Screening for diabetes in optometric practice

HOWSE, JENNIFER,HELEN

Screening for diabetes in optometric practice

Jennifer Helen Howse

Submitted for the degree of Doctor of Philosophy

May 2010

Durham University

Abstract

Diabetes is an increasing problem worldwide and is placing increasing strain on the healthcare system. It often goes undiagnosed for many years until complications occur. Identifying undiagnosed disease presents a challenge to all healthcare professionals. In the UK, screening has traditionally been the role of general practitioners, although other professionals such as pharmacists have recently become involved. Optometrists may also be in a good position to carry out screening tests themselves. Their role in screening for diabetes has not been previously investigated.

The first part of the thesis takes a qualitative approach to explore optometrists' perceptions, attitudes and beliefs about diabetes and screening for the disease. It demonstrated that if certain barriers, such as cost and training, can be overcome, some optometrists are willing to carry out screening tests. It also raises issues regarding their professional roles and their relationship with other healthcare providers.

The second part of the thesis describes the development and implementation of a screening scheme using random capillary blood glucose (rCBG) tests. Over three-quarters of eligible adults participated in the screening. We found that around one third (318) of those had a rCBG level requiring further investigation. Half of these people reported attending their GP and receiving further investigation. 16 (5%) were subsequently diagnosed with either diabetes or pre-diabetes. Those who participated in the screening programme found the test procedure to be comfortable, convenient and would recommend it to others.

Analyses of strategies to identify those most at risk who would benefit from screening suggest that offering rCBG tests to those who are aged over 40 years with either a BMI of 25kg/m^2 or more, or a family history of diabetes or both, would be effective for detection purposes.

This research confirmed the feasibility of testing for diabetes in optometry practices and opens the door for another, PCT-based, study. This novel approach has never been tried before.

Acknowledgements

Firstly, I would like to thank my supervisors, Professor Pali Hungin and Dr Steve Jones for their help, support and guidance during the last three years.

I would like to thank all those who took part, in particular the staff of the five practices who welcomed myself and my team of assistants, and provided encouragement; Campbell & McDearmid and Specsavers in Redcar, Pagan & McQuade and Keith Walker in Hartlepool and Specsavers in Peterlee. Thanks also to those who helped carry out the testing; Steve Brock, Tony Longstaff, Roy Martin, Sally Barker and Joanne Barker. Without their help the screening would have taken much longer.

Thanks go to Professor James Mason, who provided help with the statistical design of the screening study.

Thanks must also go to Dr Helen Hancock and Dr Helen Close who helped me understand qualitative research methods and Dr Harshini Rajapakse who helped code the transcripts and Helen Taylor who transcribed the focus groups and interviews

Thanks to all my family and friends who provided support and read through numerous questionnaires and information sheets for me, in particular Derek Parry who has proofread many of the sections for me.

Finally, thanks must go to my husband Ian, who has helped and supported me throughout.

Publications

Articles

Howse JH, Jones S, Hungin APS. Screening and diagnosing diabetes in optometrists' practices: an evaluation of perceptions, attitudes and beliefs. Practical Diabetes Int. 2010; 27(2):55-58

Abstracts

Howse JH, Jones S. Hungin APS. An evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes. Diabetic Medicine. 2009:26 (suppl. 1), P534.

Howse JH, Jones S, Hungin APS. Prevalence of elevated random capillary blood glucose in "at risk" people attending high street opticians. Diabetic Medicine. 2010:27 (suppl.1) P489

Howse JH, Jones S, Hungin APS. Acceptability of random capillary blood glucose tests in high street opticians practices. Diabetic Medicine. 2010:27 (suppl.1) P490

Declaration of authorship and statement of copyright

I confirm that this is my own work and the use of all materials from other sources has been properly and fully acknowledged. This thesis represents new material and has not previously been submitted for a degree at this or any other university.

Content

Abstract ii

Acknowledgements iii

Publications iv

Declaration of authorship and statement of copyright v

Table of content vi

Table of figures xi

Chapter 1 Introduction 1

Chapter 2 Literature review 5

2.1 Diabetes 6

2.1.1 Classification 6

2.1.2 Prevalence and predictions 8

2.1.3 Risk factors 10

2.1.4 Diagnosis 14

2.1.5 Symptoms & complications 14

2.2 Pre-diabetes and non-diabetic hyperglycaemia 19

2.2.1 Impaired Glucose Tolerance 19

2.2.2. Impaired Fasting Glucose 19

2.2.3 Progression to and prevention of diabetes 20

2.2.4 Pre-diabetes and cardiovascular disease 21

2.3 Screening for diabetes 21

2.3.1 Screening using capillary blood glucose 27

2.3.2 Screening by other health care professionals 29

Screening by chiropodists 30

Screening by dentists 31

Screening by pharmacists 32

2.4 Optometrists role in health care provision 37

2.4.1 Provision of sight tests 38

2.4.2 Optometrists role in detecting, screening and referring diseases 40

2.4.3 Challenges and developments in the role of optometrists 42

Chapter 3 A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes: Part 1 – Background, aims and methods 44
Abstract 45
3.1 Introduction 46
3.1.1 Optometrists in the UK: training and role in UK healthcare 47
3.2 Choice of method 49
3.2.1 Research method 49
3.2.2 Sampling 54
3.2.3 Sample size 55
3.3 Methods 55
3.3.1 Subjects, setting and sampling 55
3.3.2 Analysis 57
Chapter 4 A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes: Part 2 – results, analysis and discussion 60
Abstract 61
4.1 Results 63
4.1.1 Respondent validation 63
4.2 Results of focus groups and interviews 64
4.2.1 Awareness of undiagnosed diabetes 64
Patients' awareness of undiagnosed diabetes 64
Optometrists' awareness of undiagnosed diabetes 66
4.2.2 Acceptability of screening service 69
Acceptability to patients 69
Acceptability to optometrists 76
Acceptability to general practitioners 80
4.2.3 Barriers to, and implementation of a screening service 84
Cost 84
Infection control and sharps handling 89

Training and protocol 91
Liability 94
4.2.4 Current and developing role of optometrists 95
4.3 Discussion 104
4.3.1 Awareness of diabetes 104
4.3.2 Acceptabilty of screening 105
4.3.3 Barriers 106
4.3.4 Role of optometrists 110
4.3.5 Limitation and strengths 112
Chapter 5 Detection of diabetes in optometric practice – A feasibility study: Part 1 – Background, aims and methods 113
Abstract 114
5.1 Introduction 115
5.2 Methods 117
5.2.1 Methodology 117
5.2.2 Objectives 117
5.2.3 Outcomes 117
5.2.4 Participants and setting 121
5.2.5 Protocol 121
Risk questionnaires 122
Cut off points for random capillary blood glucose levels 126
Random and fasting blood glucose levels 127
5.2.6 Location and practices 134
Chapter 6 Detection of diabetes in optometric practice: Part 2 – Results of capillary blood glucose testing 137
6.1 Participants 138
6.1.1 Demographics of participants 139
6.2 Results 141
6.3 Discussion 148
Chapter 7 Detection of diabetes in optometric practice: Part 3 – results of referral to GP following capillary blood glucose testing 149

7.1 Participants 150
7.2 Results 151
7.3 Discussion 160
7.3.1 Limitations and strengths 165
Chapter 8 Acceptability of blood glucose testing to users in high street opticians practices 167
Abstract 168
8.1 Introduction 170
8.2 Methods 170
8.2.1 Choice of method 171
8.2.2 Questionnaire development 171
8.2.3 Sample size 172
8.3 Results 173
8.3.1 Demographics 173
8.4 Discussion 181
8.4.1 Limitations and strengths 184
Chapter 9 Detection of diabetes in optometric practice: Resource implications & economics 186
9.1 Cost of screening: a ready reckoner 187
9.2 Different screening strategies 190
9.2.1 55-75 years with hypertension 190
9.2.2 Age, family history and BMI 191
9.2.3 Age family history, BMI and symptoms 192
9.3 Resource and economic implications of screening 194
9.4 Discussion 198
Chapter 10 Discussion and conclusions 203
10.1 Attitudes of optometrists and professional roles and relationships 204
10.2 Attitudes and acceptance of the public 206
10.3 Findings of the screening study 208
10.4 Cost consequences of screening and organisational challenges 209
10.5 Feasibility 210

10.6 Reflections 212
10.7 Future work 214
10.8 Limitations 214
10.9 Conclusions 217
Appendix 219
A Invitation letter and consent form for focus groups and interviews 220
B Inclusion criteria 223
C Information leaflet and consent form 225
D Participant results forms 231
E GP information and results forms 235
F Quality control of blood glucose meters 238
G Follow up questionnaire for participants with rCBG of 6.1mmol/l or more 249
H Acceptability questionnaire 251
References 254

Figures

Figure 1	WHO criteria for diagnosis of diabetes	14
Figure 2	Prevalence of diabetic retinopathy in people with newly diagnosed Type 2 diabetes	17
Figure 3	Appropriateness of screening	22
Figure 4	Risk factors included in diabetes risk questionnaires	26
Figure 5	Cut off levels used in studies using capillary blood glucose as a screening test	28
Figure 6	‘At risk’ groups	35
Figure 7	Summary of referral criteria	36
Figure 8	Reasons for a sight test to be reimbursed by the NHS	38
Figure 9	Minimum intervals between rNHS sight tests	39
Figure 10	Sight test volumes by patient age group and NHS reimbursement	40
Figure 11	Demographics of participants	57
Figure 12	List of risk factors to determine if a person should be screened for diabetes	124
Figure 13	Guidelines for referral using random and fasting capillary blood glucose measurements	128
Figure 14	Participant pathway	130
Figure 15	Pathway for participants who receive a capillary blood glucose test	133
Figure 16	Health indicators for Redcar & Cleveland, Hartlepool and County Durham	135
Figure 17	Predicted prevalence of Type 2 diabetes, diagnosed and undiagnosed, and total prevalence of diagnosed diabetes	136
Figure 18	Numbers of adults sight tests, adults with diabetes and adults eligible to participate, attending the 5 practices (A-E) during the study period	139
Figure 19	Demographic details of the participants by practice, by gender and by practices type	140

Figure 20 Frequency of sight tests for all participants and by practice type 142
Figure 21a&b Prevalence of presence of self reported risk factors 143
Figure 22 Distribution of random capillary blood glucose measurements 145
Figure 23 Age, blood glucose and risk factors by gender and practice type 146
Figure 24 rCBG category by gender and practice type 147
Figure 25 Logistic regression predicting the likelihood of rCGB measurement of 6.1mmol/l or more 147
Figure 26 Response rate to follow up questionnaire for each practice and characteristics of respondents 150
Figure 27 Summary of participants who were referred following random capillary blood glucose test 152
Figure 28 Mean age, rCBG, risk factors, gender and practice type of participants who reported attendance or non-attendance at their GP 154
Figure 29 Mean age, rCBG and risk factors for those attending their GP who reported further investigations or no further investigations carried out 155
Figure 30 Mean age, rCBG and number of risk factors of those diagnosed with hyperglycaemia and normal hyperglycaemic levels 156
Figure 31 Box plot of rCBG measures for those diagnosed as having diabetes, pre-diabetes and normal blood glucose 157
Figure 32 Diabetes and pre-diabetes for different cut off points 157
Figure 33 PPV of rCBG for pre-diabetes & diabetes and diabetes 158
Figure 34 Characteristics of those diagnosed with diabetes, IGT, IFG, borderline diabetes or pre-diabetes 159
Figure 35 Demographic details for all participants returning questionnaires and all participants in the screening 174
Figure 36 Table of participants responses 175

Figure 37 Responses by gender, previous test, rCBG measurement and practice type 177
Figure 38 Where respondents would seek screening if they had not participated in the screening study 178
Figure 39 Fixed costs for rCBG screening 188
Figure 40 Cost of training assuming 4.72 test per day 189
Figure 41 Comparison of four strategies for indentifying people at risk to undergo screening 193
Figure 42 Costs to PCT and England of screening those aged 40 years or over with a BMI of 25kg/m^2 and over and/or family history of diabetes 195
Figure 43 Costs to PCT and England of screening those aged 40 years or over with one of the following risk factors: BMI of 25kg/m2 and over, a family history of diabetes if 50% take up and optical assistants and optometrists carry out tests 197
Figure 44 Cost of screening if tests are carried out by different people within optometry practices 198

Chapter 1

Introduction

Chapter 1

Introduction

Diabetes is an increasing issue in today's society, with frequent news reports about the dangers of increasing prevalence of the disease. Despite frequent media coverage, many people are unaware of the risks and symptoms of the disease and the rate of undiagnosed disease is thought to be high.

Identifying those people who are at risk of having undiagnosed diabetes is a challenge. Although in the UK health care is free at the point of delivery and cost or lack of insurance is not a factor in accessing services, there are still many people who do not use medical services such as GPs' practices for preventative care or earlier diagnosis. Currently most testing for diabetes in the UK is carried out in GPs' practices, though some pharmacies offer screening services using capillary blood glucose testing (1). The National Health check programme, which is currently being rolled out across the UK, includes fasting plasma glucose or HbA_{1c} tests for those who are determined to be at risk of developing diabetes (2). Even with these services, there are still people who have undiagnosed disease and are not accessing healthcare professionals able to screen or diagnose the condition.

Optometrists carry out around 17million sight tests a year (3) and may be seeing many people who may have undiagnosed diabetes. Currently, they are not involved in screening for any systemic diseases, though their training requires them to study various systemic conditions including hypertension and diabetes, both of which have ocular complications (4). It has been suggested that optometrists are in a position to measure blood pressure to identify those requiring treatment for hypertension (5). This was felt to be an approach to advance the profession. However, their role in detecting undiagnosed diabetes in routine practice has not been considered.

Optometrists, as a profession, are currently positioned between business and healthcare. The majority of UK optometrists are working in high street practices. They provide services on behalf of the National Health Service (NHS), but are not employed by them. Due to the way the NHS funds sight testing, the business side of selling spectacles is essential for practices to continue to provide services. This conflict between business and healthcare affects the way optometrists are viewed by other healthcare professionals and the public and how they perceive themselves and their role.

Like pharmacists, optometry practices are often situated in high street locations, and often have longer opening hours, including weekends, than GPs practices may have, making access easier for some people. However, while pharmacists have been included in screening services, optometrists have not yet taken up these initiatives. This may be for a variety of reasons. Optometrists may not see it as their role to offer these services, or might feel that other professionals do not want them to do so. The attitudes of healthcare professionals and the public towards optometrists will impact on whether it is feasible for optometrists to offer services outside their traditional sight testing role, such as screening for diabetes.

This thesis aims to explore some of these ideas, firstly using qualitative methods to evaluate the perceptions and attitudes of optometrists themselves to screening, diabetes itself and their possible role in such extended healthcare. Secondly, a screening service will be tested in high street practices to establish the feasibility of such a service in this new location. Finally, a study embedded in the screening project will consider the acceptability of the new service to the participants.

Chapter 2 is a review of the literature. Diabetes and pre-diabetes are discussed in terms of prevalence, diagnosis and risk factors. Screening

for diabetes is considered, and the role that other healthcare professionals have in screening. Finally the current role of optometrists within the UK health care system is considered.

Chapters 3 and 4 describe a qualitative evaluation of optometrists' beliefs and attitudes towards diabetes and screening. The background and study design is described in chapter 3 and the results discussed in chapter 4.

Chapter 5 describes the design of a feasibility study using random capillary blood glucose (rCBG) to screen for diabetes and pre-diabetes in optometry practices. The results of the rCBG tests are described in chapter 6. The follow up with participants who had a rCBG measurement requiring further investigation is considered in chapter 7.

The design and results of a study to evaluate acceptability of the screening service to participants is discussed in chapter 8.

The economic implications of using optometrists and optometry practices as a location to screen for diabetes is discussed in chapter 9. The costs of screening and the use of different strategies for identifying those at risk of diabetes who would benefit from participating in screening is considered.

Chapter 10 discusses the findings and implications of the studies described in the previous chapters.

Chapter 2

Literature review

Chapter 2

Literature review

2.1 Diabetes

Diabetes mellitus was has long been recognised. A description of a polyuric condition has been found in ancient Egyptian papyrus dating from 1550BC. Diabetes was used as a term in the 2nd century AD to describe conditions where there was an increase in urine and is derived from the Greek ‘to pass through’. Polyuria in association with sweet tasting urine was first recorded in India in the 5th and 6th century AD. The term mellitus, which is derived from the Greek and Latin terms for honey, was added in the 17th century. This was used to distinguish diabetes mellitus from different other polyuric conditions where there is no glycosuria and so do not feature sweet tasting urine (6).

2.1.1 Classification

Diabetes mellitus describes a metabolic disorder that causes chronic hyperglycaemia due to either defective insulin secretion or insulin action, or both. (7).

The first World Health Organisation (WHO) classification of diabetes mellitus was published in 1980 (8) and revised in 1985 (9). The 1980 report proposed two classifications, IDDM (insulin dependant diabetes mellitus) or Type 1 and NIDDM (non insulin dependant diabetes mellitus) or Type 2. The nomenclature Type 1 and 2 was not used in the 1985 study group report, with the terms NIDDM and IDDM used only.

In 1999 WHO recommended that the terms NIDDM and IDDM should no longer be used, as they can cause confusion. Type 1 and Type 2 were reintroduced to ensure that classification was based on disease aetiology rather than treatment method (7). Type 1 Diabetes covers those cases where disease is due to pancreatic islet beta-cell destruction. This can be

idiopathic or more commonly is due to autoimmune processes. It does not include cases where beta-cell destruction is due to a specific disease such as cystic fibrosis. Type 2 diabetes covers those cases that result from defects in insulin secretion and is often combined with a degree of insulin resistance. This category covers a range from defective insulin secretion with no insulin resistance to largely insulin resistance with a degree of defective secretion. The deficiency in insulin secretion is usually relative rather than absolute.

The WHO classification names other specific type of diabetes that do not fit in to the Type 1 and 2 categories. These include drug or chemical induced disease, gestational diabetes, diseases of the exocrine pancreas and genetic defects of beta-cell function (7).

Diabetes can be further subdivided into three groups corresponding to treatment requirements unrelated to the initial cause. ‘Insulin required for survival’ which corresponds with the class IDDM. The groups ‘Insulin required for control’ and “Not insulin requiring ‘ correspond to the classes of NIDDM.

Type 2 is the commonest form of diabetes. Of the estimated 2,168,000 people with all types of diabetes (both diagnosed and undiagnosed) in England in 2001, 92.3% were thought to have Type 2. 667,000 of these people are likely to not have been diagnosed. (10).

The onset of Type 1 diabetes typically occurs earlier than Type 2, with onset peaking between 10 and 14 years. In the UK the incidence of Type 1 diabetes in this age group is 26 per 100,000 per year (11). In contrast, the incidence and prevalence of Type 2 diabetes increases with age. The prevalence of Type 2 diabetes in Middlesbrough is between 4.22 and 5.51 cases per 1000 in the 20 to 39 year age groups. This rises to between 43.50 and 47.12 cases per 1000 of the population aged over 70 years (12).

2.1.2 Prevalence and predictions

Diabetes Mellitus is an increasing problem in Western society and worldwide. The worldwide prevalence of diabetes in 2000 was estimated to be 171 million (2.8% of the population). The prevalence was set to increase to 366 million by 2030 (4.4% of the population) (13). A higher prevalence of 4.0% in 1995 increasing to 5.4% in 2025 has also been reported (14).

Predicted estimates of the prevalence of diabetes in the United States vary from 11.5% in 2011 increasing to 13.5% in 2021 (considering both diagnosed and undiagnosed disease)(15) and 4.72% in 2010 increasing to 5.89% in 2025 (considering those with diagnosed diabetes only)(16). The estimated number of people with diagnosed diabetes in 2050 has been revised from 7.21% of the population (16) to 12.0% (17). The increase in estimated prevalence is due to an increase in the incidence of diagnosed disease and a small reduction in the relative risk of mortality associated with diabetes between 2000 and 2004 (17). The models used to predict future prevalence assume that there will be no changes in treatment, average life expectancy, disease prevention or cure.

The estimated prevalence of all types of diabetes (Type 1 and Type 2, both diagnosed and undiagnosed) in England in 2001 was 4.41%. The prevalence of diabetes in England varies between different ethnic groups, with highest prevalence in South Asian and Black African Caribbean populations (6.6% and 5.7% respectively)(10). In a population of older people (60-79 yrs) in the United Kingdom 7.6% of men and 5.1% of women were known to have diabetes, with a further 6.7% and 6.0% found to have diabetes when tested (18).

The crude annual incidence of newly diagnosed Type 2 diabetes has been reported as 1.93 cases per 1000 people in the UK. It was

acknowledged that this rate may not represent the true incidence of new cases of diagnosis as it was recorded in a predominately white Caucasians and in a population where no screening procedures were in place (19).

Incidence of Type 2 diabetes increases with age. The estimated prevalence ranges from 0.32% in those under 29 years to 13.47% in the over 60 years age group (10).

There has been an increase in the incidence of childhood Type 2 diabetes. In a twelve month period in 2004 and 2005, 67 cases of Type 2 diabetes were confirmed in children less than 17 years in the UK, giving an incidence of 0.53 cases per 100,000 per year. Incidence was found to be higher then average in Black and South Asian populations, 3.9 and 1.25 case per 100,000 per year respectively. 95% of the children diagnosed with Type 2 diabetes were found to be overweight and 84% had a family history of the disease (20). 5% of people under the age of 30 years attending diabetic clinics in Leeds were diagnosed with Type 2 diabetes(21). Children with Type 2 diabetes are often South Asian, overweight and have a strong family history of diabetes. Many of these children are diagnosed coincidentally (22).

The average age at which Type 2 diabetes is diagnosed appears to be changing. In the US, the average age for diagnosis in 1988 to 1994 was 52.04 years. In the period 1999 to 2000 the average age was 46.01 years. Whether this is a real change in the onset of disease or a reflection of increased screening and earlier diagnosis is not clear (23). The increasing rates of obesity worldwide may also have an influential role in the earlier diagnosis of the disease.

The prevalence of Type 2 diabetes increases with age in all populations studied, with the increases more pronounced in populations who have high prevalence of diabetes (24).

2.1.3 Risk factors

Diabetes has a number of risk factors. These can be modifiable, such as obesity and lack of exercise, or non-modifiable such as age or ethnicity.

Diabetes is a polygenic disease. Several genes have been identified as being candidate genes for Type 2 diabetes including USF1, CAPN10, HNF4α, PPARγ, ADRB3, KCNJ11, TCF7L2 and ENPP1 (25) (26) (27). These genetic factors cannot be used for clinical diagnosis as other modifiable factors such as environmental influences will also play a role in disease development (25).

Family history has been shown to be a risk factor for the development of diabetes, with people with a sibling with Type 2 diabetes having a four times greater risk of developing diabetes in their lifetime than the general population (28). It has been suggested that a strong family history is associated with earlier onset of Type 2 diabetes, though family history does not appear to affect the clinical characteristics or complications (29) (30).

Ethnicity has also been shown to a risk factor for Type 2 diabetes. Prevalence has been shown to be higher in South Asians than White Europeans living in the same area. In an area of Coventry it was found that the prevalence of diagnosed and undiagnosed Type 2 diabetes was 11.2% in Asian men and 8.9% in Asian women compared with 2.8% in white men and 4.3% in white women(31). It was found that the prevalence of diabetes in Asians in an area of London was nearly four times higher than in Europeans, with seven times as many Asians diagnosed as having diabetes between the ages of 40 and 64 years than white Europeans (32). Higher prevalence in South Asian populations compared with European populations has also been demonstrated in urban populations in Norway (33). Higher prevalence has also been

shown in African Caribbean populations when compared with white Europeans populations (34, 35).

