

# Awareness of diabetic retinopathy among diabetics in the Cape Town Metropole

by

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# Awareness of diabetic retinopathy among diabetics in the Cape Town Metropole, South Africa

## Statement

The research presented in this dissertation is based on independent work performed by myself. Neither the whole work nor a part of it has been, or is being, submitted for another degree to another university. This work has not been reported or published prior to registration for the abovementioned degree.

Signature:

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## Abstract

### Objective

To investigate the awareness of diabetic retinopathy (DR) among diabetics in the Cape Town Metropole by assessing:

- Whether diabetics know that diabetes can affect their eyes.
- Whether the awareness of DR differs according to subtype of diabetes, place of treatment (private versus public sector), level of education and socio-economic status.
- Knowledge of systemic risk factors for developing DR.
- Knowledge of treatment of DR.

### Methods

A population-based cross-sectional study was conducted as part of the Rapid Assessment of Avoidable Blindness (RAAB) survey undertaken in 2010. For the RAAB survey, a sample size of 3077 was chosen based on 3% prevalence of blindness amongst people 50 years and over, 25% precision rate, design effect of 1.4, 95% confidence level and a 10% non-response rate. In total, 77 clusters of 40 people were required. For logistical reasons, 82 clusters were included in the survey.

For the DR component, a sample size of 2061 participants was required based on an expected DR prevalence of 4.5% and the parameters mentioned above. The 2001 census data, updated using expected population growth, was used as the sampling frame. Clusters ('small areas') were selected by probability proportionate to size. Two-thirds of the clusters were randomly allocated to the RAAB and Diabetic Retinopathy (RAAB+DR) survey, while the remaining clusters were only allocated to the RAAB survey.

### Results

Of the 1784 eligible survey participants, 305 were known to be diabetic, and 226 (80%) of those were aware of DR. Diabetics' understanding of preventive measures was as follows: following a diabetic diet 43 (46%), using diabetic medication 126 (40%), maintaining good glycaemic control 54 (17%) and maintaining good blood pressure control 6 (2%). Ninety diabetics (29%) did not know of any risk factors. Type 1 (insulin dependent) diabetics were significantly more aware of DR than type 2 (non-insulin dependent) diabetics (97% versus 75% respectively:  $p < 0.0001$ ). There was no significant difference in awareness between diabetics receiving treatment in the private sector versus those receiving treatment in the public sector. Of the known diabetics, 136 (48%) were aware that annual retinal examinations are required and 198 (70%) were not aware what the treatment for DR is.

### Conclusion

Although a large proportion of diabetics in the Cape Metropole are aware that diabetes can affect their eyes, they have a poor understanding of prevention of DR through control of the systemic risk factors, of the importance of annual retinal examinations and of the treatment of DR.

Diabetics' understanding of the risk factors for developing DR, the need for retinal examinations and the treatment of DR, need to be greatly improved in order to decrease the number of cases of blindness resulting from DR in Cape Town.

# Awareness of diabetic retinopathy among diabetic patients in the Cape Town Metropole, South Africa

Publication ready format

## A. Protocol

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## Background

Diabetes mellitus (DM), particularly type 2 diabetes, is a major public health concern worldwide. According to the World Health Organization (WHO), over the next two decades there will be a significant increase in the number of people with type 2 diabetes mellitus, both in developed and developing countries. In the developed world, the estimated increase is approximately 46%, from 55 million in 2000 to 83 million in 2030. In developing nations, such as South Africa, the estimated increase is approximately 150%, from 30 million in 2000 to 80 million in 2030.(1)

Diabetic retinopathy (DR) is a potentially blinding complication of diabetes and is the leading cause of blindness in working-age populations in high-income settings.(2) DR is expected to become an increasingly dominant cause of vision loss in low- and middle-income countries (LMICs) as the diabetes epidemic unfolds and other blinding conditions such as cataracts are better controlled. With the growing burden of diabetes in LMICs, reliable up-to-date estimates of DR prevalence are urgently required to plan appropriate DR services. However, few population-based DR surveys have been undertaken in low- and middle-income settings.(3) Previous South African DR prevalence estimates are based on figures from health facilities that may not be generalizable.(4)

The subjective experience of doctors working at Groote Schuur Hospital is that the majority of diabetics who present to the ophthalmology department are not aware that diabetes can affect their eyes, nor that they should have annual retinal examinations to detect diabetic retinopathy. This may be one of the reasons why a large number of diabetics present with advanced diabetic retinopathy. Also, many diabetics are not aware that there is treatment available once they have developed sight-threatening diabetic retinopathy (STDR).

When advanced diabetic ophthalmic complications are presented to ophthalmologists, there is often a delay in referral. Poor awareness of the importance of regular eye examinations and the benefits of treatment among both primary care physicians and their patients may contribute to this delay.(5) One study revealed that people who were uninformed about diabetes care had a fourfold increased risk of major diabetes-related complications compared to those who were informed (5).

The principal risk factors for the development and progression of DR are duration of diabetes, glycaemic control,(6) hypertension,(7) dyslipidaemia,(8) nephropathy,(9) and pregnancy(10). However, optimal metabolic and blood pressure control is not always achieved, and even among patients with good control of the systemic risk factors, DR may develop and progress. Therefore active screening is used in many countries to ensure that STDR can be recognised and treated by laser photocoagulation before it causes visual impairment. In the 1980s, the Early Treatment Diabetic Retinopathy Study (ETDRS) found that among patients with clinical significant macular edema, the risk of visual loss of those patients that received focal photocoagulation was halved.(11) The Diabetic Retinopathy Study (DRS) found that among patients with proliferative diabetic retinopathy, laser photocoagulation reduced the risk of severe visual loss from 16.3% to 6.4% at two years.(12)

It does not appear from the literature available that any population-based studies on the awareness of diabetic retinopathy among diabetics in Africa have been conducted. In this study,

a number of aspects were explored, such as diabetics' lack of awareness of DR as a possible complication of diabetes, and issues such as adherence to DR screening guidelines. The 'DR awareness' study is part of a larger study: the Rapid Assessment of Avoidable Blindness and Diabetic Retinopathy (RAAB+DR) survey.

The following data will be collected from previously diagnosed diabetics:

- Subtype of diabetes (based on medication used, such as oral agents and/or insulin)
- Awareness of:
  - DR as a possible complication of diabetes
  - The systemic risk factors for developing STDR
  - The availability and type of treatment for STDR.
- Prior retinal screening examinations
- Whether a retinal examination has been performed in the preceding year
- Socio-economic status
- Highest education level achieved.

The RAAB is a relatively simple, affordable population-based survey methodology that provides district-level data on the prevalence and causes of blindness among people aged 50 years and over.(13) An additional component to RAAB was recently developed to estimate the prevalence of diabetes and DR (RAAB+DR). The aim was to generate relatively low-cost data for the planning of DR services. This method has been piloted in Mexico(14), but it still needs to be tested in different settings to assess its reliability and resource requirements.

The prevalence of diabetes in South Africa is significant and increasing. The prevalence of diabetes in Cape Town in people over 30 years of age is 8%, with 260 000 diabetics being cared for at a primary level.(15) Approximately 11% of these diabetics have regular eye examinations.(16) Glycaemic control is suboptimal, with 49.4% (95% CI 45–53%) of public sector patients having a HBA1C (glycated haemoglobin count) of less than 7%. Poor glycaemic control has been shown to be associated with the increased incidence and progression of DR(17) in both type 1 and type 2 diabetes.(18)

In this context, it is imperative to investigate and improve diabetics' understanding of the various aspects of diabetic eye disease.

## Aim

To assess the awareness of diabetic retinopathy and other related factors among diabetics in the Cape Town Metropole.

Specifically this study will investigate:

1. Whether diabetics know that diabetes can affect their eyes.
2. Whether there are differences in awareness of DR between the different subtypes of diabetes.
3. Whether there is a correlation between:
  - a. Diabetics' level of education and their awareness of DR.
  - b. Diabetics' socio-economic strata and their awareness of DR.
4. Diabetics' understanding of the risk factors that play a role in the development of DR.
5. Diabetics' understanding of the need for screening examinations to detect DR and the recommended frequency of those examinations.
6. Diabetics' understanding of the treatment for STD.

## Materials and methods

A RAAB survey will be undertaken in the Cape Town Metropole between September 2010 and November 2010. A DM and DR component will be included in selected clusters (RAAB+DR).

## Study sample

For the RAAB survey, a sample size of 3077 will be selected based on a 3% prevalence of blindness amongst people aged 50 years and over, a 25% precision rate, a design effect of 1.4, a 95% confidence rate and a 10% non-response rate. In total, 77 clusters of 40 people will be required. For logistical reasons, 82 clusters will be included in the survey. For the DR component, a sample of 2061 participants will be required (52 clusters of 40 people), based on an expected DR prevalence of 4.5%(14) and the parameters mentioned above.

