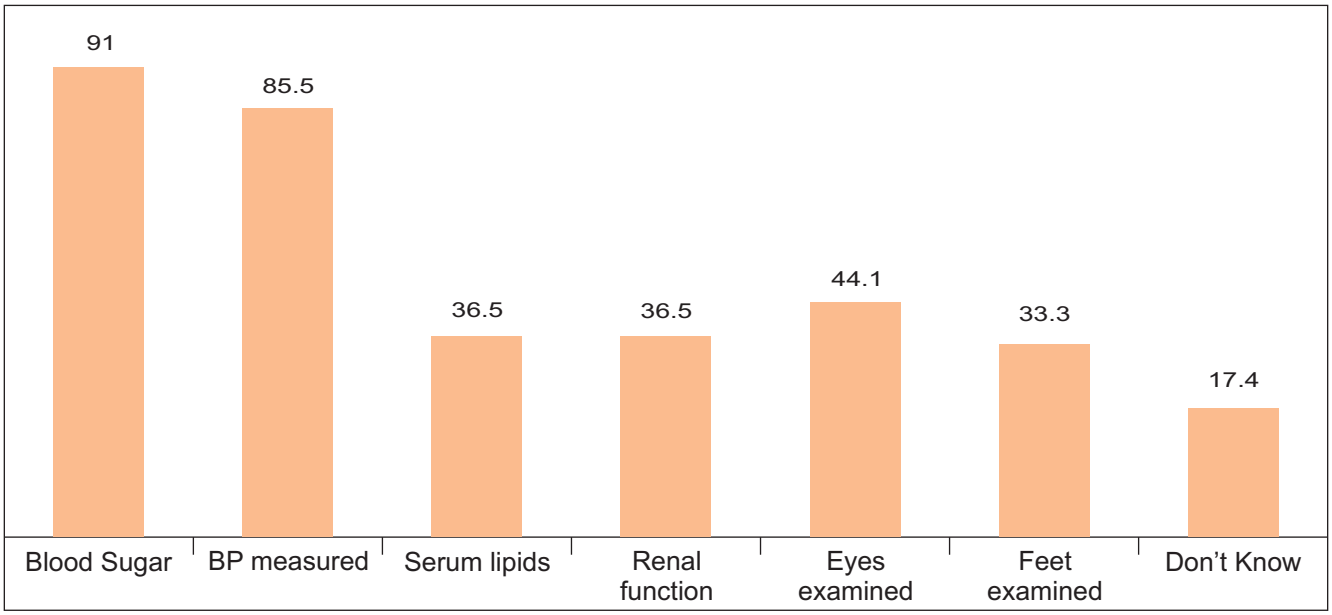
'Integration of services helps more to save time and getting organized'

Investigation for screening and management of diabetes

17% of DM patients did not know what investigations are required to assess good control of DM. Only 44% of all DM patients knew that eyes need to be examined. This is the highest among all the other complications – renal function (36%) and feet (33%). Measurement of blood sugar and blood pressure was known to more than 85% clients.

Further, of all clients interviewed, only 21% knew that the retina is affected in diabetes and 29% had never had a dilated eye examination (Figure 11). About 9% said that there was no need for eye examinations and 16% would get eyes examined only if there was a problem.

Figure11. Patients' Awareness of Investigations in Diabetic Clinics (%)



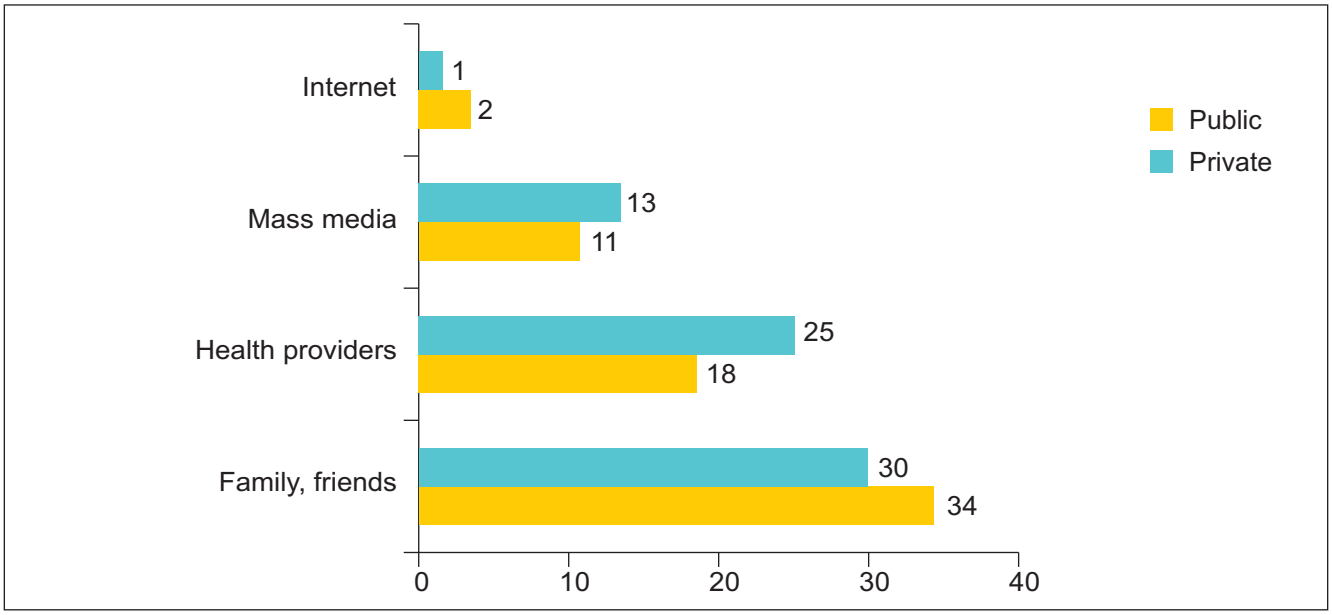
Sources of information accessed

The primary source of information cited by clients in both public and private facilities was interpersonal communication by family and friends (Figure 12). Health providers in public facilities were considered less accessible than their private counterparts by people living with DM.

Although mass media is recognized as a source of information by clients, it is not given significant prominence. The Internet as a channel of information was used by a small proportion of persons, citing the need for a credible, dedicated website by reputed partners that could potentially provide information in the form of daily tips regarding DM and DR management.

40% of patients in public and 13% in private facilities were given no information about diabetes and its complications.

Figure 12. Channels of information on DR



Client Needs

'Education program on complications of diabetes should be covered in media frequently. Awareness at an early phase of diabetes will help us to avoid complications.'

Perceptions on management of diabetes and its complications

A significant proportion of physicians, ophthalmologists and diabetic patients advocated for an integrated care package where diabetes and its complications could be managed under one roof.

B. OVERVIEW OF EYE CARE PROVIDERS

Information regarding the annual case load for DR among all hospitals was collected to understand the nature, efficacy and comprehensiveness of ongoing services. Nearly double the numbers of STDR cases were detected in the private sector than in the public sector. In addition, the public sector contributed only 12% of all vitreo-retinal (VR) surgeries conducted annually, based on the reports provided by the hospitals. The description below highlights important facets of the current state of eye care service delivery with respect to DR and draws attention to challenges and opportunities in its wake:

I. General Health Systems

Human Resource gaps

A number of challenges for eye care providers emerged from the findings. The need for trained personnel in public-funded institutions was significantly greater than in the private sector (Figure 13). Private sector facilities had a higher proportion of trained counsellors and qualified nurses compared to public facilities. Low vision personnel and retinal photographers were in much lower numbers, overall. 50% of all private hospitals did not have a trained low vision professional. The mean number of full time retina specialists was higher in the private sector(3.8) compared to the public-funded institutions (2.92). Training of ophthalmologists was required in both sectors; nearly 40% in the private sector and 20% in the public sector said training of ophthalmologists was required. In terms of support for potential capacity building initiatives, about 67% hospitals stated that they had the capacity to train others for DR screening and 56% stated that they had the capacity to train for laser.

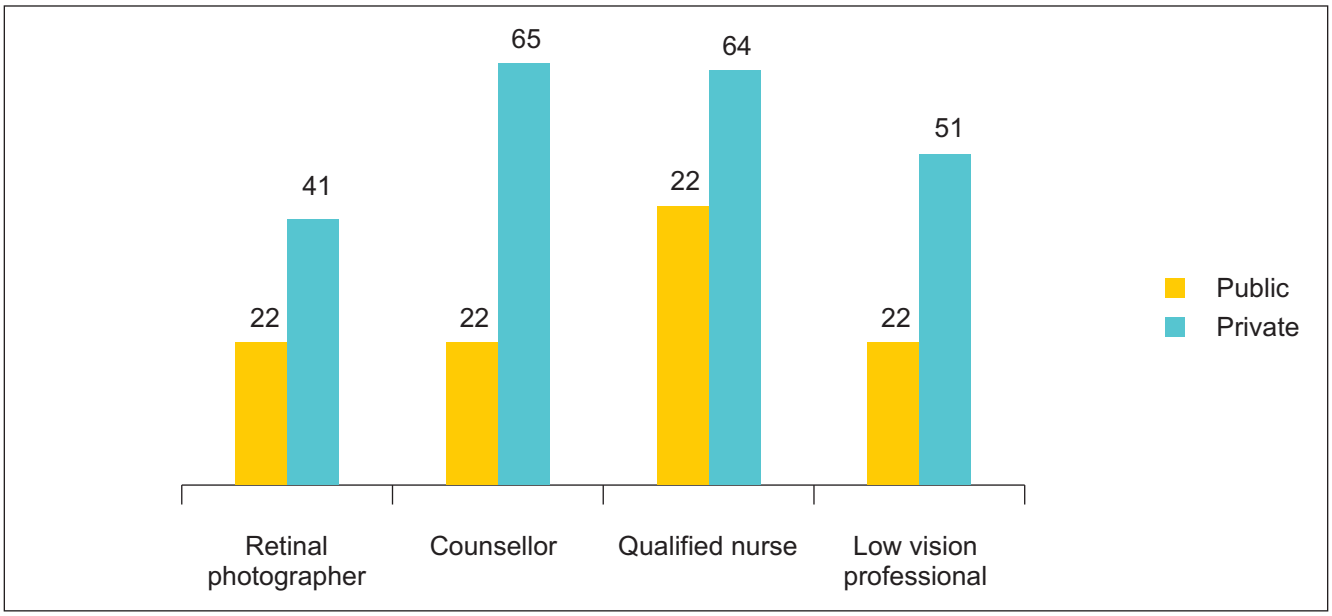
Ophthalmologists' Speak

'Non-clinicians would have a major role in early detection of diabetic retinopathy'

'I think that a retinal camera is going to be a major development, as one can manage easily by non-ophthalmologists also'

'I think that a retinal camera is going to be a major development, as one can manage easily by non-ophthalmologists also'

Figure 13. Availability of human resources at Eye Hospitals in the public and private sector (%)



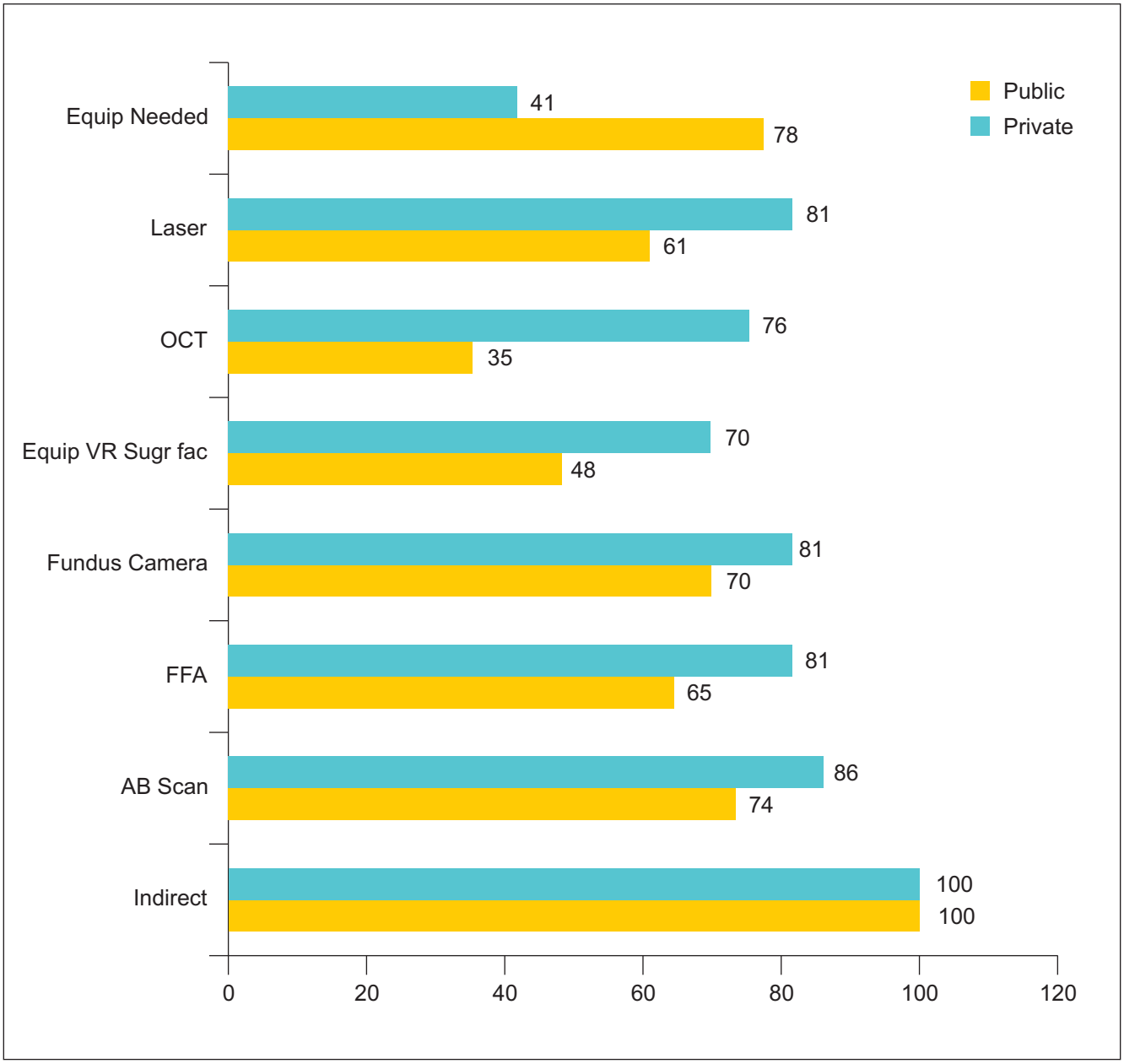
Only 55% hospitals reported engagement in research (significantly higher in public funded hospitals). This could indicate a lack of trained personnel to undertake research or a lack of time available to ophthalmologists for consolidation of clinical experience in the form of research. It could also indicate a relative lack of interest in undertaking research.

Infrastructure and diagnostic equipment

60% of public and 80% of private eye care facilities provided dedicated retina clinics for clients.

78% of public-funded and 41% of private facilities required further equipment to improve services for the diagnosis and/or treatment of DR. There was a good availability of indirect ophthalmoscopes both at the public-funded and private hospitals. In terms of AB scan, FFA and fundus camera the difference between government and private eye hospitals was about 10%, whereas for Optical Coherence Tomography (OCT) and equipment for VR surgery the gap was much wider. Overall, 73.3% of all eye facilities had functional lasers, with a significant difference between private (81%) and public-funded (61%) institutions.

Figure 14. Functional equipment status at Eye Hospitals (%)



Protocols / patient information sheets: Lack of a well-defined screening and treatment protocol

Two-thirds of eye hospitals did not have readily accessible, written treatment protocols (67%). Only about a third routinely used HbA1c to monitor their DR patients (37%). Only half the hospitals provided printed information sheets to patients with DR. 54% hospitals lacked systematic patient follow up systems and protocol (significantly better in the private sector)

Health Information Systems and connectivity

Maintenance of records was also not adequate as less than 50% of hospitals could identify sight threatening diabetic retinopathy (ST-DR) from their records, although this was noted to be significantly higher in private funded hospitals. It was observed that 54% of hospitals lacked systematic patient follow up systems, though this was significantly better in the private sector.

About 60% hospitals faced difficulty in retrieving paper records for follow up visits and this was nearly double in the public sector. Only 14% of hospitals had fully electronic records (Public: 4; Pvt: 18). While 70% perceive Electronic Medical Records (EMR) software to be very useful for clinics, only 41% think it was feasible to implement in their set-ups.