The age of onset of diabetes is also associated with ethnicity. Seven times as many Asians as Europeans were diagnosed as having Type 2 diabetes between the ages of 30 to 54 years in an area of London (32). In one study in the UK, all the cases of childhood onset Type 2 were reported in children of Indian, Pakistani and Arabic origin (22). A Danish study reported Type 2 diabetes in children with Turkish and Pakistani backgrounds (36). In the US, prevalence of Type 2 diabetes in adolescents is highest in American Indian and African American groups and lowest in non-Hispanic white children (37).

The estimated prevalence of all types of diabetes, both diagnosed and undiagnosed, in the UK in 2001 was 0.33% in the 0-29 years age group rising to 13.92% in the population aged 60 years and more (10).

Diet is considered to be a factor in the development of diabetes. It is difficult to determine exactly what effect individual nutrients have, as they are taken as part of a wider diet (38). It has been suggested that increased consumption of vegetables, fresh fruit and wholemeal bread reduce the risk of diabetes whereas daily consumption of meat increases the risk (39).

Obesity as determined by body mass index (BMI) and abdominal obesity are modifiable risk factors. Abdominal obesity, measured by waist to hip ratio (WHR), has been shown to increase the risk of developing diabetes even when adjusted for BMI (40).

Hypertension is a known risk factor for diabetes. In study of 99 patients attending a hypertension clinic in a UK hospital, 58 were found to have abnormal glucose tolerance (24 diabetes, 18 impaired glucose tolerance and 16 impaired fasting glucose) (41). Certain antihypertensive drugs,

including beta-blockers and thiazide diuretics, are associated with increased risk of diabetes (42).

Prevalence of diabetes and impaired glucose tolerance is known to be higher in women with polycystic ovary syndrome (PCOS) (43) (44) (45). PCOS is relatively common with an estimated prevalence of around 5-10% in premenopausal women (46). PCOS is associated with other risk factors for diabetes, such as obesity. However, obese women with PCOS have a higher prevalence of IGT and diabetes than age and weight matched population of women without PCOS (46). Women with PCOS are at increased risk of developing the metabolic syndrome, a condition characterised by increased abdominal obesity, raised triglyceride levels, decreased HDL cholesterol, raised blood pressure and dysglycemia (47). It is considered to be a risk factor for the development of diabetes (42). Traits of metabolic syndrome have shown to be useful in determining whether a person should undergo OGTT to detect IGT and diabetes (48).

Gestational diabetes is known to affect between 4 and 12% of pregnancies in the US (49). Blood glucose levels will usually return to normal levels after pregnancy. However there is an increased risk that they will develop Type 2 diabetes. A systematic review of studies considering Type 2 diabetes in women with a history of gestational diabetes found cumulative incidence of Type 2 diabetes ranged from 2.6% to 70% with follow up lasting from 6 weeks to 28 years postpartum (50). The Diabetes Prevention Programme showed that women with IGT and a history of gestation diabetes where more likely to progress to diabetes compared with women who had IGT and no previous history of gestational diabetes (51).

There is known to be a link between depression and diabetes. The risk of depression has been shown to be higher in people with diabetes than those without (52), with a prevalence of depression between 8.5% and 32.5% among people with diabetes (53). There is evidence to show that,

as well as increased risk of depression in people with diabetes, there is an increased risk of developing diabetes among people with depression. In the Diabetes Prevention Programme (DPP), antidepressant medication was found to be associated with the risk of developing diabetes in those group given lifestyle intervention or placebo even when weight and initial fasting glucose was controlled for. Antidepressant use did not affect progression to diabetes in the group given metformin. However, participants who reported symptoms of depression while not taking medication did not show an increased risk of developing diabetes when adjusted for other factors such as weight (54). Depressive symptoms have been associated with factors that are known to increase the risk of diabetes, such as BMI and physical inactivity. However, some studies have found increased risk of developing diabetes in people with depressive symptoms after demographic and lifestyle factors have been taken into account (55).

Diabetes has a higher prevalence among people with schizophrenia than those without with prevalence of 15% reported in some studies (53). As with depression, schizophrenia is associated with factors that influence the development of diabetes, such as physical inactivity, obesity and smoking. Some antipsychotic drugs have been linked with hyperglycaemia. Atypical anti-psychotics, which were used in around 90% of people with schizophrenia in the US, have been shown to increase risk of developing diabetes when used long-term (56). Several mechanisms for this have been suggested for this, including insulin resistance, weight gain and toxic effects on the pancreatic islet cells (53).

Physical inactivity increases the risk of developing diabetes. (57). Physical activity has been shown to reduce the risk of diabetes, whether it is leisure activity (58) (59), occupational activity (58) or commuting either by foot or bike (58). Though moderate to vigourous activity decreases risk of developing diabetes significantly (60), lower intensity activity, such

as walking or gardening has been shown to reduce the risk of developing diabetes by 17% when controlled for BMI (61).

2.1.4 Diagnosis of diabetes

The oral glucose tolerance test (OGTT) has been used as the standard diagnostic test for diabetes. However, the use of fasting plasma glucose (FPG) was recommended by WHO in 1997 and the lower threshold was lowered from 7.8mmol/l to 7.0mmol/l (62). OGTT is still a valid method for diagnosis, though it is recognised that it is more inconvenient than FPG measurements.

The criteria for diagnosing diabetes has changed over time. The current WHO criteria are shown in figure 1 (7).

Figure 1 - WHO criteria for diagnosis of diabetes

	Venous whole blood	Capillary whole blood	Venous plasma
Fasting	≥6.1 mmol/l	≥6.1 mmol/l	≥7.0mmol/l
2 hours post glucose load	≥10.0 mmol/l	≥11.1 mmol/l	≥11.1mmol/l

2.1.5 Symptoms and complications

Diabetes is often described as presenting with a classic triad of symptoms consisting of polyuria, thirst and weight loss (63). The American Diabetes Association (ADA) list seven symptoms associated with diabetes, frequent urination, excessive thirst, extreme hunger, unusual weight loss, increased fatigue, irritability and blurry vision. The International Diabetes Federation (IDF) includes the same symptoms, but excludes irritability and adds slow wound healing and recurrent infection (64).

A study of patients newly diagnosed with Type 2 diabetes investigated the presence and duration of typical symptoms prior to diagnosis. Over half the participants reported abnormal thirst (63.7%), fatigue (61.0%) or frequent urination (53.9%). Other commonly reported symptoms included cramp in calves (31.9%), genital itching (27.2%) and visual disturbances (24.9%). 89% of patients reported having at least one symptom in a two year period prior to diagnosis (65).

Complications of diabetes can be macrovascular or microvascular (66). Macrovascular complications, such as stroke and cardiovascular disease are not specific to diabetes, but more prevalent in people with diabetes than those without. There has been a report in the reduction in mortality due to cardiovascular disease in the general population that has not been seen in the population with diabetes (67).

In the United States, between the period 1971-1975 and 1982-1984, age adjusted heart disease mortality declined by 36.4% men with no diabetes compared with a decline of 13.1% in men with diabetes. During the same period women without diabetes experience a decline in mortality of 27%, however women with the disease showed an increase in heart disease related mortality of 23%(68). Following first myocardial infarction, people with Type 2 diabetes have been shown to have increased mortality by 40% when compared with people without diabetes. The risk increases for younger people with diabetes (69).

Microvascular complications include neuropathy, retinopathy and nephropathy (66).

Diabetic retinopathy is thought to account for 4.8% of global cases of blindness (70). It is thought the be the leading cause of blindness in adults of working age, with age related macular degeneration causing more blindness in people aged over 65 years (71, 72).

In people with newly diagnosed Type 2 diabetes, retinopathy has been found to be present in between 4.0% (65) and 36.7% (73) of cases. There has found to be a considerable difference in prevalence in different studies. Drivsholm et al. (65) and Olivarius et al. (74) found the lowest prevalence of retinopathy among newly diagnosed patients (between 4 and 5%). These Danish studies took place between 1989 and 1992 and relied on fundoscopy by an ophthalmologist to diagnose retinopathy, with the presence of microaneurysms only being classified as the least severe for of the disease. The UKPDS study, which found 36.7% of newly diagnosed patients to have some form of retinopathy used retinal photographs which were assessed by two independent readers to determine the presence of eye disease, with the presence of one microaneurysm in one eye being classified as having diabetic retinopathy present. Retinal photography began as part of the UKPDS study in 1983 (75). Both the UKPDS (75) and Danish studies (65) (74) considered patients diagnosed with Type 2 diabetes by their GP in the course of their normal practice, rather than in a dedicated screening programme. Mitchell et al. (76) found a higher prevalence of retinopathy than the Danish studies, but lower than in the UKPDS. The 39 participants in this were newly diagnosed as a result of blood glucose testing as part of the Blue Mountains Eye Study rather than through their GP. Like the UKPDS study, retinal photographs were used to determine the presence of diabetic retinopathy, instead of fundoscopy. There is a wide range of reported prevalence of diabetic retinopathy in those newly diagnosed. This may relate to several factors; the method used to examine the fundus, criteria used to diagnose the disease and the method of the detection of newly diagnosed participants, whether through screening or after presenting to a GP. Figure 2 summarises the prevalence of diabetic retinopathy in newly diagnosed patients.

Figure 2 - Prevalence of diabetic retinopathy in people with newly diagnosed Type 2 diabetes

Authors	Year	County	Notes	% Prevalence
Drivsholm et. al. (65)	2005	Denmark	Female n=548	4.0%
Drivsholm et. al. (65)	2005	Denmark	Male n=589	5.4%
Olivarius et. al. (74)	2001	Denmark	n=1251	5.0%
Litwin et. al. (77)	2002	UK	n=1953	18.4%
Mitchell et. al. (76)	1997	Australia	n=39	15.8%
Rema et. al. (78)	2001	India	n=438	7.3%
Stratton et. al. (75)	2001	UK	n=1919	36.7%
Ramachandran et. al. (79)	1996	India	n=69	6.7%

Retinopathy is described as non-proliferative or proliferative according to whether abnormal new vessels are present. Early stages of retinopathy are asymptomatic. Non-proliferative diabetic retinopathy (NPDR) is graded as background or pre-proliferative by the UK National Screening Committee or as mild, moderate or severe background retinopathy by the Scottish Diabetic Retinopathy Grading Scheme (80). Proliferative retinopathy is characterised by neovascularisation and can cause vision loss due to pre-retinal or vitreous haemorrhages or through tractional retinal detachment. Neovascularisation can also occur in the iris and anterior chamber angle leading to rubeosis iridis and rubeotic glaucoma.

Vision loss can also occur through macular oedema that can occur at any stage of retinopathy (81).

Ocular complications other than retinopathy can also occur. Refractive changes have been reported in poorly controlled diabetes (82). Although refraction changes in hyperglycaemia have traditionally been thought to be myopic, transient hyperopic shift have also been reported (83) (84).

Age-related cataracts are common in patients with diabetes and tend to present at a younger age than in people without diabetes (85). Diabetes has been shown to be a risk factor in posterior subcapsular (PSC), cortical and mixed cataract (86) (87). In some rare cases, cataracts can be reversible when glycaemic control is obtained (88).

Ocular muscle palsies are known complications of diabetes and often present with sudden onset diplopia. In the cause of third nerve palsy associated with diabetes, the pupil is often spared (89).

Duration of diabetes and glycaemic control are both known factors in the progression of some ocular complications, including retinopathy. 3 to 4 years after diagnosis around 19% of patients with Type 1 diabetes and 24% of those with Type 2 will have some form of retinopathy (90). In the UKPDS study, 22% of those with no retinopathy at diagnosis had developed retinopathy within 6 years of diagnosis of Type 2 diabetes. They reported that development of diabetes was associated with both baseline glycaemia and glycaemic exposure over the follow-up period (75). This suggests that earlier diagnosis of diabetes and good glycaemic control may reduce the progression of diabetic retinopathy. Intensive glycaemic control is also thought to reduce the risk of other microvascular and macrovascular complications (73).

2.2 Pre-diabetes and non-diabetic hyperglycaemia

The term pre-diabetes was used in the 1960s to describe a condition where there was an increased risk of diabetes either due to a strong family history of diabetes, for example an identical twin, or a condition occurring in pregnancy, such as large baby. The World Health Organisation rejected this term in 1980 as it was considered not to be a useful description and had the potential to carry negative connotations. By 2005 the term ‘pre-diabetes’ was being used again to describe the condition of non-diabetic hyperglycaemia (NDH), both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) (91). These hyperglycaemic states are known to be precursors of diabetes and can occur in isolation; isolated Impaired Fasting Glucose (i-IFG) or isolated Impaired Glucose Tolerance (i-IGT); or in combination (IFG/IGT). (92)

2.2.1 Impaired Glucose Tolerance

The diagnostic category IGT was recommended in 1979 by the US National Diabetes Data Group and accepted by WHO the following year (93). It was intended to indicate the range of values between normal glucose levels and those levels where there was known risk of developing diabetic complications, in particular retinopathy (94).

Currently IGT is defined as fasting plasma glucose (FPG) of <7.0mmol/l and 2hr post challenge plasma glucose of >7.8 to <11.0 mmol/l (91).

Prevalence of IGT in 40 to 74 year age group is 15.8% (95). The NHANES II study estimated that the prevalence of IGT in the adult US population was 11.2%, rising from 6.4% in 20-44 years age group to 22.8% in the 65-74 years age group (96).

2.2.2 Impaired Fasting Glucose

In 1997 an International Expert Committee re-examined the classification of diabetes and recommended that fasting plasma glucose (FPG) could be used for the diagnosis of diabetes and that the cut off point for

diabetes should be lowered to 7.0mmol/l from 7.8mmol/l. Normal FPG was considered to be <6.1mmol/l. IFG was introduced to indicate the range between normal and diabetic FPG ranges (62). Currently IFG is defined by WHO as FPG of 6.1-6.9 mmol/l and by American Diabetes Association as FPG of 5.6-6.9 mmol/l (91). The lower cut-off point used by the ADA increases the prevalence of IFG to similar levels as IGT. In a population of 1040 adults without diabetes, aged between 40-69 years, 25% were found to have IFG using the WHO criteria. If the ADA criteria was applied to the same population, the prevalence rose to 61% (97).

Prevalence of IFG in the US population aged 20 years and over is 6.9%. In the 75 years and over age group, the prevalence was found to be 14.1% (17.9% Male, 11.9% female) (95).

2.2.3 Progression to and prevention of diabetes

IGT and IFG have been shown to be an independent risk factor for the development of diabetes (98). The rates of progression to diabetes in people with IGT has been shown to be higher then in those with IFG. In turn, people with IFG have a higher rate of progression than then in people with normal glucose tolerance (93) (99). The highest rate of progression to diabetes is seen in those with both IGT and IFG, where is a 12-fold increase in annualised relative risk (93).

Both lifestyle and drug interventions have shown that it is possible to reduce the progression to diabetes. In the Dream study, Rosiglitazone reduced incidence of diabetes in people with IGT, IFG or both by 60% compared with a placebo (25.0% progression to diabetes in placebo group compared with 10.6% in rosiglitazone group) (100). In the DPP study, Metformin reduced the incidence of diabetes by 31% when compared to the control groups (101).

Lifestyle (exercise, diet or both) intervention in people with IGT showed decreased incidence of diabetes in both Chinese (102), Finnish (103) and UK populations (104).

These studies have shown that intervention is successful in reducing progression to diabetes in those individuals with IGT. However, there is less evidence to show to similar effects in people with IFG (105).

2.2.4 Pre-diabetes and cardiovascular disease

Diabetes is a recognised risk factor for cardiovascular disease and is known to increase mortality following myocardial infarction (68). It has also been recognised that non-diabetic hyperglycaemia is also a risk factor for cardiovascular disease (106) (107) (108). IGT is associated with increased incidence of cardiovascular disease and mortality associated with it (105) (109) (110).

2.3 Screening for diabetes

One of the earliest examples of mass community based screening for diabetes is from the United States where around 70% of the population of Oxford, Massachusetts were screened in 1946-47 using urine and blood tests (111).

In the UK, the National Health check programme is currently being implemented. This screening programme for those aged between 40 and 74 years includes a risk assessment of factors including smoking status, BMI measurement, physical activity and blood pressure measurement. For those at risk of developing diabetes, a fasting plasma glucose or HbA_{1c} measurement is included.

Screening for a disease is justified if seven conditions can be met (112). These are shown in figure 3.

Figure 3 - Appropriateness of screening - from Engelgau et. al. (112)

Does diabetes represent an important health problem that imposes a significant health burden on the population?
Is the natural history of Type 2 diabetes well understood?
Does diabetes have a recognisable clinically silent stage during which the disease can be diagnosed?
Does treatment after early detection of Type 2 diabetes yield benefits superior to those obtained when treatment is delayed?
Are there tests that can detect preclinical (asymptomatic) diabetes that are reliable and acceptable?
Are the costs of case finding and treatment reasonable and balanced in relationship to health expenditure as a whole?
Will screening be an ongoing process?

Does diabetes represent an important health problem that imposes a significant health burden on the population?

Diabetes places a considerable burden on the population. The cost of treating complications not only occurs at the time when a complication occurs, but also in following years (113). It has been estimated that though the prevalence of diabetes in the US is around 5%, 15% of health care expenditure was on patients with the disease. The prevalence of diabetes is increasing (13) so increasing health care costs are likely. The burden diabetes places on society is not simply due to health care costs, but also social care and loss of productivity due to early mortality and illness (114).

Is the natural history of Type 2 diabetes well understood?

The biochemical onset of diabetes is followed by a clinically silent period when the disease is undiagnosed. Initially it may be difficult to detect with a screening test, but as hyperglycaemia increases it will become easier to detect. This detectable preclinical stage is followed by the development of symptoms, then complications due to the disease (112).

Does diabetes have a recognisable preclinical stage during which the disease can be diagnosed?

Diabetes can be diagnosed in asymptomatic individuals in the same way that it can be diagnosed in patients with further complications. Based on the occurrence of complications on diagnosis it has been estimated that the clinically silent stage can last up to 12 years (115).

Does treatment after early detection of Type 2 diabetes yield benefits superior to those obtained when treatment is delayed?

It is known that improved glycaemic control can improve the outcomes for patients with diabetes (116) (73). However it is not clear how much the outcomes are changed by the earlier detection of the disease in the clinically silent stages in people with screen-detected diabetes. If patients comply with the treatment and lifestyle advice they receive at diagnosis, early detection due to screening is likely to be beneficial. However, if advice is ignored and medication not used correctly the benefits of screening are not likely to be big (112). There is currently no evidence from randomised controlled trials on the outcomes of screening for diabetes (117).

Are there tests that can detect asymptomatic diabetes that are reliable and acceptable?

Screening tests are available that can be used to detect asymptomatic diabetes. A number of different tests are available. Ideally such tests should be reproducible, reliable and give a reasonable balance between sensitivity and specificity (112).

Are the costs of case finding and treatment reasonable and balanced in relationship to health expenditure as a whole?

The cost of the screening process itself varies depending on the method used. Screening allows diabetes to be diagnosed earlier before symptoms may have developed. Earlier diagnosis will have the effect of

increasing the cost of treatment for the condition, as there will be a greater number of years that the treatment is needed for. However, if earlier intervention decreases the occurrence or severity of complications, the cost involved in treating complications would be decreased by screening. There is currently some uncertainty as to whether screening is cost effective (118). Screening the population as a whole is inefficient and would not be considered cost effective (117). However the National Screening Committee does consider targeted screening to be cost effective (119). Screening hypertensive patients of all ages has been shown to be more cost effective than screening the whole population. When the age of the patient is taken into account it was found to be more cost effective to screen people aged 55-75 years rather than younger people (120).

Will screening be an ongoing process?

A one off screening test is unlikely to be 100% specific and so some people with diabetes will not be diagnosed. As new cases of diabetes will be developing with time screening need to be repeated at regular intervals. Currently with no national screening programme in the UK this is not necessarily happening. The American Diabetes Association recommends screening those at risk every 3 years (112). Screening every three years has been shown to be cost effective (121).

There are various tools available for screening for diabetes including risk questionnaires, urinalysis and blood tests. Screening tests for diabetes tend to fall into two broad categories, questionnaires or biochemical tests.

Biochemical tests tend to perform better than questionnaires, with venous and capillary glucose measurements performing better than urinary glucose or HbA_{1c}(112). Breath tests have also been suggested as a screening method, though this is not used at present (122).

Urinalysis has been used in a number of studies to detect undiagnosed diabetes, with participants asked to self-test for glycosuria (123) (124) (125) (126).

Screening tests recommended by the American Diabetes Association (ADA) include the ADA risk assessment questionnaire and capillary blood glucose using a cut off point 140mg/dl(7.8mmol/l) (127). A comparison of these screening tests showed a sensitivity of 72-78% and a specificity of 50-51% for the ADA questionnaire and sensitivity and specificity of 56-65% and 95-96% respectively for the capillary blood glucose test with a cut off point of 140mg/dl(7.8mmol/l). If the cut off point was lowered to 120mg/dl(6.6mmol/dl) the sensitivity increased to 75-88% while specificity decreased to 86-88%. When the lower cut of level was combined with the ADA questionnaire the sensitivity and specificity is 58-63% and 92-94% (127).

The ADA risk assessment questionnaire has been used to prompt clinicians to carry out further investigative tests. It has been shown that if the questionnaire is completed by the patient then handed to the clinician when attending a clinic for an unrelated matter, it results in a small increase in the rate of diagnosis of diabetes (128).

Risk questionnaires have been used both as a stand-alone screening tool (129) and in conjunction with another tests such as capillary blood glucose tests (130).

Questionnaires have used a number of factors to assess the risk of diabetes in an individual. Some use the presence of one or more risk factor to identify individuals at risk (131) (132) (130). Others give each risk factor a score and indicate a total score over which a person is considered to be at risk (129). Others use a formula to calculate risk (133). Figure 4 shows risk factors considered by different questionnaires.

Figure 4 - Risk factors included in diabetes risk questionnaire

	RPSGB /Diabetes UK (131)	**American Diabetes Association risk questionnaire**	**Finrisk (129)**	**Cambridge risk score (133) (134)**	**Swiss pharmacy (132)**	**Australian pharmacy(130)**	**ARIC**(135)	**Diabetes risk calculator** (136)
Method of calculating 'at risk'	1 risk factor	Score over 9[a]	Score over 9[b]	Risk factors entered in formula	2 risk factors	1 risk factor	Scoring system	Classification tree used
Age		Y	Y	Y	Y	Y	Y	Y
Family history of disease	Y	Y		Y	Y	Y	Y	Y
Waist Size	Y		Y				Y	Y
BMI	Y	Y	Y	Y	Y	Y	Y	
Ischemic heart disease/ cerebrovascular disease	Y					Y		
Hypertension	Y		Y	Y	Y	Y	Y	Y
Gestational diabetes	Y		Y			Y		Y
Polycystic ovary syndrome	Y					Y		
Mental health problems	Y							
Hypertriglyceridemia	Y							
Women with baby over 9lb		Y			Y			
History of high blood glucose	Y		Y			Y		
Lack of physical activity			Y		Y			Y
Daily intake of fruit/veg			Y					
Steroid medication				Y				
Smoking				Y			Y	
Ethnicity	Y					Y	Y	Y
Cholesterol							Y	
Rapid pulse							Y	
Symptoms	Y							

Many of the screening questionnaire and algorithms to determine risk have been validated on particular groups. Many questionnaires are tested on Caucasian population and are known to perform less well when tested on other populations (137) (138).