The 2001 census data will be used as the sampling frame and updated using expected population growth. Clusters ('small areas') will be selected by probability proportionate to size. Two-thirds of the clusters will be randomly allocated to the RAAB+DR survey, while the remaining clusters will only be allocated to the standard RAAB survey.

## Rapid assessment of avoidable blindness

Detailed descriptions of RAAB methods are presented in other literature.(13) In summary, households within clusters will be selected using 'compact segment sampling', whereby one segment containing approximately 40 (or 35) people aged 50 years or over is randomly selected for each cluster.(19) The survey team will conduct door-to-door household visits in selected segments to identify eligible people until the target cluster size is reached. Visual acuity (VA) will be measured using a tumbling "E" chart. People whose eyes have a VA of less than 6/18 will be examined by the ophthalmologist to assess the main cause of vision loss.

## Diabetes mellitus and diabetic retinopathy component

In the RAAB+DR clusters, all participants will be asked whether they have ever been diagnosed with diabetes by a health professional and whether they are taking diabetic medication. Random blood glucose (RBG) will be tested in all participants using a digital glucometer. Participants will be classified as diabetic if they have had a previous diagnosis of diabetes, are receiving treatment for glucose control, or have a RBG  $\geq 11.1$  mmol/l.(20)

## Additional variables

Data will be collected on age, gender, education, and asset ownership, from which a socioeconomic status (SES) index will be created using principal component analysis.(21) Previously diagnosed diabetics will be asked about their history of diabetes and eye examinations.

## Survey teams and training

The questionnaire was compiled in English and Afrikaans. The two versions of the questionnaire will be piloted on two consecutive days to assess whether patients understand the questions and whether the answers can be matched to the options on the questionnaire. There will be five survey teams, each consisting of one ophthalmologist and two community-based eye workers. The survey teams will receive six days of training.

## Ethical considerations

Informed written consent will be obtained from all participants. Ethical approval was granted by the University of Cape Town Health Sciences Human Ethics Committee and the London School of Hygiene & Tropical Medicine. All participants with ophthalmic conditions that require treatment or further investigation will be referred accordingly. People with newly diagnosed or poorly controlled diabetes will be referred to the nearest health centre.

## The questionnaire

A questionnaire will be completed by all known and newly diagnosed diabetics in the sample.

## Data analysis

The same data will be entered into two databases by two different people. Inconsistencies in the data entered will be identified using Epi Info<sup>TM</sup> (epidemiology statistical software), and corrections will be made by referring back to the original data capture sheets. The data will then be analysed using STATA 11 (data analysis and statistical software).

## Expected outputs

The data from the proposed study could provide information on the awareness of diabetics in the Cape Town Metropole of the potential secondary ocular complications of diabetes.

The information could be used for DR awareness advocacy and to inform planning of eye care services in Cape Town. The findings of this study could well be generalizable to other urban populations in other Southern African countries with intermediate economies.

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## B. Literature review

The number of people with diabetes in the world is increasing due to population growth, population ageing, urbanisation and the increasing prevalence of obesity and inactivity. In 2000, the number of cases of diabetes worldwide was estimated to be 171 million.(1)

According to the World Health Organization (WHO), over the next two decades there will be a significant increase in the numbers of people with type 2 diabetes mellitus, both in developed and developing countries. In the developed world, the estimated increase is approximately 46%, from 55 million in 2000 to 83 million in 2030, whereas among developing nations, the estimated increase is approximately 150%, from 30 million in 2000 to 80 million in 2030.(2) Population-based surveys performed in urban Sub-Saharan Africa have estimated the prevalence of diabetes to be between 1.5% among people aged 24–74 years old in Cameroon, and 8.2% among people aged 25 years and older in South Africa. The estimated prevalence in urban South Africa is between 4.4% among people aged 15 years and older, and 8.2% among people aged 25 years and older.(3)

Current estimates of the prevalence of DR among people with diabetes in developing regions range from 19% in Bangladesh, 17–22% in India, 30.3% in Cambodia, 37% in Iran, 43.1% in rural China and 63% in South Africa. Many of these studies have demonstrated comparable rates to those observed in developed nations such as Australia, UK and the USA, which have a 29.3%, 39% and 50.3% prevalence of DR among diabetics respectively.

The principal risk factors for the development and progression of diabetic retinopathy are duration of disease, poor control of diabetes,(4) hypertension,(5) pregnancy,(6) dyslipidaemia(7) and nephropathy.(8) The implications of untreated DR are significant, not only in terms of loss of quality of life, but also financially.(9) Blindness caused by diabetes is estimated to cost the USA \$500 million dollars annually.(9)

In the 1980s, the Early Treatment Diabetic Retinopathy Study (ETDRS) found that among patients with clinically significant macular edema, the risk of visual loss of those patients that received focal retinal photocoagulation was halved.(10) The Diabetic Retinopathy Study (DRS) found that among patients with proliferative diabetic retinopathy, laser photocoagulation reduced the risk of severe visual loss from 6.4% to 16.3% at two years.(11) Recent studies indicate that a large proportion (37–79%) of the diabetic population is not following recommended guidelines to prevent visual impairment and blindness. The American Academy of Ophthalmology and the American Diabetes Association have published guidelines regarding the timing and frequency of dilated retinal examinations in diabetics, the aim being to detect retinopathy in its most treatable stages. Type 1 diabetics should have annual examinations beginning five years after diagnosis, and type 2 diabetics should have an examination at the time of diagnosis of diabetes and at least annually thereafter.(12,13) Despite comprehensive reporting of the DRS and ETDRS findings over a decade ago, and the development of DR screening guidelines, the translation and adoption of these guidelines into clinical practice has been lagging, raising increasing concern among vision care professionals.(9)

## Objectives

The objectives of the literature review were to investigate:

1. Diabetics' awareness of DR elsewhere in the world.
2. Diabetics' understanding of the risk factors that play a role in the development of DR.
3. Diabetics' awareness of the need for annual retinal screening examinations to detect STDR.
4. Diabetics' understanding of the treatment for DR.
5. Whether there is a difference in awareness between diabetics receiving treatment in the private sector versus those receiving treatment in the public sector.
6. Whether there is a correlation between a person's awareness of DR and their level of education.
7. Whether there is a correlation between a person's awareness of DR and their socio-economic status.
8. Whether there is a difference in awareness of DR between type 1 and type 2 diabetics.

## Literature search strategy

The PubMed library was searched using the following keywords: awareness, knowledge, attitude, practices, diabetic retinopathy.

## Quality criteria

Not applicable.

## Summary and interpretation of the literature

The literature review revealed 13 journal articles on the awareness of diabetic retinopathy amongst diabetics.

**Table 1: Studies on the awareness of diabetic retinopathy**

Country	Study designs	Number of participants	Year	Awareness
India (Hyderabad)(14)	Population-based cross-sectional survey	531	2001	27%
India (Kanchipuram, Vellore)(15)	Cohort study			Not investigated
India (Tamil Nadu)(2)	Population-based cross-sectional survey	1938	2008	37%
India (Tamil Nadu)(16)	Population-based cross-sectional survey	204	2004	52.9%
Israel(17)	Hospital-based cross-sectional survey	165	2000	35%
Italy(18)	Institution-based cross-sectional survey	70	2002	84%
Japan(19)	Cohort Study	1333	2003	98%
Maryland, USA(20)	Population-based cross-sectional survey	204	2008	52%
Myanmar(1)	Institution-based cross-sectional survey	200	2008	86%
Nepal(21)	Hospital-based cross-sectional survey	210	2012	63%
Singapore(22)	Population-based cross-sectional survey	227	2013	15.3%
Turkey(23)	Hospital-based cross-sectional survey	181	2013	88.1%
Wales(18)	Institution-based cross-sectional survey	128	2002	65%

### 1. Level of awareness of DR amongst diabetics

It appears from the literature that diabetics' level of awareness of DR as a possible complication of diabetes varies widely, being very high in Italy(24), Japan(25), Myanmar(1) and Turkey(23) and poor in Israel, India,(2,14,15,26) Maryland(20) and Singapore(22). One would expect clinic- or hospital-based studies to show higher levels of awareness, as attendance at clinics and hospitals implies contact with health professionals and therefore possibly more exposure to information and counselling.

### 1.1 Awareness of DR between diabetics receiving care in the private sector versus diabetics receiving care in the public sector

The literature on the awareness of DR did not include studies on whether there is any difference in awareness between patients in the private and the public sectors. It could be reasonable to assume that diabetics' awareness in the public sector would be less than in the private sector, because public sector medical personnel have less time to spend with patients than private sector medical personnel. This study examines this possible relationship.

### 1.2 Awareness of DR between type 1 and type 2 diabetics

It could be assumed that type 1 diabetics have had diabetes for longer than type 2 diabetics and would therefore have spent more time in the health care system. The type 1 diabetics could therefore have had more exposure to health care providers and education about the complications of diabetes. The study done in Nepal(21) found no difference between awareness of DR in type 1 versus type 2 diabetics.