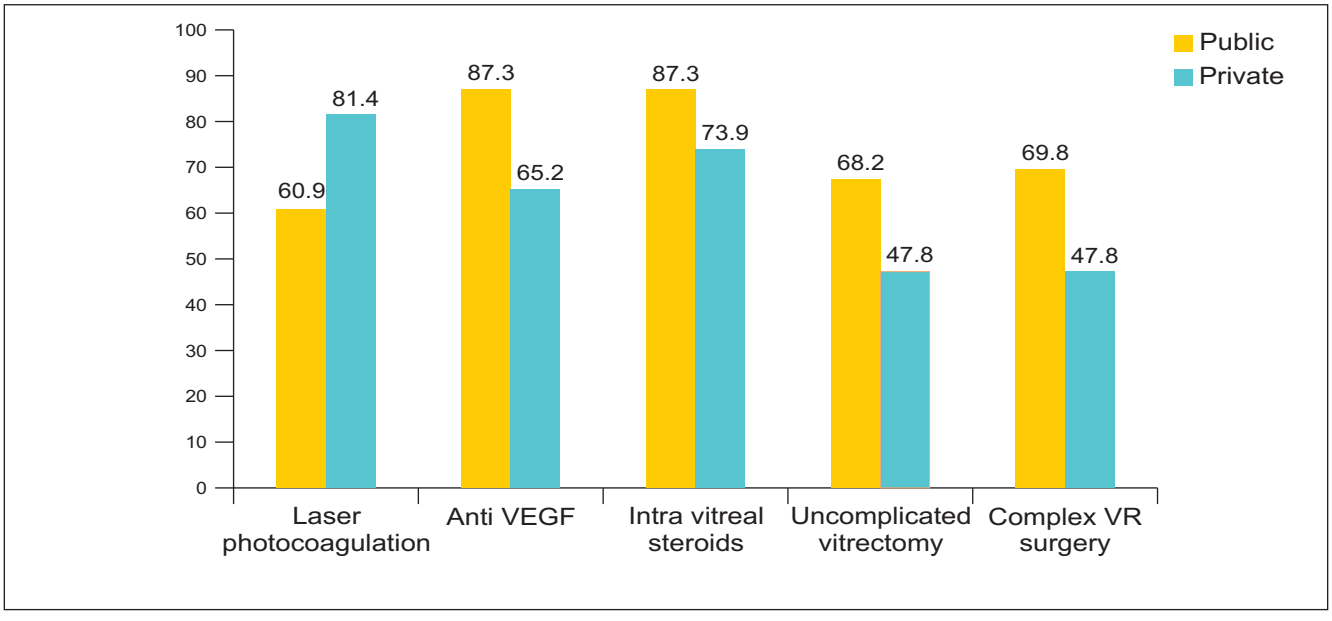
Referral systems between physicians and eye care providers need strengthening

The majority of eye hospitals (80%) regularly received referrals from physicians and 74% of ophthalmologists referred patients to physicians. However, only a fifth of ophthalmologists had access to patients' diabetes case records (from the treating physician).

Services at eye care facilities

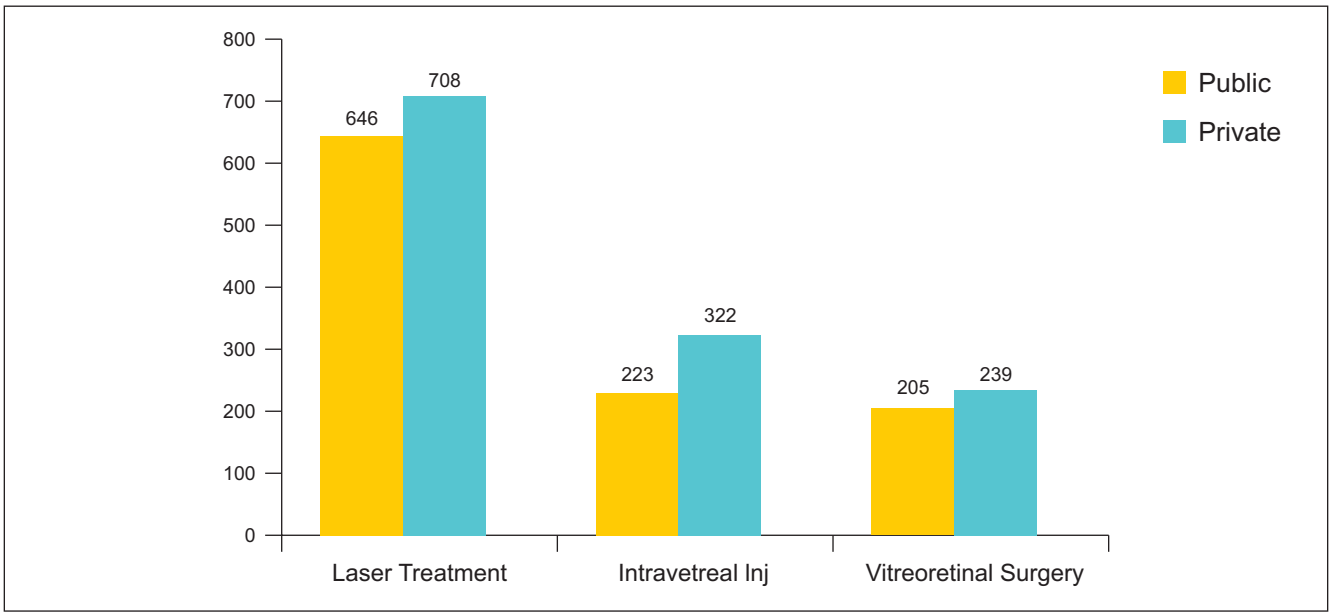
Information was collected on the different treatment facilities offered at the eye hospitals. There was a significant difference between the services provided by private and public-funded hospitals (Figure 15). 79% (68/86) had laser photocoagulation facilities available (Private: 85.7%; Public-funded: 60.9%), 81.4%(70/86) provided anti-VEGF (Private: 87.3%; Public-funded: 65.2%), 83.7% (72/86) intra vitreal steroids/ triamcinolone (Private: 87.3%; Public-funded: 73.9%). Though most eye care institutions provided services for uncomplicated vitrectomy, less than half (47.8%) of public-funded institutions provided services for complicated VR surgery.

Figure 15. Proportion of eye hospitals providing different treatment options for DR



Not all hospitals could provide information on the number of procedures conducted annually. 52.1% (12/23) public-funded and 66.7% (42/63) of private hospitals could provide information on lasers while 39.1% (9/23) public-funded and 61.9% (39/63) private sector hospitals could provide information on VR surgery. At the same time, 14 hospitals in the public sector (60.9%) and 42 hospitals in the private sector (66.7%) could provide information on annual intra vitreal injections given. The performance in terms of the mean annual procedures conducted by reporting hospitals, in relation to laser treatment and intra-vitreal injections was higher in the private sector compared to the public sector (Figure 16).

Fig 16. Mean annual procedures for diabetic retinopathy in public and private eye hospitals

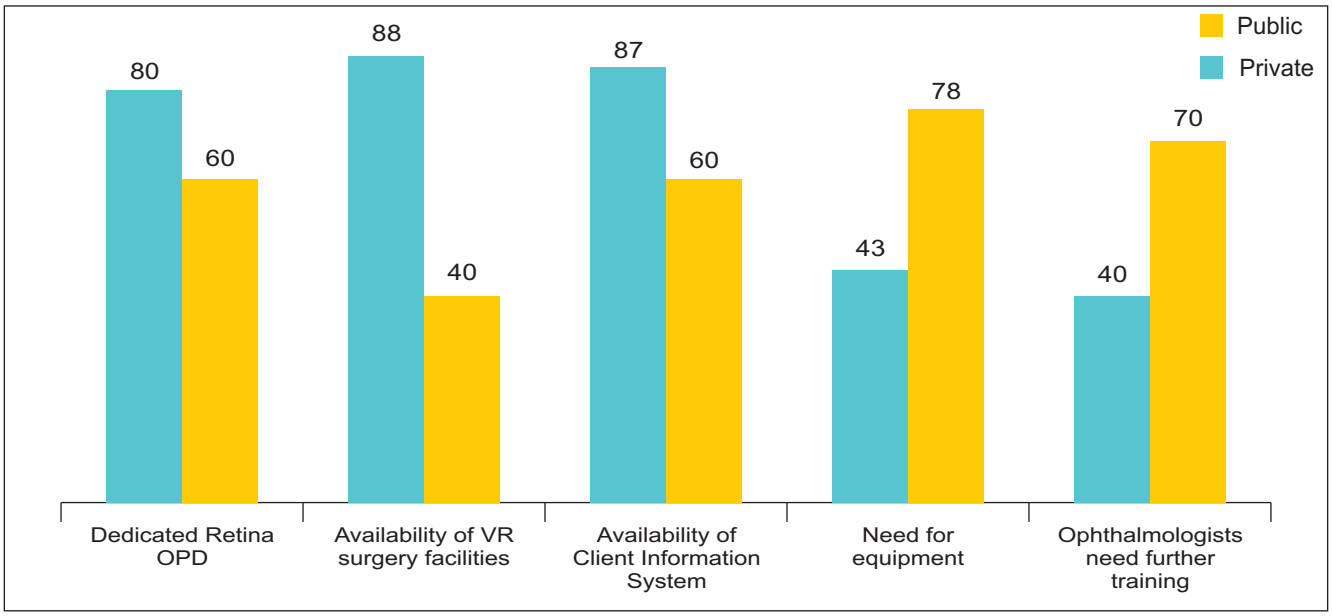


A quarter (24%) of all hospitals had a waiting list for laser treatment being significantly higher in public facilities. Over a third (37%) doesn't test HbA1c routinely for patients with DR.

Although dedicated retina out-patient clinics were operational in both public and private facilities, equipment and the number of personnel trained in vitreo-retinal surgery limited their efficacy (Figure 17). Training of ophthalmologists was required in both sectors; nearly 40% in the private sector and 20% in the public sector sought training to bridge the gap.

78% of public-funded and 43% of private facilities required further equipment to improve services for the diagnosis and/or treatment of diabetic retinopathy (Figure 15). Information sharing with patients was also observed to be lower in public facilities when compared to the private sector. Only 42% of patients were provided an information sheet (Figure 15).

Fig 17. Comparison of facilities at public and private funded Eye care facilities(%)



Eye care provider's perspective

Need to strengthen infrastructure including diagnostic equipment

Almost all the eye care providers interviewed felt there was a substantial delay in 40-60% of DR cases for timely management as clients reach an ophthalmologist late in the disease. Many felt that strengthening DR screening at Diabetes/ physician clinics can potentially address this delay. But there were varied opinions on how this could be done. Many felt that physicians do not have the time, skill and equipment to screen for DR. Others felt task shifting with imaging technology can solve this problem and that a trained technician can take images which either they can be trained to interpret or can be sent to an ophthalmologist based at a remote location. Almost 80% of the ophthalmologists interviewed suggested a need for strengthening referral mechanisms and also that EMR will facilitate referral and record sharing.

Ophthalmologists' Speak

'Instead of having stand - alone diabetic retinopathy centers it will be ideal to have all the things under one roof'

'For rural India, we need to explore how to make use of the PHC in detection DR or how to make use of tele-ophthalmology and fundus cameras'

'Team work and a good ophthalmologist team must exist in the facilities for diabetic care'

'Non-clinicians should have a major role in early detection of diabetic retinopathy'

'Screening programs should be done right at the level of the physician or diabetologist because patient with diabetes generally go to their diabetologist or physician'

'I think that a retinal camera is going to be a major development as it can be managed easily by a non-ophthalmologist also'

Clients at DR Clinics

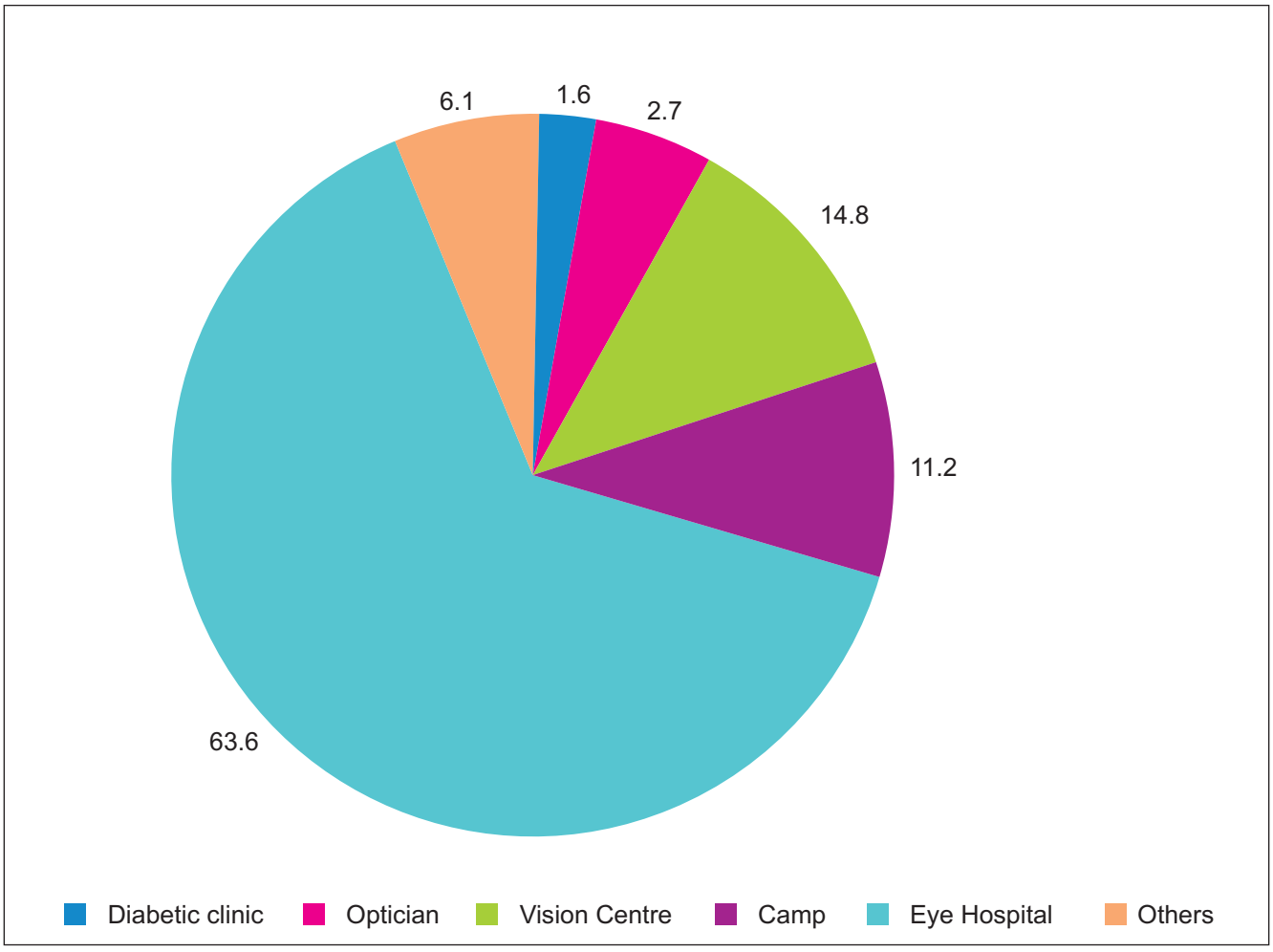
376 patients with DR were interviewed in eye facilities. 44% had been diabetic for more than 10 years and a further 7% had been diabetic for more than 20 years. The average duration of diabetes was 11 years.

43% of the diabetics interviewed already had visual loss from DR.

Place where DR is diagnosed

Patients rarely reported that their DR had been detected in a diabetic clinic (1.6%). The majority had been diagnosed by eye care providers of different types, principally eye hospitals (63.6%)(Figure 18).