2.3.1 Screening using Capillary Blood Glucose (CBG)

It has been suggested that capillary blood glucose tests are suitable for epidemiological studies and screening as a cost effective alternative to venous blood samples (139). Capillary blood tests, both random and fasting, have been used in screening for Type 2 diabetes in several studies. Different cut off points have been used in different situations (36, 130, 140, 141). These have ranged from 4.5 mmol/l (140) to 11 mmol/l (130). Cut off levels used are shown in figure 5. The equipment used to measure capillary blood glucose uses whole blood, but some machines convert to the reading to give a plasma equivalent reading. In many of the studies below it is not clear whether the reading are whole blood or plasma equivalent.

Figure 5 - Cut off levels used in studies using capillary blood glucose as a screening test.

Author	Year	Country	Random/ Fasting	Referral levels
Sandbaek et al.(140)	2005	Denmark	Random	≥4.5 mmol/l
Krass et al. (130)	2007	Australia	Fasting	≥5.5 mmol/l
			Random	≥11.0 mmol/l (5.5-11.0 mmol/l retest)
Eborall et al. (142)	2007	UK	Random	≥11.0 mmol/l (5.5-11.0 mmol/l retest)
Simmons et al. (31)	1989	UK	Random	≥6.0 mmol/l
			Fasting	>4.0 mmol/l
Moses et al. (143)	1985	Australia	Random	≥8.0 mmol/l
Engelgau et al. (141)	1995	Egypt	Random	30 years+ ≥115mg/dl (6.3 mmol/l) 75 years+ ≥140mg/dl (7.7 mmol/l)
George et al. (144)	2005	UK	Random	≥7.0 mmol/l
Andersson et al. (145)	1993	Sweden	Random	≥8.0 mmol/l
Lidfeldt et al. (146)	2001	Sweden	Random	≥8.0 mmol/l
Hersberger et al. (132)	2006	Switzerland	Random	≥11.0 mmol/l (5.3-11.0mmol/l retest fasting – refer if ≥5.3 mmol/l)
			Fasting	≥6.1 mmol/l (5.3-6.0mmol/l retest fasting – refer if ≥5.3 mmol/l
RPSGB/ Diabetes UK Guidelines (131)	2006	UK	Random	≥11.1 mmol/l (5.6-11.0 mmol/l retest)
			Fasting	≥6.1 mmol/l (5.6-6.0mmol/l refer as risk of IGT/IFG)
Leiter et al. (147)	2001	Canada	Random	>5.5mmol/l
Mann et al. (148)	2009	UK	Random	≥5.5mmo/l

A WHO study group report states that a random capillary blood glucose level of 11.1 mmol/l suggests that diabetes is likely. A measurement of 4.4 mmol/l or less indicates that diabetes is unlikely. There is an range of measurements from 4.4 mmol/l to 11.1 mmol/l where there is uncertainty as to the presence of diabetes (9). The ADA recommendations for screening with capillary whole blood uses cut off levels of 6.1mmol/l for fasting and 7.8mmol/l for random measurements (112).

The specificity and sensitivity of capillary blood glucose as a screening test depends on two factors, the cut off levels used and the conditions that are to be screened for. It has been calculated that the most efficient cut off point for screening for diabetes is 120mg/dl (6.67 mmol/l) and 100 mg/dl (5.56 mmol/l) for diabetes and pre-diabetes. Sensitivity of these cut off points were calculated at 68% for 120 mg/dl (6.67mmol/l) (diabetes only) and 62% for 100 mg/dl (5.56mmol/l) (diabetes plus pre-diabetes). Specificity for these cut off points for diabetes and diabetes plus pre-diabetes were calculated as 89% and 70% respectively (149).

Puavilai et al. carried out random capillary blood glucose and oral glucose tolerance test (OGTT) In a group of 845 people with at least one risk factor of diabetes. All the participants who had random capillary blood glucose over 13.3 mmol/l were confirmed to have diabetes following oral glucose tolerance test. Just under 50% (402) had random capillary blood glucose between 6.1 and 13.3 mmol/l and about 20% of these were found to have diabetes when the oral glucose tolerance test was completed (150).

2.3.2 Screening by other health care professionals

Currently in the UK there is no national screening programme for diabetes. However, with the introduction of the National Health Checks, screening for those between 40 and 74 years is beginning to be implemented (2). Previously, screening programmes have been either

organised locally (151) (126) (152) or screening has been done opportunistically when a patient attends the GPs practice (153).

Other health care professionals are in the position to see patients in different settings than in GPs surgeries. As diabetes is a disease that can cause a wide range of complications, healthcare professionals other than medical doctors often receive some training in diabetes. They may be in a position to offer screening services.

Dentists (154), chiropodists (123) and pharmacists (132) have all considered some form of diabetic screening. There is no information about screening by other allied health professionals, such as orthoptists, dieticians or physiotherapists. Orthoptists have been involved in screening patients with known diabetes for eye disease, but not in screening for the disease itself (155).

Screening by chiropodists

People with diabetes are at risk of developing peripheral neuropathy and so are at high risk of diabetic foot ulceration. It has been estimated that one in seven patients with Type 2 diabetes have some form of foot ulcer or pre-ulcer (156). Chiropodists are experienced in seeing patients with diabetes.

Screening was trialled in a Liverpool chiropody clinic by asking patients aged 40 – 75 years to test a urine sample at home and ring the clinic if a positive result was recorded. In a three-month period 17.3% of the patients in this age group were known to have diabetes. 1158 took the screening test home. 11 of these reported a positive result. Following a glucose tolerance test, 4 were confirmed as having diabetes (0.4% of those given screening tests). This is a low rate of diagnosis, possible due to the fact that the population being tested had a high rate of diagnosed diabetes (123). They concluded that, while the screening was relatively

cost effective, it only lead to relatively low rates of diagnosis of diabetes. The authors of this study did not feel that screening in clinic could be recommended.

This screening method of issuing tests to be administered at home is easier to administer and less time consuming in a clinical situation, but it cannot be determined whether all those patients who received a test used them. It is possible that people either did not use the test or did not use them correctly. It is also not possible to tell if all positive results were reported.

Screening by dentists

Diabetes has been shown to be a risk factor for some dental conditions such as gingivitis and periodontitis, with higher prevalence and severity of disease in patients with poor glycaemic control (157).

It has been estimated that patients with family history of diabetes, hypertension, high cholesterol and a clinical finding of periodontal disease have a 27-53% chance of having diabetes. Attendance at a dental practice may be a good opportunity to screen individuals with these risk factors (154). In the US and UK approximately 60% of all adults visit the dentist at least once a year for routine examinations (154) (158). Dentists are likely to encounter some patients with undiagnosed disease.

There have been few reported screening programmes in place in dental practices. Testing gingival crevice blood has been considered as a possible method of screening. Blood oozing from the gingiva following periodontal probing has been tested using glucose self-monitoring devices such as would be used for a finger pinprick test. The gingival crevice blood glucose measurements and capillary fingerstick blood glucose measurements have been shown to be correlated, either moderately (r=0.75 (159)) or highly (r=0.98 (160)). When compared with

laboratory standard gingival crevice blood had a correlation coefficient of r=0.975 and capillary fingerstick blood, r=0.98 (161). Samples of capillary blood glucose levels from left and right hands have been reported to have a correlation coefficient of r=0.93 (159).

Though it has been suggested that screening using gingival crevice blood is feasible (161) (160), it does not appear that is has currently been used as method of screening at present. Concern has been raised over using blood samples collected after periodontal probing as there is a risk of lower glucose measurements due to contamination with saliva and other material from the gingiva (159).

Screening by pharmacists

Pharmacists have been involved in screening for diabetes in several countries. Swiss and Australian pharmacists have offered a free 'sequential screening' where a risk questionnaire is followed by a capillary blood glucose test and referral when necessary (130, 132).

Referral to the GP following a risk questionnaire only has been trialled alongside the sequential screening in Australia (130) and in Belgium (162).

In Belgium, community pharmacists distributed information on Type 2 diabetes to people visiting the pharmacy. This included a list of questions based on risk factors such as obesity, hypertension, age and family history of diabetes. If at least one risk factor was present, people were advised to consult their own doctor. 782 people were referred in a 3 month trial period, leading to 39 new diagnosis of diabetes (162).

The Australian study compared the effectiveness of referral on risk factors only to sequential screening, where those patients with risk factors

are offered a capillary blood glucose test and referral is made on the basis of the glucose levels (130).

Over a three month period, 1286 people were screened with pharmacies being randomly allocated risk factor assessment only (Tick tests TT), or risk factor assessment followed by capillary blood glucose test (Sequential screening SS).

Following the administration of the risk factor assessment, the two groups found similar proportions of those with risk factors (77% in TT group and 78% in SS group). Of those with risk factors, those offered sequential screening were more willing to go on to the next step of testing, with only 36% of those with risk factors in the TT group taking up the offer of referral for further testing. 81% of those with risk factors in the SS group were willing to undergo capillary blood glucose testing.

Of those patients known to have attended their GP for further testing only 1.6% of the TT group were found to have diabetes compared with 16% of the SS group. The authors suggest that the sequential screening method is more effective with a lower rate of patients offered referral (72% in TT compared with 24% in SS), but higher uptake of the referral. They suggested that a system such as sequential screening can be effective in community pharmacies and is a cost effective method (130).

A similar pilot has been carried out in Swiss community pharmacies using sequential screening, with risk factor assessment followed by capillary blood glucose testing if necessary. 6.4% of those tested were referred to their GP for further testing. A further 73.7% received targeted lifestyle advice. As there was little feed back from GPs about the outcomes of the referrals, it is not possible to say how many of the referrals resulted in a diagnosis of diabetes (132).

A lower referral rate to GP was found in the Swiss study compared with the Australian study (6.4% (132) compared with 24.4% in the sequential screening group (130). It is not known how many of those referred in the Swiss group were diagnosed with diabetes. The Swiss study only initiated blood glucose testing if two or more risk factors were present, whereas the Australian study offered the finger-prick test if only one risk factor was present. Different criteria for referral from the capillary blood glucose tests were also used. If referral levels are set high the specificity increases but the sensitivity decreases. While fewer patients without diabetes are referred for further testing the chances that cases of the disease are missed is increased.

In the UK, a plan for the 'early identification of diabetes for community pharmacists' has been developed with Diabetes UK and the Royal Pharmaceutical Society of Great Britain (RPSGB) (131). They recommend screening of people with one or more risk factors (see figure 6).

Figure 6 - 'At risk' groups (from Diabetes UK)

- White people aged over 40 years, or people from black, Asian and minority ethnic groups aged over 25 years with one or more of the following risk factors:

  - First degree family history of diabetes
  - People who are overweight/obese/morbidly obese with body mass index (BMI) of 25 kg/m^2 and above and who have a sedentary lifestyle
  - A waist measurement of ≥94cm(37inches) for white and black men, ≥80cm(31.5 inches) for white, black and Asian women and ≥90cm(35 inches) for Asian men.

- People who have ischemic heart disease, cerebrovascular disease, peripheral vascular disease or treated hypertension
- Women who have had gestational diabetes
- Women with polycystic ovary syndrome who have a BMI≥30
- Those known to have impaired glucose tolerance or impaired fasting glycaemia.
- People with severe mental health problems
- People who have hypertriglyceridemia not due to alcohol excess or liver disease.

Two methods of screening are suggested, urine testing and finger prick test. The overnight fasting capillary blood glucose level is described as the most useful, but it is acknowledged that it is not popular with patients and compliance is low. It is not suitable for screening people who undergo opportunistic screening while in the pharmacy for other reasons. Random capillary blood glucose is more useful for opportunistic testing, but can be misleading depending on when the person last ate. The RPSGB guidelines suggest that urine testing can be carried out either randomly or two hours after a meal, though if a person has risk factors

and a negative random test, they should be advised to carry out another test two hours after a meal. Any glucose detected should be reported. Figure 7 shows the criteria for referral.

Figure 7 - Summary of referral criteria. Taken from RPSGB care recommendation guidelines (131)

Overnight fasting, finger prick test	
<5.6 mmol/l (Whole blood) <6.1 mmol/l (Plasma equivalent)	Low probability of diabetes. Give advice about healthy living and reduction of risk factors
5.6 to 6.0 mmol/l (Whole blood) 6.1 to 6.9 mmo/l (Plasma equivalent)	Probability of impaired fasting glycaemia(IFG)/impaired glucose tolerance(IGT). Refer to GP
6.1 to 11.0 mmol/l (Whole blood) 7.0 to12.1 mmol/l (Plasma equivalent)	Probability of diabetes. Refer to GP more urgently.
≥11.1 mmol/l (Whole blood) ≥12.2 mmol/l (Plasma equivalent)	High probability of diabetes. Refer to GP with fast track appointment
Random finger prick test	
≥11.1 mmol/l (whole blood) ≥12.2 mmol/l (Plasma equivalent)	Refer to GP practice with fast track appointment
5.6 to 11.0 mmol/l (Whole blood) 6.1 to 12.1mmol//l (Plasma equivalent)	Re-test on fasting sample. Discuss with GP practice
Urine-stick test, two hours after meal	
Glucose present	Refer to GP practice
Random urine-stick test	
Glucose present	Refer to GP practice

In a UK pharmacy, just over two fifths of those tested had a random blood glucose measurement of 6.1mmol/l or over, 5.5% of those had a blood glucose over 12.2 mmol/l. The incidence of capillary blood glucose measurement of 6.1mmol/l or more ranged from 18.3% in white participants to 63.2% among South Asian participants (1). There is no report of follow up of these to patients to determine how many were subsequently diagnosed with diabetes.

2.4 Optometrists role in health care provision

In the UK, primary eye care and sight tests are provided by optometrists (previously known as ophthalmic opticians) and ophthalmic medical practitioners (OMPs). Optometrists provide the majority of services. In 2002 there were 566 OMPs compared with 7,856 optometrists. Around half of the OMPs were also employed as hospital doctors (163). In 2005/06, the number of registered optometrists had risen to 9,242. 6,079 were full time and 3,163 part-time, equating to 7,695 whole-time equivalents (3).

Optometrists are regulated by the General Optical Council (GOC), one of a group of thirteen health and social care regulatory bodies which includes the General Medical Council (GMC) and General Dental Council (GDC).

The GOC was created by the Opticians Act 1958. The 1989 Opticians Act sets out the powers of the GOC to set out rule and regulation in certain areas, such as registration, fitness to practice and sight testing rules. The act was modified in 2005 to include compulsory continuing education and training (CET) for all full registrants.

The Opticians Act states that one of the duties of an optometrist or OMP is ‘to perform such examinations of the eye for the purpose of detecting injury, disease or abnormality in the eye or elsewhere as the regulations

require' (164). Optometrists use techniques such as direct or indirect ophthalmoscopy to detect disease. This allows the internal eye to be viewed, in particular the vascular system which is susceptible to change and damage in systemic conditions such as hypertension and diabetes.

2.4.1 Provision of Sight Tests

Sight tests may be reimbursed by the NHS (rNHS) or non-reimbursed (nrNHS) (sometimes referred to as private sight test). Reasons for a test to be reimbursed by the NHS are shown in figure 8.

Figure 8 - Reasons for a sight test to be reimbursed by the NHS (165)

- Under 16
- Aged 16, 17 or 18 in full time education
- Aged 60 or over
- Diagnosed glaucoma patient
- Advised by ophthalmologist that at risk of glaucoma
- Aged 40 or over and is a parent, brother, sister, son or daughter of a diagnosed glaucoma patient
- Diagnosed as diabetic
- Registered as severely sight impaired/blind or sight-impaired/partially sighted
- Needs complex lenses
- Are getting, or partner gets:
    - Income Support
    - Income-based Jobseekers allowance
    - Pension Credit Guarantee Credit
- Are entitled to, or named on, a valid NHS tax credit exemption certificate
- Are named on a valid HC2 certificate

The majority of people claiming an rNHS test would be entitled to a sight test once every 2 years. Some groups are entitled to a reimbursed test at more frequent intervals. These groups are shown in figure 9.

Figure 9 - Minimum interval between rNHS sight tests

- Under 16 years and no binocular vision anomaly – 1 year
- Under 7 years and binocular vision anomaly or corrected refractive error – 6 months
- Between 7 years and 16 years with binocular vision anomaly or rapidly progressing myopia – 6 months
- 70 years and over – 1 year
- 40 years and over and family history of glaucoma or with ocular hypertension – 1 year
- Diabetic – 1 year

In 2005/06 17.5 million sight tests were performed in Great Britain. Of these, 5.5 million were nrNHS. The majority of the sight tests were carried out by optometrists, with OMPs carrying out 2.3% of all tests conducted (3). People aged over 60 years accounted for 54% of rNHS tests in 2005/06.

Though it is known that optometrists carried out 17.074 million sight tests during 2005/06, it is not known how many people this would equate to. Details of the number of sights tests are given in figure 10. There are some groups of people who are entitled to an rNHS sight test more frequently than annually (figure 9), however these groups are not large. The majority of people who would not receive an rNHS test are advised to have eye examinations every two years.

Figure 10 - Sight test volumes by patient age group and NHS reimbursement (3)

	No of tests in thousands		
Age	rNHS	nrNHS	Total
Under 16	2,533	31	2,564
16 to 59	3,017	5,369	8,386
60 and over	6,437	87	6,524
Total	11,411	5,786	17,473

It is likely that around 16 million people received an eye examination in 2005/06.

Optometrists may be in an ideal position to screen the ‘at risk’ population who may not be seen by other health care professionals.

2.4.2 Optometrists role in detecting, screening and referring diseases

The role of the optometrist in detecting systemic disease has been considered with respect to hypertension and it has been suggested that blood pressure measurements should be included as part of the routine eye examination (166). Recent surveys show that though around one tenth of practices have equipment to measure blood pressure it is used infrequently with referrals for hypertension made on ocular findings alone (5).

Optometrists have been shown to be able to effective in detecting and managing retinopathy associated with diabetes (167, 168). Current literature concentrates on the optometrists role in a specific complication of the disease, diabetic retinopathy, with the emphasis being on their role in diabetic retinopathy screening (169). In many parts of the UK, diabetic retinopathy screening services are being set up using digital cameras,

taking the traditional diabetic screening away from the high street optometrist practices (170). Retinopathy screening services are only effective for patients with known diabetes. People with diabetes, both known and undiagnosed, are still seen routinely in high street practices and the optometrist can still have a role in the management of these people.

Currently, in most situations, optometrists refer patients who they feel need further assessment to the GP. The GP then either deals with the patient or refers on to the required speciality, usually the Hospital Eye Service (HES).

Referral are often made on a general ophthalmic services form (GOS18), of which one copy is retained by the optometrist with two copies sent to the GP, so that one can be sent on to the HES. These forms can also be used to notify the GP that a condition has been noted, but does not require treatment at the present time, for example early cataracts have been noted but the patient does not wish to have surgery.

It has been found that nearly 3% of patients seen by optometrist are referred and 1% have notification letters sent to the GP. Around two thirds of those referred are to an ophthalmologist via the GP. A quarter of referrals are to the GP only (171).

The majority of referrals from optometrists are in relation to cataracts (over one third of referrals received by one hospital department (172)). Studies that look at referrals received by the HES (172) (173) may not reflect the full extent of referrals made by optometrists. Not all patients that are referred will need to be seen by hospital departments. One study reported that 44% of referrals received by one GP practice were for cataracts. Not all of these were passed on to the HES as some patients decided not to go ahead with surgery(174). For patients where mild retinal changes are noted that would not require treatment, a referral to

the GP only would be required to ensure that the underlying systemic condition could be diagnosed and treated. There are little data on the number of patients that are referred to GPs with suspected diabetes as these referrals do not usually involve the HES unless there is a complication that required treatment. Most people with newly diagnosed diabetes who have retinopathy present at diagnosis do not have retinopathy at a level that would require referral to the HES.

In a few areas some optometrists have direct referral to HES clinics for specific conditions, such as the posterior capsular opacification direct referral scheme in Taunton and North Somerset NHS trust. This scheme was shown to be accurate and effective and reduced waiting time and administration when compared with referral via a GP (175).

2.4.3 Challenges and development of the role of optometrists

Optometrists receive a significant amount of technical training during the years before they qualify, both in knowledge about systemic diseases, such as hypertension and diabetes, and in clinical techniques. Their current role involves identifying ocular and systemic disease when signs are present. An extension of this role may be into screening for disease when they identify risk factors, but no signs are present.

The current professional role of the high street optometrist has two, sometimes conflicting aspects, health care and retail. Optometrists are not employed by the NHS, but they do carry out sight tests on some groups of people which are then reimbursed by the NHS. It has been recognised that the fee received by optometrists for performing the sight test is inadequate. In 2005-06 optometrists received £18.32 for each rNHS test, though the cost of a sight test was estimated to be £37 (176). This difference leads to a conflict between business and health care provision as spectacle sales have to make up the shortfall caused by the under-funding. In the last 30 years, with the introduction of advertising

and the growth of the multiple practices (177), the optometrist has had to become a businessman as well as a clinician.

Pharmacists, many of who also operate in high street shops have taken a lead role in providing services such as screening for diabetes, blood pressure measurements and cholesterol checks. Roles that would traditionally been carried out in GP practices. Like pharmacists, optometrists are in a position to use their clinical training to provide services outside their traditional roles of refracting and selling glasses. It is timely to explore the potential roles optometrists can have in extended clinical roles.

Chapter 3

A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes: Part 1- Background, aims and methods

Chapter 3

A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes: Part 1- Background, aims and methods

Abstract

Background

Diabetes is an increasing problem in the UK. Optometrists carry out around 17 million sight tests a year in the UK and see a wide range of people. They see many people who are at risk of diabetes. It is known that optometrists refer people whom they suspect of having diabetes to general practitioners. Currently, optometrists do not routinely carry out any clinical tests that are not directly related to the eye. In their training as health care practitioners they develop skills and knowledge in many areas, including systemic diseases such as diabetes, which is not currently routinely utilised in their daily practice.

Aim

To investigate optometrists' perceptions, attitudes and beliefs towards diabetes and screening for and diagnosing the disease in their practice.

Methods

A qualitative approach was used. A series of focus groups and interviews with 21 optometrists were held in two locations in the north of England. The discussions were transcribed and analysed using principles of grounded theory.

Results

Results of the focus groups and interviews are discussed in chapter 4.

3.1 Introduction

Diabetes is an increasing problem with more people with Type 2 diabetes being diagnosed (178). The estimated prevalence of all types of diabetes in England in 2001 was 4.41%. This included an estimated 2,002,000 people with Type 2 diabetes, of which only two thirds were diagnosed (10). The worldwide prevalence of diabetes in 2000 was estimated to be 171 million (2.8% of the population). The prevalence was set to increase to 366 million by 2030 (4.4% of the population) (13). Due to the insidious nature of the disease, many people are unaware that they have diabetes until complications occur (75).

The National Service Framework for diabetes has a number of standards for the prevention, diagnosis and management of the disease that are to be achieved by 2013. Standard 2 states that, 'The NHS will develop, implement and monitor strategies to identify people who do not know they have diabetes' (179).