### 1.3 Awareness of DR and level of education

Studies conducted in India (Hyderabad and Tamil Nadu),(2,14) Maryland,(20) Nepal,(21) Singapore(22) and Turkey(23), which examined the level of awareness of DR and people's level of education, found that the higher the level of education, the higher the level of awareness of DR. It could be that diabetics who are better educated have a better understanding of the explanation given to them by medical personnel on diabetes, its complications, the importance of preventative strategies and the importance of regular eye examinations to detect STDR, which can be treated if diabetics present early.

### 1.4 Awareness of DR and socio-economic status

Three studies looked at the possible correlation between awareness of DR and socio-economic status. The studies done in India (Hyderabad, Tamil Nadu)(2,14) and Singapore(22) demonstrated that there was a lower awareness of DR amongst diabetics belonging to lower socio-economic strata.

## 2. Awareness of the importance of an annual retinal examination

### 2.1 The proportion of diabetics that was aware of the importance of a retinal examination

The literature revealed five studies that reported on diabetics' awareness of the importance of annual retinal examinations to detect STDR. Apart from a study done in Tamil Nadu, India, where it was found that 80% of diabetics were aware of the importance of retinal examinations, the studies showed that generally, diabetics had a poor awareness of the importance of having an annual retinal examination to detect STDR.(14,16,20,23) Almost all people with diabetes will experience some degree of diabetic retinopathy over time, with the prevalence increasing with the duration of the disease.(9)

## 2.2 Proportion of diabetics that have had a previous retinal examination

Table 2 indicates that two-thirds of the diabetics in the studies in Japan and Turkey have had previous retinal screening examinations to detect DR.(23,25) The other studies showed that only half (or fewer) of the diabetics have had a previous examination.(15,16,25,27,28) An interesting finding in the studies conducted in India in Kanchipuram and Vellore(15) was that only half of the diabetics that were seen at a screening camp for diabetes mellitus attended the screening camp for diabetic retinopathy one week later. These studies suggest that a large proportion of diabetics have never had a retinal examination.

**Table 2: Awareness of the need for retinal examinations and the proportion that have had them**

	<b>Awareness of the need to have annual retinal examinations</b>	<b>Proportion that have had a previous exam</b>	<b>Proportion that have had a retinal exam in the preceding 12 months</b>
Cape Town(29)		23.6%	5.5%
India (Kanchipuram and Vellore)(15)		50% of diabetics that had attended a diabetic screening camp attended a diabetic retinopathy screening camp a week later.	55% of rural diabetics and 50% of urban diabetics with STDR.
India (Hyderabad)(14)	34.3%		
India (Tamil Nadu)(16)	80%	56.5%	
Israel(17)		47%	35%
Japan(19)		70%	
Myanmar(1)	23%	57%	
Maryland, USA(20)	48%	48%	30%
Nepal(21)		50%	
New York, USA(30)		66%	
Turkey(23)	41.9%	77.3%	

## 2.3 Proportion of diabetics that have had a retinal examination in the preceding year

Very little data have been published on the proportion of diabetics that go for annual screening retinal examinations. The literature review showed that those studies that dealt with this issue found that the majority of diabetics do not have annual retinal examinations as recommended.(15,20,28) The proportion of diabetics that have had a retinal examination in the

last 12 months ranged from 5.5% in Cape Town to 50% in Kanchipuram and Vellore in India.(15,27)

These results imply that although the level of awareness of diabetics regarding diabetic retinopathy might be reasonable, a large proportion of diabetics have never had a screening retinal examination and/or do not have exams annually, as stipulated by diabetic retinopathy screening guidelines. The literature review identified several reasons why diabetics have a poor understanding of the importance of annual retinal screening examinations, why a large proportion of diabetics have not had a retinal examination, and why diabetics that have had eye examinations have not had them annually, as recommended.

#### 2.4 Reasons identified by previous studies why a large proportion of diabetics do not go for screening retinal examinations

One of the studies found that the reason why many people did not go for retinal screening examinations was that those people did not believe that they had retinopathy.(21) Another reason was found to be poor awareness among patients and health care providers of retinopathy as a complication of diabetes. In some cases people knew that DM could affect their eyes, but were unaware that it could lead to blindness and that severe nonproliferative diabetic retinopathy (NPDR) can be asymptomatic.(15,21,31) These factors led to poor motivation among diabetics to go for eye examinations.(15) A study conducted in Myanmar revealed that only 49% of general practitioners (GPs) examined their diabetic patients' eyes. Possible reasons for this were postulated to be a lack of ophthalmoscopy equipment, a lack of familiarity with ophthalmoscopic fundal examination techniques, a lack of familiarity with the ophthalmic signs of diabetes and the time constraints of a busy urban practice.(1) The study in Myanmar found that 34% of patients only decided to go for an exam once they had developed problems with their eyesight.(1,22) Cultural beliefs also played a role,(22) as did poor physician-patient communication(22) and poor literacy.(22) Other reasons included the belief that laser treatment was uncomfortable.(31) Overall, a general lack of awareness was the main barrier to people having eye examinations.(31)

The patients themselves identified fear and guilt as key barriers that prevented them from attending clinics for retinal examination.(32) Although good control of blood sugar and blood pressure reduces the risk of ophthalmic complications, it does not eradicate the risk entirely.(31) Educators and physicians should avoid implying that retinopathy is due to patients' carelessness and poor diabetic control, as this causes fear and guilt, which further prevents patients from attending clinics for retinal examinations.(31)

Other factors identified by patients for nonattendance for retinal screening included clinic waiting times, social and employment concerns, such as the loss of income on the day of treatment.(32) Patients often end up spending the better part of a day at hospitals and clinics while having eye drops administered to dilate their eyes and waiting to be attended to. After being seen, some patients require laser treatment.(31) If patients need to come for regular follow up visits, some fear losing their jobs due to the frequent absenteeism.(31) Logistical concerns (distance of the hospital from where patients live and transport difficulties) are other cited barriers to retinal screening.(15)

### 3. Diabetics' understanding of the risk factors that play a role in the development of DR and the treatment of STDR

Only four studies were identified that reported on diabetics' understanding of the risk factors that play a role in the development of DR. In a study conducted in Tamil Nadu, India, it was found that only 46.1% of patients were aware of the risk factors for the development of DR, and more alarmingly, only 44.9% of paramedical personnel were aware of the risk factors for the development of DR.(16) A study conducted in Italy found that 61% of diabetics were aware of the risk factors; a study in Maryland, USA, found that 34% of diabetics knew of the risk factors; and a study done in Wales found that 53% of diabetics were aware of the risk factors.(20,24) Although a limited number of studies examined this issue, it appears that a large proportion of diabetics have a poor understanding of the risk factors that play a role in the development of DR.

Awareness of the treatments available for STDR may motivate diabetics to attend retinal screenings. Only two studies were identified that commented on diabetics' understanding of the treatment available for treating STDR, both of which were conducted in India. In Hyderabad, it was found that 68.2% of diabetics were aware what treatment was available. In Tamil Nadu, 29% of the community and only 24% of paramedics(14,16) were aware what treatment was available for DR. The paucity of published data shows that very little is known about patients' awareness of the treatment of diabetic retinopathy. Both studies demonstrated that a large proportion of diabetics do not know that there is treatment available for STDR.

#### 3.1 Suggested methods to improve the awareness of DR amongst diabetics

Methods to increase diabetics' awareness of DR, the risk factors that play a role in the development of DR and the importance of annual eye examinations to detect STDR are postulated in the literature.

There is a need for awareness campaigns about diabetic eye disease that involve social workers, voluntary organisations and local community leaders.(15) Screening examination reminders could be communicated to patients by telephone, sms, post, e-mail and visits by social workers.(15,31) Educational programmes, such as group teaching sessions, leaflets, brochures, and greater publicity in the media are also recommended.(15,24) Information should not only be provided about the ocular complications of diabetes, but also about the risk factors for developing DR, the importance of control of systemic risk factors, what treatment is available for DR, and what that treatment entails. Screening retinal examinations of hospitalised diabetic patients were also found to be effective in creating a greater awareness of DR.(28)

In terms of concerns about employment, the early involvement of social workers could mitigate against the fear of job loss due to absenteeism.(31) Making screening available at a primary care level increases attendance, in part due to the fact that it is more convenient for patients.(31) Improving physician-patient communication is important, and any such engagements should be tailored according to patients' levels of education.(22)

### 4. Conclusion

Diabetics have a poor understanding of the risk factors that play a role in the development of DR. Diabetics also have poor awareness of the need for annual retinal examinations and poor

awareness that treatment is available for the disease in the early stages. There are no published data dealing with awareness among diabetics receiving treatment in the public sector compared to those receiving treatment in the private sector. A correlation was found between the level of awareness of DR and the level of education, as well as between the level of awareness of DR and socio-economic status. Only two studies investigated whether there is a difference in awareness between the different subtypes of diabetes. There are numerous suggestions in the literature of ways in which compliance with screening examinations can be improved.