Figure 18. Location where patient's retinopathy detected (%)

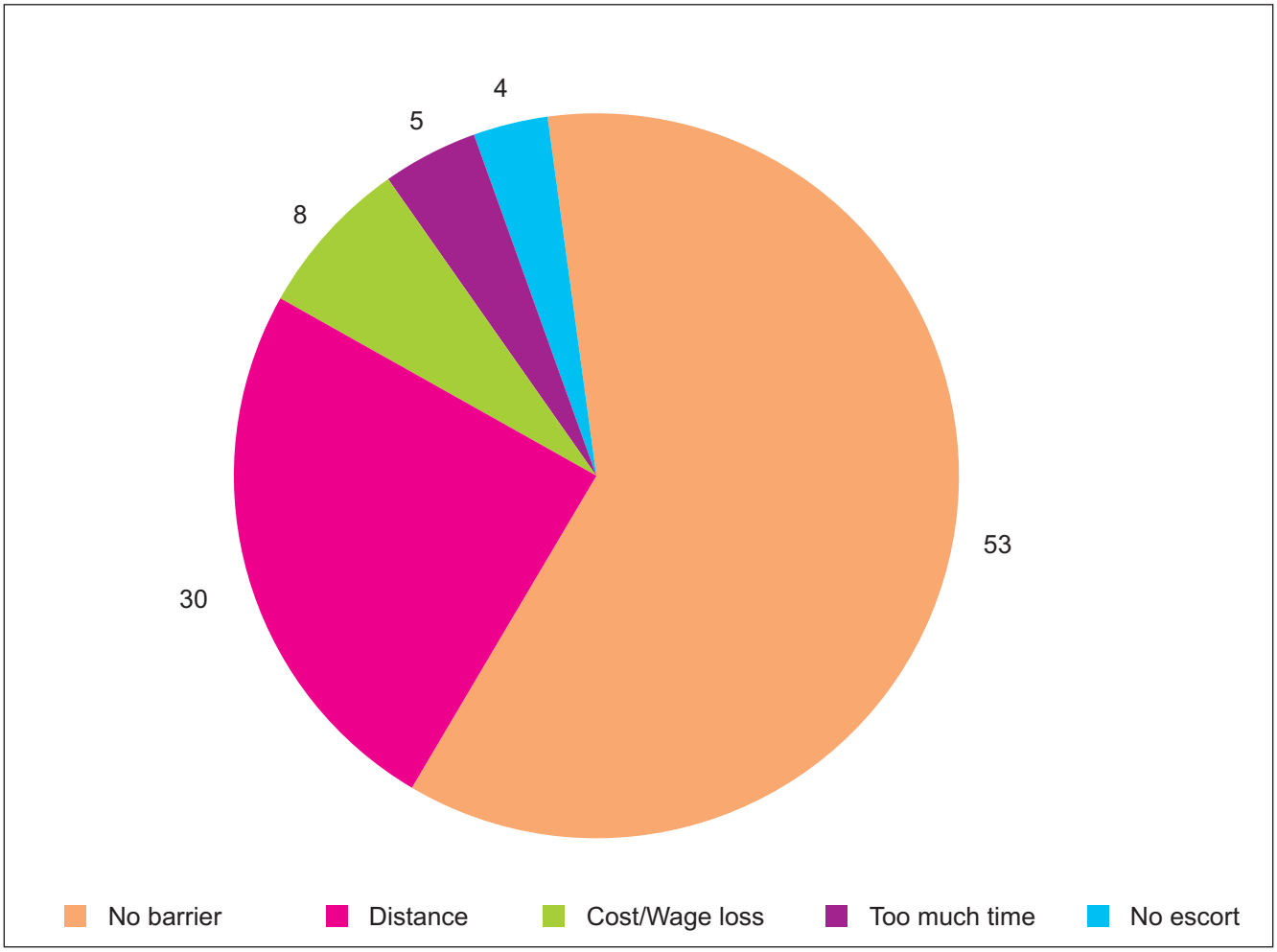


- 84% of DR patients were aware of complications
- The most significant complication that DR patients were concerned about was blindness or visual loss, stated by 63%.
- And yet, 45% of DR patients presented to an eye hospital with vision loss.

Clients access to eye clinics

Approximately half the patients reported no difficulties in accessing eye care facilities (53%)(Figure 19). The commonest problem reported was distance followed by costs and loss of wages.

Figure 19. Barriers in accessing Eye Clinics for DR patients (%)



Challenges in controlling diabetes

50% of diabetics with retinopathy correctly understood what control of their disease meant and 21% thought their disease to be poorly controlled.

Challenges faced by patients with DR in controlling their diabetes were very similar to those reported by people diagnosed with diabetes (Table 5), with difficulty in making life style changes as predominant.

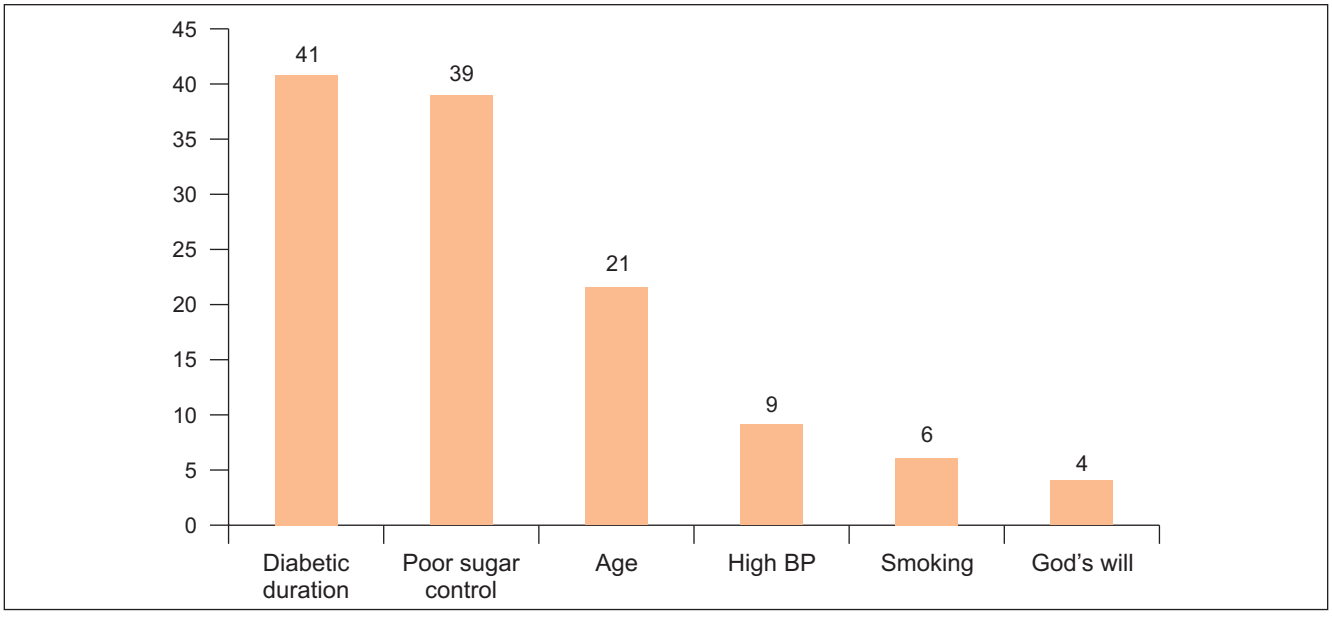
Table 5. Challenges stated by DR patients in controlling diabetes

	Challenges in controlling diabetes	%
Life style factors	Changing diet	47%
	Exercise	22%
Costs	Cost of Investigation	18%
	Cost of Medication	8%
	Loss of wages	2%
remembering	Clinic appointment	13%
	Remembering medication	13%
Other reasons	Lack of time	12%
	Distance to the clinic	9%
	Accept being diabetic	8%
	Other	13%

Client perceptions on causes of DR

The most important causes of DR as perceived by patients with DR was the long duration of diabetes and poor control of sugar (Figure 20). Age, high blood pressure and smoking were the other important causes mentioned.

Figure 20. Perception of causes of DR (%)



Awareness of complications of diabetes

84% of patients with DR were aware of the complications of diabetes.

A. ASSESSMENT OF DIFFERENT MODELS FOR THE DETECTION AND TREATMENT OF DIABETIC RETINOPATHY

Fourteen different hospitals were visited to assess the different models in place for screening and management of DR (Annexure 2). Many of the findings reflect the challenges of the general health system, but in addition, there were important features particular to each of the models.

Some of the key findings are captured in Table 6.

Table 6. Observations from established DR screening programmes (n=14)

Parameter	N	%
Population of diabetics being screened		
Start with known diabetics	12	85.7
Report >50% of known diabetics covered	2	14.3
Screening / case detection		
No written screening protocols available	9	64.3
Refer only Sight Threatening DR to base hospital	5	35.7
Refer any retinopathy to base hospital	9	64.3
Not assessed validity of screening procedures	10	71.4
No systems in place for annual screening	8	57.1
Screening programs in place for >10 years	2	14.3
Use customized mobile van for screening	8	57.1
Confirmatory diagnosis		
<50% clients report for confirmation	8	57.1
<50% cost recovery achieved	11	78.6
Treatment		
Written information on treatment to patients	7	50.0
Early treatment outcomes monitored	14	100
Follow up		
Systems for improving follow up	9	64.3
Other		
Costing of diabetic services done	7	50.0
No integration with other stake holders	6	42.9

Identifying diabetics to be screened

The majority of programmes used community based approaches to identify diabetics to be screened (comprehensive eye camps; dedicated camps for diabetics; door to door blood glucose testing etc.). Some screened known diabetics while some started with first identifying diabetics in the community. Some of the programmes concentrated on rural areas while others focused on urban slums.

Only two models had recently starting screening in diabetic clinics, one of which used physicians trained in ophthalmoscopy, while in the other ophthalmologists visited to examine patients. Both providers commented that this was effective, efficient and was welcomed by physicians and patients. Otherwise there was virtually no communication between eye care providers and physicians.

Approaches used for screening of DR

There was a very wide range of approaches to screening in terms of identifying the diabetics to be screened, the combination of who did the screening / equipment used and the indications for referral for confirmatory diagnosis (Table 7).

The earliest DR screening program was established in 1990 and the most recent was as recent as 2013. Only in 14% of hospitals screening programs were in place for more than 10 years

85% of the screening programmes had a defined catchment area where the hospital operated. 43% hospitals had an ongoing screening programme which visited either the same location or a different location every working day.

A third of the screening programs also did laboratory examinations to look at other complications like nephropathy while a few hospitals offered a comprehensive complication detection package including neuropathy, nephropathy and retinopathy.

Only a third of the screening programmes involved an optometrist/ ophthalmic assistant/ vision technician for the initial screen. The rest were ophthalmologist-led.

Indirect ophthalmoscopy or digital imaging was used by 85% for screening for retinopathy. Overall, only 28% (4) of the screening processes used were validated by the concerned hospitals where they established the sensitivity and specificity of the approaches used.

Confirmatory diagnosis

Most of the providers referred patients ‘suspected’ in camps or other outreach locations/ satellite clinics to the base hospital for confirmatory diagnosis and further management.

Table 7. Detecting diabetic retinopathy: location, method of detection and personnel involved

Location	Method	Case detection by whom
Community based approaches		
House to house identification of diabetics	• Population screened for diabetes, with referral to base hospital for assessment • All known diabetics referred to base hospital for assessment • Digital imaging with referral of DR suspects	• Eye hospital staff • Optometrists
Standard outreach camp	• Dilated retinal examination of known diabetics • Referral of diabetics with reduced vision to base hospital for assessment	• Ophthalmologist or optometrist
Outreach camp for people with diabetes e.g. in urban slums / other locations	• Dilated retinal examination • Referral of diabetics with reduced vision to base hospital for assessment • Digital imaging, often using a mobile van with referral of DR suspects	• Ophthalmologist or optometrist
Fixed schedule mobile camp	• Fully equipped mobile van providing local ophthalmologists to examine and treat known diabetes on a cost sharing basis	• Ophthalmologist
Facility based approaches		
Primary Health Centres/District Hospitals	• Imaging using optometrists with remote interpretation at the base hospital • Static camps at health centre where ophthalmologists examine and refer for treatment if required	• Ophthalmologist or optometrist
Vision Centres	Imaging using a facility based non-mydriatic system by Ophthalmic Assistant with • Immediate interpretation • Remote interpretation at the base hospital	• Ophthalmic Assistant • Ophthalmologist
Physicians clinic	• Direct ophthalmoscopy with referral of DR suspects • Digital imaging with remote interpretation of images	• Physician • Ophthalmologist • Trained technicians
Diabetics identified in eye hospitals / satellite clinics	• Clinical examination	• Eye hospital staff
Other locations		
Pharmacies	• Digital imaging with remote interpretation of images	• Ophthalmic Assistant takes images
Industrial settings	• Digital imaging with remote interpretation of images • Dilated retinal examination	• Ophthalmologist or optometrist
Laboratories	• Digital imaging with remote interpretation of images	• Ophthalmic Assistant takes images

In one approach, vision centres prepared a register of known diabetics and invited them to come to the vision centre the day an ophthalmologist was scheduled to visit.

93% of the screening programmes provided information on the findings at the screening site to those who were screened.

Individuals failing the screening test are asked to report to the satellite/ base hospital for further management and confirmatory diagnosis but less than 50% actually report to the base hospital for confirmatory diagnosis/ further management.

50% hospitals used ETDRS classification for categorising DR.

43% hospitals made arrangements for transportation of the patients needing confirmation to the base hospital but these services were underutilized. Similarly, free diagnostic tests/ discounted prices for investigations, priority in out-patient clinics were also offered by some hospitals to improve attendance rates for confirmation of diagnosis.

Table 8. Barriers to uptake of confirmatory tests as perceived by providers

Reason	No. (n=14)	%
Not perceived as a priority	8	57.1
Need not felt	6	42.9
Distance	5	35.7
Lack of awareness	5	35.7
Costs	4	28.6
None to accompany	4	28.6
See another ophthalmologist locally or seek second opinion	4	28.6

Criteria for referral

57.1% of hospitals referred all diabetics with any degree of retinopathy to the base hospital while 42.97% only referred to the base hospital if there was STDR. In some programmes, any diabetic with vision loss irrespective of retinopathy is referred to the base / satellite hospital for further treatment. Patients are also referred to the base hospital for treatment for conditions like cataract before their retina is evaluated.

Use of standard protocols

In 43% of the hospitals conducting screening programs, written screening protocols were available to the screeners. A similar proportion also stated that written treatment protocols were available. Only 43% had established a protocol for annual screening of known diabetics. Cost recovery was reported to be poor with only 21.4% of the hospitals stating that they were able to recover more than 50% of the costs expended.

Summary in relation to screening and confirmatory diagnosis

- 15% screening programs do not start with known diabetics
- Only a few relatively recent initiatives screen patients attending diabetic clinics/ physicians clinics
- Very little consultation or collaboration with physicians was observed
- Written protocols for screening not in place in 64% of programmes both for screening and treatment
- Ophthalmologists and/or optometrists are frequently used in screening (i.e. in clinical examination and in interpreting digital images), with trained technicians being the exception
- Many programmes (64%) refer diabetics with any stage of DR for confirmatory diagnosis rather than restricting referral to those considered to have STDR
- Mechanisms for annual screening were not in place in over half the programmes (57%)
- Screening using mobile vans with telemedicine was the approach used in 29% of programmes
- 2 (14%) programs used a fully equipped diagnostic and treatment mobile van on a cost-sharing basis with local ophthalmologists.
- Most programmes (71%) have not assessed the validity of the screening methods used
- Half the programmes (50%) do not give patients any information about DR at the time of screening
- Less than 50% of diabetics referred for confirmatory diagnosis attend for diagnostic assessment

Treatment of diabetic retinopathy

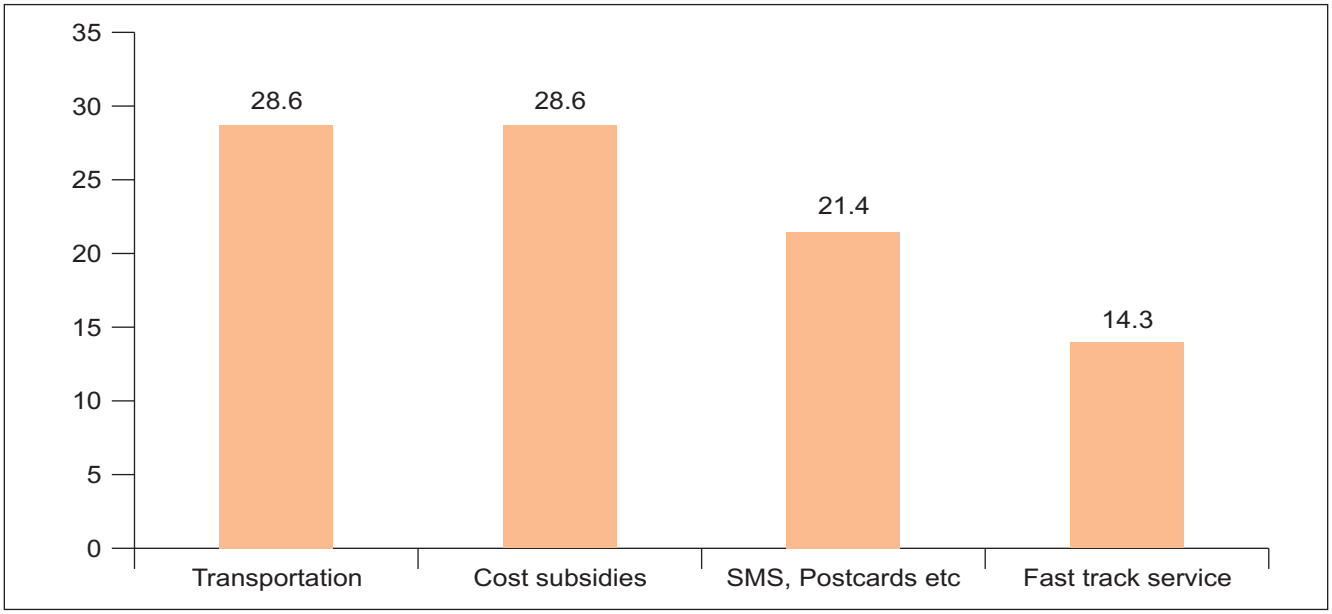
All providers assessed were able to provide the full range of treatment required for DR.