Diabetes is a chronic disease that is suitable for screening as it is common, has a screening test and effective management. The National Screening Committee suggested that universal screening is unjustified in the United Kingdom, but targeted screening of “at risk patient groups” may be of benefit (117). Cost effectiveness analysis of universal screening compared with targeted screening of people with hypertension has shown that screening is more cost effective when targeted. Screening hypertensive patients aged 55 to 70 years was more cost effective than screening younger age groups (120). Optometrists may be in a suitable position to assess those patients who are at risk and then further assess need for formal testing by measurement of capillary blood glucose levels.

Optometrists are in an ideal position to be involved in the process of detecting elevated blood glucose and helping in diagnosis of Type 2

diabetes. They see many patients who, while having no formal diagnosis of diabetes, may show signs or have symptoms of diabetes, or may even appear completely “normal”.

Diabetes UK estimates that around half of people with newly diagnosed Type 2 diabetes have some form of advanced complication such as retinopathy, nephropathy or neuropathy. Presence of retinopathy has been reported in between 4.0% (65) to 36.7% (75) of people with newly diagnosed Type 2 diabetes.

Diabetes can produce other ocular complications such as variable refraction (82), recurrent infections, early onset cataract (180) and ocular nerve palsies (89). Visual disturbances are a common symptom of diabetes. A Danish study showed that 24.9% of people with newly diagnosed Type 2 diabetes had complained of visual disturbances prior to diagnosis (65).

3.1.1 Optometrists in the UK: training and role in UK healthcare

Currently, UK optometrists have to obtain a degree level qualification at one of 8 UK universities (five in England, one in each of Wales, Scotland and Northern Ireland). They must achieve at least a 2ii degree to go on and undertake the pre-registration year where they work supervised and sit professional qualifying examinations. During the course of the four years of training (five years in Scotland), students follow a course of study to achieve core competencies set out by the General Optical Council (4).

The majority of UK optometrists work in high street practices. A small proportion are employed by the NHS in hospitals or work in an academic setting. High street practices are often categorised as independent or multiple practices. The multiple practices, such as Specsavers, Vision Express, Boots and Optical Express, have varying degrees of autonomy. Some operate as franchises, with each individual practice having some

limited independence while others are run from a main head office. The independent practices are often owned by the optometrist, and are often family run businesses. They have a high degree of autonomy when compared with the multiple practices.

Individual optometrists working in high street practices may work in both independent and multiple practices. Employed optometrists will tend to work for one practice, or group of practices. However, self-employed locum optometrists often work in a number of practices.

At present, optometrists do not have a role in diagnosing or screening for diabetes. Optometrists do not have the facilities to carry out diagnostic tests. They are thought to be in a position to carry out a capillary blood test (finger-prick test) such as is used by people with diabetes to monitor their condition.

Optometrists are in a position to ask every patient about some diabetic risk factors during the course of a sight test. The College of Optometrists guidelines state that history should include ‘relevant personal or family history of an ocular or general health nature.’ 79% of Australian optometrists reported that they always or often asked patients over the age of 40 about diabetes (168).

Optometrists may be in a good position to reach a section of the population who may not routinely access other healthcare professionals. In a Dutch community, 83% of inhabitants aged over 40 years of age attended an eye examination over a 5-year period (181). Anxiety is a common reason for people not to seek health care. This has been well documented in dental practice (182, 183), but has not been studied to any great extent in optometric practice (184). It is not known whether people are more or less likely to attend an optometrist than other health care providers.

Optometry, as a profession, is relatively new when compared with others such as medicine. When the NHS was formed in 1948 and free sight tests were introduced, it was envisaged that sight care would be provided within hospitals. However, it was realised that this would not be possible (185). The General Optical Council was formed to maintain the registers of optometrists, oversee training and provide disciplinary powers. The Opticians Act of 1958, which introduced the General Optical Council, occurred a century after the Medical Act of 1858 gave the General Medical Council similar powers to keep registers of qualified doctors and monitor their training and disciplinary procedures.

In the 60 years since the Opticians Act regulated the profession and prevented unqualified people practising as optometrists there have been several significant changes in the way optometrists work, including business changes such as the introduction of advertising and competition from unregistered sellers, and professional changes such as supplementary prescribing, mandatory continuing education and training and involvement in extended care roles (177, 186). Even with these professional changes, there is a sense that the training and knowledge that the optometrist has is not used to the full in the narrow field that is allowed in routine sight testing in the high street.

It is envisaged that this research will explore some of the ways optometrists view their professional role and development, and how they perceive the way others view the profession.

3.2 Choice of method

3.2.1 Research method

A qualitative approach to investigating the beliefs and attitudes of optometrists to screening and diagnosing diabetes has been used as the method of choice. Qualitative methods are effective in discovering the views of a group of people. They can be used when the aim is to uncover views on a subject rather than quantify the size or number of the

responses (187). Qualitative methods include questionnaires, observation, interviews and focus groups.

Written questionnaires are useful if the information required is clearly defined. They can provide a cheap and simple way to reach a large population. Administration of written questionnaires is simpler than seeing people for face to face interviews as they can be completed in the participant's own time. There are not the scheduling problems of arranging for the participant and interviewer to be available at the same time. It can allow a greater degree of anonymity, as they do not have to speak to the interviewer. Questionnaires allow for information to be collected more quickly than is possible in interviews.

Problems with this method include poor response rate and lack of control of who completes the questionnaire (188). Written questionnaires need careful preparation to ensure that they are understandable to the respondent. Questionnaires can be more suitable for quantitative research than qualitative. Questionnaires with 'tick box' responses where the number of each response can be calculated can be a useful quantitative method, but cannot be used for qualitative research. For qualitative information, open questions must be used where the respondent is free to answer how they wish. This can lead to more complex coding required when analysing the results.

Interviews can overcome some of the problems of questionnaires. Response rates can be higher as the interviewer is present. However they are more time consuming. They can be structured, semi-structured or unstructured.

Structured interviews consist of the interviewer asking questions in a standardised way, similar to a questionnaire (189). They will often have fixed answers and there is no difference in the way the interview is conducted between subjects.

Semi-structured interviews, on a one to one basis, follow a loose structure from which the interviewer or respondent can deviate to follow ideas and thoughts in detail (189). This has the advantage over structured interviews in that the language in the questioning can be adapted to the individual. They are useful for covering one topic in depth.

The flexibility of questioning allows for the interviewer to follow topics and adapt questioning depending on the respondent. However, this means that the interviews are not the same for all subjects.

Unstructured or open-ended interviews are often similar to a conversation. Subjects can respond in any way that they want and the conversation will flow from the responses that the interviewees gives. The interviewer's role is to give direction to the interview so that respondents can 'tell their story' (190).

Advantages of unstructured interviews are that they allow the interviewee to express their views and opinions in a way that is natural to them. The researcher is able to direct the conversation to more fully explore the topic and so get more detailed and, hopefully, more accurate information on a person's attitudes to a subject. Disadvantages are that the process is time consuming; a single interview can take a few hours and so collecting information in this way is limited to a few respondents. This may mean that information cannot be generalised to a larger population. As a wide variation of information can be collected from each participant, analysis can be more complicated that it would be for a structured interview.

Observational studies involve watching people to determine behaviours and interactions. It differs from other forms of qualitative research as it takes place in the normal setting for the behaviour that is being observed. Observation can be covert or overt. Covert observation is rarely used as it

can be difficult to justify ethically. In overt observation the role of the observer can take different forms, from complete observer, where their only role is to observe and they are not involved in any of the processes that they are there to observe, or complete participant, where the observer is also fully involved in the events in which they are interested (191). The main advantage of the observational study is that the behaviours are observed in a setting that is relevant. The disadvantage of the presence of a known observer is that behaviours and interactions may be altered. This is known as the ‘Hawthorne effect’ (192).

Focus groups are group interviews typically involving between six and ten people (193). Groups are usually made up from people with some common feature, such as profession or experience. A certain degree of homogeneity is usually needed in the background of the participants, but not in their attitudes.

Focus groups use the communication between individuals in the group to generate responses. They make use of communication methods used on a day-to-day basis such as jokes, anecdotes (194) and humour (195). They can allow group norms to be investigated and can encourage open conversation, bringing people in who would not feel comfortable contributing on a one to one interview (196).

Focus groups can also use the participants to generate further questioning which can be useful in identifying group norms and values.

It has been suggested that interviews are more useful when the aim is to establish the behaviour of an individual, whereas focus groups are useful in looking at group behaviours (197).

Certain groups have been found to give different opinions in focus groups and interviews. Teenage boys in Glasgow were asked about their relationships with the opposite sex. The first group initially discussed the

subject in focus groups, where they expressed macho views. They were then interviewed individually, where the macho views continued to be expressed. By contrast the second group of boys were initially interviewed individually where they expressed a much more sensitive attitude towards girls. However, when they then joined together to discuss the topic as a group, they, too, expressed macho views similar to the first group (198).

People will normally give consistent views throughout an individual interview, whereas they may change opinions during the course of a focus group discussion. This is not necessarily a weakness of the technique as people's views can often change over time when presented with different facts or opinions (199).

One advantage of the focus group is that information can be collected from different participants at one session and so information can be gathered from a greater number of participants than would be possible with individual interviews. A disadvantage of the method is that it is possible for a dominant individual to take over the discussion. To overcome this, the group moderator should aim to ensure that all participants are heard from in the course of the discussion.

Both focus groups and individual interviews were used in this study. Focus groups were used initially as they provided a good method of bringing optometrists together as a group of professionals to discuss the subject. Screening for diabetes is not a procedure that optometrists are currently involved in and the interaction involved in focus groups may help them consider aspects of the subject that they would not have considered in an individual interview. Further individual interviews enabled themes to be explored in more depth and to see if there were any different opinions expressed in the one to one situation compared with the group environment.

3.2.2 Sampling

Normally the samples used for qualitative research are much smaller than for quantitative methods. Quantitative methods will often use a large randomly selected sample relying on probability to give a representative sample that can be generalised to the whole population. Qualitative methods will use non-random selection. Random selection is not necessarily appropriate for qualitative methods. Random selection is effective in selecting a representative population if a large sample is taken from a normally distributed population. However, it is not known whether people's values, beliefs and attitudes are normally distributed through a population and a small random sample is unlikely to produce a representative sample (200). Purposeful selection or judgement selection (200) is used to select a group that will allow the central issues to be brought out. There are different strategies for sampling, including extreme case, typical case, criterion based, homogenous and stratified purposeful sampling (201).

Theoretical sampling uses the researchers' knowledge to identify features that may affect the focus group. Stratification identifies the different characteristics of the different subgroups within the sample (202).

Convenience groups may be used. Pre-existing groups, such as work colleagues, have advantages in that the group is established and already has relationships established which can be useful. This method provides an easily accessible group (200). However, there can be problems if there is an established hierarchy within the group, which may discourage contributions from some members of the group. A group of strangers will overcome this. However there will not be any pre-existing relationships.

The focus groups used in this study were homogenous in that only optometrists have been involved. Stratified sampling was used to select a group that includes different subgroups (gender, part-time or full-time, practice type). They were selected from optometrists listing practice

addresses on the publicly accessible General Optical Council (GOC) register.

3.2.3 Sample size

While quantitative research requires certain sample sizes for the research to be valid, qualitative research relies on reaching “saturation” instead of reaching a particular number of participants. The number of participants can depend on the population and the research question being asked. “Theoretical Saturation” is the point at which no new concepts are being brought out in the analysis of the transcripts (203). At this point there is a likelihood of reduced or no new ideas and concepts and further groups or interviews are unlikely to useful.

For research using focus groups, it is often suggested that three or four groups are needed (204), though more groups may be required if the research question is particularly complex.

3.3 Methods

3.3.1 Subjects, setting and sampling

Focus groups and interviews with optometrists were used. The initial groups were set in North East England. As the groups progressed, it appeared that there were local issues with regards to relations between hospitals, GPs and optometrists following the local implementation of a diabetic retinopathy screening service, as some optometrists felt that they had been excluded from the retinopathy service by the hospital. A further group was held in the North West of England to overcome any potential bias due to the local issues.

The optometrists in the North East were selected from the General Optical Council register. All optometrists are listed on the publicly accessible list, though a practice address is not always listed. Letters were sent to optometrists giving a practice address on the register. The

invitation letter and consent form is included in appendix A. As many of the optometrists listing practice names would be either employed or practice owners, simply using these addresses can exclude those optometrists working as locums who may not work in the same practices consistently. Local knowledge was used to invite locums who were known to work in the area, but did not include a practice address on the GOC register. Stratification was used to ensure that there was proportional representation of gender, practice type (multiple, independent or domiciliary), employment type (employed, locum, own practice) and employment status (full or part time).

The groups and interviews were held locally to maximise participation. An early evening time was used so that it did not interfere with the normal working day. Letters were sent to 50 optometrists. This was followed up by telephone contact. Three groups were arranged, one of six people and two of five people. In the first two groups, two people cancelled on the day resulting in groups of four and three people respectively. In the third group one participant cancelled on the day and one did not arrive. Interviews were carried out with participants who were unable to attend the initial groups. If several optometrists from the same practice agreed to take part, they were put into different groups so there were no current work relationships within a group. Many participants knew each other and some had previously worked or studied together as there is a relatively small number of optometrists in the area. The group held in the North West of England consisted of a group who had studied together, but who did not work in the same practice. Reasons given for not taking part included work and family commitments. The demographics of those not taking part did not appear to be significantly different to those who took part.

21 participants (12 male, 9 female, qualified between 3 to 37 years) included optometrists who worked in multiples, independents and domiciliary practices. 15 were full time, 6 worked part time. Nationally,

around one third of optometrists are part time. The same is true of the participants. 11 were employed, six owned a practice and three were locums. 16 worked in one or two practices only. 5 regularly worked in three or more practices. Demographic details are listed in figure 11.

Figure 11 - Demographics of participants

Participant	Gender	Years qualified	Employment type	F/T P/T	No of practices	Type of main practice
A1	M	32	Employed	F/T	1	Multiple – large
A2	F	33	Employed	P/T	1	Independent – small
A3	F	22	Employed	F/T	1	Multiple – small
A4	M	12	Own practice	F/T	2	Independent – small
B1	M	23	Own practice	F/T	1	Multiple – large
B2	F	26	Own practice	F/T	1	Independent – small
B3	F	12	Employed	P/T	1	Multiple – large
C1	F	37	Locum	P/T	2	Multiple – small
C2	M	35	Own practice	F/T	2	Independent – small
C3	M	27	Own practice	F/T	3	Independent – small
D1	F	7	Locum	P/T	2	Independent – small
D2	M	7	Own practice	F/T	2	Independent – small
D3	F	7	Employed	F/T	2	Independent – small
D4	F	7	Employed	F/T	2	Independent – small
D5	M	3	Employed	F/T	3	Independent – small
D6	M	7	Employed	F/T	3	Independent – small
D7	M	7	Employed	F/T	2	Independent – small
E1	M	6	Employed	F/T	3	Independent – small
F1	M	20	Employed	F/T	1	Multiple – small
G1	M	21	Locum	P/T	4+	Independent – small
H1	F	7	Employed	P/T	1	Domiciliary

3.3.2 Analysis

“Pragmatic variant” grounded theory and content analysis approach was used. The data collected was used to develop themes and categories that could then be built on in further interviews. (205) (203). Grounded theory, as developed by Glaser and Strauss, produces theories from the data that are collected and analysed instead using the data to prove or

disprove the researchers' own ideas (206) (203). Theories are developed from the data that are collected only and previous work and knowledge is not considered (203). In "pragmatic variant" grounded theory, prior knowledge and understanding is considered and used to develop the theory (205). "Constant comparative" methods were used to compare the perceptions, beliefs and attitudes of the participants (207) (208). An iterative process is used, analysing each transcript after the interview or focus group and before the next is carried out. Themes that are identified can then be developed in further interviews. The themes are also compared with those in previous groups to refine the developing theories.

Each interview and focus group was recorded and transcribed by an experienced transcriptionist. The transcripts were then checked and corrected by listening to the original recordings. Each transcript was coded and themes identified before the next focus group or interview took place so that ideas could be developed in the next interview.

Each of the transcripts were coded by two researchers, working independently, and the themes identified. The themes were then discussed to see if agreement was reached before the next interview. In all cases, the two coders agreed on the general themes. Multiple coding has been described as the qualitative equivalent of "inter-rater reliability" in quantitative research (209). By using multiple coders working independently, the risk of personal influence on the codes identified is reduced.

After three groups, saturation appeared to have been reached and no new themes were identified (203). A further group was held in a different locality (North West England) to investigate whether the issues identified in the North East area were specific to the North East. No different themes were identified in the different location.

The focus groups were then followed by a series of one to one interviews. After 4 interviews, saturation was judged to have been reached.

The focus groups and interviews are reported together.

Chapter 4

A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes: Part 2 – Results, analysis and discussion

Chapter 4

A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes: Part 2 – Results, analysis and discussion

Abstract

Results

Results were spilt into four main themes: awareness of undiagnosed diabetes, acceptance of a screening service, barriers towards implementation of a service and the developing role of optometrists.

Though it was felt that the public had an awareness of the risks of diabetes, this was often not fully understood or was underestimated. Optometrists' understanding of diabetes was mixed, though all had seen people that they suspected had undiagnosed disease.

The participants felt that the attitudes of optometrists, the public and other medical practitioners towards optometrists being involved in a scheme to detect undiagnosed diabetes would be mixed. It was felt that some doctors would not want optometrists to be involved. Optometrists were concerned that the patients most at risk would be the ones most likely to refuse screening, though it was suggested that successful communication would be the key to public acceptance. However, they felt that they did see some people who would be at risk of developing diabetes, who would not access other healthcare providers. Some participants questioned the need to identify people with asymptomatic diabetes, while others considered early detection to be beneficial in the long term for both the patient and society. Barriers to successful implementation included cost, appropriate remuneration, time and fear of litigation.

It was believed that optometrists' knowledge and training is underutilised and underestimated, and that optometrists are ideally situated, both in

skills and locations, to take on more extended roles. Conflicts between the healthcare and retail aspects of the profession have lead to uncertainty among optometrists about their position in the UK health service.

Conclusions

Some optometrists would be willing to carry out capillary blood glucose tests, provided that the scheme was simple for them to carry out, they had the support of other healthcare professionals and it could be financed in a way that did not cause practices to run the scheme at a loss. It might be possible to identify people with undiagnosed diabetes who attend an optometric practice who may not attend other healthcare providers. Involvement in screening for diabetes may be a step in development of the profession for some optometrists.

4.1 Results

Four main themes were identified:

a. Awareness of undiagnosed diabetes
b. Acceptability of a screening service
c. Barriers to and the implementation of a screening service
d. Current and developing role of optometrists

These broad themes were split into several categories:

a. Awareness of undiagnosed diabetes
    i) Patients' awareness
    ii) Optometrists' awareness
b. Acceptability of a screening service
    i) Acceptability to patients
    ii) Acceptability to optometrists
    iii) Acceptability to general practitioners
c. Barriers to and implementation of a screening service
    i) Cost
    ii) Infection control/sharps handling
    iii) Training and protocol
    iv) Liability
d. Current and developing role of optometrists

4.1.1 Respondent validation

There are two main techniques to assess validity of qualitative research, triangulation and respondent validation. Triangulation uses different methods of collecting information to see if both methods arrive at the same conclusions (210) (211), such as combining interviews and focus groups with participant observation (209). Respondent validation is used to show a correspondence between the researcher's understanding of the findings and the participants' understanding (210) (211). In this case, respondent validation was chosen to assess the validity of the

interpretation, as all the information was collected through similar methods.

Respondent validation can be done in a number of ways. Participants can check through the original transcripts prior to analysis to ensure that there are no errors and then read drafts as the research progresses. However, this is time consuming for the participant and may not be appropriate if the research topic is likely to be distressing for the participants (209).

Each participant was sent a summary of the group or interview they participated in along with a summary of the results of all the groups. A simple response form was sent with a Likert scale, from 1 (Strongly agree) to 5 (strongly disagree), for them to rate their agreement with the findings. A section of the form invited any comments they may have.

The results of this were that eleven participants (52.3%) responded to the summary. All indicated that they agreed or strongly agreed with the summary. Ten did not reply. Responses were received from at least one participant in each group.

4.2 Results of focus groups and interviews

The quotations have been annotated with a code to indicate the participant (from table 11), Gender (M – male, F – Female), practice type in which they work (M- Multiple, I – Independent) and line number from the transcripts.

4.2.1 Awareness of undiagnosed diabetes

Patients' awareness of undiagnosed diabetes

There was a belief expressed that many people were aware of the risks of diabetes, whether they picked them up on information from magazines, TV or friends and relatives with the disease.

"people know, I don't know, from women's magazines or whatever they get little snippets like 'I'm thirsty all the time so does that mean I'm diabetic?' so they do have little bits of knowledge" A2FI, 454-456

"Well quite often they do because it has a tendency to be hereditary so many diabetics have diabetic relatives and diabetes is extremely common as you know. Most older people will know somebody who's diabetic anyway …….a lot of them would be aware of the possibility" C2MI, 28-32

It was the perception of several participants that the demographics of the practices influenced patients' understanding awareness of diabetes. It was believed that in some more deprived areas, awareness of general health issues was lower than in more affluent areas. They believed that in the areas where awareness was lowest, the prevalence of risk factors was likely to be higher.

"I think most of them are but I think again it depends on what area you're from. I think a lot of patients from East Cleveland and probably a lack of information up there, or not wanting to know is, you know, sizeable" F1MM, 24-27

"Depends very much on the demographics of the practice and some of the practices where you might say, the lower end demographics, I don't think health awareness is as prominent in, when you talk to patients, and they are the people that are more at risk really. If you go to a higher end I think, because I've had a chance to work in both types, the more affluent, the more educated, they may be more aware because they've read or they've watched programmes. Yeah. And they know that they have to look

after themselves because of the risk of developing problems." G1MI, 22-29

There was also a perception that, while some people were aware of diabetes and the risk factors, the understanding of the disease and what that meant was limited. There was also a perception that there was an unwillingness to act on some lifestyle advice, even if people were aware of what they should be doing. This was felt to be particularly true of younger people who were felt to be more likely to deny that they were at risk.

"Well particularly with younger people, they connect poor health style with diabetes so if a younger person gets diabetes, type 2 diabetes, then it's almost telling them that they're not looking after themselves properly" C2MI, 46-48

***"**I mean most people are aware of sort of general health and just having a good diet and things is important but they probably choose to ignore that." E1MI, 29-31*

Optometrists' awareness of undiagnosed diabetes

There was limited knowledge of the extent of undiagnosed diabetes. There was a belief expressed that GPs were diagnosing more people with diabetes.

"I thought it was 50% that was undiagnosed" B2FI, 21

"I was very surprised to find that, you know, that the percentages that you were saying, you know, there were ever so many people undiagnosed, I was just, I thought the GP's were on the case" A3FM, 74-76

There was some awareness that they must see patients who were likely to have undiagnosed diabetes as they felt diabetes to be prevalent in the population they were seeing. However, one participant expressed the view that they felt they saw less undiagnosed diabetes in their current practice, compared with previous practices due to the difference in the patients access to their GPs.