Increasing diabetic patients' knowledge of DR improves their understanding and acceptance of the importance of routine eye examinations for early detection and treatment. Studies conducted in Hyderabad and Tamil Nadu found that better knowledge of diabetic retinopathy leads to lower prevalence of visual impairment and blindness from diabetic retinopathy, and decreases the cost associated with eye care in diabetics.(2,14) The literature yielded little information about the effectiveness of different methods of educating diabetic patients about retinopathy.

## 5. Shortfalls in the literature

- Few studies assessed diabetics' understanding of the risk factors that play a role in the development of DR.
- Little is known about diabetics' understanding of the importance of annual retinal examinations to detect STDR.
- Little is known about diabetics' understanding of the treatment of DR.
- Few studies assessed a possible difference in awareness of DR between the different subtypes of diabetes.

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### 3. Manuscript

## The Awareness of diabetic retinopathy amongst diabetics in the Cape Town Metropole

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### Abstract

#### Objective

To investigate the awareness of diabetic retinopathy (DR) amongst diabetics in the Cape Town Metropole.

#### Methods

A population-based cross-sectional survey was conducted as part of the Rapid Assessment of Avoidable Blindness (RAAB) survey that was done in 2010 in Cape Town.

#### Results

Of the 1784 eligible survey participants, 305 were known to be diabetic and 226 (80%) of those were aware of DR. Diabetics' understanding of measures to prevent DR was as follows: following a diabetic diet 43 (46%), using diabetic medication 126 (40%), maintaining good glycaemic control 54 (17%) and maintaining good blood pressure control 6 (2%). Ninety (29%) diabetic participants were not aware of preventative measures. Type 1 (insulin dependent) diabetics were significantly more aware of DR than type 2 (non-insulin dependent) diabetics (97% versus 75% respectively:  $p < 0.0001$ ). There was no significant difference in awareness between diabetics receiving treatment in the private sector versus those receiving treatment in the public sector. Of the known diabetics, 136 (48%) were aware that annual retinal examinations are recommended and 198 (70%) were not aware what the treatment is for DR.

#### Conclusion

Although many diabetics are aware that diabetes can adversely affect their eyes, they have a poor understanding of the risk factors for the development of DR, the importance of retinal examinations and the treatment available for DR.

## Introduction

According to the World Health Organization (WHO), over the next two decades there will be a significant increase in the number of people with type 2 diabetes mellitus (DM). In developing countries, the projected increase is estimated to be 150%, from 30 million in 2000 to 80 million in 2030.(1) Population-based surveys performed in urban Sub-Saharan Africa have estimated the prevalence of diabetes to be between 1.5% among people aged 24–74 years old in Cameroon, and 8.2% among people aged 25 years and older in South Africa.(2)

Diabetic retinopathy (DR) is a potentially blinding complication of diabetes, and is the leading cause of blindness in working-age populations in high-income settings.(3) DR is expected to become an increasingly dominant cause of vision loss in low- and middle-income countries (LMICs) such as South Africa, as the diabetes epidemic unfolds and other blinding conditions such as cataracts are better controlled.

The risk factors for developing DR are the increased duration of diabetes, poor glycaemic control, pregnancy, hypertension, nephropathy, hyperlipidaemia, smoking, obesity and anaemia. The impact of untreated DR is significant, not only in terms of the loss of quality of life, but also in terms of the cost of health care.(4) Greater awareness of DR, the risk factors for developing DR and the need for retinal screening is critical for the timely diagnosis and early treatment of the disease.(5) In South Africa, DR is the third leading cause of blindness after cataracts and glaucoma, and is responsible for 5% of cases of blindness.(6)

The subjective experience of doctors working in the ophthalmology department at Groote Schuur Hospital is that diabetics have a poor awareness of DR, the risk factors for DR and the treatment of DR, and that the majority of diabetics presenting with advanced eye disease do not undergo retinal screening as per established guidelines.

## Objectives

Two objectives of the study were to assess the level of awareness of DR amongst diabetics in the Cape Town Metropole and their understanding of possible preventative measures to delay the onset of DR. Other objectives were to investigate whether awareness of DR varies according to subtype of diabetes, education level and socio-economic status, as well as the source of treatment (public or private sector).

## Materials and methods

A RAAB survey was undertaken in Cape Town between September 2010 and November 2010.(7) A diabetes mellitus (DM) and diabetic retinopathy (DR) component was included in selected clusters.

## Study sample

For the RAAB survey, a sample size of 3077 was selected based on a 3% prevalence of blindness amongst people aged 50 years and older, a 25% precision rate, a design effect of 1.4, a 95% confidence rate and a 10% non-response rate. In total 77 clusters of 40 people were required. For

logistical reasons 82 clusters were included. For the DR component, a sample of 2061 was required (52 clusters of 40 people), based on an expected DR prevalence of 4.5% (8) and the parameters mentioned above.

The 2001 census data were used as the sampling frame and updated using expected population growth. Clusters ('small areas') were selected by probability proportionate to size. Two-thirds of the clusters were randomly allocated to the RAAB+DR survey, while the remaining clusters were allocated to the standard RAAB survey only. Two clusters were considered unsafe and were replaced by selecting the next suitable area on the sampling frame list.

After the first week of the survey, it was apparent that information gathering from clusters of 40 people using the RAAB+DR protocol was not manageable for one team in a single day. Therefore the RAAB+DR cluster size was reduced to 35 people, and two clusters were randomly selected from the 'RAAB only' group and allocated the RAAB+DR protocol in order to maintain an adequate sample size for the DR component.

### Rapid assessment of avoidable blindness

Detailed descriptions of the RAAB methods are presented in other literature.(8) In summary, households within clusters were selected using 'compact segment sampling', whereby one segment containing approximately 40 (or 35) people aged 50 years or over was randomly selected for each cluster.(9) The survey team paid door-to-door visits to households in selected segments to identify eligible people until the target cluster size was reached. Visual acuity (VA) was measured using a tumbling "E" chart. People with eyes with a VA of less than 6/18 were examined by the ophthalmologist to assess the primary cause of vision loss.

### Diabetes mellitus and diabetic retinopathy components

In the RAAB+DR clusters, participants were asked whether they had ever been diagnosed with diabetes by a health professional and whether they were taking diabetic medication. Random blood glucose (RBG) was tested in all participants using a digital glucometer. Participants were classified as diabetic if they had had a previous diagnosis of diabetes, were receiving treatment for glucose control, or had a RBG  $\geq 11.1$  mmol/l.(10)

### Additional variables

Data were collected on age, gender, education and asset ownership, from which a socio-economic status (SES) index was created using principal component analysis.(11) Previously diagnosed diabetics were asked about their history of diabetes and eye examinations.

### Survey teams and training

A questionnaire was compiled in English and Afrikaans. The two versions of the questionnaire were piloted on two consecutive days to assess whether patients understood the questions and whether the answers could be matched to the options on the questionnaire. There were five

survey teams, each consisting of one ophthalmologist and two community-based eye workers. The survey teams received six days of training.

## Ethical considerations

Ethical approval for RAAB+DR was granted by the University of Cape Town Health Sciences Human Ethics Committee and the London School of Hygiene & Tropical Medicine. All participants with ophthalmic conditions that required treatment or further investigation were referred accordingly. People with newly diagnosed or poorly controlled diabetes were referred to the nearest health centre. The purpose of the study and the examination procedure was explained to the subjects, and informed written consent (or in some cases thumb-printed consent) was obtained prior to completion of the questionnaire.

## The questionnaire

A questionnaire was completed by all known and newly diagnosed diabetics in the sample.

## Data analysis

The same data were entered into two databases by two different people. Inconsistencies in data entry were identified using Epi Info<sup>TM</sup> (epidemiology statistical software), and corrections were made by referring back to the original data capture sheets. The data was then analysed using STATA 11 (data analysis and statistical software).

## Results

The total number of eligible survey participants in the RAAB and DR clusters was 2110, of which 1872 were examined in the survey. 119 (16%) people were unavailable, 116 (5%) declined to participate and 3 (0.1%) were unable to communicate with the survey teams. Out of the 1872 people included in the RAAB+DR survey, diabetes status was assessed in 1784 participants (95%), of whom 343 were found to have diabetes (19.1% 95% CI 16.7–21.6). Out of 343 people with diabetes, 305 (89%) were already known diabetics. The questionnaire was completed by 284 of the 343 diabetic participants, which equates to a response rate of 93%.

### What proportion of diabetics is aware of diabetic retinopathy?

Table 1 indicates that 80% of known diabetics in the Cape Town Metropole are aware of DR as a possible complication of diabetes. When comparing the awareness of DR between private and public sector patients, the results showed that 63 diabetics (86%) in the private sector were aware of DR, and 153 diabetics (80%) in the public sector were aware of DR, as shown in Table 2 (p-value 0.27). Table 2 also reveals that 69 type 1 diabetics (97%) were aware of DR as a possible complication compared to 155 of type 2 diabetics (75%).