Only two programmes undertook treatment during screening, both of which transported diagnostic equipment and a laser in a specially converted mobile van. All others referred patients to the base hospital even if the hospital was hundreds of miles away. Programmes which monitored uptake of treatment after confirmatory diagnosis had a high uptake, and all reported that they monitored visual acuity and short terms outcomes of treatment.

Improving access to treatment

To improve uptake of treatment some programmes provided transport (29%), subsidized costs (29%), sent SMS or postcard reminders (21%) or provided a fast-track service at the base hospital (14%).

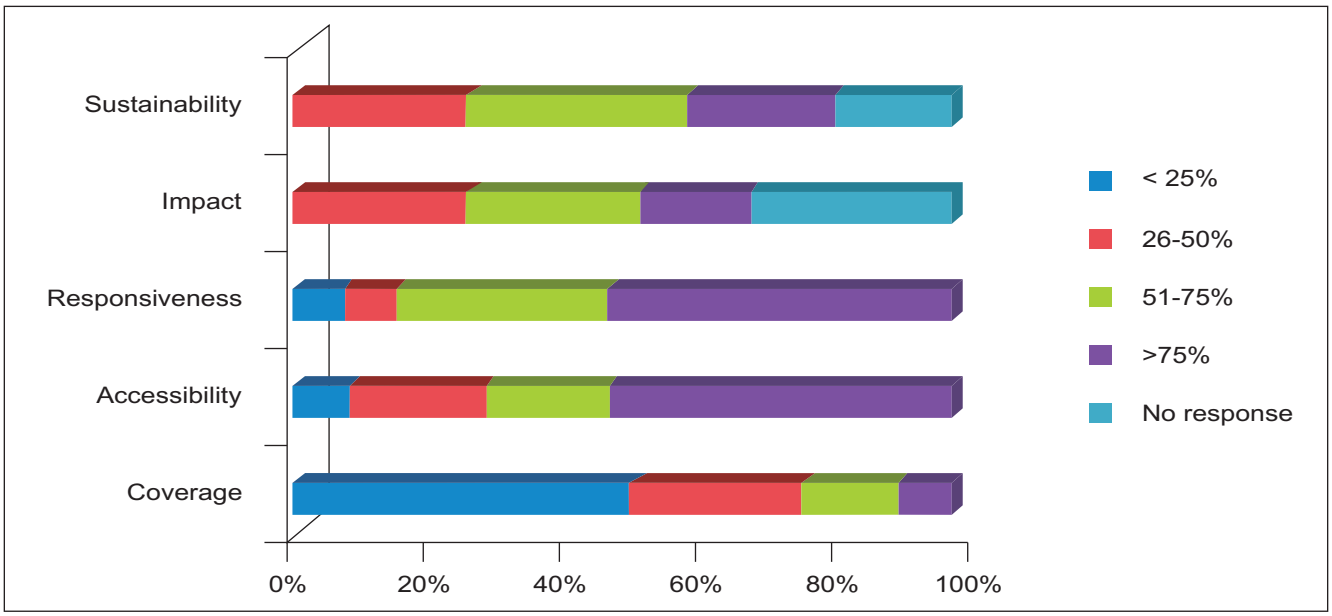
Figure 21. Mechanisms to improve uptake of treatment



Self-evaluation of different parameters

Eye hospital representatives, comprising Senior administrators or persons responsible for managing the programme, were asked to gauge their own programme in relation to sustainability, impact, responsiveness, accessibility and coverage (Figure 22):

Figure 22. Self- assessed scores on different parameters



Sustainability

The feasibility of continuing operations based on financial and resource viability was a key question. 75% of all hospitals ranked their programmes as having moderate or high levels of sustainability. The remaining hospitals were less than confident that their operations were sustainable in the long run, as they could barely recover more than half the costs of the service. None of the programmes self-reported their capacity building as high and 50% reported that their programme was not integrated into the health system at all.

Impact

Four hospitals (28.6%) did not respond to questions regarding impact, citing that they had never assessed impact or that the duration of operations was insufficient to gauge the same with reasonable accuracy. Among the 10 hospitals who responded, 10% believed that their level of impact was above 75%, while 30% stated that they achieved impact between 26-50% while the remaining 60% achieved impact between 51-75%.

Responsiveness

The level of responsiveness was to be gauged with regard to the screening process, proportion of persons attending treatment and completing sessions, improving uptake of follow up and repeat screening. Half of all hospitals felt that their services were more than 75% responsive (50%). 35% (n=14) of all hospitals believed that they provided a level of sensitivity to patient needs that was above average (51-75%) and the remaining 15% stated that they had a less than average response rate.

Accessibility

50% of providers categorised their programmes as having high levels of accessibility and responsiveness. A little more than 20% stated that they had above average access and the remaining 30% felt that they were not easily accessible.

Coverage

78% of all hospitals stated that their reach was less than half the district/catchment area population. Only one facility or 7% of the hospitals were able to reach more than 75% of the population and the remaining had sub-optimal reach.

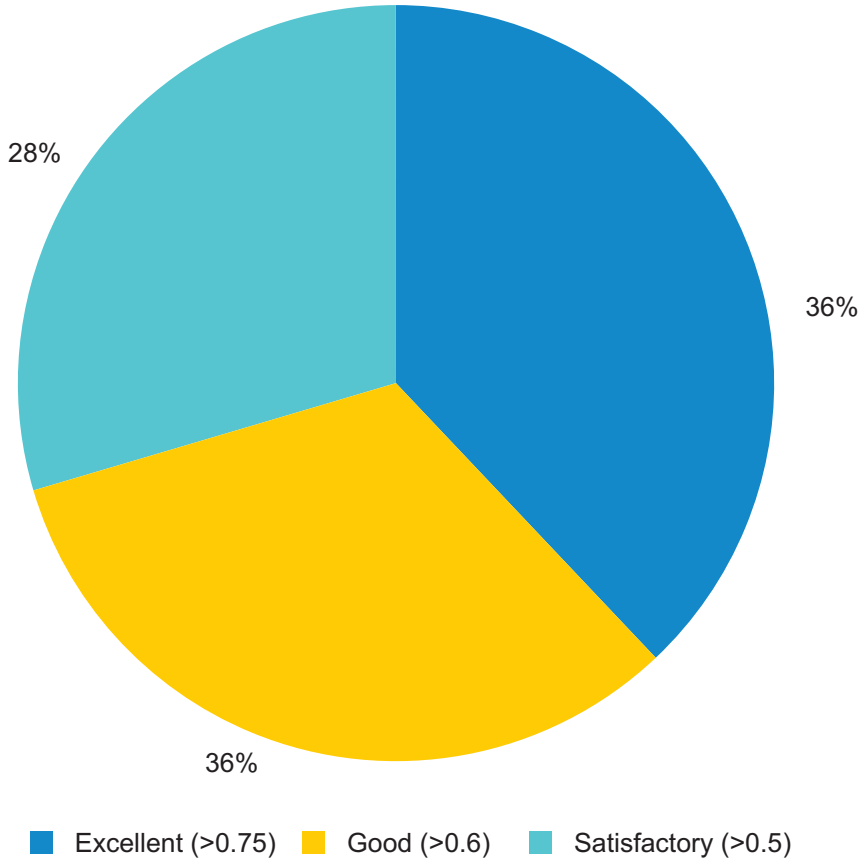
Objective evaluation of different parameters

The research team from PHFI assessed the following parameters through observation and through interviews and discussion with those managing each programme: quality of the clinical services provided, effectiveness, integration, partnerships, capacity building and cost recovery.

Quality of clinical services provided

All programmes were providing high quality services based on a range of criteria covering screening, confirmatory diagnosis, treatment and follow up.

Figure 23. Assessed Scores on Technical Components



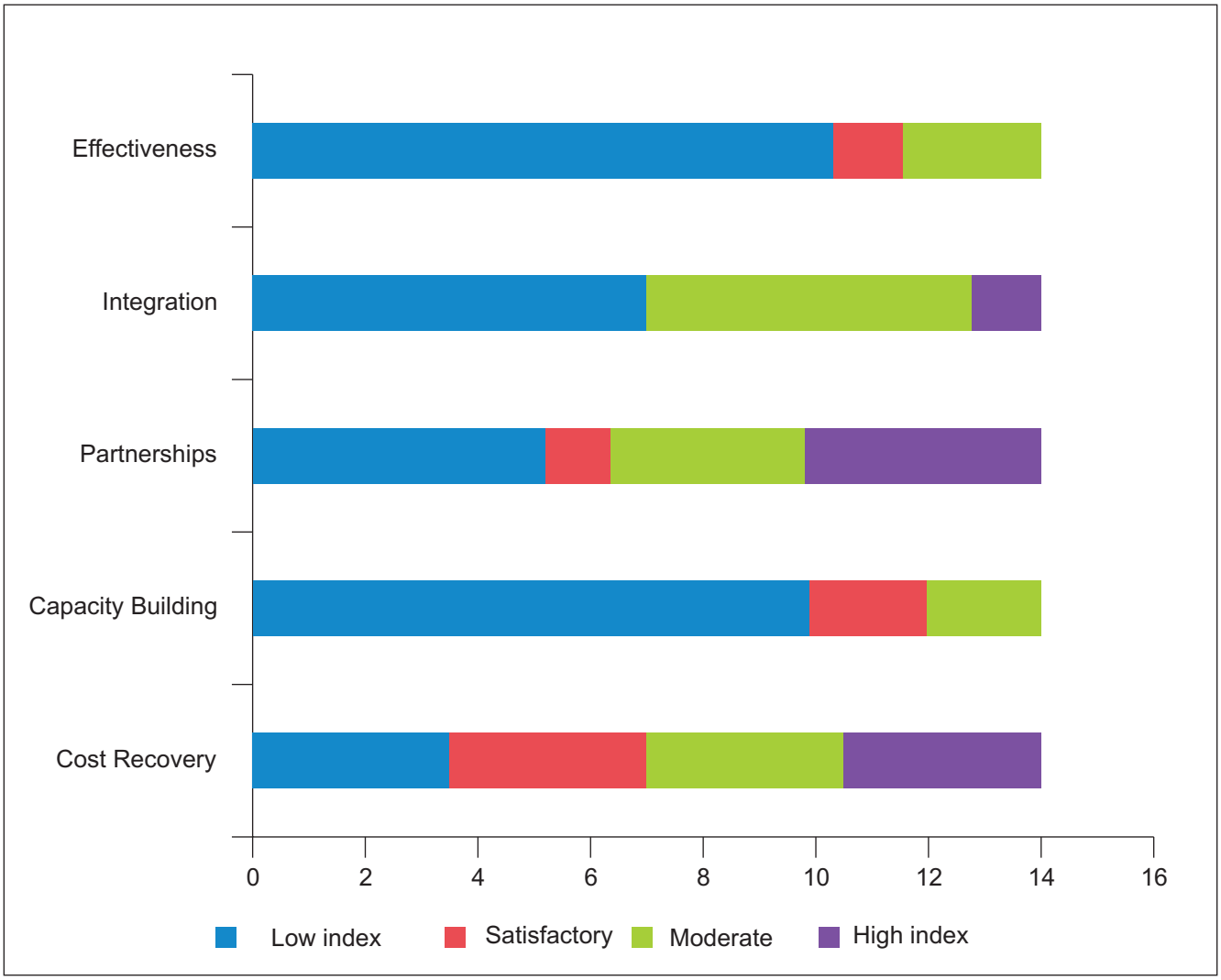
The high scores on technical components of the programme may be attributed to several factors:

- Excellence of available infrastructure and facilities
- Availability of skilled, trained personnel and
- Supportive and responsive management structure.

Effectiveness, integration, partnerships, capacity building and cost recovery

Nearly three-fourth of the hospitals had not focused on capacity building in a significant way and showed low levels of integration in terms of service delivery for DR. Less than half had paid attention to developing partnerships. A little more than half the hospitals reported moderate cost recovery of DR screening and management (57%), while another 21% reported very poor cost recovery. Only one in five hospitals reported excellent cost recovery. However, there were elements of success in the programmes that have been studied further to highlight potential directions for lasting action.

Figure 24. Assessed scores on different parameters (Effectiveness, integration, partnerships, capacity building and cost recovery) (%)



Partnership, collaboration and referral between physicians and eye care providers

In the majority of approaches there was very little communication between physicians and eye care providers. In two of the more recently established initiatives, whereby screening was being undertaken in diabetic clinics, there had been joint planning of the approaches to be adopted.

Use of highly trained personnel

Half the models relied on ophthalmologists who were on-site to provide a diagnosis of STDR (e.g., during outreach screening camps for diabetics). Primary screening was being conducted by an ophthalmologist (50%) rather than task-shifting to an optometrist (29%) or trained technician (21%). These approaches are not an efficient use of scarce, highly skilled personnel. In one model, general physicians were trained in ophthalmoscopy to conduct a basic screening for DR, referring 'suspected cases' to ophthalmologists to confirm the diagnosis.

Conclusions and recommendations

A total of 86 eye units and 73 diabetic care units were covered in the study across 11 most-populated cities in India. In addition 376 persons with DR attending eye clinics and 288 persons with diabetes attending diabetic physician clinics were also interviewed. 98% of the proposed study units proposed to be included in the study were covered over the 4 month period of data collection.

The study also assessed existing DR screening programmes being implemented by 14 hospitals across the country which were visited for a detailed assessment of the modalities adopted.

Care of people with diabetes

The availability of qualified support human resources at diabetic clinics was inadequate. This includes categories of personnel like dieticians, counselors, laboratory technicians etc. Similarly, 70% of the physicians were not confident of their ophthalmoscopy skills for screening for DR. This is a great opportunity to develop need-based short term / distance learning modules to augment the knowledge and skills of comprehensive diabetic care teams to highlight what is required to reduce the risk of complications, including DR. Programmes like the Certificate Course in Evidence-Based Management of Diabetes Mellitus have been very popular in India. A similar educational package could be developed for early detection and management of DR and scaled up across the country using web-enabled features. Many diabetic physicians were unaware of the National Programme for Prevention and Control of Diabetes, Cardiovascular Disease and Stroke (NPCDCS). This programme was initiated recently and needs to be popularized among the physicians through coordinated efforts by both the Government and professional associations.

An inventory of the equipment and support infrastructure at the diabetic clinics revealed that most clinics were neither engaged in nor prepared for screening for DR. Most clinics were not even recording visual acuity amongst the diabetics. This weakness is also a great opportunity as it could lead to a paradigm shift by initiating a robust DR screening programme embedded in the physician clinics. Different modalities that can make this possible are available. The technology revolution that characterizes the present day has led to great strides in imaging technology and smart phone applications. Harnessing this technology can provide cost-effective solutions for early detection of DR using non-ophthalmic human resources. Evidence is needed on what approach(es) could be adapted to the Indian context.

The study also highlights gaps in patient awareness and practices. There is an urgent need to develop communication and support packages for people with diabetes and their families as well as the general population at risk of diabetes. Tools like conversation maps, information technology as well as peer support groups can all be useful in different contexts. Modalities will need to be developed to provide a comprehensive information and awareness package. Advocacy efforts will also be needed to garner support from policy makers, programme managers and the informal and formal community leadership to help persons with diabetes.