> *"Well I don't know, I think you can't really say that because you know that diabetes is incredibly prevalent so you must see patients who have it, particularly if you think about all your horrendously obese patients who come in and you think 'you must be ….'" D7MI, 28-31*

> *"I would have said less now than when we started practising. Whether that's the area I'm in now or where I'm working compared to, but I used to find more in mid Wales because of people not having GPs" D2MI, 8-10*

Optometrists were aware that they saw some people who had undiagnosed diabetes and that they were able to identify signs of diabetes. There was a perception that, currently, the profession was picking up some cases of undiagnosed diabetes, usually due to the presence of ocular signs rather than symptoms. Prescription changes, such as a myopic shift, were a common reason for optometrist to suspect a patient had diabetes. Proliferative diabetic retinopathy was rarely seen, but participants reported seeing mild retinal changes and were being more aware that they should look for such signs in patients who reported risk factors.

> *"sometimes you get really unusual prescription change and you think 'I'm not going to risk prescribing this until this person's at least gone and had some tests'" A2FI, 59-61*

"Well I've certainly picked up undiagnosed patients with proliferative retinopathy so for those ones, yes but they are few and far between" B2FI, 530-531

"It's rare to find somebody who's showing retinopathy and is an undiagnosed diabetic. I think that knowing that there is a lot of undiagnosed out there and knowing of the risk factors involved, I have it always at the back of my mind that I should be questioning myself – 'am I going to expect to see anything?' and certainly my techniques that I use for routine ophthalmoscopy have changed over the years and I feel I'm in a better position with the new techniques I'm using to be able to give a better examination and should be hopefully picking up things if they are there to be picked up." G1MI, 4-12

There was a feeling that, currently, there is a lack of communication between GPs and optometrists. All had referred patients with suspected diabetes to a GP, but few received feedback from the GP. They felt that the GP did not report the outcome of referrals back to the referring optometrist, with information on the diagnosis tending to come from the patient on their next visit to the optometrist. It was also reported that, in some cases, the GPs' diagnosis of diabetes may come several years after signs were noted by the optometrist.

"From GPs? Very rarely any. Usually the next time the patient comes in, I find out" B2FI, 27

"I think that's the consensus really, you don't get an awful lot back from GPs" B1MM, 29

"Yes, the feedback is usually verbal and through the patient. I mean classically you'll find somebody who's prescription has changed unexpectedly and equally and you send them off and they come back, they pop in a couple of weeks later and say 'well look you know, I was diabetic, it's sorted out now, can I get my eyes done now?" C3MI, 71-75

"GPs can write letters?" D2MI, 21

The question was raised by a few participants as to whether cases of undiagnosed diabetes needed to be diagnosed if the patient were currently free of symptoms.

"…do they really want to be, have all those people diagnosed? At the minute, what they don't know doesn't hurt them" B3FM, 215-217

"…the people that do present who are early diabetics and they may well be for years, their visual problems certainly are minor, and I would think also the rest of their general health is relatively minor because they have come in asymptomatic, usually. Very few occasionally do present with something more severe but I would argue that they're probably bordering between Type 2 and Type 1 anyway. You know?" B1MM, 598-603

4.2.2 Acceptability of screening service

Acceptability to patients

It was believed that the public would express a range of attitudes toward being screening as part of a routine sight test. There was a concern expressed that the patients who were most at risk of diabetes would be

the ones most likely to reject the offer and those who would be more health conscious and more likely to access other service who would accept it.

> *"I wonder whether the ones that end up taking it are the ones that would have gone to their GP and said 'look, I want my MOT' or whatever anyway and would have routinely had it…. you'd have to think of a serious way of how you were going to market it to ensure that you were actually getting the people who wouldn't be taking proper responsibility for their health anyway because that's really the ones that you're wanting to get through the system." H1FD, 210-217*

> *"My patients I feel would [accept] because they've come for donkey's years, know us very well and sort of, sometimes I think we know more about their health problems than what the GPs do!" B2FI, 221-223*

It was felt that while some would be willing to accept diabetes testing by the optometrist, others may be put off from having a sight test because of it, which may then impact on the chance to pick up on other diseases.

> *"It might put people off as well, more, because some people won't go for an eye test and if they think they're going to be, have their finger stabbed as well, it might stop people coming for eye tests where we pick up other things as well as possible diabetes" D3FI. 174-178*

There was a belief expressed that people would only be willing to attend optometry practices for things related to eyes and may not be ready to accept services which they did not relate directly to eyes. However, the

example of hearing services in some practices was given to illustrate a non-ocular service provided in practices that was accepted.

> *"I think they'd rather go to an optometrist if it's eyes, otherwise no" C3MI, 199*

> *"Some practices are doing hearing aids and things and people seem quite happy with that? And that's nothing to do with the eyes really. It's only close!" C3MI, 374-375*

They believed that different people expected different things from a sight test, some simply wanting new glasses whereas other expected a full health check. Some believed that older patients may be more willing to accept the service that younger patients who, they believed, would be less health conscious.

> *"they're [younger patients] just there for a refraction and some specs but as they get older as I say they're more health conscious, a lot more people are aware, certainly about diabetes and macula problems" B1MM, 98-100*

> *"I think there are always going to be patients that see the sight test as a barrier to 'I want some new glasses' and there will always be the people who want an eye examination to know that everything's healthy and don't necessarily care [about glasses]" D2MI, 113-116*

There was a belief that some patients who access optometrists do not necessarily access other healthcare services such as GPs. Some participants felt that those who would accept the offer of screening would be those who may not access their own GP due to time constraints.

"I suppose on the other hand it might pick up, it might pick up the ones where you say 'I've seen this and I think you should probably see your doctor about it to have some sort of regular test done' it might pick up the ones that wouldn't actually bother to go to their GP but would be happy for you to do it while you're sat there because it means they don't have to take another day off work to go and sit in a queue in a doctor's surgery, so you might pick up those people. Because you know there's those people, where you say 'oh I told you last year to get your blood pressure checked. Have you done that?' 'Well, no I've been quite busy over the last two years' …. Right!" D7MI, 227-235

"I think people will respond to a need that's urgent to them and if they can't see ……, they can't drive or whatever, they will be forced to come in and see, whereas otherwise they might grumble on with little aches and pains and just ignore those and never go to the GP' G1MI, 61-66

It was felt that, though the public are not always aware of what optometrists are able to do, they are increasingly aware of, and accepting of, optometrists offering services that are not part of their traditional sight testing roles. It was believed that some patients were aware that optometrists had the ability to detect some health issues by ophthalmoscopy. It was felt that patients accepted changes as long as they were explained to them. Communication was felt, by some, to be the key as to whether a service would be accepted.

"I don't think they realise what we can do anyway with anything else, some of them will come in and when you've done the ophthalmoscopy they'll suddenly say 'you can tell all sorts of things can't you?' as though we can, you know, it's a crystal ball." C1FM, 99-102

"Yeah I mean I think that having seen the way that our roles have changed over the years, I think people wouldn't be that surprised if we offered, if we were offering that sort of service because if suddenly if you say 'right you know we're going to, this is, we're going to just do the screening for diabetes, which is part of the general screening, are you happy to have it done?' most would say 'yes'. " C2MI, 368-373

It's changing, it's changing as well, they'll [the public], to be honest they will probably do whatever we do and they'll get used to whatever we do so if we carry on doing exactly as we're doing now, then they'll expect that when they come to an eye test whereas if we start changing things and telling them why we changing, they will expect that when they come to an eye test. I mean it won't change quickly but it will change" D7MI, 97-102

There was a belief that some would be reluctant to accept a screening test as they would be unwilling to make the lifestyle changes if they were found to have the condition. There was a belief that some people would not be willing to accept lifestyle advice from optometrists, whereas they would from a GP or nurse.

"Big difference between different people I think. Somebody like, somebody in Northallerton that goes to every screening possible and eats all the right food would be there regularly, wanting their finger pricked, but somebody from a different area that no way are they going to give up smoking or change their diet or anything they'll just say 'oh it's a load of rubbish' and not turn up. It might even become

a reason for not getting your eyes done if they thought you were going to take blood as well" C1FM, 357-363

"I think there are patients who will access a service only if they feel they absolutely need it and consequently if somebody, you suspect of having other health problems, not necessarily diabetes, that you want to refer on, there's sometimes a great deal of reluctance to take that on board and it's whether it's their pride or whether it's burying their head in the sand and 'I'm alright type of thing' but you can usually tell as soon as they walk through the door if that's an issue, don't even need to look at their, look in their eyes" C2MI, 200-206

"The question is are the people who are most likely to have diabetes going to refuse it because they think they might have diabetes but don't want to know about it because they know that as soon as you're diagnosed with it you've got to stop eating tasty food and change your life style and .." D7MI, 191-194

"I think the only problem we would have would be if we told patients they should exercise more or lose weight, they might sort of take it the wrong way. Because they didn't come for that, if you see what I mean; whereas they would more expect that from a GP or you know a practice nurse" F1MM, 43-46

It was felt that the people most likely to accept the service would be those attending independent practices. It was felt that they would be more health conscious, attending the test for a health check rather than for cheap glasses. However, it was believed that this group may be most likely to have tests done elsewhere. It was suggested that the patients

attending multiples may be less health conscious and would be least likely to take up the offer, but would be the group that would be less likely to be tested elsewhere.

The type of practice and location was also felt to have an effect on whether the public would be willing to be involved in screening. This was due to the way different practices were perceived, and the reasons why the patient attends the practice.

> *"I think it depends where we are, if the city centre or a high street practice, it is different. Because they see that practice as, as a high street shop. As opposed to a small, independent, well even in the multiple independent type practice which is on, in the suburbs somewhere, which they see as a health centre." B1MM, 226-230*

> *"I think the independent sector of the market or the patients that would come to an independent practice are those who would be more conc, less price sensitive and more concerned about the service they receive therefore want the additional services that you can offer is what differentiates you from the crowd as it were" D2MI, 444-448*

It was felt that convenience would be a factor in whether a service would be accepted by the public. If the optometrist was more convenient than other health care providers and provided the service at no extra cost to the patient it was believed that people would accept it.

> *"But most of them they just want some glasses, they only really want us to do screening like that if we were more convenient to get to than the doctors" C1FM, 102-104*

"Yeah the majority of patients particularly the elderly would hate the inconvenience and hate the atmosphere in hospitals and they would very much like to get everything done either by the GP or the community optometrist or the community pharmacist. The whole health care package. They would rather not go into hospital at all if that were possible, so, but they also would expect the health service to pay for all these secondary care packages. But yes the patients would very much like to have it done locally, particularly in somewhere like myself where there isn't a hospital nearby" C3MI, 105-113

Acceptability to optometrists

It was thought that the attitudes of the profession of the whole towards offering screening services would cover the whole range of responses. Some believed that the majority of optometrists would be willing to be involved as long as it was not made too difficult for them to do so. Financial consideration, time constraints and the screening protocol would influence the willingness of optometrists to offer a blood glucose test in their practice. On the other hand, a few felt that there would be some people who would not want to be involved.

"I think probably the majority of optometrists would be interested in doing it and I think they'll be, I don't know, maybe two thirds or so would be interested in doing it" A1MM, 514-517

"I think if it was a case of carrying out a pinprick test and the optometrists themselves not having to even carry it out, maybe all they've got to do is look at the results and go 'yes' and put them on a 'refer to GP / not refer to GP pile' …. reckon you'd get about a 70% uptake. If there was more

responsibility than that on the optometrist…. I think you'd get about 25, maybe." H1FD. 253-260

"I'd be happy to do it, … if it would be useful I'd be more than happy to do it but it would need to be remunerated" D7MI, 273-275

It was perceived that the attitude towards offering the screening would depend on the practice as well as the individual optometrist. Some felt that independent practices would be more willing to be involved than the larger multiples. However, it was also suggested that there would be some multiples and independents who would be willing to be involved and others, both multiples and independents, who would not.

"If you speak to independents, people who are working in their own practice, or working in small groups….., I think they'll look at it and it will be the majority [willing to take it up]. If you're looking at employed optometrists for corporate bodies, then it's possible that corporate bodies at head office level may look at a local protocol and say 'well, you know, if it doesn't fit in with our business plan, we're not interested'. … so you'll find I think that depends on who you talk to." G1MI, 179-189

" [multiple practices] is more business orientated whether we like it or not" B3FM, 180-182

The type of practice was felt to be a factor in the willingness of people to be involved. It was felt that individual optometrists tended to work in practices in which they were comfortable and that provided the clinical environment they wanted.

"I think if you, that some sectors where people just want to do the job, straight forward and then go home, I think they'd probably be resistant to it. But in other sectors where people are actually interested to do things a bit differently, are a bit different and explore different avenues, I think they'd welcome it with open arms, so it depends on a) the particular practitioner and b) the working environment" C1FM, 385-390

"I think you that you'd tend to find to a large extent, practitioners' work environments that they're comfortable and if they're clinically motivated then they'll often, you'll find that they're working in an environment that's sympathetic to that anyway so I think you'd probably find that the two go hand in hand, the individual practitioners are, would be open to it because they know that the establishment that they work in would be open to it" C2MI, 407-413

It was also believed that offering a blood glucose testing service would result in the practice standing out from the others. Some believed that this would encourage independents to take it up. However, others felt that it would help any type of practice.

"I think it would certainly make your practice stand out a little bit better if you, looked to be more than just selling spectacles to people, because obviously we're still, we're still looked on like that I think, you know if you start offering sort of other things" F1MM, 241-244

I think a lot of the independents would offer it and this isn't coming down, reflecting as like a negative on the multiples but the independents increasingly need to look at ways of

being unique and offering something different to keep their patients because they can't do the low budget specs and things so I think a lot of the independents would go for it." H1FD, 192-196

The financial implications were felt to be of importance to some of the larger companies, whereas clinical implications would be more important to other practitioners. An interest in being involved was felt to be an important factor in whether screening was accepted.

"I think it, increasingly the large multi national companies, not so much in this area but certainly in the south east, they would only be interested in it if there was a financial reason to do it, …. Whereas I think an independent can do it if they feel they want to do it." C3MI, 414-418

"There'd be some people that just, if they don't think there's any monetary gain, just won't be interested but I think there just would be some people that just want to increase their clinical skills and find that that motivates them more than the money really." C1FM, 421-424

"Yeah, the driving force within a practice is the key issue, if you've got someone in a multiple who's quite keen, they might be able to swing it and that practice may adopt, it depends how autonomous the practice is from head office. As from an independent's point of view, you can talk round any independent if you can say something like 'well this is going to enhance the perspectives the patient has for you, it's going to give you variety during your day and your, you're going to be, you safeguard the income by covering the cost'" G1MI, 196-203

The length of time that the optometrist had been in practice was also considered a factor in their willingness to take part in such a scheme. It was suggested that younger optometrists are more willing to take on new techniques and, as more people take it on, the technique becomes commonplace and more accepted.

> *"I think that's perhaps, I find that some of the newer ideas aren't, or newer techniques I find really hard to get to grips with whereas my younger colleagues have taken to it and just expect to do it as a matter of course "C2MI, 184-187*

> *"But if it started back in the training at uni, then it would just be accepted then and then they would just do it, they wouldn't even think about it "C1FM, 399-400*

Acceptability to general practitioners

Many of the optometrists were concerned that general practitioners would feel that the optometrists were trying to do the GPs jobs.

> *"I think that the relation we have, well we all have, with the GPs is very good but they'll feel as if we're doing their job." A4MI, 296-297*

> *"I wonder whether they'd think they're having their toes treaded on a bit? I think it would depend on the GP, some would say 'great, this is fantastic' others will think that we're treading on their toes." H1FD, 151-153*

It was felt that the GPs may feel that optometrists would be simply replicating work that they were doing. Some believed that GPs would not trust the results.

“I don’t think they’ll trust our results, I think they’ll recheck it” A4MI, 98

“I mean something like that is really duplicating what happens in the GP’s surgery and the GP’s surgery is usually no harder to get to than the optometrist, so I don’t really see the point if they think they might be diabetic then surely they should be sent to the practice nurse “C1FM, 188-191

However, it was also suggested that GPs would not object to optometrists carrying out the service. It was suggested that it would be the kind of service that GPs would carry out, but that they would not object if they did not have to do it.

“I don’t know if they’d [GPs] necessarily see the point of it, would be my opinion. I don’t think they’d be bothered about us doing it, because it’s not really taking any work off them particularly, nothing that they enjoy doing” D7MI, 242-245

There was some concern that GPs may feel that optometrist led screening would conflict with initiatives they were trying to put in place. However, it was felt that, if the GPs were consulted in developing protocols for the service, they would be more willing to accept the results. The example was given of the cataract referral system where optometrists can refer directly to cataract clinics.

“If you had them actually involved in designing the protocol, then you would probably get a better response than if you designed it all and said ‘right we’re going to do this, lump it or leave it!” B2FI, 198-200

“Unless they were signed, you know on board and happy with it, they might not be too comfortable, they might feel that they’d have

to check it out themselves, they might think it conflicts with things that they're doing, they might have initiatives where they're trying to pull into their practices, people that they're not seeing. I mean the point we're making here is we are seeing a lot of the people that may not normally be pulled in so it is an opportunity to grab 'em and we've got to get everybody clear on that" G1MI, 132-138

There was a perception among a minority of participants that GPs were not happy with the way the blood glucose measurements were being handled in the pharmacies.

"They [GP] get very upset when the, they've [their patients] had a blood stick test at the pharmacist and the pharmacist has told them that they're diabetic" B2FI, 110-112

There was a feeling that some GPs in the area do not want optometrists to be involved in screening and joint care schemes. It was perceived that there was a poor relationship between some medical professionals and optometrists.

"I don't get the impression … certainly that the GPs want us to be really that involved, you know, diagnosing and sort of screening" B3FM, 108-109

'Very rarely since the system changed here and the DRSS [Diabetic Retinopathy Screening Service] system came in, so I really think they're not terrible interested in what we think, so, to be honest" F1MM, 64-65

On the other hand, it was felt that the relationships with some GPs were good. Though feedback from referrals was felt to be an issue, it was believed that if a scheme was put in place, GPs would use it. It was also

felt that some schemes to manage patients in an optometry practice instead of a GP's surgery, such as 'red eye referrals', were accepted by both optometrists and GPs.

> *"We've got a couple of GPs, we've got a good relationship with and they quite often let us know but that's more because we're more friends rather than any sort of professional thing really" E1MI, 66-68*

> *"I think they're aware of the problems that, with, about lack of feedback, …… 'you're going to screen this many diabetics AND you're going to feedback to the optometrist who've sent them there' and they got money for that then they would do it. I think that's the bottom line." E1MI, 224-230*

> *"As long as we each understand what our drives are, what we're trying to do and we're not conflicting, I think GPs generally do see optometrists as being the eye specialists, doing things that they can't do and we've got more opportunity to work with them, keeping people away from the GPs; often, their only referral path will be into secondary care and they're always looking for alternatives, keeping people in primary care and they've certainly looked at initiatives like 'red eye' referral schemes very favourable and got on board" G1MI, 141-148*

It was also believed that doctors would not want the extra work that a blood glucose testing service may involve.

> *"But I guess even if you've done a pinprick test you've still got to do a still full blood test to confirm results. I expect some of the GPs would look on it and think we're creating extra work for them even because we're going to send all these new patients who didn't know they were diabetic into them, so …" H1FD, 153-157*

4.2.3 Barriers to, and implementation of, a screening service

Cost

The concerns raised over the cost of the service were based around two broad themes, costs of the service itself and the cost of the new cases discovered by the screening.

It was generally agreed that a service could not be offered under the current GOS (General Optical Service) fee for carrying out a NHS sight test. It was felt that this fee was inadequate to cover the cost of a standard test.

> *"optometry does rely on cross subsidy because of the woefully inadequate funding …… it's [screening] going to be adequately funded to cover the true cost or it's going to be an extra, almost like an interest; but we still have to carry on with the core business and that is producing prescriptions to dispense and cross subsidise." G1MI, 232-238*

> *"Already the test that we do for the NHS is filled to the brim with tests that we're doing and obviously underpaid for so I think many opticians may be a little bit concerned about adding an additional test and not getting any remuneration" D6MI, 142-145*

It was felt that a screening service fell outside the normal sight test requirements and that the service could not be met with the standard NHS sight test fee. The general attitude was that it would only be feasible if it was funded by the Primary Care Trust (PCT).

> *"If there's no funding then I wouldn't want to take responsibility for it" B1MM, 163-164*

"you would probably expect the PCT to pay for it, how much I don't know." A1MM, 345-346

It was felt that, if the PCT was willing to fund a service, there would be no reason not to offer it. However, there was also a belief that the PCT wouldn't necessarily fund it.

"if the PCTs put that to us, that's that what they wanted done and funded it appropriately, then I, then yeah there would be no reason not to" C3MI, 264-266

"For me it would be sorting out the finance I think. I'd probably be very happy to do it if the payment was right" D5MI, 272-273

"Well it's wide open for a formalised scheme isn't it? I mean there's an obvious need there and that should drive the PCT but whether it would or not, because PCTs tend to be driven from the Department of Health and not from the patients unfortunately" C3MI, 503-506

It was felt that it would not be possible to offer screening services unless they were funded, even if the practitioner wanted to, as the profitability of the practice needed to be considered.

"otherwise there is a danger that you start diluting the, effectively the profitability of a practice by doing clinical skills which, or developing clinical skills which will certainly enhance your kudos and enhance your feel good but not your bottom line." C2MI, 435-438

"you don't mind offering the service but,……, you don't want to do it for nothing, not that we're being greedy because I don't think we are particularly. But you know, it's just so long as it's fair, it's got to be fair ."F1MM, 252-254

There was a feeling expressed that the NHS expected optometrists to carry out extra services for little or no financial reward.

> *"That's the big issue though isn't it? The NHS are going to give us 50p and say 'oh now we want you to do all of this' and before you know it you'll be prostate exams and everything else!" D2MI, 62-64*

> *"they [local GPs] said 'we'd really love you to do this glaucoma referral refinement for us; can you do that because we think you're quite good locally at doing this' and we thought 'well that will be ….. we turned to the GPs surgery and said 'well how much would you like to pay us?' and they went very, very quiet and that was the end of that! … I think they assumed that we were just going to do it as some sort of 'oh this would be nice for us to do' and so it was, you know whether that will get the same sort of response with the diabetic thing" D2MI, 254-264*

General cost effectiveness was considered. Two main concerns were raised. One was that the NHS would not consider it cost effective if they were to reimburse optometrists, and so they would find cheaper alternatives. The other concern was that only the independent practices would take up the service, leaving a large number of people attending multiples without access to a screening service.

> *"I mean my concern would be that it wouldn't be cost effective for the NHS to do it through optoms" D5MI, 408-409*

> *"Yeah, but then that adds on to the question is, is it cost effective again because even, just because the independent needs all these extra bits to help him out if you're only seeing the patients who come to independents which out of the population of patients who go to see opticians is actually still very, very small compared to the*

big four [multiples], it's, is that a cost effective way of screening for diabetes" D7MI, 454-459

The time involved in carrying out the tests and the extra tasks related to the screening was of concern to the participants in the focus group as well as the related costs of the time.

"it's not actually the actual taking the test, doing the readings, that is not going to take any time or anything at all, it is the amount of questions you're going to have to be able to answer." B2FI, 187-189

"I think anything that takes time and I know it's not a great lot of time but it would take, if you mounted it up during the day, it would take a bit of time, I think you need to be, whether it's the optom or the staff, the person that's doing it, you know, trained up for it. You know, it's, they're taking a bit of responsibility on" F1MM, 233-237

The attitude was expressed that members of staff other than the optometrist would be capable of carrying out the test, thereby reducing the cost of the optometrist's time. It was felt that some optical assistants would be willing to be trained to carry out such tests, though it was believed that some would be more willing to take on these roles than others.