**Table 1: Knowledge and awareness of eye complications of diabetes among people with known and newly diagnosed diabetes**

	<b>All diabetes</b>	<b>Newly diagnosed diabetes</b>	<b>Previously known diabetes</b>	<b>*p-value</b>
<b>Can diabetes affect the eyes?</b>				
No	72 (23%)	17 (57%)	55 (20%)	<0.0001
Yes (correct answer)	239 (77%)	13 (43%)	226 (80%)	
<b>Can glasses can help?</b>				
No (correct answer)	91 (29%)	8 (27%)	83 (30%)	0.05
Yes	113 (36%)	6 (20%)	107 (38%)	
Don't know	107 (34%)	16 (53%)	91 (32%)	
<b>How often should eyes be examined?</b>				
At least once a year (correct answer)	145 (46%)	9 (30%)	136 (48%)	0.04
Less than once a year	16 (5%)	0 (0%)	16 (6%)	
Don't know	152 (49%)	21 (71%)	131 (46%)	

\*P-value comparing new/known diabetics using chi square or Fisher's exact test.

Note: some questionnaire responses were missing.

**Table 2: Comparison of responses between type 1 and type 2 diabetics, and between public and private sector patients (known diabetics only)**

	Type of diabetes			Source of diabetes medicine		
	Type 1	Type 2	p-value	Public	Private	p-value
<b>Can diabetes affect the eyes?</b>						
Yes	53 (25%)	2 (3%)	<0.001	37 (19%)	10 (14%)	0.27
No	155 (75%)	69 (97%)		153 (80%)	63 (86%)	
<b>Can glasses help?</b>						
No	62 (29%)	21 (30%)	0.95	46 (24%)	34 (47%)	0.002
Yes	81 (38%)	25 (36%)		76 (40%)	22 (30%)	
Don't know	68 (32%)	23 (33%)		69 (36%)	17 (23%)	
<b>How often should eyes be examined?</b>						
At least once a year	98 (47%)	38 (54%)	0.49	95 (49%)	37 (51%)	0.004
Less than once a year	13 (6%)	3 (4%)		5 (3%)	9 (12%)	
Don't know	100 (47%)	29 (41%)		92 (48%)	37 (37%)	

\*P-value using chi square or Fisher's exact test.

Note: Some questionnaire responses were missing.

**Table 3: Association between the awareness of diabetic retinopathy and socio-economic variables**

	Can diabetes affect the eyes?			Can glasses help?			How often should eyes be examined?		
	Yes	No	p-value	No	Yes or don't know	p-value	Annual	< 1 year or don't know	p-value
All diabetes	239 (77%)	72 (23%)		91 (29%)	220 (70%)		145 (46%)	168 (54%)	
<b>Socio-demographic variables</b>									
<b>Gender</b>									
Male	65 (82%)	14 (18%)	0.69	31 (31%)	67 (68%)	0.53	45 (46%)	53 (54%)	0.92
Female	158 (80%)	39 (20%)		60 (28%)	153 (72%)		100 (47%)	115 (53%)	
<b>Age (years)</b>									
50–59	97 (85%)	17 (15%)	0.057	40 (31%)	90 (69%)	0.21	58 (43%)	76 (57%)	0.19
60–69	78 (83%)	15 (16%)		29 (27%)	77 (72%)		57 (55%)	47 (45%)	
70–79	39 (70%)	17 (30%)		21 (34%)	40 (66%)		25 (41%)	36 (59%)	
80+	9 (69%)	4 (31%)		1 (7%)	13 (93%)		5 (36%)	9 (64%)	
<b>Education status</b>									
None	6 (75%)	2 (25%)	0.34	1 (9%)	10 (90%)	0.004	3 (27%)	8 (73%)	0.20
Primary	150 (79%)	39 (21%)		52 (25%)	156 (75%)		91 (44%)	118 (57%)	
Secondary	57 (85%)	10 (15%)		65 (40%)	48 (60%)		44 (54%)	37 (46%)	
Higher	9 (82%)	2 (18%)		6 (60%)	4 (40%)		6 (55%)	5 (45%)	
<b>Socio-economic status</b>									
Low	51 (68%)	24 (32%)	0.098	15 (19%)	63 (81%)	<0.001	31 (40%)	46 (60%)	0.03
Medium	91 (77%)	27 (23%)		24 (21%)	91 (79%)		47 (40%)	70 (60%)	
High	89 (82%)	20 (18%)		50 (46%)	58 (54%)		62 (56%)	48 (44%)	

	Can diabetes affect the eyes?			Can glasses help?			How often should eyes be examined?		
	Yes	No	p-value	No	Yes or don't know	p-value	Annual	< 1 year or don't know	p-value
<b>Diabetes and treatment variables</b>									
<b>Diabetes status</b>									
Newly diagnosed	13 (43%)	17 (57%)	<0.001	8 (27%)	22 (73%)	0.74	9 (30%)	21 (70%)	0.05
Previously known	226 (80%)	55 (20%)		83 (29%)	198 (70%)		136 (48%)	147 (52%)	
<b>Type of diabetes</b>									
Type 1	155 (75%)	53 (25%)	<0.001	62 (29%)	149 (71%)	0.87	98 (47%)	113 (53%)	0.26
Type 2	69 (97%)	2 (3%)		21 (30%)	48 (70%)		38 (54%)	32 (45%)	
<b>Source of diabetes medicine</b>									
Public	153 (81%)	37 (20%)	0.27	46 (24%)	145 (76%)	<0.001	95 (49%)	97 (51%)	0.86
Private	63 (86%)	10 (14%)		34 (47%)	39 (53%)		37 (51%)	36 (49%)	

\*P-value using chi square or Fisher's exact test.

SES/education: these figures show trends that increased awareness is associated with higher education and SES level, but not all of these correlations are statistically significant.

Note: Some questionnaire responses were missing.

### What is diabetics' understanding of the risk factors that play a role in the development of diabetic retinopathy?

From Table 4 it is apparent that 90 diabetics (29%) were unaware of measures that may prevent DR. In terms of possible preventive actions, 143 diabetics (46%) thought that a diabetic diet was important and 126 diabetics (40%) thought that taking diabetic medication was important.

**Table 4: Breakdown of the actions that diabetics thought could prevent diabetes-related eye damage.**

	Number	%
Diabetic diet	143	46%
Taking medication as prescribed	126	40%
Exercise	60	19%
Losing weight	23	7%

	Number	%
Keeping blood sugar under control	54	17%
Keeping blood pressure under control	6	2%
Other	19	6%
Don't know	90	29%

### What is diabetics' understanding of the importance of retinal examinations to detect STDR and the treatment of STDR?

The results shown in Table 1 demonstrate that 136 diabetics (48%) were aware that annual retinal examinations are required, and 131 diabetics (46%) did not know how often they should go for a retinal examination.

The treatment for STDR is argon laser photocoagulation and intravitreal anti vascular endothelial growth factor injections. In the survey, diabetics were asked whether they believed that glasses would help in the treatment of diabetes-related eye damage. Over a third of diabetics believed that glasses would help. A third of diabetics was unaware of the existence of treatment for DR.

### Discussion

To the best of the authors' knowledge, this survey is the first population-based survey in Africa on the awareness of DR in diabetics, the risk factors for DR and the need for retinal screening for DR, and one of only a few conducted internationally.(1,5,12)

The results of this study indicate that the majority of diabetics in the Cape Town Metropole are aware that diabetes can affect their eyes, which is not in keeping with the subjective experience of doctors working in the Groote Schuur Hospital's Eye Clinic, an example possibly of the skewed experience of practitioners in a tertiary institution. The awareness level of DR in Cape Town is similar to that found in some studies(13-16), but much better than that found in other studies(1,12,17). An interesting finding of this study is that diabetics obtaining treatment in the private sector do not have a greater awareness of DR than those being cared for in the public sector. This finding belies the assumption that diabetics receiving medical care in the public sector would be less informed about their disease due to public sector medical personnel having less time to impart relevant information, compared to medical personnel in the private sector.

This study showed that both a higher socio-economic status and a better education level correlated with a better awareness of DR, which was in keeping with several other studies in the literature.(1,5,12,16,18,19) One possible reason for this correlation might be that diabetics who are better educated are better able to understand the explanations given to them by health care personnel about diabetes and its complications, and may have greater access to both written and audio-visual health information in the public domain.

It is clear from this study, that being aware that diabetes can affect one's eyes does not imply an understanding of the risk factors for developing DR, possible preventative measures and the need

for regular screening examinations. Interestingly, a relatively high proportion of diabetics highlighted the need for following a diabetic diet and taking diabetic medication, but a much smaller proportion understood the importance of glycaemic control. A disturbingly high proportion of patients (29%) were not aware of any measures they could implement to help prevent DR.