Care of patients with diabetic retinopathy

The most significant finding from patient interviews was that 45% of patients with DR attending eye clinics were blind/visually impaired at the time of their presentation to the eye clinic. This despite the finding that patients are aware that diabetes can affect the eyes, and the complication that most patients are concerned about is going blind. Since diabetes is a chronic disease, the urgency is not felt by the patient. This also implies that it will be too late if one waits for the patient to report to an eye clinic. Therefore, initiating a process of early detection of all complications, including DR at a physician clinic is very important. Awareness generation also needs to be emphasized and people should know that EVERY diabetic is at risk of complications like loss of vision and the only way to reduce the risk would be by good control of diabetes and annual examination of the retina.

Analysis of data from eye providers showed that both public and private eye care facilities are offering high level services for the treatment of DR, with a range of treatment options. However, only about half the providers were engaged in any research. Many of these treatments need empirical evidence and the best people to gather such evidence would be those who are providing the treatment. Therefore, building a research capacity and support is important.

Need for integrated care

Semi-structured interviews with physicians, ophthalmologists and patients with diabetes clearly brought out that all stakeholders prefer an integrated approach where care of diabetes and its complications is available under one roof, literally a 'one-stop shop.' This is again indicative of a paradigm shift compared to what is currently practiced, but seems the most logical way going forward.

Current approaches to detecting and managing diabetic retinopathy

An assessment of the screening programmes being implemented by 14 leading eye hospitals in the country highlighted the strengths and weaknesses of these programmes. It is laudable that the philosophy of excellence permeates all efforts at the community-level as it does at the hospitals. The quest for the best options has provided many of these hospitals an opportunity to experiment with different approaches to reach diabetic patients. Most approaches have been ophthalmologist-led or ophthalmologist-based. This will be a strain on the existing, scarce human resources in the country, especially as imaging provides an opportunity to harness the support of non-ophthalmic personnel for the initial screening. This also impacts the sustainability and cost-effectiveness of these programmes.

Some programmes were using eye hospital staff in screening for diabetes in the community. This negates the spirit of coordination, partnership and integration as there are other personnel who are charged with this responsibility. It is important that the screening for DR and effective treatment should be the prime concern of the eye providers and therefore starting with known diabetics rather than searching for diabetics in the community is not the correct approach to be followed. Protocols for patient follow up, annual re-examination etc. need to be established for the programmes to be effective, efficient and responsive.

A health systems approach is essential if tangible results are to be seen. This approach will need to look at all the components of health systems as envisaged by WHO – Human resources, service delivery, financing, evidence, leadership and governance etc. The study provided ample evidence on why this is necessary – Need for skill augmentation of existing human resources, inputs for enhancing service delivery, need for networking and adequate referral linkages, need for cost containment, need for establishing standard guidelines and protocols for screening and treatment were all highlighted from the findings of the study.

Partnerships and referral networks

Referral consultations between physicians and ophthalmologists were not optimal. This indicates a lack of co-ordination, communication and continuum of care. It was observed that though the two groups of professionals (physicians and ophthalmologists) stated that they referred cases to each other, they did not know what actually happened with the referral. This shows that the referral process is not dynamic and is not providing essential feedback to both groups of professionals. Processes like EMR that allow all patient records to be shared across the two professional groups need to be established. Trust is an essential element in this process and unless the two groups sit down and plan jointly, trust cannot be fostered. Guidelines prepared jointly will bring the two groups together and unless this happens, a paradigm shift as envisaged cannot occur. This will help in standardizing the care package that can be offered – How frequently should a diabetic visit the physician; How frequently should sugars be monitored and how; How should risk factors be assessed and monitored; How frequently, how and where eyes should be screened etc. Unless a concerted effort is made in this direction, things cannot change.

Annexure 1: Survey Instruments

Information sheets and consent forms

PUBLIC HEALTH FOUNDATION OF INDIA

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: situation analysis, and evaluation of existing programmes for screening and treatment of diabetic retinopathy

Information sheet for key informant interviews

My name is.....I am a member of a team of researchers undertaking a study across India. This study is a collaboration between the Public Health Foundation of India (PHFI), and the London School of Hygiene and Tropical Medicine. The Principle Investigator is DR GVS Murthy, Director, PHFI Institute in Hyderabad.

Background: As in many countries, diabetes and its complications are becoming an increasing problem in India. As the number of people with diabetes continues to increase, and as they live longer, the rate of complications such as diabetic retinopathy is also likely to increase. This will place increased demand on services for diabetes and for those detecting and treating diabetic retinopathy.

Services for preterm infants are also expanding, and as a result more babies are surviving and at risk of retinopathy of prematurity.

The purpose of this study, which is being undertaken in the 10 largest cities in India and 6-8 second tier cities, is to better understand the services that are available for managing diabetes and its complications, and for detecting and treating retinopathy of prematurity. The diabetic retinopathy component will focus on the mega cities whole the retinopathy of prematurity component will focus on a few mega cities as well as second tier cities where coverage with programmes is currently lacking.

All the findings in relation to diabetic retinopathy will be pooled and presented anonymously at a stake holder meeting in early 2014, when decisions will be made concerning the most appropriate strategies for controlling diabetic retinopathy. The findings from the retinopathy of prematurity component will also be used for strategic planning. Financial support for these initiatives, which will be in line with government policies, will be provided by the Queen Elizabeth Diamond Jubilee Trust.

Why have I been selected to take part? We would like to interview you because of your role and position. We want to ensure that any initiatives supported by Queen Elizabeth Diamond Jubilee Trust, working through Indian partners, is in line with current policy, and takes account of current plans and priorities.

What will happen if I agree to take part? With your consent, we would like to interview you. The interview is likely to take 20-30 minutes and will take place at a time and place convenient to you. We would like to record the interview, with your permission, so we don't have to rely on memory of what was said.

Confidentiality: We will do our utmost to preserve your confidentiality, although this may not be possible given your unique role and the fact that we will only be interviewing a limited number of senior people such as yourself. We will not record your name on paper or in the recording, only a unique study code and your role in general terms e.g. “government policy advisor – state level”. After transcribing the interview the recordings will be destroyed. All data will be kept in password protected computers, and only senior research staff will have access to the data. We may also like to use anonymous quotes in reports or other documents, but again, only if you agree..

Further information about this study can be obtained from

Add name of Epidemiologist, to be appointed, and contact telephone number.

Information sheet for providers of services for diabetes

PUBLIC HEALTH FOUNDATION OF INDIA

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: situation analysis, and evaluation of existing programmes for screening and treatment of diabetic retinopathy

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Background: As in many countries, diabetes and its complications are becoming an increasing problem in India. As the number of people with diabetes continues to increase, and as they live longer, the rate of complications such as diabetic retinopathy is also likely to increase. This will place increased demand on services for diabetes and for those detecting and treating diabetic retinopathy.

The purpose of this study, which is being undertaken in the 10 largest cities in India, is to better understand the services that are available for managing diabetes and its complications. All the findings will be pooled and presented anonymously at a stake holder meeting in early 2014, when decisions will be made concerning the most appropriate strategies for controlling diabetic retinopathy. Financial support for these initiatives, which will be implemented by Indian partners in line with government policies, will be provided by the Queen Elizabeth Diamond Jubilee Trust.

Why has this hospital / department been selected? We drew up a list of all the large clinics providing services for diabetics in the government and private sectors, and we have chosen which hospitals to visit by random selection.

What will happen if I agree to take part? With your consent, we would like to interview you about the services you provide, and also make some observations. The interview is likely to take about an hour. If there is someone else in the facility better placed to provide some of the information, then we would be grateful if you could let us know. We would also like to interview about 6 patients who will be selected at random. We will also gain their consent before proceeding.

Confidentiality: We will do our utmost to preserve your confidentiality and the anonymity of this facility. We will only enter a unique study code into the database, all data recording forms will be kept in locked filing cabinets, and only the research staff will have access to them. All data will be kept in password protected computers, and only senior research staff will have access to the data.

We would like to record part of the interview with you, when we ask more open ended questions, with your consent, and again, we will only use a unique code, which will give your role and qualifications. We may also like to use anonymous quotes in reports or other documents, but again, only if you agree. As we will be conducting about 50 interviews across the country it will not be possible to identify you or this facility.

Further information about this study can be obtained from

Add name of Epidemiologist, to be appointed, and contact telephone number.

Information sheet for providers of eye care services

PUBLIC HEALTH FOUNDATION OF INDIA

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: situation analysis, and evaluation of existing programmes for screening and treatment of diabetic retinopathy

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Background:

As in many countries, diabetes and its complications are becoming an increasing problem in India. As the number of people with diabetes continues to increase, and as they live longer, the rate of complications such as diabetic retinopathy is also likely to increase. This will place increased demand on services for diabetes and for those detecting and treating diabetic retinopathy.

Services for preterm infants are also expanding, and as a result more babies are surviving and at risk of retinopathy of prematurity.

The purpose of this study, which is being undertaken in the 10 largest cities in India as well as 6-8 second tier cities across the country, is to better understand the services that are available for managing diabetes and its complications, and for detecting and treating retinopathy of prematurity.

All the findings in relation to diabetic retinopathy will be pooled and presented anonymously at a large meeting in early 2014, when decisions will be made concerning the most appropriate strategies for controlling diabetic retinopathy. The findings in relation to retinopathy of prematurity will also be used to identify priorities for control. Financial support for these initiatives which will be in line with government policies will be provided by the Queen Elizabeth Diamond Jubilee Trust.

Why has this hospital / eye department been selected?

We drew up a list of all the large eye hospitals and eye departments clinics in the government and private sectors. Most of the hospitals have been selected at random, but some have been deliberately selected because of the services they are known to provide.

What will happen if I agree to take part?

With your consent, we would like to interview you about the services you provide, and also make some observations. The interview is likely to take about an hour. If there is someone else in the facility better placed to provide some of the information, then we would be grateful if you could let us know. We would also like to interview about 6 patients who will be selected at random. We will also gain their consent before proceeding.

If your facility provides outreach services for detecting and treating diabetic retinopathy we may want to come back again, for a more indepth evaluation of this element of your work. This will entail talking to as many staff who are involved as possible; looking at registers and other sources of information, and may entail visits to the outreach sites. If selected, we will inform you in advance to arrange a date that is convenient, and to give you more details of the information we would like to collect.

Confidentiality:

We will do our utmost to preserve your confidentiality and the anonymity of this facility. We will only enter a unique study code into the database, all data recording forms will be kept in locked filing cabinets, and only the research staff will have access to them. All data will be kept in password protected computers, and only senior research staff will have access to the data.

We would like to record part of the interview with you, when we ask more open ended questions, with your consent, and again, we will only use a unique code, which will give your role and qualifications. We may also like to use anonymous quotes in reports or other documents, but again, only if you agree. As we will be conducting about 50 interviews across the country it will not be possible to identify you or this facility.

Further information about this study can be obtained from

Add name of Epidemiologist, to be appointed, and contact telephone number.

Information sheet for persons with diabetes and diabetic retinopathy

PUBLIC HEALTH FOUNDATION OF INDIA

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The emerging epidemic of diabetic retinopathy in India: situation analysis, and evaluation of existing programmes for screening and treatment of diabetic retinopathy

My name is..... and I am a member of a team of researchers undertaking a study across India. This study is a collaboration between the Public Health Foundation of India (PHFI), and the London School of Hygiene and Tropical Medicine. The Principle Investigator is DR GVS Murthy, Director of the PHFI Institute in Hyderabad.

Background:

In many countries diseases associated with increasing age and a more urban life style are increasing, and the same is true in India. We are particularly interested in diabetes and some of the eye conditions that can be associated with diabetes. The purpose of this study is to find out about the services being provided for diabetics, to find out how the services could be improved.

The study is being undertaken in the 10 largest cities in India. All the findings of the study will be pooled together and presented at a large meeting in early 2014, when decisions will be made on how best to improve services for diabetics, including the eye conditions associated with diabetes. Financial support for these initiatives, which will be in line with government policies and implemented by Indian partners, will be provided by the Queen Elizabeth Diamond Jubilee Trust.

Why has this hospital / eye department been selected?

We drew up a list of all the large hospitals in the government and private sectors in the city. Most of the hospitals were then chosen at random for inclusion in the study, but some have been deliberately selected because of the services they are known to provide.

Why have I been selected to take part?

We are interested in finding out the views of those who use these services, and in each hospital or clinic we will select 6-8 patients.

For diabetic clinics: We have selected people for interview at random so that men and women are represented as well people with a range of ages. So you have been included in the study by chance, because you attended the clinic today.

For eye hospitals/departments: We are particularly interested in the views of people with eye conditions from diabetes, and so we have selected people who either have had treatment for this problem, or where this treatment has been recommended. We will select individuals at random from the list of names given to us today, so that men and women are represented as well as people with a range of ages.

What will happen if I agree to take part?

With your consent, we would like to interview you about your views on the service you receive at this clinic. The interview is likely to take 20-30 minutes. We will not record the interview but only take notes. We do not envisage that you will find any of the questions embarrassing or stressful, but you are free to stop the interview at any time, or not answer specific questions, without giving a reason. Withdrawing from the study will not have any bearing on the care you receive at this facility.

Confidentiality:

We will do our utmost to preserve your confidentiality and the anonymity of this facility. We will only enter a unique study code into the database, all data recording forms will be kept in locked filing cabinets, and only the research staff will have access to them.

What will be the benefit to me in taking part?

There will be no direct benefit to you in taking part in this study. However, the information you provide will contribute significantly to any decisions made concerning how services for people with diabetes might be improved.

Will I be reimbursed for my time?

No. We anticipate that the interview will take place while you are waiting to be seen by the staff in the clinic, or while you are waiting for treatment. We do not envisage taking much of your time.

Further information about this study can be obtained from

Add name of Epidemiologist, to be appointed, and contact telephone number.

Consent form for service providers and key informant interviews

PUBLIC HEALTH FOUNDATION OF INDIA

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: situation analysis, and evaluation of existing programmes for screening and treatment of diabetic retinopathy

The study has been explained to me	Yes/No
Any questions I have had have been adequately addressed	Yes/No
I agree to the interview being recorded	Yes/No
I agree that anonymous quotes can be used in reports, documents (such as publications) or presentations	Yes/No
I agree to take part in this study	Yes/No

Eye care providers only:

If selected, I agree to the outreach programme for detecting and treating diabetic retinopathy being evaluated, which will entail data and information being collected from a range of sources

Name of participant ..... Date .....

Signature of participant.....

Name of researcher ..... Date .....

Signature of researcher.....

Consent form for persons with diabetes and diabetic retinopathy

PUBLIC HEALTH FOUNDATION OF INDIA

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: situation analysis, and evaluation of existing programmes for screening and treatment of diabetic retinopathy

The study has been explained to me	Yes/No
Any questions I have had have been adequately addressed	Yes/No
I agree to take part in this study	Yes/No

Name of participant ..... Date .....

Signature of participant.....

Name of researcher ..... Date .....

Signature of researcher.....