"I think in a large practice where they have, you know an optical assistant who does all your ancillary testing …. you probably would get one of them trained up to do it because your, you know, your time is more valuable than their time. In a small practice where you didn't have an optical assistant you'd probably just have to do it yourself." A2FI, 691-697

"the kinds of people who are training up to do all those extra bits, rather than just be you know receptionists, they must have

something about then that makes them wasn't to do more and more stuff" A3FM, 700-713

"some member of staff would be far more willing to stick needles in people than others; their very nature; they're the ones that like doing the NCT [non contact tonometry] as well." A3FM, 708-710

The cost of the new cases and the burden on GPs and other related diabetic services was also considered. The perception of some participants was that some of these services were overstretched already and that it would not be positive to find more cases of diabetes.

"if they [GP] check it and find out that somebody is indeed diabetic then it's still going to be a greater load on their resources isn't it?" A3FM, 100-101

"if they did find the 50% of diabetics that are undiagnosed, it would be a catastrophe for the NHS and their role in diabetes" B3FM, 55-57

"not only the GPs, it's in the screening, it's in the , you know the dieticians and everyone else, it's it's that's what I mean it's if you; do they really want to be, have all those people diagnosed?" B3FM, 187-189

Other participants felt that, though diagnosing more patients with diabetes would cost more initially, it was beneficial in the long term.

"And the more that are diagnosed the more they've got to spend them on them haven't they" C1FM, 507-508
"Yes it's counter intuitive isn't it? The better they get at health care the more it's going to cost them" C3MI, 511-512

“Ah but the better the health of the nation in the long term” C2MI, 513

“The PCT could fund it…..and whether a case could be put forward to persuade them that in the long run it was going to save money because I think it would; if you pick up undiagnosed diabetes early you’re less likely to be spending money on those people because of the complications later on.” H1FD, 176-180

Infection control and sharps handling

Infection control and handling of sharps was considered one of the major obstacles. Taking blood samples would be more invasive than any other procedures normally offered in optometric practices, and would result in clinical waste and the associated costs, both of which practices are not used to handling at the present.

“The immediate thought I have is that you, you’re entering a whole new sphere in terms of using, getting bloods from people, using sharps, clinical waste disposal which is something that we’re not involved in at the moment and it’s just the administrative side of that and the regulatory side of it that I see as the, probably the biggest stumbling block” C2MI, 170-174

“I thought one of the problems would be the infection control because we’re not to the same guidelines as GP surgeries or hospitals” A4MI, 172-173

There was concern about the extra risk assessments and audits that it was believed, would have to be undertaken to satisfy the PCT.

"the other thing I would worry about there would be the PCT and all the clinical governance with sort of the safety aspect of having blood and I can just see what the, how that would go! You'd have to have a whole different level of audit governance and stuff" E1MI, 140-143

However, it was acknowledged that some body fluids are already handled, but that blood samples would be higher risk than tears.

"I mean, what do we do about handling contact lenses and tears because in effect that's clinical waste as well? A2FI, 737-738

"the risk of kind of contracting hepatitis from tears is much less than from blood" A4MI, 764-765

Although handling and disposal of sharps was considered by many to be a problem, some believed that this could be easily overcome.

"Exactly so a lot of areas have actually got these collection schemes now in place where they pay the PCT or they pay a company to come and collect a box and they keep the box for six months and they pay something a year or something so you can easily organise that if that's something that you would consider doing in the practice." D7MI, 163-167

Some participants believed that there would be patient groups on whom it would be unsafe to carry out blood tests.

"what about warfarin patients and like this, you could, you know a patient on warfarin, if you needles stick then you

could create a significant problem, that or reduced immune system" B2FI, 168-170

The reaction of both patients and optometrists to sharps and blood were also a concern. It was acknowledged that not everybody would be happy handling blood and sharps.

"You're more likely to have somebody fainting as well and having had two people faint in the consulting room anyway, it's a fairly, especially when they come round and start being sick as well you know" D2MI, 170-172

"I think there'll also be opticians that won't want to get involved in drawing blood. I mean not everybody likes the sight of blood" D3FI, 296-298

Training and protocol

The development of protocols and related training was considered. It was considered that there would need to be strict protocols on who to offer screening to. Some felt that it would be difficult to set up protocols, but if developed correctly they could be used to develop other services

"my only fear is that there will be an awful lot of protocol compliance. Say we're doing the finger prick test, there's going to be issues about hygiene, protocols about where you store, how you dispose, who you're going give it to, how you get consent, all these sort of things that for a new thing in today's environment, you've got to set up, for such a small thing" G1MI, 113-117

"Great idea, my only concern is that it would take such a lot of effort to set something up ….. I think if we got the right ear, of the right people, they would be so enthusiastic they would start to look at how we could do that with other things. You could do a full

screening check on all sorts of things and it would still seem relevant and it's a great opportunity to expand on the current role that optometrists have in the NHS" G1MI, 122-128

A few participants expressed concern as to whether a random blood glucose test would be worthwhile. There was a belief that random measurements would cause patients unnecessary worry.

"But really if they're not going to be fasting, what is the point? You know if it's not going to be an accurate test? You know you're going to be worrying a patient 'ah well your sugar level's a bit high'" B3FM, 495-497

The levels of blood glucose at which patients would be referred was also of concern for some of the participants, particularly with patients who would be seen by the optometrist on a Saturday and so would not be able to contact their GP for several days.

"you know there would have to be additional training as to what is safe, can you tell the patient they're ok, what is minimal 'go and see a GP within a couple weeks', 'you're going to go and see a GP today!' or you know, 'hang on, here's a taxi, get yourself off to hospital now!" B1MM, 164-168

"Especially if you do it on a, if you do do it on a Saturday morning and there's no GPs open until next Monday" B2FI, 520-521

There was a perception that further training would be required as the service would take optometrists outside their general knowledge areas, unless they had a specialist interest in diabetes. It was felt that optometrists did not have the knowledge to give patients information when referring for suspected diabetes following a pin prick test. However,

it was also reported that optometrists will currently refer patients who they suspect to have undiagnosed diabetes if ocular signs are present.

> *"on our general training levels at the moment we wouldn't have that information unless you had a specialist interest in it." B2FI, 194-196*

> *"no it's really the extra level of training and knowledge we would have to have about diabetes to be able, because you can, you just, you couldn't sort of say 'oh right, this reading's high' there is a sort of, you've got to go and see that, you'll get away with that with some patients, fair enough, a lot of others will want to know the ins and outs of everything and you can't give advice and, without the knowledge base so I do feel there would be training, not just the actual mechanics training implications I think that would.." B2FI, 432-439*

It was felt that finger-prick tests are not a procedure that optometrists are currently used to carrying out and that they would need training before being confident enough to carry these out.

> *"It's a sphere of health care that I don't have any experience and training in basically" C3MI, 227-228*

> *"it would be something that I would be doing so infrequently that I would not be confident in my abilities to do that compared say with somebody like a practice nurse who can do that sort of thing with ease and had years of experience, I mean a lot of cases of doing it" C2MI, 229-232*

However, it was also felt that it would not be difficult to achieve the extra level of training needed to carry out the role, either for an optometrist or an optical assistant, but there was a concern that the PCT may make training more difficult than it need be.

"I think if it was as straight forward as like the one at the blood donors, just some training and it would be alright" C1FM, 445-446

"I would say, not much [training] really, maybe an afternoon, but having recent dealings with the PCTs I can imagine they would spin that out to six or seven months of lectures and all sorts here, there and everywhere and signing things off, so, but personally I'd only say maybe… if it was just a simple protocol and how to do something, that's clearly written down, then just an afternoon possibly?" E1MI, 356-361

Liability

Liability and insurance was a concern for a small number of the participants. There was a perception that, if optometrists undertook the blood test service, they would be liable for any cases of diabetes that were missed in their practice. It was felt that, if a GP missed a case of undiagnosed diabetes the GP would not be liable, whereas the optometrist would be. There was concern expressed that any advice given would result in the optometrist becoming responsible for any outcomes for the patient.

"I think my concern about it would be what additional legal ….. for example if you've forgotten to offer them the test and then five years later it turns out they're diabetic …. are you going to be legally responsible for the fact that you didn't, so I think from that point of view I'd be nervous about where the optometrist's legal responsibility for findings and if test results went adrift and things, what that would be because it's entering a completely new realm really" H1FD, 129-138

"[GP] seeing them maybes two three times about an ulcer and really they're not liable then if, you know whereas we, if we'd seen a patient who's gone minus one fifty after being plano and we hadn't referred them, you know, then we would be responsible." B3FM, 300-305

There was concern raised over whether current insurance would cover the service. It was felt that people would be unwilling to carry out any test that would not be covered by public indemnity insurance.

"the receptionist that's doing the pressures and the visual fields could do a quick click as well but you'd need to take legal advice wouldn't you because there's rules about, the receptionist can teach them to put contact lenses in and out then if they get one stuck it has to be an optometrist that actually goes fishing to find it doesn't it" C1FM, 290-294

"Well you see presently our professional indemnity insurance wouldn't cover that because it's not an accepted procedure for an optometrist and it would have to be an accepted procedure for an optometrist before the insurance people would cover it and I'm not doing anything I'm not insured for" C3MI, 295-298

4.2.4 Current and developing role of optometrists

It was felt that optometrists had some role to play in raising awareness of general health, in particular when it related to the eye. Many of the optometrists felt that their current role included a responsibility for general health issues, particularly with systemic diseases that may have ocular complications. Some believed that the eye examination was a good opportunity to introduce patients to healthy living or smoking cessation information.

"Well I think as health care professionals we've got a responsibility to tell people about things that might affect their eyes. …..same as you know you get a patient in who smokes, family history of macula …. you going to inform them that smoking is not the best of things to be, you know, doing for that as it were or giving up smoking is. " D2MM, 79-85

"I would agree that it's an opportunity to do a full health check because we're not just refracting for vision, we are checking for eye disease and we're also looking for systemic problems and a thorough examination should try to highlight all of these things and it's an opportunity to sort of talk about things like healthy living, nutrition, smoking cessation could be ….we could we be working with pharmacists and the doctors to try and lower blood pressure, try and reduce on smoking related diseases and all these kind of things, yeah" G1MI, 36-44

The belief that optometry, as a profession, must develop was a recurring theme. The perception was that optometrists must get involved in extended care roles and disease monitoring.

"I mean some places already measure blood pressure, this would just be an extension of that, I mean we do fundus photography already" A1MM, 147-149

"There are a lot of schemes starting up throughout the country where monitoring and screening is occurring outside the GOS and that is the way forward, it's happening very much in Wales and in Scotland. There's various schemes being kicked off all round the country… Now there's going to be GOS and other schemes, a lot of other schemes" C3MI, 316-322

"That actually involve eyes; certainly diabetic retinopathy screening I think we could get and should get more involved with, particularly as the health service system they're using at the moment is full of holes, glaucoma monitoring I think is our bag, things like punctal plugs is something that have already been fitted and we're actually insured for" C2MI, 469-473

The measurement of blood pressure was given as one area where some optometrists had tried to develop their roles and provide services to people who may not access other services.

"There was a time when I know some of my colleagues were buying these automatic spignometers and that, I thought, might have been a way … I think that would be a great way forward, there's no reason at all why we can't grab people, it's a great way of grabbing people to do screening for other things because they are coming in on a rolling basis every two or three years and they might never ever go anywhere else" G1MI, 49-58

Some participants, though they believed they were capable of taking on extended roles, felt that other healthcare professionals did not want them involved and did not appreciate the role of the optometrist.

"I think just our profession seems to get kicked from being in it long enough, 20 years, you just seem to get kicked all the time. The diabetes one was the last big kick we got….There's no doubt we can do it, I mean it's just a case of how they react, you know. They, being GPs and the hospitals, you know, so, I mean they've been pretty much anti optoms for years, so, we're just a means to an end for them really, you know, we write nice little referral letters for them to do their job……. You know, so I've no doubts we can do it but it's a case of how they see it, stepping on their toes or you know; some of them will be against it" F1MM, 377-388

Some participants were not happy with the way the retinal photography schemes for diabetic retinopathy monitoring had been implemented. Some would have liked to have been involved and had invested in equipment, but were not involved by hospitals. This generated the feeling that other healthcare professionals did not appreciate the role of the optometrist.

> *"we were actually doing our own retinal photography before the health service actually; in my naivety I thought we were going to be involved with it but we actually got cut dead on this one." C3MI, 126-129*

> *"We were doing retinal photographs before the NHS framework was up and running so there were retinal cameras, there was one at [Hospital] which was, was broken down more than it was working or had no funding for staffing for years and so we provided the service to all our patients" C2MI, 130-134*

Although some participants reported negative experiences of the diabetic retinopathy monitoring schemes, most reported a positive attitude towards taking on extended roles, such as the 'emergency eye care scheme' as it was making use of the knowledge that they had and would not use in routine refractions.

> *"I remember thinking at university, how many anterior uveitis am I going to see in a week? ..... then the reality's not like that at all but I mean locally we're doing this emergency eye care scheme now, so we're seeing maybe one patient a day on that with all sorts wrong with them and that's great, again it probably just covers costs, it doesn't you know make any money out of it, we don't lose on it but it makes the day a lot more interesting which, it's just something*

different really and it's quite enjoyable, it's quite sort of satisfying you know from that point of view." E1MI, 267-276

It was felt that optometrists were over-trained if they were only expected to refract. It was felt that refraction alone was not rewarding and did not utilise the full extent of optometrists' skills and knowledge.

"what happens is you learn about a huge spectrum of stuff and then you go away and practice one tiny bit of it" A3FM, 1070-1072

"refracting is pretty boring, so if it was something different then that's great" E1MI, 249-250

"We'd have to be more pro-active, I mean just standing still is not good enough. We're all trained to be, for what we do, if we just sort of sit in a room and just examine eyes all day, we're probably well overtrained. I mean you can get anyone who can do refraction if you're, probably teach them in two hours to do a refraction but yeah, I mean the skills are there, you've just got to use them you know and up until now they've probably been very under-used" F1MM, 193-199

It was noted that the profession is changing from simply providing glasses to diagnosing pathology.

"If you go back 30 years, our main job was to provide an optic correction and if we found something pathological on the way then we picked it up and referred it and that was it but it's much more complex than that" C3MI, 343-345

"We're expected to diagnose now aren't we. 30 years isn't that long for a big change like that really" C1FM, 348-349

It was believed that the role would become more clinical, as long as there was no opposition form the medical profession. The attitude towards increased clinical roles was generally positive.

> *"it would have been nice to have had more clinical stuff to do. You think, when you start off training you think you're going to be doing more than you do but then you help patients in other ways" C1FM, 340-342*

> *"I think it will need to and hopefully it will change so there's more clinical stuff to be done" C1FM, 310-311*

> *"yeah it's moving in that direction inexorably and there's as long as there isn't any resistance to this from the medical establishments then I see that the roles clinically, clinical roles expanding all the time. I think it will be unrecognisable in say 30 years time" C2MI, 312-315*

One of the major changes to the profession that was felt to be coming in the future was the introduction of independent prescribing. It was felt that, while initial take up of that would be slow, it would be commonplace in the future. Several participants were unsure of how positive this would be in the current framework as the opportunities to use it would be limited. It was suggested that, for such roles to work, there would need to be changes in the way optometrists work with other professions.

> *"Independent prescribing is going to happen this year and that's the first time we've ever had that so there will be a trickle to begin with, of independent prescribers but I can see another 10, 15 years we'll all be independently prescribing; with extra training. Certainly the younger ones will, I'm not sure I will! C2MI, 333-337*

"I keep looking at this, all the independent prescribing and things that's going on and even that I'm questioning how in reality, how useful that is….., I think you'd need to be working a lot closer with GPs, with other primary care practitioners of other professions and with the secondary health care;" H1FD, 224-230

Changes in equipment was also given as a way in which optometry had changed within the time that participants had been in practice.

"But on the other hand, when I started off, practices didn't have a tonometer so you didn't, you didn't do pressures, but now" C1FM, 300-301

"Then, you know and now it's the sort of thing that you get the extra kit so you aren't doing you know different things; if you'd said to me seven years ago, 'well you'll be charging £49 for a check up' I'd have looked at you and said 'you can't charge £49 that's not sustainable' and people are coming in, paying the money, to have their fundus photos, to sit and talk about the state or their retina with you and you know it's the face to face time, you're selling your own, you know, personal company if you like, your personal skills to talk to the patient about their eyes" D2MI, 520-527

One of the main barriers to taking on extended and more clinical roles was the attitudes of other professionals and the PCTs towards optometrists. Some felt that the PCTs were already becoming more interested in involving optometrists.

"I think that PCTs are more interested in taking optometrists on board. I mean we've had much more communication with PCTs in the last few years than ever before" A1MM, 797-799

It was felt that there was a problem with the interaction between the retail side of optometry and the health care aspect, which may affect some people's view of the profession. A few participants felt that there was a need to split the two aspects so healthcare and retail were entirely separate.

> *"I think our big problem is that we're neither healthcare or retail" A4MI, 138*

> *"I think that the NHS is disintegrating and we'll be able to pick up the pieces in lots of different area and I think we'll be very good at picking those pieces up but the thing that always hold us back is the fact that, is the retail side, it's we're not health care, we're more retail. You know until we split the two up, that's always going to hold us back I think." A4MI, 792-796*

> *"I would love to get rid of them [glasses], and not that hassle and just be a healthcare professional." A4MI, 858-859*

However, other optometrists felt that the public would rather have the two aspects side by side.

> *"you know if the people are happy to mix the two why should we not mind" A2FI, 815-816*

> *"the vast majority of the general public want to come through the door, have their eyes tested and go leave with a pair of your specs on the end of their nose, they just want it, one stop shop!" A3FM, 887-890*

Many of the participants felt that there would be a partial split in the profession, with the majority providing a sight testing and dispensing service as is currently done, with a small number of optometrists, who

would receive further training, providing more extended and clinical services. It was felt that there was not a need for every optometrist to take on all clinical roles, and there was a place for people who wanted to concentrate on refraction and dispensing.

> *"I think they'll still be as it is at the moment, a big mix where, because the thing is people won't want to get to the point where they have to decide if they're going to be a refractionist or a clinical optom. …. I think, I suspect it will go that way but you can't afford to have every optom as master clinician doing blood tests, glaucoma management and so on because there aren't enough patients for that and most patients just need a straight forward eye examination and some glasses." D7MI, 478-496*

> *"we're going to get two tiers of optometrists, we're going to get the optometrist who is in the normal practice, just refracting for dispensing and we're going to get the other optometrists who have an interest in extending the role, do some extra training, develop new skills, and get involved in local protocols. I think generally optometry is going to stay pretty static otherwise because of the nature of the retail aspects of optometry." G1MI, 223-228*

> *"I think there'll be a split but I think some of the multiples are trying to take that on board and Specsavers in particular are starting to realise that there's a big clinical market out there that they can take hold of as well so I think there will be a shift but I think there'll still be refractionists as well" D7MI, 470-473*

For the role of the optometrist to develop, it was felt that work needed to be done to explain what optometrists are capable of doing. It was also believed that the public's perception of what optometrists do needs to be changed.

“I think optometry has the great potential and I think that the, we need to sort of carry on advising the people who are in the, in the position to actually change things and that’s the fund-holding bodies, that we can do things, reassure them that it’s going to be correct and adequate for needs and I think slowly, bit by bit, the role of an optometrist will change” G1MI, 218-223

“I think you still get people that are very surprised at what we actually do you know. …, but people are just, still see us just as like reading letters off a chart and in and out in five minutes but you know. So changing their perceptions to what we do is probably quite difficult, you know it will probably take a little bit of time” F1MM, 184-188

4.3 Discussion

4.3.1 Awareness of diabetes

The participants believed that the general public has some awareness of diabetes, but that the knowledge was often limited or inaccurate. Some participants felt that those people who were at risk would often not recognise the risk or not be willing to make necessary lifestyle changes. It has been shown that people do perceive diabetes to be a serious disease (212). However, those with risk factors often perceive their risk of developing diabetes to be low (213) (212).

There was limited knowledge among the participants of the extent of undiagnosed diabetes, though most participants were aware that they have seen people whom they suspected of having undiagnosed diabetes. Refractive changes, such as myopic shifts, were the most commonly reported signs of diabetes. Most could name factors that would raise suspicion of diabetes, and reported having referred people to their GP with suspected diabetes. Even though they had previously identified and referred patients with suspected diabetes, a minority of the participants

felt their knowledge was insufficient to refer someone on the basis of a screening test.

The knowledge of diabetes as a disease was also mixed. While some were confident in their knowledge, others were less sure. There was some confusion between different types of diabetes and the disease progression in a minority of the participants. A few questioned the need to identify people with diabetes if they were not experiencing any symptoms or showing complications.

4.3.2 Acceptability of screening

It was felt that some people would be willing to accept screening by optometrists, while others would not. Concern was expressed that, if some people believed they would be tested for diabetes as part of the sight test, they would be unwilling to attend. Some participants felt that different groups of people would be more likely to accept screening than others, with younger people and those attending multiple practices being less health conscious than older people and those attending independent practices. Others though, felt that, with effective communication of the reasons for offering screening, there would be no differences in the type of people taking up the offer of screening. It has been shown that the socioeconomic factors affecting uptake of cervical screening are age, educational level and marital status. Attitudes such as “not needing to be screened if you have no symptoms” also lead to reduced uptake of screening (214). However it may be that communication will not increase uptake in certain groups as it has been suggested the informed choice may reduce uptake in those people who are ‘present orientated’ while increasing uptake in those who are ‘future orientated’. ‘Present orientation’ has been associated with deprivation, so it has been suggested that informed choice may lower the uptake of breast cancer screening in those groups who may be at higher risk (215).

Some concern was expressed as to the levels of anxiety caused by screening and positive results. In some studies, small increases in anxiety have been shown in those patients who are determined to be at risk after screening compared with those with normal results soon after the initial test (216), but one year or more after screening there is no significant increase in anxiety (217) (218). Anxiety during screening tests, prior to being given the results, was shown to be low or moderate, with men showing less anxiety than women. However, nearly half this group reported that they thought that diabetes was a minor condition and less than a third knew that diabetes could cause complications, which may be a factor in the low level of anxiety reported (219).

There was a perception among the optometrists that they did see some people who did not access other healthcare services. It was suggested that, while some would access all services available to them for routine services, whether they were experiencing symptoms or not, others will not access healthcare until they are experiencing symptoms. If people experience difficulty with daily routine tasks such as driving or reading they may visit an optometrist before they visit any other healthcare provider.

4.3.3 Barriers

The attitudes expressed to carrying out screening in practices were mixed, with convenience being a key factor in the extent of the take up by optometrists. The practice type was considered to be a factor by some, suggesting that independent practices may be more likely to take up screening initiatives than multiple practices. Others felt that the practice type was not important, but that the factors influencing acceptance of screening would be the interest of the optometrist and management.

A recurring theme was the lack of communication between optometrists and other health care professionals. It was felt that, if a referral was made to the GP, the only feedback was often via that patient. A survey of

ophthalmology notes showed that only 16% of optometrist referral letters resulted in information being reported back to the optometrist (220). It has been suggested that feedback is poor as referral letters are sometime illegible and do not include all necessary details (173) (172). However, it has been shown by one practice, that even if the letters are typed, all contact details are included and a reply is requested, feedback is still only received in around 13% of cases (221). It has been noted that response to referrals would be useful in several respects. Firstly, the patient is likely to return to the optometrist at some point following the referral and information would be helpful for continuity of care (220). Secondly, it provides the optometrist with the opportunity to learn and refine or improve further referrals (222).