To prevent diabetics from losing their sight due to STDR, diabetics should have annual retinal examinations to detect STDR. However diabetics in this study have a very poor understanding of the need for retinal examinations. The finding that a relatively low proportion of diabetics are aware of the need for regular retinal examinations is in keeping with data from several other studies.(12,15,16,18) Despite the clear value of laser photocoagulation in preventing visual loss from STDR, diabetics in Cape Town have a poor understanding of the treatment of DR, with a sizable proportion of patients (38%) believing that spectacles will help to restore vision.

### In summary

This study provides the first population-based data in Africa that demonstrate that despite a reasonable level of awareness of DR as a possible complication of diabetes (80%), many have a poor understanding of the risk factors for the development of DR, a poor understanding of the importance of annual retinal examinations and a lack of knowledge about the treatment of DR. The study findings suggest that awareness of the importance of the control of systemic risk factors in the prevention of DR and the need for regular retinal examinations needs to be greatly improved. This increased awareness, combined with access to and uptake of retinal screening and DR treatment services, should result in a decrease in the prevalence of visual impairment and blindness due to diabetic eye disease in Cape Town.

### Limitations of the study

The questionnaire was compiled in Afrikaans and English. Xhosa-speaking community eye workers translated the questionnaire into Xhosa during interviews with Xhosa-speaking diabetics. This could have introduced bias into the results. Univariate analysis was only performed when examining the relationship between variables such as awareness, socio-economic level and education level.

### Funding

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## Specification of roles of authors

1. Dr. F. Joubert: Planning of survey, Compiling of questionnaire, Piloting of questionnaire, Administration of questionnaire, Data Entry, Mmed write up
2. S. Pollock: Planning of survey, Supervising survey, Data analysis
3. Prof C. Cook: Administration of questionnaire
4. Dr. K. Lecuona: Administration of questionnaire
5. Dr. D.W. Steven: Administration of questionnaire
6. Dr. G.J. Rogers: Administration of questionnaire
7. Dr. N. Cockburn: Planning of survey, Compiling questionnaire, Administration of questionnaire, Supervisor

## D. Appendices

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# 1. Participant information sheet

## a. English version

Participant information sheet: Survey of blindness and diabetic eye disease in Cape Town

### **What is the purpose of the study?**

We are doing a study to find out how many people in Cape Town are blind and what the causes of blindness are. People with diabetes can develop an eye disease which can damage sight. As diabetes is a big problem in South Africa, we would also like to find out the best way to diagnose eye disease from diabetes during community surveys of blindness. We hope this information will help the planning of eye care services in Cape Town

### **What will happen if I agree to take part in the study?**

- We will ask you a few questions about yourself.
- You will then have your eyesight checked and your eyes examined by a doctor.
- We will then do a finger prick blood test to see whether or not you might have diabetes. If the test shows that you might have diabetes, you will be given some eye drops so that the doctor can examine your eyes in more detail to see if the diabetes has affected your eyes. The eye drops may sting a little and may make your vision blurred for a few hours, and you should not drive until your vision has returned to normal.
- If you may have diabetes and show some changes in your eyes on examination, we will give you an appointment to attend Groote Schuur Hospital on a Saturday morning for a thorough eye check.
- When you get to the hospital, we will pay you R150.00 to cover the cost of your transport to and from hospital.

### **Why have I been chosen?**

We have randomly chosen areas in Cape Town and are inviting all people aged over 50 years in these areas to take part. You've been chosen because your house is in one of these areas.

### **What are the advantages to me to take part in the study?**

You will receive a free vision test. If anything abnormal is detected, you will receive a free eye examination with further referral for treatment if needed. You will also be tested for diabetes. This is useful, as many people who have diabetes do not know they have the condition and so are not on treatment for it.

### **Confidentiality**

All information which is collected about you during the study will be kept strictly confidential.

### **Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you have any other questions that are not answered here, or which need any further information or explanation, please contact: Dr Nicky Cockburn, Groote Schuur Hospital, Tel: 021-4045060

## b. Afrikaans version

Deelnemer inligtingsblad: Opname van blindheid en diabetiese oogsiekte in Kaapstad, Suid-Afrika.

### **Wat is die doel van die studie?**

Ons is besig met 'n studie om uit te vind hoeveel mense in Kaapstad blind is en wat die oorsaak van die blindheid is. Persone met suiker diabetes kan 'n oogsiekte ontwikkel wat hulle sig kan beskadig. Aangesien diabetes 'n groot probleem in Suid-Afrika is, wil ons ook uitvind wat die beste manier is om oogsiekte a.g.v. diabetes gedurende gemeenskap opnames te diagnoseer. Ons hoop hierdie inligting sal die beplanning van oogsorg dienste in Kaapstad.

### **Wat sal gebeur as ek instem om deel te neem aan die studie?**

- 'n Dokter sal jou gesigsvermoë nagaan en jou oë toets.
- Ons sal dan 'n vinger prik bloedtoets doen om vas te stel of jy diabetes mag hê of nie.
- As die toets toon dat jy wel diabetes mag hê, sal jy oogdruppels gegee word sodat die dokter jou oë beter kan toets om vas te stel of jou oë skade opgedoen het a.g.v. diabetes. Die oogdruppels mag 'n bietjie brand en mag ook jou visie vir 'n paar uur verdof. Dit sal veroorsaak dat jy vir die res van die dag nie sal kan bestuur nie. Ons sal jou verwys vir behandeling as jy 'n oogprobleem het of moontlik diabetes.
- As die vinger prik bloedtoets toon dat jy diabetes mag hê, sal ons vir jou 'n afspraak maak by Groote Schuur hospital op 'n Saterdag, vir 'n deeglike ondersoek van jou oë. Wanneer jy by die hospitaal opdaag, sal ons jou R150.00 betaal om jou vervoerkoste na die hospitaal en huis te dek.

### **Hoekom is ek gekies?**

Ons het d.m.v. 'n steekproef gebiede in Kaapstad gekies en nooi alle persone oor 50 jaar in hierdie gebiede om deel te neem aan die studie. Jy is gekies omdat jou huis in een van hierdie gebiede val.

### **Wat is die voordele indien u aan die studie deelneem?**

U sal 'n gratis visietoets ontvang en indien u visie nie normaal is nie, ook 'n gratis oogondersoek en verwysing indien nodig. U sal ook getoets word vir diabetes. Die rede is omdat baie mense met diabetes nie weet hul het diabetes nie en gebruik daarom nie behandeling nie.

### **Vertroulikheid**

Alle inligting wat oor jou versamel is met die studie is streng vertroulik

### **Moet ek deelneem?**

Nee. Dit is jou besluit om deel te neem of nie. As jy besluit om deel te neem is jy steeds vry om enige tyd te onttrek en u hoef nie 'n rede te gee nie.

As jy enige vrae het wat nie hier beantwoord is nie of as jy enige ander inligting of verduideliking nodig het, kontak asb: Dr. Nicky Cockburn, Groote Schuur Hospitaal, Tel: 021-4045060

### c. Xhosa version

Uxwebhu lwenkcukacha lomthathi nxaxheba: Ucwangingo lwesifo zamehlo kunye neswekile eKapa, eMzantsi Afrika.

#### **Ingaba yintoni injongo yoluphando?**

Senza oluphando ukufumanisa ukuba bangaphi abantu apha eKapa abangaboniyo kwaye kudalwa yintoni ukungaboni/iyintoni ekudalayo. Senza uphandoukuze sifumanisise ukuba bangaphi abantu eKapa abangaboniyo kwaye yintoni ebangela ukungaboni. Abantu abanesifo seswekile bangathi babe nesifo samehlo esithi simoshe amehlo. Kuba ke isifo seswekile siyingxaki enkulu eMzantsi Afrika, singathanda ukufumana indlela hlola isifo samehlo kwiswekile ngexesha kwenziwa uphando lokungaboni ekuhlaleni. Siyathemba ukuba ezinkcukacha kungathi kukwazi ukuncedisa ekuncwanciseni inkonzo zoku khathalela amehlo apha eKapa kunye nezinye izixeko kwalapha eMzantsi Afrika.

#### **Ingaba kuzokwenzeka ntoni ukuba ndithe ndavuma ukuba yinxalenye yoluphando?**

Sizokuthi sikubuze imibuzo embalwa ngawe kunye nabantu abahla endlini yakho. Uyokuthi ujongwe amehlo kwaye amaehlo akho axilongwe nguqgirha. Sizokuthi senze utsalo gazi kumnwe wakho ukuze sibone okanye unayo okanye awunaso isifo seswekile. Ukuba iziphumo zithi kungase ubenaso isifo seswekile, unikwe iyeza lamehlo ukwenzela uqgirha awaxilongwe ngokucophelela ukuze abone ukuba yintoni unobangela kumehlo akho kwisifo seswekileto . Iyeza lamehlo lingathi likuphandle kancinci kwaye ingenza ukuba ibengathi amehlo abenkungu okweyure ezimbalwa. Kuyofuneka ulinde unde uzive ukuba unofifi lokubona kakuhle ngaphambi kokuba uqhube. Singathi sikuthumele kwindawo onokufumana khona amayeza amehlo ukuba unegxaki yamehlo okanye yesifo seswekile. Ukuba ingaba unokuba nesifo seswekile kwigazi elitsalwe emnweni kwaye kunotshitsho kuxilongo lwamehlo akho, siyakuthi sikunike usuku lokuya kwisibhedlele iGrootte Schuur Hospital ngentseni yangomqibelo ukuze uzojongwa ngokucophelela amehlo akho. Xa ufika esibhedlele uyakuthi ubhatale R150.00 leyo iyakuthi ibe yimali yokukusa esibhedlele nokukubuyisela ekhaya kwakhona.