SERVICES FOR DIABETIC PATIENTS IN RELATION TO DIABETIC RETINOPATHY

Study no | | | | | | |
City Facility

Interview senior physician(s)

1 State _____ **2** City _____

3 Name of Facility _____

4 Type
- 1 Multi speciality Hospital
- 2 Polyclinic
- 3 Stand Alone Diabetes Clinic

5 Sector
- 1 Government
- 2 Private not for profit
- 3 Private for profit

6 City Type
- 1 Metro
- 2 Non metro

7 Type of provider
- 1 Teaching
- 2 Non-teaching

8 Type of clinic where diabetics are attended to
- 1 Clinic dedicated to diabetics
- 2 General medical clinic which includes diabetics

9 Does the hospital have an eye unit/access to eye unit?
- 1 Yes
- 2 No
- 3 Have a tie-up with an ophthalmologist

10 Who is interviewed *[May be more then one]*
- 1 Physician with qualifications in management of diabetes
- 2 General physician without specific qualification in diabetes
- 3 Other _____

11 **Staffing in clinics where diabetics are seen:**

		In post	*Full time
Physicians - numbers	Endocrinologists (qualified)		
12	General Physicians (MD/DNB)		
13	Medical Officer (MB BS etc)		
14	Residents		

* For example, if someone works half time = 0.5

		Nutritionist/ Dietician	Counselor
15 Non-physician staffing of clinics with diabetic patients	Attends every clinic diabetics attend	1 see to left	1 see to left
	Attends most clinics diabetics attend	2 see to left	2 see to left
	Attends only a few clinics	3 see to left	3 see to left

16 Other staff at diabetic clinics
- Laboratory technician
- Nurses (qualified)
- Other paramedical staff

17 Other (non-lab) technical staff, specify _____

18 Is any member of staff skilled in direct ophthalmoscopy
- 1 Yes
- 2 No

Infrastructure:

	For HbA1C	For Blood sugar	For Lipids	Renal function
Yes, provided by the hospital	19 [1]	20 [1] *see to left*	21 [1] *see to left*	22 [1] *see to left*
Yes, contracted out	[2]	[2] *see to left*	[2] *see to left*	[2] *see to left*
No. Patients have to be referred	[3]	[3] *see to left*	[3] *see to left*	[3] *see to left*

23 Pharmacy for DM medication

- [1] Yes, provided by the hospital
- [2] Yes, but contracted out
- [3] No. Prescription only

Equipment

	24 BP apparatus	25 Weighing scale
Yes, at least 1 is functioning	[1]	[1]
Available but none functioning	[2]	[2]
None	[3]	[3]

	26 Fundus/retinal camera	27 Direct ophthalmoscopes
Yes, at least 1 is functioning	[1]	[1]
Available but none functioning	[2]	[2]
None	[3]	[3]

28 Visual acuity charts

- [1] Yes, enough
- [2] Yes, but not enough
- [3] None

Policies/programmes:

29 Do they know about the National programme for prevention and control of Diabetes, Cancer and Stroke?

- [1] Yes, knows about the programme and what it entails
- [2] Yes, but knows little about what it entails
- [3] Has not heard of it *(If option 3, skip to Q 36)*

30 Are they receiving any support from NPCDCS?

- [1] Yes, on a regular basis
- [2] Yes, occassionally
- [3] No
- [4] Does not know

Workload:

31 Number of clinics seeing diabetics/week [ ][ ] clinics

Outpatient workload **diabetic patients ONLY**

In 2011	In 2012
32 [ ] New diabetics	**33** [ ] New diabetics
[9999=not known] "New" = new to the clinic	*[9999=not kno "New" = to the clinic*
34 [ ] Old+new diabetics	**35** [ ] Old+new diabetics
[9999=not known] "Old"=follow ups	*[9999=not kno "Old"=follow ups*

36 Are there enough staff to manage the number of patients

- [1] Yes, always
- [2] Yes, most of the time
- [3] Usually not

37 How often do they receive referrals from ophthalmologists

- [1] Very often: at least one per out patient session
- [2] About once a month
- [3] Rarely or never
- [4] Does not know

Practice patterns

		Management of diabetes	Detection/management of complications
38	Are there printed protocols in clinic	1 Yes, and readily available 2 Yes, but not readily available 3 No	1 Yes, and readily available 2 Yes, but not readily available 3 No
39	Are there information sheets diabetics in the clinic	1 Yes 2 No	If yes, is there mention of: 1 Eye complications 2 No mention of eye complications
40	Does each diabetic have their own diet card?	1 Yes 2 No	
41	Does each patient have their own card for monitoring glucose?	1 Yes 2 No	**42** If yes: ..... 1 Eye examination included 2 Eye examination not included
43	Does every diabetic attending the clinic go through a standard set of procedures/assessments?	1 Yes 2 No: only what is needed at each visit 3 Does not know	

Follow up and medical /patient records

44 Are patients sent a reminder to attend the diabetic clinic for follow up?

1 Yes
2 No

45	Type of records	1 Paper records only	*Go to Q53*
		2 Paper records entered into database	*Go to Q54*
		3 Fully electronic	*Go to Q55*
		4 None	*Go to Q56*
46	If paper records only are used, are they available for follow ups?	1 Yes, for the majority of patients 2 For about half of the patients 3 For less than half of the patients	
47	Would fully electronic patient records be useful in this clinic	1 Yes 2 No	If yes.....
48	Do they have access to records from the eye unit/department	1 Yes 2 No 3 Not applicable	
49	Is information on eyes/vision routinely recorded in the medical records?	1 Yes 2 No	

Fees for service

50 Do patients pay for the service?

1 No, it is free
2 Yes, but it is subsidised
3 Yes, they pay full fees
4 A mixture of the above

Diabetic retinopathy

How is diabetic retinopathy dealt within this clinic?

[Circle ALL that apply]

What is done

In this clinic *.....if examined clincially, by whom.....*

51

1	Retina examined clinically, routinely at first attendance
2	Retina examined clincally, annually
3	Retina examined clinically but only if a problem is suspected
4	Retinal photography routinely at first attendance
5	Retinal photography, annually
6	Retinal photography if a problem is suspected

By whom*

52

1	Physician
2	Ophthalmologist
3	Optometrist
4	Technician
5	Other _____

Referred *.....if referred, where.....*

53

1	Referred routinely for retinal exam - at first attendance
2	Referred routinely for retinal exam - annually
3	Referred for retina examination if a problem is suspected
4	Other _____

54 Where referred

1	Eye dept, this hospital
2	Eye dept, other hospital
3	Private ophthalmologist
4	Optometrist
5	Other

Other

55

1	Nothing is done
2	Does not know

If nothing is done, what are the reasons…

Referrals:

56 How frequently are patients referred to this clinic by ophthamologists?

1	At least one a week
2	About once a month
3	Less than once a month
4	Do not know

57 How frequently are patients referred to an ophthamologist?

1	At least one a week
2	About once a month
3	Less than once a month
4	Do not know

Knowledge of diabetic retinopathy

58 In your clinical practice, what are the major risk factors for diabetic Retinopathy?

[Question only for Physicians? Circle ALL that are metionned]

[Write down others not listed in Other]

1	Age at onset
2	Duration of diabetes
3	Poor control of diabetes
4	Hypertension
5	High lipids
6	Renal/kidney failure
7	High sugar diet
8	Smoking
9	Lack of excercise
10	Obesity
11	Other_____
12	Does not know

59 How often do you suggest diabetic patient have their eyes assessed for diabetic retinopathy?

1	Once a year
2	Once every two years
3	When they complain of vision probs
4	Others _____

60 When should diabetics start having their eyes examined for retinopathy?

1	As soon as they are diganosed
2	After several years of diabetes
3	When they complain of problems
4	Does not know

61 Interested in receiving training in diabetic retinopathy

1	Yes
2	No

Comments:

62 Interested in setting up a DR screening service

1	Yes
2	No

Comments:

OBSERVATION:

		On diabetes management		On complications	
Printed protocols in clinic	**63**	1 Yes, and readily available 2 Yes, but not readily available 3 None	**64**	1 Yes, and readily available 2 Yes, but not readily available 3 None	
Information sheets for diabetics	**65**	1 Yes 2 None	**66** If yes:	1 Eye complication mentioned 2 Eye complications not mentioned	
67 Individualized diet card		1 Yes 2 No	**68** Patient monitoring cards	1 Yes 2 No	
			69 If yes:	1 Eye examination included 2 Eye examination not included	

Equipment

70 Functioning BP apparatus [ ] (number)

71 Functioning weighing scales [ ] (number)

72 Functioning direct ophthalmoscopes [ ] (number)

73 Visual acuity charts [ ] (number)

74 Functioning retinal camera [ ] (number)

	75 HbA1C	**76 Blood sugar**	**77 Lipids**	**78 Renal function**
Visit the laboratory to see tests they do on site:	1 Yes 2 No	1 Yes 2 No	1 Yes 2 No	1 Yes 2 No

Comments

INTERVIEW WITH DIABETIC PATIENTS IN DIABETIC CLINIC

Study number [ ][ ][ ][ ][ ][ ][ ]

City *Facility* Patient

Study participants

Select 3 men, AND 3 women one in each of the age groups:- less than 40 years; 40-60 years; older than 60 years

Include: *Patients who are waiting to be seen*

Exclude: *Patients who have already completed all their consulations, as they will want ot leave the clinic*

1 State _____ **2 City** _____

3 Name of clinic _____

4 Sector
- [1] Government
- [2] Private not for profit
- [3] Private for profit

5 City type
- [1] Metro
- [2] Non metro

6 Age [ ][ ] years

7 Gender
- [1] Male
- [2] Female

8 Education
- [1] None: cannot read or write
- [2] Only primary
- [3] Secondary
- [4] Graduate or above

9 Occupation

	Working age	or	Retired
[1]	Unskilled		Unskilled
[2]	Semi-skilled		Semi-skilled
[3]	Skilled		Skilled
[4]	Professional		Professional
[5]	Housewife		Housewife
[6]	Unemployed		Was unemployed

10 How long ago was your diabetes diagnosed? [ ][ ] years

11 How long have you been attending this clinic? [ ][ ] years *<1 if less than one year*

12 How frequently do you visit this clinic? Every [ ][ ] months *If > 12 months go to Q14*

13 Why do you visit this clinic less than once a year?
[Cicle ALL that aree mentionned]
- [1] Happy with General Pracitionner
- [2] As per doctors instructions
- [3] I also attend another hospital clinic
- [4] No need: my diabetes is stable
- [5] Forgot
- [6] Not enough time
- [7] Financial reasons
- [8] No-one to accompany me
- [9] I treat myself
- [10] Other _____

14 Do you also go to a General practitionner about your diabetes?
- [1] Yes *Go to Q15*
- [2] No *Go to Q16*

15 How frequently do you visit the General Practitionner? Every [ ][ ] months

16 How you manage your diabetes?
[Circle ALL that apply]
- [1] Diet only
- [2] Oral medication
- [3] Insulin
- [4] Traditional Indian medicine
- [5] Exercise
- [6] Yoga
- [7] Nothing

17 Have you been given any information about diabetes by this clinic?

1	Yes. Leaflet or pamphlet	
2	Yes. Video	
3	Yes. Counseling	
4	Yes. Poster	
5	No	*Go to Q19*

18 Was this information helpful to you?

1	Yes
2	No

19 Apart from this clinic, have you found out about diabetes from any other sources?

1	Yes.	*Go to Q20*
2	No	*Go to Q21*

20 Where was this information obtained?

[Circle ALL that apply]

1	Oher physician/clinic
2	Family, friends, neighbour
3	Health worker
4	TV / Radio / newspaper
5	Posters
6	Internet
7	Other _____

21 What do you think is the cause of your diabetes?

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

1	Being overweight
2	Lack of exercise
3	Family history
4	High sugar intake
5	High food intake
6	Increasing age
7	God's will
8	Do not know
9	Stress
10	Other _____

22 Does anyone else in the family have diabetes?

1	Yes
2	No

23 Do you also have high blood pressure?

1	Yes
2	No
3	Does not know

24 What tests or assessments do you usually have when you attend this clinic?

[Circle 1, 2 or 3 for each]

	Yes	No	Does not know
Blood tests for glucose	1	2	3
Blood tests for fats/lipids	1	2	3
Blood tests for kidney function	1	2	3
Blood test but not sure why	1	2	3
Urine check	1	2	3
Weight measured	1	2	3
Blood pressure check	1	2	3
Foot check	1	2	3
Eye examination	1	2	3

25 How long ago was the last check done for the following:

Blood tests	☐☐ months	*[99=does not know]*
Urine check	☐☐ months	*[99=does not know]*
Weight measured	☐☐ months	*[99=does not know]*
Blood pressure check	☐☐ months	*[99=does not know]*
Foot check	☐☐ months	*[99=does not know]*
Eye check	☐☐ months	*[99=does not know]*

26 In addition to the doctor, do you usually see the following people when you come to this clinic?
[Circle 1, 2 or 3 for each]

Yes	No	Does not know	
1	2	3	Counselor/social worker
1	2	3	Dietician
1	2	3	Nurse
1	2	3	Optometrist/eye doctor

27 How much time does the doctor usually spend with you in this clinic? ☐☐ minutes

28 Do you monitor your own diabetes at home?

1	Yes. Glucometer
2	Yes. Urine testing
3	No

29 How well do you think your diabetes is being controlled?

1	Very well
2	Well
3	Adequate
4	Poor
5	Very poor
6	Does not know

30 What do you understand "good control of diabetes" to mean?

1	Blood glucose/HbAC1 within certain limits
2	Any other response

31 What are the main challenges you face in controlling your diabetes?
[Do not read out list]
[Circle ALL that are mentionned]

Comments

1	Found it hard to accept being diabetic
2	Making a clinic appointment
3	Don't have time
4	Remembering to take medication
5	Changing diet
6	Taking exercise
7	Cost of Investigation/Tests
8	Cost of Medication
9	Loss of wages
10	Distance to the clinic
11	No challenges
12	Others _____

32 Has anyone in this clinic ever spoken to you about the complications of diabetes?

1	Yes
2	No

33 Do you know of any serious complications of diabetes?

1	Yes *Go to Q34*
2	No *Go to Q36*

34 Which complications do you know about?
[Do not read out the list]
[Circle ALL that are mentionned after asking this question]

Complications *If any mentionned go to Q35*

1	Foot ulcers
2	Tingling or numbness
3	Losing a leg
4	Kidney failure
5	Blindness / visual loss
6	Heart attack
7	Stroke
8	Other _____

35 Which complication concerns you most?

1	Foot ulcers
2	Tingling or numbness
3	Losing a leg
4	Kidney failure
5	Blindness / visual loss
6	Heart attack
7	Stroke
8	Other _____

36 Are you receiving treatment for any complications?

1	Yes, retinopathy / eye problems
2	Yes, other complications
3	No

37 Diabetes can sometimes affect the eye: do you know how it can affect the eye?

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

1	Yes. It can cause cataract
2	Yes. It can affect the retina
3	Yes. Blindness / loss of vision
4	Does not know

38 Have you ever had an eye examination after eye drops where put in your eyes?

1	Yes	*Go to Q39*
2	No	*Go to Q42*
3	Does not know	

39 If yes, how long ago was the last eye examination?

[ ][ ] months *[99=cannot remember]*

40 If yes, who did the last examination

1	Physician
2	Eye doctor
3	Optometrist
4	Other

41 Where was the examination done?

1	In this clinic
2	In General practice clinic
3	In Private diabetes clinic
4	In an eye department/clinic/hospital
5	Optometrist/optician shop in the market
6	Other _____

42 Has anyone in this clinic ever said you should have your eyes checked?

1	Yes
2	No

43 What is your opinion about having your eyes checked every year?

[Do not read out the list]

[Circle one after asking this question]

1	There is no need
2	Only if I have an eye problem
3	Yes, I would agree to this
4	I am doing this already
5	Other _____

44 In what way could the diabetic services provided in this clinic be improved?

Comments

45 Do you have any other comments or questions?

Comments

INDEPTH INTERVIEW WITH HEAD OF DEPARTMENT or SENIOR PHYSICIAN

(Please record the whole interview after taking necessary consent)

Study no | | | | | |

Name of hospital _____ City _____ Facility _____

1 What are the main challenges you and your colleagues confront in managing your diabetic patients?

Probe: Staffing levels; equipment; patient awareness / socioeconomic status etc

Probe: Has the situation changed over the last 10 years? If so, in what way?

Probe: What do you envisage the situation will be like in 5-10 years?

2 Do diabetics monitor their own DM? If so, how do they monitor their diabetes? (urine testing; glucometer)

Probe: How well do patients comply with monitoring their diabetes? What are the main problems/difficulties faced by them?

3 Are patients given their own "patient monitoring records"

Probe: How well do patients comply with a) monitoring b) diet c) taking medication d) attending clinic

4 Is there a system for prioritising which patients need to be seen by senior staff and how often?

5 Please can you describe the usual procedure for a diabetic patient who attends the clinic for the first time?

Probe: What tests and proceudures are routinely done; which member(s) of staff do they see;

Probe: What are patients told; are they given any information

Probe: Are patients counselled about the possible complications of diabetes

6 What about follow up patients?

Probe: Do patients usually attend regularly?

Probe: What are the main factors which prevent regular clinic attendance?

7 Do you hold outreach camps for diabetes?

Probe: If yes, are these specifcaly for diabetes, or for other conditions too?

Probe: How often do you hold these camps and where

8 Do you have much communication with ophthalmologists?

Probe: Do they send you referrals?

Probe: How often do you refer patients to an ophthalmologist

9 What do you and your colleagues do about diabetic retinopathy

Probe: What are the main constraints you face?

Probe: Where do you refer patients for eye examination?

Probe: [If applicable] Are eye examinations routinely conducted?