It was believed that GPs would have mixed attitudes towards optometrists taking on screening roles. Some felt that GPs would not want optometrist involvement, while others would be happy. Success of any screening service would require GPs to be willing to undertake the further testing required. For both optometrists and GPs to be willing to participate in such a screening service and for the screening to run effectively with both groups of professional delivering the same information to the public, both optometrists and GPs must be involved in developing and agreeing on the protocols.

The main perceived barriers to undertaking a role in diabetes identification included cost, appropriate reimbursement, infection control and legal responsibilities. These factors have been reported as barriers to optometrists undertaking other extended roles such as prescribing therapeutics (186) (223). Infection control was felt to be a barrier that could be easily overcome with training.

Cost was felt to be one of the biggest barriers. There was strong feeling that the current funding for the sight test was inadequate and extended roles could not be carried out as part of the current GOS sight test. In

2005-2006 the reimbursement for a sight test was £18.32. However, the actual cost of a sight test at that time was calculated to be around £37 (176). This under-funding of the sight test and need to cross-subsidise from spectacle sales results in funding of extended schemes being an important factor in the uptake of extended roles. In a survey in which around 14% of UK optometrists participated, 70% listed remuneration as a factor that would prevent them being involved in extended therapeutic roles (223). Schemes that had been successfully implemented at a local level which use optometrists to screen people with known diabetes for diabetic eye disease have been funded separately to the standard GOS sight test fee (169) (224). With the current method of funding sight tests, any scheme for testing blood glucose levels would have to be funded separately to the routine sight test for it to be financially viable for optometry practices. There was a concern that the PCTs would not consider optometrists providing services as cost effective.

It was suggested that using optometrists to undertake the blood tests may not be the most cost effective way of providing the service. It was suggested that, in practices where auxiliary staff were trained to carry out tests such as intra-ocular pressures and visual field tests, these staff members also could carry out the diabetes screening. It has been shown that a trained assistant can carry out tonometry as effectively as an optometrist (225). The training that would be required for someone to carry out the screening tests would fall into two broad categories: firstly, the simple mechanics of carrying out the test and, secondly, the knowledge and extra understanding required to explain the results to the participants. Knowledge of systemic diseases and the ability to discuss ‘the importance of systemic diseases and its ocular impact and its treatment’ is a core competency assessed during the pre-registration year (4). Though optometrists’ training does include systemic diseases as well as ocular diseases, these focus groups and interviews show that some training would be required to ensure the knowledge of diabetes is sufficient to provide the public with the correct information.

Some were concerned that the increasing screening for diabetes would place an unacceptable burden on health services such as GPs and dieticians, and questioned the need to diagnose people who showed no diabetic complications. However, more felt that the initial increased spending on screening and treating the disease before significant complications occurred would be cost effective in the long term as better management would result in fewer complications.

Some optometrists were concerned that people would not accept advice or services that are not directly related to the eye. However, it has been suggested that optometrists are in an ideal position to provide information or refer for non-ocular issues such as smoking cessation services (226) or depression (227). It was suggested that the optometrists do have a role to play in general health education.

Many of the factors that were discussed in the course of the focus groups and interviews: cost implications, GPs attitudes towards optometrists, public perception of the role of optometrists and the expectations of what optometrists can do and should do; relate to the development of the professional role of the optometrist and the conflicts between the professional aspect and business aspect of the profession. Concerns over conflicts between professional motives and business motives have been acknowledged in optometry in the United States (228), The same factors apply to UK optometrists, where business motives for the need to make profit can conflict with the professional motive of providing a health care service. The introduction of advertising and competition from unregistered spectacle sellers in 1984 (177), and the growth of the multiple practices changed the business model of optometry. The relative under-funding of the GOS sight test and the resulting need for cross-subsidisation of the sight test by spectacle sales (176) creates further conflict between the professional and business motives.

4.3.4 Role of optometrists

This research raises some questions as to how optometrists view their profession, how others perceive optometry and what a profession is. Thistlethwaite and Spencer define several characteristics of a profession. They see it as driven by a sense of vocation and a distinctive knowledge base. They see it as setting its own standards and controls with access to the profession by examinations. They also see it as having a special relationship with those it serves, being guided by particular ethical issues and being self regulating and accountable (229). Hafferty defined three factors that distinguish a profession; core knowledge and skills, ethical principles and service orientation (230).

It can be argued that optometry does reflect many of the features that distinguish a profession. It is regulated by the General Optical Council, which is the equivalent of the General Medical Council. The College of Optometrists lays down a code of ethics and professional behaviour and defines the core competencies that must be achieved for registration (4). However, professionalism can also be defined as relating to the public's expectations. The participants in this study felt that the profession was viewed in different ways, with the high street multiple viewed in a different way to the independent practices.

The results suggest that the participants consider optometry to be a changing profession moving from refraction only to checking eye health and diagnosing some eye diseases in the lifetime of some of optometrists. Even participants who had been qualified for less than 10 years felt that the profession had changed in the time they had been practicing, citing changes in equipment and shared care. The introduction of independent prescribing was given, by many, as an example of the changes, though there was no agreement as to whether this scheme would prove to be useful. Retinal screening programmes were given as an example of a scheme where optometrists wanted to be involved, but felt they were excluded by other healthcare professionals in their area.

Development of a profession involves developing and defending the boundaries of their roles. In the US, where there is different legislature concerning the role of optometry in different states, those states with the greatest professional roles for optometrists were the ones where the optometry professional groups were more effective in mobilising to effect change in the state legislation. For example, in changing legislation to allow optometrists to use drugs for diagnostic purposes. In others, where ophthalmologists were more effective in working as a group to defend their own professional boundaries, optometrists failed in their bid to allow diagnostic drug use by optometrists, a move that was strongly opposed by ophthalmologists (231).

In the UK, regional variation in legislation is not as extensive as in the United States. Scotland has recently introduced a new way of funding the eye test, but the legal requirements for sight tests in England and Wales are the same. Though there are no legal differences in the way optometrists practice across England, there are differences in local extended care schemes. These extensions to the professional boundaries of optometry are not universal across the country, but vary regionally, such as glaucoma shared care in Bristol (232) and direct referral of posterior capsular opacification following cataract surgery in Taunton and Somerset (175). These schemes have been set up where local groups felt that there was a service that is required and could be provided. Optometrists are pushing their professional boundaries and are successful because there is cooperation with other professional groups.

It was clear from the discussions that carrying out refraction alone was not felt to fully utilise the full range of optometrists training and knowledge. It was felt that there were two aspects to optometry, healthcare and retail. Some felt that the profession had to separate in to two aspects in the future, predicting a total split between clinical practices and retail, while others felt that there would be a two-tier system with

some predominately carrying out refractions and others taking on more extended roles. It is maybe not surprising that some optometrists do not seem to be happy with the role that they currently have in some high street practices where they are predominately carrying out tests that can be done by assistants, such as field tests and tonometry, or performed by new technologies, such as refraction and ocular photography. There is no aspect of optometry that cannot be performed by another group. Doctors can treat eye diseases and can train to carry out refractions, dispensing opticians can train to fit contact lenses, orthoptists are able to manage binocular vision problems and, since the 1980s, with the Opticians Act (1989) and the Health and Social security act (1984), unqualified people are allowed to supply spectacles, with a small number of exemptions. The clinical training that optometrists receive during the course of their university and pre-registration training covers a much wider range of topics than is routinely used in day-to-day practice. Optometrists are currently struggling with the dilemma that, in their current role, they are unable to utilise fully the skills and knowledge that they have, but often feel limited by their relationship with the UK health service. Though the NHS funds some sight tests, it is inadequate, and this results in cross-subsidisation from spectacle sales (176) and some optometrists believe that other professions view optometry as a business rather than a health care profession. It was expressed that, as optometrists demonstrated what they were capable of doing, gradually public and other professionals opinion of what they could do would change, though it requires optometry to be proactive as a profession and define what it could do.

4.3.5 Limitations and strengths

No substantial differences were noted in the themes identified in the interviews and the focus groups and so these have been reported together. It has been suggested that, in some situations, views and attitudes expressed in focus groups can differ from those in one to one interviews (198). In this situation, this was not found to be the case.

Chapter 5

Detection of diabetes in optometric practice – a feasibility study: part 1 – background, aims and methods

Chapter 5

Detection of diabetes in optometric practice – a feasibility study: part 1 – background, aims and methods

Abstract

Introduction

It is estimated that around one third of all Type 2 diabetes is currently undiagnosed. At present, there is no national screening programme, but the National Service Framework for diabetes states that "The NHS will develop, implement and monitor strategies to identify people who do not know they have diabetes." This makes it important to identify and develop strategies for diabetes detection in non-conventional settings. This research explores the potential role of optometrists in diabetes detection

Objectives

a) To ascertain the feasibility and practicality of using random capillary blood glucose tests (rCBG) in optometry practices as a method for the early detection of diabetes in the "at risk" population.

b) To determine the acceptability of a diabetes detection service using rCBG in optometry practice to the "at risk population" attending optometry practice.

c) To ascertain blood glucose levels in the "at risk population" attending optometry practices, with a view to identifying diabetes and pre-diabetes.

Design

A community-based prospective survey

Setting and participants

People attending high street optometry practices in the North East of England

5.1 Introduction

Universal screening for diabetes is currently not recommended. However, targeted screening has been found to be justified for detecting diabetes (117). As there is no national screening programme in place, screening often takes place opportunistically when patients attend their GP for other reasons or when complications present.

Healthcare professionals other than GPs do have the ability to carry out screening tests and may be able to see individuals who would not present at their GPs' practice. Both pharmacists and chiropodists have investigated the feasibility of screening within their routine practice. Currently, in the UK, pharmacists are the group most involved in screening for diabetes and have developed a protocol with Diabetes UK and the Royal Pharmaceutical Society of Great Britain (RPSGB) (131).

Optometrists carry out over 17 million sight tests a year in the UK with over a third of these on patients aged 60 years or over. 68.6% of tests are reimbursed by the NHS (3). This older age group has a high risk of having diabetes (10). In one group of people aged 60 to 79 years, 6.7% of men and 6% of women were found to have undiagnosed diabetes (18).

In the Middlesbrough Primary Care Trust (PCT) in the North East of England, 41,761 rNHS (reimbursed NHS test) sight tests were undertaken in the 12-month period from February 2006 to February 2007. In February 2007, 3114 rNHS sight tests were undertaken. 35% (1086) were aged 60 or over and 6.6% (205) of the tests were carried out on people diagnosed with either diabetes or glaucoma. In January 2007, 220 people received an rNHS tests in North Tees PCT as they had previously been diagnosed with either diabetes or glaucoma (personal correspondence).

Though all people with diabetes are eligible for an rNHS sight test, there are no figures available for the number of patients with diabetes who received a test. The voucher that is used to claim reimbursement for the sight test carries several statements only one of which needs to be ticked for the sight test fee to be claimed. The voucher includes diabetes and glaucoma in one statement so does not allow for differentiation between the two conditions.

If the proportion of reimbursed tests to non-reimbursed tests is similar in Middlesbrough to the rest of the country in 2005/06, the total number of sight tests, both reimbursed and non-reimbursed, carried out in Middlesbrough PCT in 2006/07 is estimated to be around 61,000.

Current predictions by the Yorkshire and Humber Public Health Observatory (YHPHO) suggest that the current prevalence of all diabetes (Type 1, Type 2 both diagnosed and undiagnosed) in the North East is likely to be 4.73%. Assuming the population attending for sight tests is representative of the population as a whole, it would suggest that nearly 3,000 people attending optometrists in the PCT would have diabetes. Around one third of these may be undiagnosed. By extrapolation, almost 1000 people with undiagnosed diabetes may be attending optometrist's practices in Middlesbrough PCT each year. The Middlesbrough PCT area is served by 12 practices and has a population of 138,000 (233)

Optometrists are in a position to ask patients about diabetes risk factors during the course of a sight test. The College of Optometrists guidelines state that the history should include 'relevant personal or family history of an ocular or general health nature.' The College of Optometrists sets down 'core competencies' for pre-registration optometrists to achieve before they are allowed to register. These include the ability 'to elicit significant symptoms', to 'elicit relevant family history' and the 'ability to discuss with a patient the importance of systemic disease and its ocular impact, its treatment and the possible ocular side effects of medication'

(4). 79% of Australian optometrists reported that they always, or often, asked patients over the age of 40 about diabetes (168).

Optometrists may be in a good position to reach a section of the population who may not routinely access other healthcare professionals. Though it is not known to what extent the population at risk of diabetes may attend an optometrist's practice, it has been shown that, in a Dutch community, 83% of the population aged over 40 years attended an eye examination over a 5-year period (181). A common reason for people not to access health care services is anxiety. This has been well documented in dental practice (182, 183), but has not been studied to any great extent in optometric practice (184). It is not known whether people are more or less likely to attend an optometrist than other health care providers.

5.2 Methods

5.2.1 Methodology

A prospective survey of capillary blood glucose levels in people attending optometry practices in North East England and determined to be at increased risk of diabetes.

5.2.2 Objectives

a) To ascertain the feasibility and practicality of using random capillary blood glucose tests (rCBG) in optometry practices as a method for the early detection of diabetes in the "at risk" population.

b) To determine the acceptability of a diabetes detection service using rCBG in optometry practice to patients.

c) To ascertain blood glucose levels in the "at risk population" attending optometry practices, with a view to identifying diabetes and pre-diabetes.

5.2.3 Outcomes

Primary Outcomes

i) An ascertainment of the proportion of the population attending optometry practices who are at risk of developing diabetes.
ii) An ascertainment of the proportion of the “at risk population” attending optometry practices who are willing to undergo tests for diabetes.
iii) An ascertainment of the capillary blood glucose levels of this group and ascertainment of the proportion of those tested who have blood glucose levels that require further investigation, either because they have diabetes or because they are in the pre-diabetic range.

Secondary Outcomes
iv) An ascertainment of the proportion of those referred for further investigation who subsequently visit their GP.
v) An ascertainment of the proportion of the ”at risk” population attending optometry practices which is diagnosed with diabetes or pre-diabetes as a result of investigations following the rCBG test.
vi) An ascertainment of the acceptability of the service to patients.

The aim of the research was to investigate whether early detection of diabetes in optometric practice was feasible. This can be considered in two parts. Firstly, whether it is worthwhile carrying out the tests. This can be determined by the yield of new cases of diabetes and pre-diabetes and those needing further medical follow up found by this particular method. The second factor to consider is the practicality and feasibility of carrying out the testing and whether it is practical to run it alongside the normal day-to-day activities of the practice

The survey is based on the use of random capillary blood glucose (finger-prick) tests using the equipment routinely used by people with diabetes to self test their blood glucose levels.

We identified three groups of people who could potentially carry out the capillary blood glucose tests.
i) Optometrists

ii) Optical assistants
iii) External researchers

The first two groups are made up of people who are normally in the practice and the third approach uses a person external to the practice, whose only role would be to carry out the blood tests. There are advantages and disadvantages to each group carrying out the tests.

Optometrists would be in a position to carry out the tests as they will see every patient attending for a sight test. However, in many practices they do not carry out basic screening tests that can be done by other trained assistants such as fields and intra-ocular pressures (IOP) using non-contact tonometry.

Trained optical assistants often carry out pre-test screening tests such as IOP measurements on those at risk of glaucoma. It has been shown that assistants can accurately measure IOP with a non-contact tonometer after 10 minutes training, as accurately as an optometrist (225). These tests are often done prior to the patient seeing the optometrist, as part of the registration process. Details such as history of diabetes, family history of glaucoma and age are recorded at this stage as this information is needed to determine whether a patient is eligible for a rNHS test. If a detection scheme is to be run on a long-term basis, it is likely that the optical assistants would be the ones to carry out the tests, or would be involved to some extent.

External researchers have the advantage in that they are not required to carry out any tasks other than the capillary blood glucose tests and recording results. Thus, patients who present with risk factors of diabetes may be less likely to be missed if the practice is busy, if the trained optical assistant is performing other tasks or if the practice is under stress.

To determine whether it is worthwhile to run a scheme to detect undiagnosed diabetes in practices, the range of rCBG measurements and the number of new cases of disease that can be detected using this method must be determined. To determine this as accurately as possible, all patients presenting with risk factors need to be offered the tests. If practices use their own staff to do this there is a risk that cases may be missed if the practice is busy or if staff are required to carry out other tasks at the time. If an external researcher is used to carry out the capillary blood glucose tests it should minimise the possibility that potential subjects may be missed.

Using an external researcher maximises the potential to find new cases of diabetes and the determination of the extent of undiagnosed diabetes in the “at risk” population attending optometrists’ practices. However, this only allows the determination of whether or not it is worthwhile offering a service to detect early diagnosis in optometric practices. If such a service is to be practical in the long-term, the tests would probably need to be carried out by a person within the practice, instead of an external researcher.

In this study, an external researcher was used to administer the blood glucose tests. This allowed us to determine whether it is worthwhile to screen in optometry practices. However, it would not allow us to determine how feasible it is with the core optometry team itself.

The researcher assistants received training in using and calibrating the monitor, carrying out the tests, explaining the test results to participants, completing the required forms and paperwork and taking informed consent. The training sessions took place at Queens Campus in 2 half day sessions.

5.2.4 Participants and setting

All optometry practices in the Teesside area were invited to take part. Letters giving an outline of the aims of the study were sent to the managers of practices listed on PCT websites. The letter described the aims of the study and how the practices would be involved. Practice managers and optometrists were asked to contact us by telephone or email if they were interested in finding out more. Meetings were arranged with staff of practices who expressed an interest in taking part and the processes explained in more detail and the equipment and forms to be used were demonstrated. These meetings took place in the practice, so that the researcher could ensure that there were sufficient facilities in the practice for the study to take place. At this meeting, we discussed the involvement of the practice, time commitment on their behalf and what facilities they would need to provide, including secure storage for participants' personal detail forms. Suitable dates for participation in the study were discussed if they were willing to allow their practice to be used as a setting for the study.

5.2.5 Protocol

When subjects attended the optometry practice for a sight test, they were provided with an information sheet explaining the study and a list of risk factors for inclusion in the study by practice staff, who asked them to read the information and let the optical assistant who would register them for the sight test know if they were interested in taking part or wished to ask any questions about the study. The information sheet was developed to give the participants information about the study, their involvement in it and general information about diabetes. The information sheet and risk questionnaire were piloted on a small group of people who were not involved in the study and had no medical background. Changes were made where necessary. The information sheet and risk questionnaire were approved by the School of Medicine and Health Ethics Committee.

The inclusion criteria and information sheet and consent form are included in appendices B and C.

Risk Questionnaires

There are a number of risk questionnaires available that have been developed and tested in different countries and on different populations. Some rely on the presence of one or more risk factors to determine whether a person is at risk (131) (132) (130). Others give each risk factor a different score. The total score is calculated and a total above a certain level indicates that a person is at risk (129).

Most risk questionnaires include factors such as age and an indicator of obesity, either BMI or waist size or both. History of hypertension and family history are also commonly included.

Online versions of the questionnaires are available from several national diabetes organisations, including Diabetes UK (234), the American Diabetic Association (235) and the Finnish Diabetes Association (236).

For this study, I used the factors listed in the Diabetes UK questionnaire. Though it is longer than some other questionnaires, it relies on the presence of one or more risk factor to determine whether a person is at risk instead of requiring an individual to carry out a calculation, which may deter some from completing the questionnaire. The time required and potential difficulty of the questionnaire is known to deter people from completing them (237). Factors included in the online Diabetes UK risk questionnaire are also currently used by pharmacists in the UK and is included in the guidelines issued by the Royal Pharmaceutical Society of Great Britain and Diabetes UK (131).

The risk factors to be included are shown in figure 12. Points A to K are based on patients self reporting risk factors as optometrists do not have

access to full history and do not normally have equipment to measure height, weight and waist size in the practice. General health, history of high blood pressure and relevant family history is routinely enquired about during the course of an eye examination. BMI is calculated from self reported height and weight. Self reported weight and height is known to be less accurate than clinical measurements since people tend to overestimate height and underestimate weight leading to underestimation of BMI (238) (239) (240). The overestimation of height is greater in the older population (241). However, this method is more useful than asking people if they are classified as overweight or obese. 25% of those with a self reported BMI of over 25kg/m^2 did not classify themselves as overweight or obese (242). Using self reported weight and height underestimates the number of people classified as overweight (BMI ≥25kg/m^2). However, if people are asked to report if they are overweight, the number of people may be underestimated to a greater extent.

Point L is not part of the Diabetes UK questionnaire and would not be given to patients as part of the initial assessment of risk. However, if the optometrist determined any of the ocular signs or symptoms during the course of the sight test in patients who had not reported any other risk factors, they would then be offered the capillary blood glucose test at that point.

Figure 12 – List of risk factors to determine if a patient should be screened for diabetes (from Diabetes UK)

A. White aged over 40 years or black, Asian and minority ethnic groups aged over 25 with first degree family history of diabetes

B. White aged over 40 years or black, Asian and minority ethnic groups aged over 25 with BMI of 25 kg/m^2 and above

C. Waist measurement of ≥94cm (≥37 inches) for white men aged over 40 years and black men aged over 25 years and ≥90cm (35 inches) for Asian men aged over 25, and ≥80cm (31.5 inches) for white women aged over 40 years and black and Asian women aged over 25 years.

D. People who have ischaemic heart disease, cerebrovascular disease, peripheral vascular disease or treated hypertension

E. People who are known to have impaired glucose tolerance or impaired fasting glycaemia

F. People with severe mental illness (SMI)

G. People who have raised cholesterol.

H. Women who have had gestational diabetes who have tested normal following delivery

I. Women who have given birth to a baby weighing more than 4kg (8lb 8oz)

J. Women with polycystic ovary syndrome and a BMI ≥ 30 kg/m^2

K. People experiencing symptoms of diabetes (Increased thirst, going to the toilet all the time, extreme tiredness, weight loss, genital itching or regular episodes of thrush, slow healing of wounds, blurred vision)

L. Ocular signs/symptoms of diabetes – dot/blot haemorrhages, recurrent infections, variable refraction, complaints of visual disturbances, early appearance of cataract.

If the patients reported that they had no risk factors present, the registration and sight test continued as normal.

If patients reported any risk factors, they were offered the opportunity to talk to the researcher regarding participation in the study. If they were interested in taking part, they were handed over to the researcher. In some practices, this occurred before the sight test and after the normal pre-screening checks. In other practices, this was done immediately after the sight test had taken place. The timing of the test was different in different practices to fit in with the way they would normally operate. In some practices, field tests and IOP measurements would be routinely measured by optical assistants prior to the sight test. In other practices, these tests would be done only if the optometrist requested them after the sight test.

If optometrists found any ocular signs possibly indicative of diabetes (Point L in figure 12), they could offer the blood test at the end of the eye examination. If patients participating in the study were found to have any signs or symptoms of ocular conditions unrelated to diabetes during the course of the eye examination, they were referred to their GP in the normal way for the practice by the optometrist.

If patients agreed to participate, they were asked to read the information sheet and the study and their study involvement was explained to them by the research assistant. Permission was sought to pass the information on to the participants' GP if the rCBG level was shown to be elevated. Permission was also sought for the researcher to contact those participants who were referred in order to determine the outcome of any investigations by the GP following the referral. The participants were asked to complete a consent form and some demographic details.