#### **Kutheni niye nakhetha mna?**

Sithi sikhetha indawo apha eKapa ngokuqikelela kwaye simeme bonke abantu abangaphezulu kweminyaka e50 kwezindawo ukuze bathathe inxaxheba koluphando. Uye wakhethwa kuba kaloku indlu yakho ithe yayinxalenye yezithe zakhethwa kulendo.

#### **Ingaba zintoni endizokuzizuzisa xa ndithatha inxaxheba koluphando.**

Uyokuthi ufumane ukuhlolwa amehlo felefele kuba akalunganga, Uxilongo lufelefele luyakuthi lukufumanise amayeza amehlo xa efuneka. Uyakuthi uhlolwe nesifo seswekile. Lento iyokuthi ibe luncedo kuba abantu abaninzi abanesifo seswekile abayazi ukuba banaso lonto ibenze ukuba bangathathi mayeza wayo.

#### **Inkcukacha ziyimfihlo**

Lonke ulwazi oluzothi luqukathwe apha liyokuthi ligcinwe emfihlakalweni kwaye alunokuthi lusetyenziswe nakubanina.

**Ingaba ndinyanzelekile ukuba ndithathe inxaxheba?**

Hayi. Kuxhomekeke kuwe ukuba uyafuna ukuthatha inxaxheba okanye hayi. Ukuba uthi uthathe isiqhobo sokuthatha inxaxheba usavumelekile ukuba urhoxe xa ufuna nanini na ngelixesha kwenziwa uphando ngaphandle kokunika izizathu.

Ukuba unemibuzo ethe ayaxukushwa/yaphendulwa apha okanye ufuna ulwazi oluthe chatha uyacelwa ukuba uqhaqhamshelane noqgirha u: Nicky Cockburn, kwisibhedlela saseGroote Schuur Inombholo yomnxeba 021-4045060

## 2. Consent forms

### a. English version

Survey of blindness and diabetic eye disease in Cape Town, South Africa

Cluster: \_\_\_\_\_ ID: \_\_\_\_\_

Participant: (first and last name)

\_\_\_\_\_

I understand **what will happen** if I take part in this study.

I have been given the **opportunity to ask questions** and my questions have been answered.

Taking part in this study is **voluntary**.

I agree to **take part** in this study.

Signature / thumb print (**participant**)

.....

Printed name (**witness**)

.....

Signature (**witness**)

.....

Date: .....

## b. Afrikaans version

Opname van blindheid en diabiese oogsiekte in Kaapstad, Suid Afrika

Cluster: \_\_\_\_\_ ID: \_\_\_\_\_

Deelnemer: (naam en van)

\_\_\_\_\_

Ek **verstaan wat sal gebeur** as ek aan hierdie studie deelneem.

Ek het die **geleentheid gekry om vrae te vra**.

Ek is bewus dat ek **vrywillig** aan di studie kan deelneem of nie.

Ek stem in om **deel te neem** aan hierdie studie.

Handtekening / duimafdruk (**deelnemer**)

.....

Naam in drukskrif (**getuie**)

.....

Handtekening (**getuie**)

.....

Datum: .....

c. Xhosa version

Uxhwebhu lwenkcukacha lomthathi nxaxheba:Ucwaningo lwesifo zamehlo kunye neswekile eKapa,eMzantsi Afrika

Iqela: \_\_\_\_\_ Isazisi: \_\_\_\_\_

Umthathi nxaxheba: ( Amagama onke)

\_\_\_\_\_

Ndinalo ulwazi ukuba **kuzokwenzeka ntoni** xa ndithatha inxaxheba koluphando. Ndiye ndalinikwa **ithuba lokubuza imibuzo** kwaye ithe imibuzo yam yaphendulwaI . Ukuthatha inxaxheba koluphando lokokuthanda kum kwaye ndingarhoxa nanini na.

Tyikitya /Faka ubhontsi - (**umthathi nxaxheba** )

.....

Bala igama (**Ingqina**)

.....

Tyikitya (**Ingqina**)

.....

Umhla: .....

### 3. Questionnaire

#### a. English version

AWARENESS OF THE OCULAR COMPLICATIONS DUE TO DIABETES IN DIABETICS IN CAPE TOWN	
Cluster: <input type="text"/> <input type="text"/> Individual no.: <input type="text"/> <input type="text"/>	
* For known diabetics, complete all questions (1-16)	
* For newly diagnosed diabetics ask questions 10, 14, 15, 16 (shaded in grey) only	
1	What age were you when you were told you had diabetes? Age <input type="text"/> <input type="text"/> years YEAR: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2	Are you currently receiving treatment for your diabetes? <input type="radio"/> (0) No (go to Q5) <input type="radio"/> (1) Yes (go to Q 3)
3	What treatment do you currently receive for your diabetes? (circle all that apply) <input type="radio"/> (1) Diet <input type="radio"/> (9) N/A <input type="radio"/> (2) Tablets <input type="radio"/> (3) Insulin <input type="radio"/> (4) Other. Specify: _____
4	Where do you normally go to get your diabetic medication? <input type="radio"/> (1) Government clinic or hospital <input type="radio"/> (9) N/A <input type="radio"/> (2) Private doctor or chemist <input type="radio"/> (3) Other. Specify: _____
5	Where do you usually go for your diabetes check ups? <input type="radio"/> (1) Government clinic or hospital <input type="radio"/> (9) N/A <input type="radio"/> (2) Private doctor or chemist <input type="radio"/> (3) I don't have diabetes check ups <input type="radio"/> (4) Other. Specify: _____
6	Do you have a machine for testing your blood sugar at home? <input type="radio"/> (0) No (go to Q10) <input type="radio"/> (1) Yes (Go to Q 7) <input type="radio"/> (9) N/A
7	If yes, have you used this to test your blood sugar in the past 4 weeks? <input type="radio"/> (0) No (go to Q9) <input type="radio"/> (1) Yes (go to Q8) <input type="radio"/> (9) N/A
8	If yes, how often do you usually check your blood sugar at home? <input type="radio"/> (1) Less than once a month <input type="radio"/> (9) N/A <input type="radio"/> (2) ≥ once a month, but <once a week <input type="radio"/> (3) At least once a week <input type="radio"/> (4) Once a day <input type="radio"/> (5) More than once a day <input type="radio"/> (6) When I feel unwell
9	If no, why not? (Record response given) <input type="radio"/> (9) N/A
10	When did you first know that diabetes can affect your eyes? <input type="radio"/> (1) Today <input type="radio"/> (2) Before today
* Was it today or before today?	
11	Did a nurse, doctor or optometrist ever advise you to have your eyes examined because of your diabetes <input type="radio"/> (0) No <input type="radio"/> (1) Yes
12	Before today, have you ever had your eyes examined specifically to check whether diabetes has affected them or not - e.g. Drops were put in your eyes before the examination or a photograph was taken of the back of your eye? <input type="radio"/> (0) No (go to Q14) <input type="radio"/> (1) Yes (go to Q 13)
13	If yes, has this examination been done by a..... (ask Qa-g) <input type="radio"/> (0) No <input type="radio"/> (1) Yes <input type="radio"/> (9) N/A a Nurse <input type="radio"/> (0) No <input type="radio"/> (1) Yes b Optometrist (person who tests for glass <input type="radio"/> (0) No <input type="radio"/> (1) Yes c Doctor at government clinic or hospital <input type="radio"/> (0) No <input type="radio"/> (1) Yes d Private doctor <input type="radio"/> (0) No <input type="radio"/> (1) Yes e Camera <input type="radio"/> (0) No <input type="radio"/> (1) Yes g Other. Specify _____ <input type="radio"/> (0) No <input type="radio"/> (1) Yes
14	If yes, have you had your eyes examined because of your diabetes in last 12 months? <input type="radio"/> (0) No <input type="radio"/> (1) Yes
15	How often do you think people with diabetes should have their eyes examined because of their diabetes ? <input type="radio"/> (1) More than once a year <input type="radio"/> (2) Once a year <input type="radio"/> (3) Every 2 years <input type="radio"/> (4) Less than every 2 years <input type="radio"/> (5) When they have problems with their eyes <input type="radio"/> (6) Don't know
16	If diabetes affects your eyes, will glasses make them better? <input type="radio"/> (0) No <input type="radio"/> (1) Yes <input type="radio"/> (2) Don't know
17	What can a person with diabetes do to decrease the chance of diabetes affecting their eyes? <input type="radio"/> (1) Diabetic diet <input type="radio"/> (2) Taking diabetic medication as prescribed <input type="radio"/> (3) Exercise <input type="radio"/> (4) Loose weight <input type="radio"/> (5) Keep blood sugar under control <input type="radio"/> (6) Keep blood pressure under control, if high <input type="radio"/> (7) Other. Specify: _____ <input type="radio"/> (8) Don't know