10 How might you be able to deal with the challengs of diabetic retinopathy in the service you provide?

Probe: Would training in ophthalmoscopy be of value?

Probe: What about having a retinal camera with images being taken by a trained technician and review by an ophthalmologist?

11 Do you think that the staff working in this clinic know enough about diabetic retinopathy?

Probe: Do they know about the risk factors?

Probe: Do they know what types of retinopathy need to be treated?

Probe: Do they know how the different types or stages of retinopathy are treated?

12 Would you and/or your staff value training in diabetic retinopathy?

Probe: If yes, as part of training on managing complications in general, or just DR

Probe: What would be your preferred training: intensive course / spread out over several sessions?

13 Please can you tell me what you know about the Ministry of Health's policies on NCDs

14 Any other comments?

INDEPTH INTERVIEWS WITH COUNSELLOR or DIETICIAN in DIABETES CLINIC

(Please record the whole interview after taking necessary consent)

Study No | | | | | | |
City Facility

1 State _____ **2** City _____

3 Name of hospital _____

4 Sector
- 1 Government
- 2 Private not for profit
- 3 Private for profit

5
- 1 Metro
- 2 Non metro

6 Who interviewed
- 1 Counselor
- 2 Dietician

7 Do you have any formal qualifications as a counselor / dietician?
- 1 Yes. Formal qualification
- 2 Yes, but on the job only
- 3 No

8 How long have you worked in this clinic? | | | Years

9 What proportion of diabetics would you say attend the clinic on a regular basis?
- 1 The majority
- 2 Most (more than half)
- 3 About half
- 4 Some (less than half)
- 5 Very few / none

10 What proportion of diabetics monitor their diabetes on a regular basis?
- 1 The majority
- 2 Most (more than half)
- 3 About half
- 4 Some (less than half)
- 5 Very few / none

11 What methods are most commonly used by patients to monitor their diabetes?
- 1 Glucometer
- 2 Urine testing

12 What are the main challenges patients in this clinic face in controlling their diabetes?

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

Comments

- 1 Patients find it hard to accept being diabetic
- 2 Making a clinic appointment
- 3 Lack of time
- 4 Remembering to take medication
- 5 Changing diet
- 6 Taking enough exercise
- 7 Cost of Medication
- 8 Cost of investiigations/Tests
- 9 Loss of wages
- 10 Distance to the clinic
- 11 No challenges
- 12 Others

13 What Topics do you usually cover when counseling a diabetic Patient?

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

1	How to control their Diabetes
2	Improving their Diet
3	Taking more excercise
4	How to give insulin injections
5	Looking after their feet
6	Checking their Blood Pressure
7	Having an Eye Examination
8	How to monitor their diabetes
9	Other _____

14 What are some of the serious complications of diabetes.

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

1	Foot ulcers
2	Tingling or numbness
3	Losing a leg
4	Kidney failure
5	Blindness / visual loss
6	Heart attack
7	Stroke
8	Other _____

15 Diabetes can sometimes affect the eye: do you know how it can affect the eye?

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

1	Yes. It can cause cataract
2	Yes. It can affect the retina
3	Yes. Blindness / loss of vision
4	Does not know

16 Do you mention the eye complications to patients?

[Do not read out the list]

[Circle ALL that are mentionned after asking this question]

1	Yes, very often
2	Yes, sometimes
3	Yes, but only if they have complaints
4	No

17 Is there a formal diabetic education program which the counsellor imparts

1	Yes
2	No

18 If yes, how many sessions or modules ____

19 In what way could the diabetic service provided in this clinic be improved?

Comments

20 Do you have any other comments or questions?

Comments

Thank you for your time

EYE CARE SERVICES FOR DIABETIC RETINOPATHY AND ROP

Study no | | | | | | City Facility

Interview head of vitreortinal / medical retina. If not available, interview senior ophthalmologist

1 State _____ **2** City _____

2A.Type of City | 1 | Metro | 2 | Non metro |

3 Hospital _____

4 Sector | 1 | Government | 2 | Private not for profit | 3 | Private for profit |

5 Type of provider | 1 | Teaching | 2 | Non-teaching |

6 Type of provider | 1 | Specialist eye hospital with satellite clinics/hospitals | 2 | Specialist eye hospital - no satellites | 3 | Eye Department in general hospital |

7 Who is being interviewed *[May be more then one per hospital]* | 1 | Person in charge of VR or medical retina service | 2 | Senior ophthalmologist | 3 | Director of the Hospital | 4 | Other _____ |

Workload

8 Number of beds for eye patients | | |

9 Statistics for 2012*

Number of outpatient attendances for NEW patients:	
Total number of outpatient attendances:	
Total number of cataract operations:	
Total number of laser sessions:	
Total number of laser treatments for diabetic retinopathy :	
Total number of diabetic patients treated with laser	
Number of VR surgeries for diabetic retinopathy	
Number of total number of patients who had ST- diabetic retinopathy	
Total number of patients treated with intrav itreal injections for diabetic retinopathy	

*[0000=none; 9999=not known]

SERVICES FOR DIABETIC RETINOPATHY IN THE HOSPITAL/DEPARTMENT

10 Are there OPD sessions specifically for patients with retinal conditions? | 1 | Yes | 2 | No |

11 Staffing in clinics where patients with diabetic retinopathy are seen

	In post	Full time equivalents*
Ophthalmologists - retina specialist**		
Ophthalmologists - fully qualified		
Ophthamology residents		
Medical Officer (MB BS etc)		
Residents		

** if someone works half time = 0.5** ** specific training in retina*

12 Would any of the ophthalmologists like further training in the management of diabetic retinopathy?

1 Yes, in medical retina, incl. laser treatment
2 Yes, in vireo-rinal surgery
3 No

13 Nurses / paramedics in OPD

Nurses - qualification in ophthalmology
Nurses - fully qualified but not in ophthalmology
Paramedics

Available in the hospital:

14 Low vision worker
1 Fully qualified
2 On the job training
3 None

15 Optometrist
1 Fully qualified
2 On the job training
3 None

Available in the hospital:

16 Retinal photographer
1 Yes
2 No

17 Equipment technician
1 Yes
2 No

Available in the hospital:

18 Counsellor
1 Fully qualified
2 On the job training
3 None

19 Social / Welfare Officer
1 Fully qualified
2 On the job training
3 None

Diagnositc equipment in outpatient depar tment (OPD)

20 Indirect ophthalmoscope
1 Available and functioning
2 Available but not functioning
3 Not available

21 Fundus camera
1 AvailableAvailable and functioning
2 AvailableAvailable but not functioning
3 Not avail Not available

22 Fluorescien angiography
1 Available and functioning
2 Available but not functioning
3 Not available

23 OCT
1 AvailableAvailable and functioning
2 AvailableAvailable but not functioning
3 Not avail Not available

Whether IDO laser or slitlamp laser? *(Make Note)*

24 Laser for diabetic retinopathy
1 Available and functioning
2 Available but not functioning
3 Not available

25 Full set of contact lenses for laser
1 Yes
2 No

26 Ultrasound (A and B scan)
1 Available and functioning
2 Available but not functioning
3 Not available

27 For vitreo-retinal surgery
1 All availa All available and functioning
2 AvailableAvailable but not functioning
3 Not avail Not available

Comments on equipment

28 Is more essential equiment required to manage diabetic retinopathy, for diagnosis as well as treatment (laser and VR surgery)

1	Yes	*If yes, specify*
2	No	

Treatment of diabetic retinopathy

29 Treatments available for diabetic retinopathy in this hospital
[Circle 1 or 2 for ALL options]

Yes	No	
1	2	Laser photocoagulation
1	2	Anti-VEGF preparations
1	2	Triamcinalone or other IV steroid
1	2	Uncomplicated vitrectomy
1	2	Complex vitreo-retinal surgery

30 Is there a usually a waiting list for diabetic patients needing laser treatment

1	Yes	*Go to Q31*
2	No	*Go to Q32*

31 How long is the waiting list typically? ____ months *[000=no waiting list]*

32 What proportion of diabetics needing laser treatment attend all the sessions required:

1	The majority (>90%)
2	Most (75-90%)
3	About half
4	Less than half
5	Not known

Comments on compliance with treatment

33 What proportion of diabetics having laser attend follow up after laser has been completed?

1	The majority (>90%)
2	Most (75-90%)
3	About half
4	Less than half
5	Not known

Comments on compliance with follow up

34 Does the hospityal have a system for tracking whether those needing treatment attend, and whether patients attend for follow up after treatment

1	Yes
2	No

Practice patterns

35 Are all adult new patients attending the hospital routinely tested for glycosuria, regardless of their presenting complaint?

1	Yes
2	No

36 Do known diabetics routinely have an HbA1C test?

1	Yes, all
2	Yes, those with retinopathy
3	No

37 Are there printed protocols for doctors working in the OPD on diabetic retinopathy?
[Circle ALL that apply]

1	Yes, on indications for treatment
2	Yes, on how to treat with laser
3	Yes, on how to treat with other methods
4	No

38 Are there information sheets for patients with diabetic retinopathy?

1	Yes
2	No

Referrals

39 How often does this hospital receive diabetics referred from local GPs or physicians?

1	Very frequently: every OPD
2	Often: about once a month
3	Uncommon: every 3-6 months
4	Rare: once or twice a year
5	Extremely rare
6	Does not know

40 How often do staff in this hospital refer diabetics to local GPs or physicians?

1	Very frequently: every OPD
2	Often: about once a month
3	Uncommon: every 3-6 months
4	Rare: once or twice a year
5	Extremely rare
6	Does not know

Medical records:

41 What type of medical records does the hospial use

1	Paper records only	*Go to Q42*
2	Paper + database	*Go to Q43*
3	Fully electronic	*Go to Q45*
4	None	*Go to Q45*

42 If paper records only are used, how often are they available for follow up visits?

1	For the majority of patients
2	For about half of the patients
3	For less than half of the patients

43 Would a fully electronic patient records be useful in this clinic?

1	Yes	*Go to Q52*
2	No	*Go to Q54*

44 Would a fully electronic patient records be feasible in this clinic?

1	Yes
2	No

45 Do they (hospitals) have access to records from the diabetic/general medical clinic?

1	Yes
2	No
3	Not applicable

OUTREACH FOR DIABETIC RETINOPATHY

46 Does this eye hospital / department have a regular outreach programme specifically for detecting diabetic retinopathy?

1	Yes	*Go to Q47*
2	No	*Go to Q50*

47 Which best describes your outreach for detecting diabetic retinopathy

[Circle ALL that apply]

		Is an equipped mobile van used?
1	House to house survey to detect diabetics who are then examined/referred	
	Outreach camps in the community with...:	
2	...clinical examination	
3	...retinal photography/imaging with interpretation there and then	1 Yes / 2 No
4	...retinal photography/imaging with interpretation via telemedicine	1 Yes / 2 No
5	...other, specify _____	
	Vision Centres (VC) with...:	
6	...clinical examination and referral by Vision Centre staff	
7	...retinal photography/digital imaging with interpreation by VC staff	1 Yes / 2 No
8	...retinal photography/imaging with interpretation via telemedicine	1 Yes / 2 No
9	...other, specify _____	
	In clinics for diabetic patients run by physicians....	
10	...clinical examination	
11	...retinal photography/imaging with interpretation there and then	1 Yes / 2 No
12	...retinal photography/imaging with interpretation via telemedicine	1 Yes / 2 No
13	...other, specify _____	
	Other	Is an equipped mobile van used?
14	Mass media campaigns	1 Yes / 2 No
15	Other approach, not listed above. Specify: _____	1 Yes / 2 No

48 During outreach what happens to diabetics detected with retinopathy needing treatment?

[Circle ALL that apply]

1 Referred to base hospital
2 Treated during outreach, if possible
3 Referred to another eye hospital
4 Other, specify _____

49 Which organization(s) supports the outreach for diabetics: _____

Training and research undertaken by the eye unit / department / hospital:

50 Has the hospital undertaken any training / awareness raising about diabetic retiopathy?

1 Yes, for the general public
2 Yes, during outreach
3 Yes, for physicians
4 Other _____
5 No

51 Are staff in the hospital engaged in research?

1 Yes, specify _____
2 No

52 Does the hospital have capacity to under take the following training

1 Physicians in prevention and management of DR
2 Ophthalmologists outside this hospital: detection of DR
3 Ophthalmologists outside this hospital: laser treatment of DR
4 Ophthalmologists outside this hospital: surgery for advanced DR
5 None of the above

RETINOPATHY OF PREMATURITY

53 Is this hospital involved in screening and treating retinopathy of prematurity:

1 Yes *Go to Q54*
2 No *Go to Q65*

54 How many NICUs are involved in the programme?

☐ Government / univeristy NICUs
☐ Private NICUs

55 Which best describes your ROP screening programme

[Circle ALL that apply]

1	Regular weekly examination of infants in the NICU by an ophthalmologist
2	Ophthalmologist visits the NICU when requested by the NICU staff
3	Babies come to the eye hospital/department for examination
4	A technician visits and uses a RetCam to take retinal images
5	Other, specify: _____

56 How are the babies eyes examined during screening?

[Circle ALL that apply]

1	Indirect ophthalmoscope
2	RetCam
3	Direct ophthalmoscope

57 Where are babies with severe ROP treated?

[Circle ALL that apply]

1	In the NICU
2	In the operating theatre of the maternity hospital
3	In the eye hospital/department

58 Treatment methods:

Most usual first treatment

1	Laser
2	Cryo
3	Anti-VEGF
4	Other, specify: _____

59 Other treatment which may also be used

1	Laser
2	Cryo
3	Anti-VEGF
4	Other, specify: _____

60 What happens to babies with very advanced ROP (Stage 4 or 5)?

1	Operated in this hospital
2	Referred to another eye hospital/department
3	It is too late for treatment
4	Other, specify: _____

61 ROP data for 2012

Total number of babies screened _____ *[9999=not known]*

Total number of babies treated with laser/cryo/AntiVEGF _____ *[9999=not known]*

62 What other services are available for preterm infants:

1	Low vision service
2	Referral for rehabilitation
3	Long term follow up for other ocular morbidity

63 Has the hospital undertaken any training / awareness raising about ROP?

1	Yes, for the general public
2	Yes, for physicians
3	Other
4	No

64 Are staff in the hospital engaged in research?

1	Yes, specify _____
2	No

65 Does the hospital have capacity to under take the following training

1	Neonaologists
2	Ophthalmologists outside this hospital: screening for ROP
3	Ophthalmologists outside this hospital: laser treatment of ROP
4	Ophthalmologists outside this hospital: surgery for advanced ROP
5	None of the above

66 Does this hospital have the capacity to extend ROP programmes to other NICUs or be willing to start a new ROP programme?

1	Yes
2	No

67 If no, what are the constraints?

Comments

INDEPTH INTERVIEW WITH SENIOR PHYSICIAN WHO SEES/TREATS DIABETIC RETINOPATHY

Study No | | | |

Greeting. Diabetes and its complications is becoming an increasing problem in many countries, including India.
I would be grateful if you could spare 20 minutes to talk about the services this hospital provides for diabetic retinopathy

1 Diabetic retinopathy is likely to become an increasing problem in India: what are your views on how this might best be tackled

Probe: Do you see a role for non-clinicians in detecting diabetic retinopathy?
Probe: Do you see a role for non-clinicians in treating diabetic retinopathy?
Probe: Are there any technological advances which would be of real value?

2 Please can you let me know how the medical records are managed in this hospital?

Probe: Would an electronic patient record system for diabetic patients be of value?
Probe: What challenges would you envisage with an electonic system?

3 Please can you let me know what your opinions on the service this hospital provides for diabetic retinopathy.

Probe: Are you able to manage the volume of patients in the OPD?
Probe: Are you able to manage the volume of patients needing treatment?
Probe: Would the service be able to manage a greater volume?
Probe: What additional resources would be required for this service to manage greater volumes?

4 Do you have any concerns about the quality of care your hospital is able to provide for patients with diabetic retinopathy?

Probe: What might make a difference to the quality

5 Are there any systems in place for contacting patients who fail to attend for laser treatment (first or follow up visits)?

Probe: What are the main challenges facing patients with diabetic retinopathy needing treatment
Probe: How do you think compliance might be improved?

6 Would any of the staff in the hospital value training in diabetic retinopathy?

Probe: Are there enough training centres in India?