## b. Afrikaans version

BEWUSTHEID VAN DIE OKULÊRE KOMPLIKASIES AS GEVOLG VAN DIABETES IN DIABETE IN KAAPSTAD			
Klein Area: <input type="text"/>		Individuele no.: <input type="text"/>	
* Vir bekende diabete, voltooi alle vrae(1-16)			
* Vir nuutgediagnoseerde diabete vra allenlik vrae 10, 14, 15, 16(in grys)			
1	Op watter ouderdom is u in kennis gestel dat u diabetes het? Ouderdom	<input type="text"/> jare	JAAR: <input type="text"/>
2	Gebruik u huidiglik behandeling vir u diabetes?	<input type="radio"/> (0) Nee(na Vr5)	<input type="radio"/> (1) Ja(Na Vr3)
3	Watter behandeling gebruik u huidiglik vir u diabetes? (omsirkel almal van toepassing)	<input type="radio"/> (1) Dieet <input type="radio"/> (2) Tablette <input type="radio"/> (3) Insulien <input type="radio"/> (4) Ander. Spesifiseer: .....	<input type="radio"/> (9) NVT
4	Waar kry u gewoonlik u diabetiese medikasie?	<input type="radio"/> (1) Staatskliniek of -hospitaal <input type="radio"/> (2) Privaatdokter of apteek <input type="radio"/> (3) Ander. Spesifiseer: .....	<input type="radio"/> (9) NVT
5	Waar gaan u gewoonlik vir u diabetes opvolg besoeke?	<input type="radio"/> (1) Staatskliniek of -hospitaal <input type="radio"/> (2) Privaatdokter of apteek <input type="radio"/> (3) Ek het nie diabetes opvolg besoeke <input type="radio"/> (4) Ander. Spesifiseer: .....	<input type="radio"/> (9) NVT
6	Het u 'n masjien om u bloedsuiker by die huis te toets?	<input type="radio"/> (0) Nee (na Vr10)	<input type="radio"/> (1) Ja(Na Vr7) <input type="radio"/> (9) NVT
7	Indien ja, het u dit die afgelope 4weke gebruik om u bloedsuiker te toets?	<input type="radio"/> (0) Nee(Na Vr9)	<input type="radio"/> (1) Ja(Na Vr8) <input type="radio"/> (9) NVT
8	Indien ja, hoe gereeld toets u u bloedsuiker by die huis?	<input type="radio"/> (1) Minder as een keer per maand? <input type="radio"/> (2) $\geq$ een/ per maand, maar < een keer/ week <input type="radio"/> (3) Ten minste een ker per week <input type="radio"/> (4) Een keer per dag <input type="radio"/> (5) Meer as een keer per dag <input type="radio"/> (6) Wanneer ek sleg voel	<input type="radio"/> (9) NVT
9	Indien nee, hoekom nie? (Noteer die antwoord)		<input type="radio"/> (9) NVT
10	Wanneer het u uitgevind dat diabetes u oë kan beïnvloed? Was dit vandag of voor vandag?	<input type="radio"/> (1) Vandag	<input type="radio"/> (2) Voor vandag
11	Het 'n suster, dokter of optometris u ooit in kennis gestel om u oë te laat ondersoek omdat u diabetes het?	<input type="radio"/> (0) Nee	<input type="radio"/> (1) Ja
12	Het u ooit voor vandag u oë laat ondersoek spesifiek om te toets of diabetes u oë beïnvloed het of nie- bv. Was druppels voor die ondersoek in u oë geplaas of 'n foto geneem van die agterkant van die oog?	<input type="radio"/> (0) Nee(na Vr 14)	<input type="radio"/> (1) Ja(Na Vr13)
13	Indien ja, was die ondersoek gedoen deur..... (Vrae Vr.a-g)	a Suster b Optometris (persoon wat vir brille toets) c Dokter by staatshospitaal of -kliniek d Privaatdokter e Kamera g Ander. Spesifiseer: .....	<input type="radio"/> (0) Nee <input type="radio"/> (0) Nee <input type="radio"/> (0) Nee <input type="radio"/> (0) Nee <input type="radio"/> (0) Nee <input type="radio"/> (0) Nee <input type="radio"/> (1) Ja <input type="radio"/> (1) Ja <input type="radio"/> (1) Ja <input type="radio"/> (1) Ja <input type="radio"/> (1) Ja <input type="radio"/> (1) Ja <input type="radio"/> (9) NVT
14	Indien ja, was die ondersoek die afgelope 12 maande ?	<input type="radio"/> (0) Nee	<input type="radio"/> (1) Ja
15	Hoe gereeld dink u behoort 'n persoon met diabetes hul oë laat ondersoek as gevolg van hul diabetes?	<input type="radio"/> (1) Meer as een keer per jaar <input type="radio"/> (2) Een keer per jaar <input type="radio"/> (3) Elke 2 jaar <input type="radio"/> (4) Minder as elke 2 jaar <input type="radio"/> (5) Wanneer daar fout is met hul oë <input type="radio"/> (6) Weet nie	
16	Indien diabetes u oë beïnvloed sal 'n bril dit beter maak?	<input type="radio"/> (0) Nee	<input type="radio"/> (1) Ja <input type="radio"/> (2) Weet nie
17	Wat kan 'n persoon met diabetes doen om die kans te verminder dat diabetes hul oë beïnvloed?	<input type="radio"/> (1) Diabetiese dieet <input type="radio"/> (2) Neem diabetes medikasie soos voorgeskryf <input type="radio"/> (3) Oefening <input type="radio"/> (4) Gewigsverlies <input type="radio"/> (5) Hou bloedsuiker onder beheer <input type="radio"/> (6) Hou bloeddruk onder beheer as dit hoog is <input type="radio"/> (7) Ander. Spesifiseer: .....	<input type="radio"/> (8) Weet nie

## 4. Department of surgery approval letter



**UNIVERSITY OF CAPE TOWN**

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### **Department of Surgery**

#### **Departmental Research Committee**

**Professor Anwar Suleman Mall**

J-45 Room Old Main Building, Groote Schuur Hospital,  
Observatory 7925, South Africa

Tel (021) 406 6168/6232/6227 FAX (021) 448 6461

Email: [Anwar.Mall@uct.ac.za](mailto:Anwar.Mall@uct.ac.za)

21<sup>st</sup> October 2013

Dr F Joubert  
Department of Surgery  
Division of Ophthalmology  
Groote Schuur Hospital  
University of Cape Town

Dear Dr Joubert,

**RE: PROJECT 2013/114**

**PROJECT TITLE:** Awareness of diabetic retinopathy among diabetic patients in Cape Town, South Africa

The above proposal was reviewed by the Department of Surgery Research Committee and I am pleased to inform you that the committee approved the study.

Please use the above project number in all future correspondence.

Yours sincerely

signature removed

**PROFESSOR ANWAR S MALL**

**CHAIRMAN: RESEARCH COMMITTEE**

**"OUR MISSION is to be an outstanding teaching and research university,  
educating for life and addressing the challenges facing our society."**

## 5. Research ethics approval letter



UNIVERSITY OF CAPE TOWN  
Faculty of Health Sciences  
Human Research Ethics Committee



Room E52-24 Old Main Building  
Groote Schuur Hospital  
Observatory 7925  
Telephone [021] 406 6492 • Facsimile [021] 406 6411  
Email: [Sumayah.ariefdien@uct.ac.za](mailto:Sumayah.ariefdien@uct.ac.za)  
Website: [www.health.uct.ac.za/research/humanethics/forms](http://www.health.uct.ac.za/research/humanethics/forms)

04 February 2014

HREC/REF: 761/2013

Dr N Cockburn  
Ophthalmology  
D-4  
NGSH

Dear Dr Cockburn

**Project Title: THE AWARENESS OF DIABETIC RETINOPATHY AMONG DIABETIC PATIENTS IN CAPE TOWN, SOUTH AFRICA (sub-study linked to 297/2010)**

Thank you for addressing the issues raised by the Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

**Approval is granted for one year until the 28 February 2015.**

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator

**Please quote the HREC REF in all your correspondence.**

Yours sincerely

signature removed

 **PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, HSF HUMAN ETHICS**

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

Hrec/ref:761/2013

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

## Acknowledgements

We would like to thank all the people who kindly participated in the survey, the community-based eye workers from the Jonga Trust, Niki Van Vuuren for data entry and Dinky Levitt for assistance in planning and with the manuscript.