7 What are your views on initiating a screening programme for diabetics in diabetic clinics in your area?

Probe: Would this be acceptable to the physicians
Probe: Would this be acceptable to the patients
Probe: What other challenges would you anticipate with this approach

8 What other appproaches to detecting DR needing treatment might be explored?

9 Are you aware of the provisions laid out in the National Plan for the Control of Blindness?

Probe: Does the hospital avail themselves of these provisions?
Are your patients aware about these provisions?

10 Are you aware of the national programme for control of diabetes, CVD and stroke?

11 What are the difficulties/delays faced by patients in management of Diabetic Retinopathy?

12 Any Suggestions to overcome them?

INTERVIEW WITH PATIENTS WITH DIABETIC RETINOPATHY IN THE EYE CLINIC

Study number | | | | | | |

City | *Facility* | *Patient*

Study population:

Select 3 men, AND 3 women, one in each of the age groups :- less than 40 years; 40-60 years; older than 60 years

Include: *Already diagnosed with diabetic retinopathy. They may have already had, or not had treatment for DR*
Patients who are waiting to be seen

Exclude: *Exclude patients who are waiting for their first laser treatment as they are likely to be anxious*
Patients who have already completed all their consulations, as they will want ot leave the clinic

1 State _____ **2** City _____

3 Name of clinic _____

4 Sector
- 1 Government
- 2 Private not for profit
- 3 Private for profit

5 City type
- 1 Metro
- 2 Non metro

6 Age ____ years

7 Gender
- 1 Male
- 2 Female

8 Literacy
- 1 Only primary
- 2 Secondary
- 3 Graduate or above
- 4 Cannot read or write

9 Occupation

	Working age	Retired
1	Unskilled	Unskilled
2	Semi-skilled	Semi-skilled
3	Skilled	Skilled
4	Professional	Professional
5	Housewife	Housewife
6	Unemployed	Was unemployed

10 How long ago was your diabetes diagnosed? ____ years *[99=does not know]*

11 Please can you tell me how you manage your diabetes?
[Circle ALL that apply]
- 1 Diet only
- 2 Oral medication
- 3 Insulin
- 4 Traditional Indian medicine
- 5 Exercise
- 6 Yoga
- 7 Nothing

12 Who looks after your diabetes:
[Circle ALL that apply]
- 1 Physician in a government hospital
- 2 Physician in a private hospital/clinic
- 3 General practitionner
- 4 Pharmacist
- 5 Traditional medicine/yoga
- 6 I manage my own diabetes
- 7 Other _____

13 Do you monitor your own diabetes at home?
- 1 No
- 2 Yes, glucometer
- 3 Yes, urine testing

14 How well do you think your diabetes is being controlled?
[Circle ONE]

1	Very well
2	Well
3	Adequate
4	Poor
5	Very poor
6	Does not know

15 What do you understand "good control of diabetes" to mean?

1	Blood glucose/HbA1C within certain limits
2	Any other response

16 How long ago was the last check done for the following:

Blood tests		months	*[99=does not know]*
Urine check		months	*[99=does not know]*
Weight measured		months	*[99=does not know]*
Blood pressure check		months	*[99=does not know]*

17 Did you have any loss of vision in one or both eyes before the diabetic retinopathy was detected?

1	Yes	*Go to 18*
2	No	*Go to 19*

18 After you noticed you had some loss of vision, what did you do?

1 _____

and then what did you do? 2 _____

and then what did you do? 3 _____

and then what did you do? 4 _____

19 How was the diabetic retinopathy detected?

1 _____

and then what did you do? 2 _____

and then what did you do? 3 _____

and then what did you do? 4 _____

20 RESEARCHER: complete the following which best describes how the DR was detected

1	At an outreach camp held by this hospital
2	At an outreach camp held by another hospital
3	At a Vision Centre run by this hospital
4	At a Vision Centre run by another hospital
5	At the diabetic clinic the participant attends
6	After referral by diabetic clinic the participant attends
7	At this hospital because of vision problems
8	At this hospital but did not have vision problems
9	At another eye hospital/department (not private)
10	At a private ophthalmic technician/optometrist's clinic
11	At a private ophthalmologist's clinic
12	Other, specifiy: _____

21 Did you have any difficulties accessing this eye clinic?

1	No
2	Yes, it is a long way to travel
3	No-one to accompany me
4	Cost of travel
5	Takes a lot of time
6	Loss of wages
7	Other _____

22 Have you been given any information about diabetic retinopathy by this clinic?

1	No
2	Yes. Leaflet or pamphlet
3	Yes. Video
4	Yes. Counseling

23 Was the information clear and adequate?

1	No
2	Yes

24 Have you found out about diabetic retinopathy from any other sources?

1	No
2	Yes *Go to Q25*

25 Where was information obtained?
[Circle ALL that apply]

1	Family, friends, neighbour
2	Health worker
3	TV / Radio / newspaper
4	Internet
5	Other _____

26 What do you think is the cause of your diabetic retinopathy?
[Circle ALL that apply]

1	Age
2	Had diabetes a long time
3	Poor blood sugar/poor control
4	High blood pressure
5	High lipids
6	Smoking
7	God's will
8	Do not know
9	Other _____

27 What are the main challenges you face in controlling your diabetes?
[Circle ALL that apply]

Comments:

1	Found it hard to accept being diabetic
2	Making a clinic appointment
3	Don't have time
4	Remembering to take medication
5	Changing diet
6	Taking exercise
7	Cost of Medication
8	Cost of Investigaton/Tests
9	Loss of wages
10	Distance to the clinic
11	No challenges
12	Others _____

28 Have you had any treatment for your diabetic retinopathy?

1	No. Told none was possible
2	No, but am waiting for treatment
3	Yes, laser
4	Yes, an injection in the eye
5	Yes, an operation
6	Other

29 Do you know of any other complications of diabetes?

1	No *Go to Q32*
2	Yes

30 Which other complications do you know about?
[Do not read out the list]
[Circle ALL that are mentionned after asking this question]

If any of the below metionned Go to Q31

1	Foot ulcers
2	Tingling or numbness
3	Losing a leg
4	Kidney failure
5	Blindness / visual loss
6	Heart attack
7	Stroke
8	Other _____

31 Which complication concerns you most?
[Circle ALL that apply]

1	Foot ulcers
2	Tingling or numbness
3	Losing a leg
4	Kidney failure
5	Blindness / visual loss
6	Heart attack
7	Stroke
8	Other _____

32 Talking about this clinic generally. Would you recommend this clinic to other people with diabetes?

1	No
2	Yes
3	Does not want to answer

33 In what way could the service provided in this clinic be improved?

Comments

34 Do you have any other comments or questions?

Comments

Annexure 2: Institutions included in the study

Hyderabad

1. Advanced Endocrine And Diabetes Centre
2. Apollo Hospital
3. Care Hospital
4. Dr. Mohan's Diabetic Centre
5. ESI
6. Gandhi General Hospital
7. Hyderabad Endocrine Centre
8. L V Prasad Eye Institute
9. Neoretina Eye Care Institute
10. Nizam Institute Of Medical Science
11. Osmania General Hospital
12. Pushpagiri Vitreoretina Eye Institute
13. Sarojinidevi Eye Hospital
14. Saduram Eye Hospital
15. Swarup Eye Hospital
16. M.S.Reddy Lions Eye Hospital
17. Tapadia Diagnostics

Surat

1. Vasan Eye Care Hospital, Surat
2. Shri Saibaba Trust Eye Hospital, Surat
3. New Civil Hospital, Surat
4. Dr. Sachdev Eye Hospital, Surat
5. Netram Eye Hospital
6. Drasti Eye Hospital Surat
7. Arvind Eye Hospital-Surat
8. Aarogyam Hospital-Surat
9. Riddhi Siddhi Hospital-Surat
10. Navjivan Hospital-Surat
11. Vision Eye Care-Surat
12. Shri Sardar Smarak Hospital
13. Divyapal Hospital
14. Venus Hospital

Bhubaneshwar

1. Capitals Hospital
2. Dr.Agarwal Eye Hospital
3. Dr. Mishra Diabetic Hospital
4. Kanungo Institute Of Diabetic Speciality

Pune

1. Chellaram Diabetes Institute,
2. Civil Hospital, Aundh, Pune
3. Deenanath Mangeshkar Hospital
4. KEM Hospital Research Centre
5. National Institute Of Ophthalmology
6. Nayanjyot Eye Hospital
7. HV Desai Eye Hospital
8. Sasoon General Hospital(B J Medical College)
9. S K Raut, M.G. Road Ophthalmologist
10. Arti Sahade Diabetologist
11. Baban Dhodas Ophthalmologist
12. Jayashree Rakecha
13. Shailaja Kale Diabetologist
14. Dr.Gadkari Speciality Eye Clinic
15. Udyan Joshi Ophthalmologist
16. Pune Diabetic Clinic (Dr.Yogesh Kadam)

Ahmedabad

1. Diacare, Ahmedabad (Dr. Banshi Saboo)
2. Swasthya Diabetes Care
3. Banker's Retina Clinic And Laser Centre
4. Retina Foundation, Asopalov Eye Hospital
5. Gujarat Endocrine Centre
6. Raghudeep Eye Clinic / Ila Devi Research Centre
7. Civil Hospital- Ahmedabad
8. Nagari Eye Hospital, Ahmedabad
9. Eye Care And Laser Center, Ahmedabad
10. Nanavaty Eye Hospital-Ahmedabad
11. Gheewala Hospital-Ahemdabad
12. Rising Retina Clinic-Ahmedabad
13. V.S.General Hospital
14. Third Eye Vitreoretina Clinic And Eye Hospital
15. Gurukrupa Hospital
16. Sterling Hospital
17. Shivam Hospital

Delhi

1 ESI,Rohini-Delhi
2 Lady Harding Hospital
3 Ram Manohar Lohia Hospital
4 UCMS G.T.B.Hospital
5 Ganga Ram Hospital
6 Rockland Hospital
7 Tirath Ram Hospital
8 Vision Eye Centre
9 Delhi Diabeties Research Centre
10 Dr.Sanjay Verma Clinic
11 Govt.Dispensary(Okhla)
12 St.Stephens Hospital
13 Venu Eye Institute
14 Centre For Sight
15 Kailash Eye Centre
16 Visitech Eye Centre
17 Dr R P Centre, AIIMS

Bangalore

1 Akshaya Nethralaya
2 Bangalore Baptist Hospital
3 Bowring and Lady Curzon Hospital
4 Centre for Diabetes and Endocrine Care
5 Dr.Agarwal's Eye Hospital-Bangalore
6 Jayanagar General Hospital
7 Janana Sanjeevini Medical Centre
8 Minto Ophthalmic Institute
9 Netra Eye Hospital
10 Netradhama Eye Hospital
11 Prabha Eye Clinic
12 Retine Institute of Karnataka
13 Samatvam Diabetes Clinic
14 St.John's Medical College Hospital
15 Vittal Eye Hospital

Chennai

1 Dr.Mohan Diabetes unit
2 Dr. Mohan eye care unit
3 Regional Institute of Ophthalmology
4 Sankara Eye Hospital
5 Sanakaranethralaya Eye Hospital
6 Moses Diabetes Centre
7 Dr. Hariharan's Diabetes Hospital
8 Govt. Hospital-Royapettah
9 Bethsaida Eye Clinic
10 Rajan Eye Care Hospital
11 Aruna Diabetes Centre
12 Radhatri Nethralaya
13 Chengal Pattu Medical Colleges

Kolkatta

1 SSKM Hospital
2 Ram Krishna Mission Seva Pratisthan
3 Susrut Eye Foundation And Research Centre
4 RG Kar Hospital
5 Dr.Nihar Munsi Eye Foundation
6 Kolkatta Medical College(Rio)
7 Kolkatta Medical College

Mumbai

1 Aditya Jyot Eye Hospital
2 Bombay City Eye Hospital
3 Haji Bancholi Hospital
4 Hinduja Hospital And Medical Research
5 J.J.Hospital
6 Jaslok Hospital
7 K.E.M.Hospital
8 Kokilaben Dhirubhai Ambani Hospital
9 Laxmi Eye Hospital
10 Lilavati Hospital and Research centre
11 Nair Hospital
12 Shroff Eye Hospital and Lasik centre
13 Sion Hospital Medical college
14 Chembur Colony Dispensary
15 Suvarna Hospital
16 Khona Private Hospital
17 Parel Dispensary
18 Karnik Nursing Home
19 Bhatia Hospital
20 Dr. Dharvadkar
21 Colaba Dispensary
22 J. Mehtalia Clinic
23 Breach Candy Hospital

Jaipur

1 ESI Hospital
2 Railway Hospital
3 SMS Hospital
4 Fortis Hospital
5 Sant Durlabjee
6 Diabetic Clinic-Jaipur
7 Jaipur Diabetic Research Centre
8 Narayana Hospital
9 ASG Eye Hospital
10 Dr.Virender Laser Centre
11 Sahai Eye Hospital
12 Dr. G.L. Verma Eye and Laser Centre
13 Max Vision Eye Care

Annexure 3: Hospitals Assessed for DR Models

1	Aditya Jyot Eye Hospital
2	Aravind Eye Care system
3	Chaithanya Eye Hospital, Tiruvanthapuram
4	Divyajyoti Trust Tejas Eye Hospital, Mandavi, Surat
5	Indira Eye Institute for Diabetics Dr Mohan's Diabetes Specialties, Chennai
6	L.V.Prasad Eye Institute, Hyderabad
7	PBMA's H.V.Desai Eye Hospital, Pune
8	C.H. Nagri Eye Hospital,Ahmedabad
9	Pusphagiri Vitreo Retina Institute, Hyderabad
10	Dr. R.P.Centre for Ophthalmic Sciences, AIIMS, New Delhi
11	Sankara Netralaya, Chennai
12	Shroff Charitable Eye hospital
13	Tirupati Eye Centre, Noida, UP
14	Vittala International Institute of Ophthalmology, Bengaluru, Karnataka

Annexure 4: Institutional Ethics Committee (IIPHH and LSHTM)

Institutional Ethics Committee

Indian Institute of Public Health-Hyderabad /
Public Health Foundation of India
ANV Arcade, Plot No.1, Amar Cooperative Society, Kavuri Hills, Madhapur, Hyderabad - 500081, A.P., INDIA

Communication of Decision of the IEC[1]
Form II

TRC-IEC No Application No:	172/2013	**Date:**	23-07-2013	
Project Title:	The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: evaluation of existing programmes for screening and treatment, and using lessons learnt, to develop and evaluate an approach that strengthens health systems.			
Principal Investigator:	Prof. GVS Murthy			
Review	**Full Review**	☒	**Expedited Review**	☐
Date of review:	21-06-2013			
Date of previous review:	*(in case of re-submitted applications)*			
Decision of the IEC:	**Approval**	☒	**Resubmission**	☐
	Conditional Approval	**Study can begin** ☐	**Study cannot begin**	☐
Requirements to be fulfilled in case of conditional approval:				
Suggested alterations in case of resubmission:	-			
In case of approval, ***recommended for a period of :***	Approval is valid for one year from the date of issue.			
Comments:	Nil			

Please note: Beginning of the research based on this approval implies acceptance of the following conditions:

1. *PI will inform the Secretariat of the start date of the study.*
2. *The PI will inform the IEC in case of any adverse events.*
3. *The PI will inform the TRC (Technical Review Committee) and IEC in case of any change of study procedure (including- changes in the informed consent form, recruitment procedure, potential research participant information), site and investigator.*
4. *The PI will inform the TRC - IEC Secretariat on termination of the study and submit a final report within 3 months of completion of the study.*
5. *Members of the IEC have the right to monitor the study with prior intimation.*
6. *Progress report to be submitted to the TRC-IEC Secretariat every 6 months from the date of start of study.*
7. *This permission is only for the period mentioned above.*

Shailaja

Dr. Shailaja Tetali
Name and signature of Member Secretary

Geeta

Dr. Geeta K. Vemuganti
Chairperson, IEC, IIPH

[1] Adapted from the ICMR form: available at
http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc

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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

GVS Murthy
Reader
CR / ITD
LSHTM

20 August 2013

Dear Dr Murthy,

Study Title: **The emerging epidemic of diabetic retinopathy and retinopathy of prematurity in India: evaluation of existing programmes for prevention and screening and treatment**

LSHTM ethics ref: **6489**

Thank you for your application of 30 July 2013 for the above research, which has now been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
LSHTM ethics application	n/a	
Protocol including Information Sheets & Consent forms		

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form. All studies are also required to notify the ethics committee of any serious adverse events which occur during the project via form E4. At the end of the study, please notify the committee via form E5.

Yours sincerely,

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