Capillary blood glucose measurement was taken using the Bayer Acensia Contour® monitor. These monitors were checked with control solutions (high, low and normal) each morning before testing began, and again if a

new box of test strips was opened. Results of quality control tests are given in appendix F.

Cut off points for random capillary blood glucose levels

Tests that can be used to screen for diabetes can also be used to screen for pre-diabetes, which is defined as either impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) or both. It has been recognised that people with IGT and IFG are at risk of going on to develop diabetes (99). BMI and waist size have been shown to be predictors of the development of diabetes in people with IGT in some studies (98). As these are modifiable risks, it suggests that the identification of people with IGT can be of benefit. It has been shown that lifestyle intervention can successfully reduce some risk factors for diabetes such as BMI and improve activity and diet (243) and reduce the risk of progression to diabetes (104) (102) (103).

It has been calculated that a cut off point of 6.7 mmol/l (whole blood (WB)) is the most efficient to screen for diabetes, while 5.6 mmol/l is the most efficient for screening for diabetes and pre-diabetes (149). Using a cut off of 6.7 mmol/l on a random capillary blood glucose test is calculated to have a sensitivity of 68% and specificity of 89% for diabetes (149). The lower cut off point of 5.6 mmol/l has been found to be 62% sensitive and 70% specific for diabetes and pre-diabetes (149). For diabetes alone it is calculated to have sensitivity of 83% and specificity of 63%(149). The Diabetes UK ‘Measure Up’ campaign recommends that people with a random capillary blood glucose of 5.6 mmol/l or more should have further investigation as there is the possibility of IFG, IGT or diabetes. UK Pharmacy guidelines state that, for random blood glucose levels between 5.6 and 11.0mmol (WB), patients should be retested using fasting blood levels. The guidance suggests that this should be carried out by the GP (244), but some pharmacies carry out the fasting test themselves and only refer to the GP if the fasting level is also raised (Lloyds Pharmacy, personal correspondence).

It would not be always be convenient for optometry practices to carry out a repeat fasting blood test.

We selected a cut off point of 5.6 mmol/l (WB) or 6.1 mmol/l (plasma equivalent (PE)) for random CBG measurements to screen for diabetes and pre-diabetes. The Bayer Acensia® meter uses a whole blood sample, but converts the results to a plasma equivalent reading.

Patients with values below this were advised that, though it is unlikely that they have diabetes at present, they still have risk factors that increase that chances of developing diabetes, so they should be aware of the symptoms and see their GP for a regular check or if they have any concerns. They were given a copy of their results with this information. The results forms are included in appendix D.

Patients with a random CBG level of 6.1 mmol/l (PE) or above were referred to their GP using a standardised form (appendix E). This form included a recommendation to the GP for the need for further investigation.

Random and fasting blood glucose levels

Random blood glucose tests cannot be used for the purpose of diagnosis. In this study, we were not aiming to diagnose diabetes, but establish the feasibility of using this method of testing and to determine the range of blood glucose levels in adults at risk of diabetes who attend optometric practices and identify those who would benefit from further fasting tests.

Fasting tests have the advantage that they can be used in the diagnosis of diabetes. However, they are not suitable for opportunistic screening. We were aiming to offer this as a service as people come in to a practice for routine sight tests. Some patients will not have arranged the sight test

in advance and it is not feasible to expect these people to be fasting. Random glucose tests are suitable for selecting patients who would benefit from a fasting blood glucose measurement.

For the purposes of this study, we did not intend to ask patients whether they were fasting. We were using guidelines for referral using random blood glucose tests as suggested by Diabetes UK and the Royal Pharmaceutical Society of Great Britain (244). A comparison of the guideline for random and fasting blood glucose measures is shown in figure 13.

Figure 13 - Guidelines for referral using random and fasting capillary blood glucose measurements

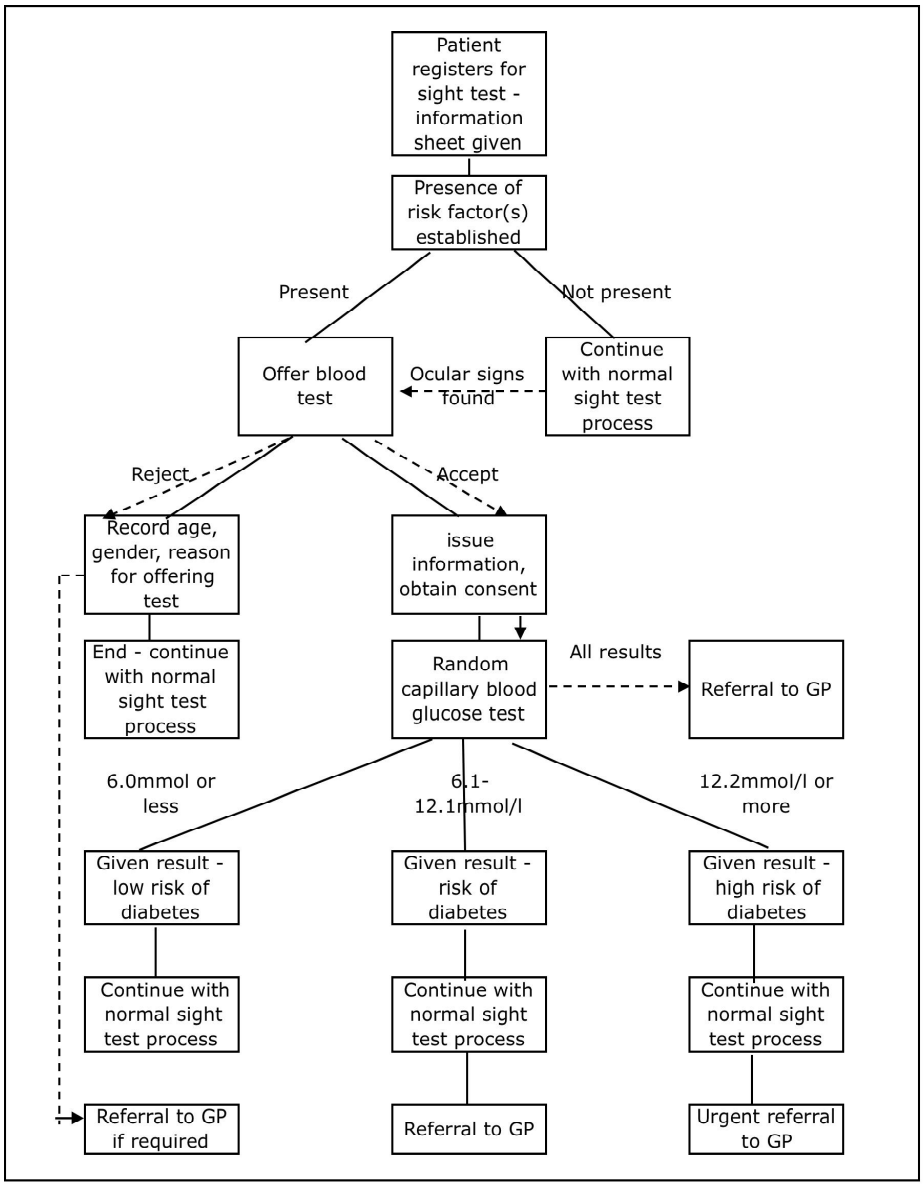
Results in mmol/l (plasma equivalent)	**Fasting**	**Random**
<6.1	Low probability of diabetes	Low probability of diabetes
6.1-6.9	Probability of IFG – routine referral to GP	Retest recommended with fasting test. Refer to GP
7.0-12.1	Probability of diabetes – routine referral to GP	
≥12.2	High probability of diabetes – refer urgently	Refer to GP soon

Using these guidelines, anyone with a blood glucose measurement of 6.1mmol/l or over were referred to their GP regardless of whether they were fasting at the time of the test.

The participants were given a copy of their result along with information about action that they should take. Participants with blood glucose levels below 6.1 mmol/l were told they had a low probability of diabetes at the present time and were given advice about the risk reduction. Those with levels between 6.1 mmol/l and 12.1 mmol/l were advised that it was not possible to rule out diabetes, IFG or IGT and further testing was required. They were asked to see their GP routinely. Those with levels 12.2 mmol/l and above were asked to see their GP within 2 days. These referral levels were chosen as they are current UK guidelines on referral for pharmacists carrying out rCBG tests. If a person was found to have a glucose level of 20 mmol/l or above and symptoms of diabetes, but did not have next day access to their GP, they were advised to go to their local casualty department or ring NHS Direct,

The pathway that a patient will follow when they attend the practice is shown in figure 14.

Figure 14 Participant pathway



The research assistant carrying out the test recorded the blood glucose level, date of birth, gender and risk categories. Each participant was identified by a code, which allowed the researcher to identify the practice where the test was carried out, but not the individual participant. The personal details of participants were held in the practice with a list of the codes and the persons to whom those codes related.

The number of adults seen in the practice each day was recorded so that the proportion of the population attending the optometry practice who reported risk factors for diabetes could be calculated. The number of people who were eligible to take part but refused and the number of adults with previously diagnosed diabetes was also recorded.

The study continued until 1000 patients had been screened. From previous research, a prevalence of 3% was predicted for undiagnosed diabetes and 6% for undiagnosed IGT, IFG and diabetes. To detect a prevalence of 6% with an acceptable deviation of 1.5% required a sample of 954 people. It was conservatively estimated that between 3 and 5 participants who are at risk of developing diabetes would be recruited per optometrist testing per day.

Testing was carried out in each practice for a 4 week period. This allowed several practices to be used so that different practice types (multiple, independent) would be included.

Each participant was given a questionnaire immediately following the blood glucose test to complete and return to determine the acceptability of the service to participants. The questionnaire development and choice of method is discussed in chapter 8.

All participants who were referred to their GP were sent a postal questionnaire to determine the outcome of the referral. The

questionnaires were sent out via the practices as they held a list linking the personal details of participant to the code held by the researcher.

Participants were asked whether they visited their GP following the results of the blood test. If they did, they were asked if they were investigated for diabetes. If any investigations were made, they were asked what the outcomes were. The questionnaire is included in appendix G. The questionnaire was piloted on a small group of people who were not involved in the study, and changes were made to the wording and layout where appropriate. The final questionnaire was approved by the School of Medicine and Health ethics committee.

A written postal questionnaire to the participant was chosen for this. We could have arranged for the further fasting blood glucose tests to be carried out at a central location. However, this would not be how we would envisage a screening service working, if implemented. The local GPs would be involved in carrying out any further testing and in the continuing care of the participants if they had the screening carried out at other locations. We could also have contacted the GP practice to determine the results of follow up testing.

Every participant in the screening service, who had a rCBG measurement of 6.1mmol/l or over, received the questionnaire four to eight weeks after being given the results of the blood glucose test.

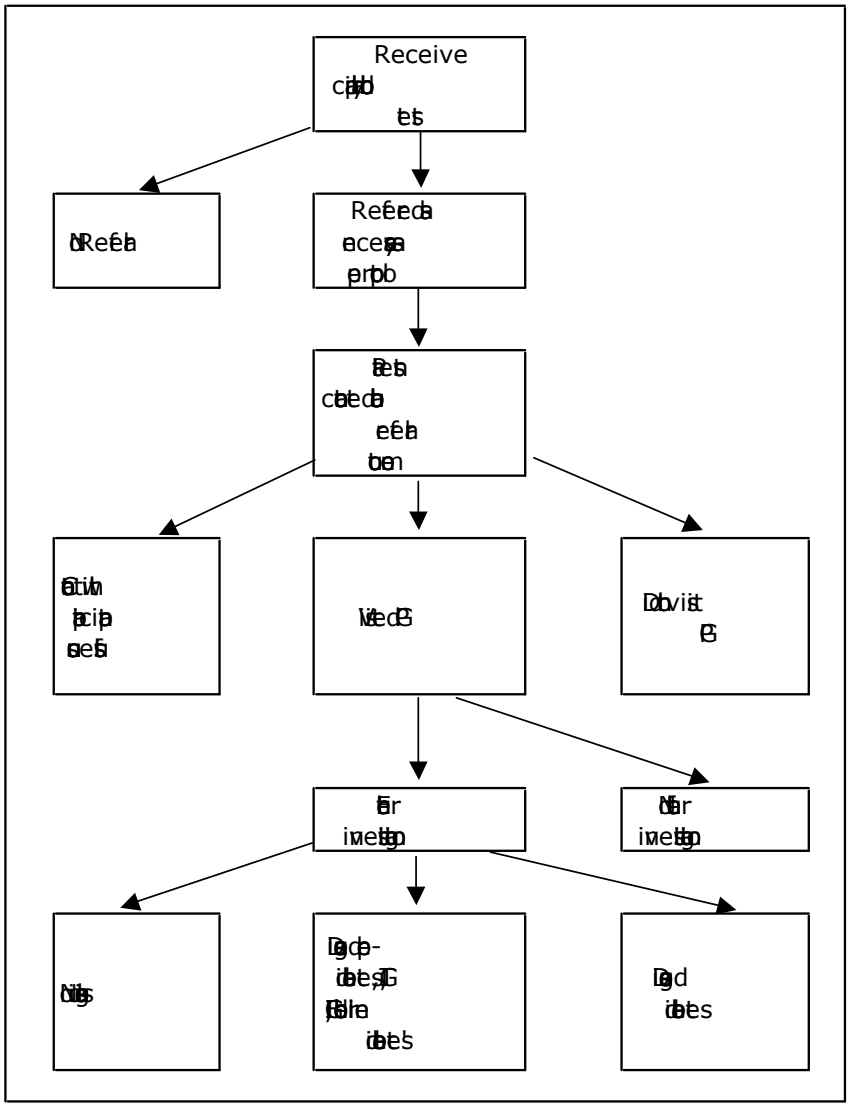
Participants were given a stamped addressed envelope to return the questionnaire to the researcher. A second letter was sent to participants who had not replied within one month of the first letter, to increase the response rate.

Each questionnaire was labelled with the participant's ID number so responses could be linked with the details of their blood glucose tests, gender and practice where the screening occurred.

The results were entered into a database and analysed in SPSS 15.0. Independent samples t-test and Pearsons chi-squared tests were used as appropriate.

The pathway for patients who received the capillary blood test is shown in figure 15.

Figure 15 - Pathway for patients who receive a capillary blood glucose test



5.2.6 Locations and practices

The screening service was implemented in five optometry practices in three towns in North East England: Redcar, Hartlepool and Peterlee.

Redcar is situated in Redcar & Cleveland, which has been designated a Spearhead area. These are the 70 Local Authority (LA) areas in England with the worst health and deprivation indicators. Life expectancy is 76.0 years for men and 80.6 years for women (Average for England is 77.7 and 81.8 years respectively). Indicators for this area which are significantly worse that the England average include life expectancy, over 65s 'not in good health', deprivation and early deaths from smoking, cancer and heart disease (245).

Hartlepool is also a Spearhead area, with life expectancy for women and rates of healthy eating among adults the worst in England. Significantly worse rates of obesity, binge drinking, over 65s 'not in good health' than England as a whole are found in this area (246).

Peterlee is situated in the Easington district in County Durham. The Health Profile for Easington designated it a Spearhead area. In 2009, Easington was not published as a distinct area, but was included as part of County Durham. Like Hartlepool and Redcar & Cleveland, the rates of over 65s 'not in good health', binge drinking and life expectancy in County Durham and Easington is significantly worse than England average (247).

Health indicators for Easington, County Durham, Hartlepool and Redcar & Cleveland are shown in figure 16, alongside average and worst values for England.

Figure 16 - Health indicators for Redcar & Cleveland, Hartlepool and County Durham (from APHO & Department of Health Health Profile 2008 and 2009)

	Redcar & Cleveland	Hartlepool	Co. Durham	Easington	England Average	England Worst
Life expectancy – Men[1]	76.0	74.5	76.1	74.9	77.7	73.2
Life expectancy – women[1]	80.6	78.1	79.9	79.2	81.8	78.1
Deprivation[2]	33.7%	46.7%	31%	64.0%	19.9%	89.2%
Adults who smoke[3]	26.8%	33.2%	24.5%	24.1%	24.1%	40.9%
Obese adults[3]	25.3%	26.2%	25.3%	28.9%	23.6%	31.2%
Over 65s 'not in good health'[4]	26.8%	27.2%	29.8%	Not available	21.5%	31.2%
Diagnosed with diabetes[5]	4.0%	3.7%	4.0%	3.6%	4.1%	6.3%

1. Life expectancy at Birth 2005-07 for Hartlepool, Redcar & Cleveland, County Durham and England. Life expectancy at birth 2004-06 for Easington
2. % of people living in the 20% most deprived areas of England 2007 (2005 for Easington)
3. % from modelled estimate from Health Survey for England 2003-05
4. % self reported general health 'not good' 2001
5. % of people on GP register with diagnosis of diabetes 2007/08 (2005/06 for Easington)

The rates of diabetes recorded in figure 16 reflect GP records from 2007/08 (2005/06 for Easington), so although they indicate that the prevalence of diabetes is lower than the national average in these three areas, it possibly reflects diagnosed diabetes rather than actual rates of disease. Predicted prevalence of Type 2 diabetes is calculated to be higher than the diagnosed rate. Figure 17 shows the predicted prevalence of Type 2 diabetes, both diagnosed and undiagnosed, in the local Authority area of Redcar & Cleveland, Hartlepool, Easington and County Durham PCT for 2005.

Figure 17 - Predicted prevalence of Type 2 diabetes, diagnosed and total prevalence (from PBS Diabetes Population Prevalence Model and APHO & Department of Health Health Profile 2009)

	Redcar & Cleveland	Hartlepool	Co. Durham	Easington (Peterlee)
Type 2 Diabetes prevalence 2005(diagnosed & undiagnosed)	4.46% (Male 3.66% Female 5.21%)	4.19% (Male 3.42% Female 4.92%)	4.32% (Male 3.50% Female 5.10%)	4.64% (Male 3.75% Female 5.47%)
Diagnosed diabetes 2007/08	4.0%	3.7%	4.0%	3.6% (2005/06)

Practices A and B are located in Redcar, C and E in Hartlepool and D in Peterlee. Practice A, C and D are independent practices, with one optometrist testing most days. A also employed a pre-registration optometrist who also tested on some days. There were 2 optometrists testing on some days in practice C. Practice B and D were both multiple franchises, with between one and three optometrist testing at one time. Practice B was open 7 days a week, whereas all the others opened 6 days.

Chapter 6

Detection of diabetes in optometric practice: part 2 – results of capillary blood glucose testing

Chapter 6

Detection of diabetes in optometric practice: part 2 – results of capillary blood glucose testing

The results were entered into a database and analysed in SPSS 15.0. Independent samples t-test were used to compare means and Pearsons chi-squared tests to compare proportions. The independent samples t-test compares means of two groups and tests the null hypothesis that there is no difference between the two groups (248). The chi-squared test is a non-parametric test used to compare groups (249).

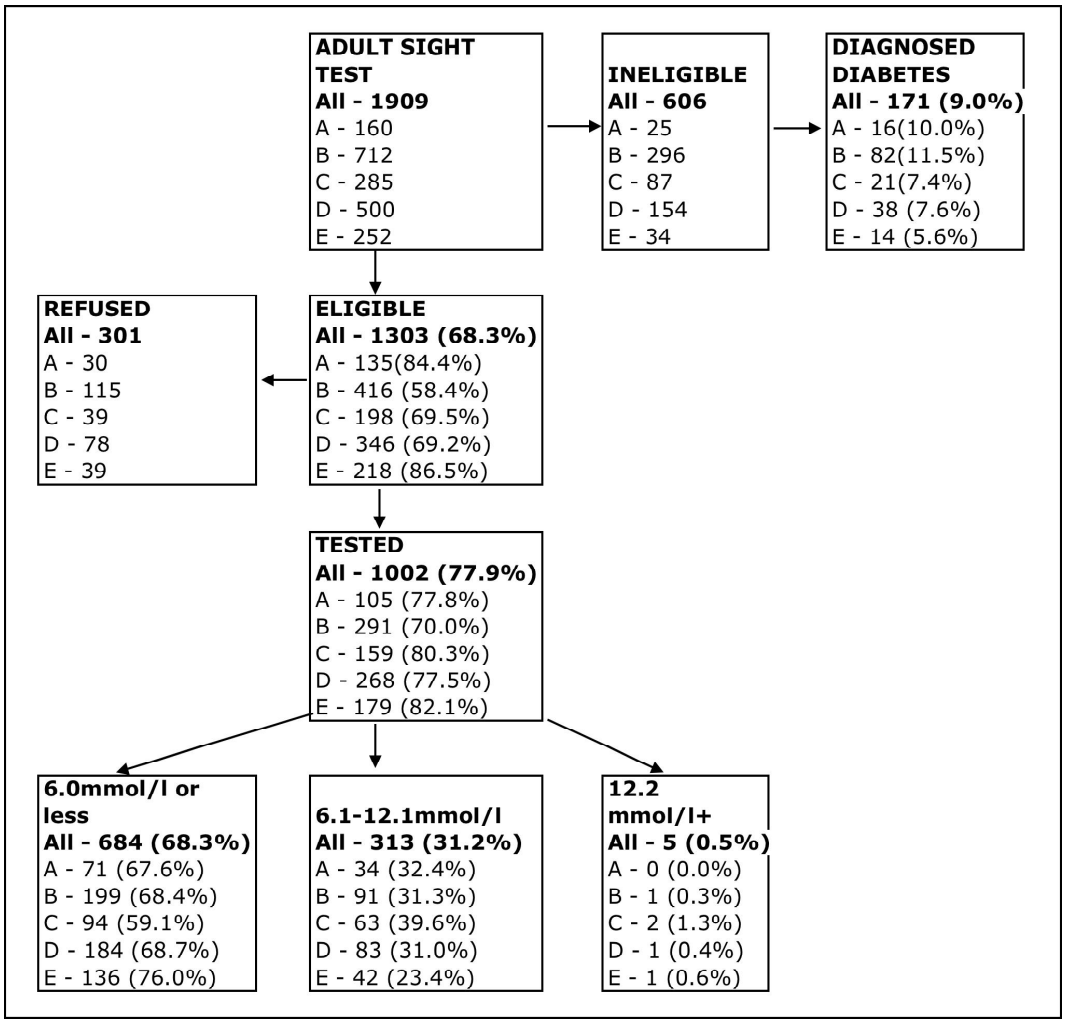
6.1 Participants

During the 20 weeks of the study (4 weeks in each of 5 practices), 1909 adult sight tests were carried out. Of these 171 (9.0%) adults had previously diagnosed diabetes (either Type 1 or 2). 1303 (68.3%, 95% CI 66.1%-70.3%) of adults attending practices) reported that they had one or more risk factor and so were eligible for inclusion in the study. 1002 (77.9%, 95% CI 74.5%-79.2% of those eligible) agreed to participate.

318 (31.7%, 95% CI 28.8%- 34.7%) had a random capillary blood glucose measurement of 6.1mmo/l or more, and so were asked to see their GP for further investigations.

Figure 18 shows the numbers of adults attending practices during the study period, their eligibility to participate and the outcomes of testing.

Figure 18 Numbers of adult sight tests, adults with diabetes and adults eligible to participate attending the 5 practices (A-E) during the study period



6.1.1 Demographics of Participants

Participants had a mean age of 54.40 years, SD=16.3 years. 65.2% were female and 99.0% were white. Demographic details of participants are shown in figure 19.

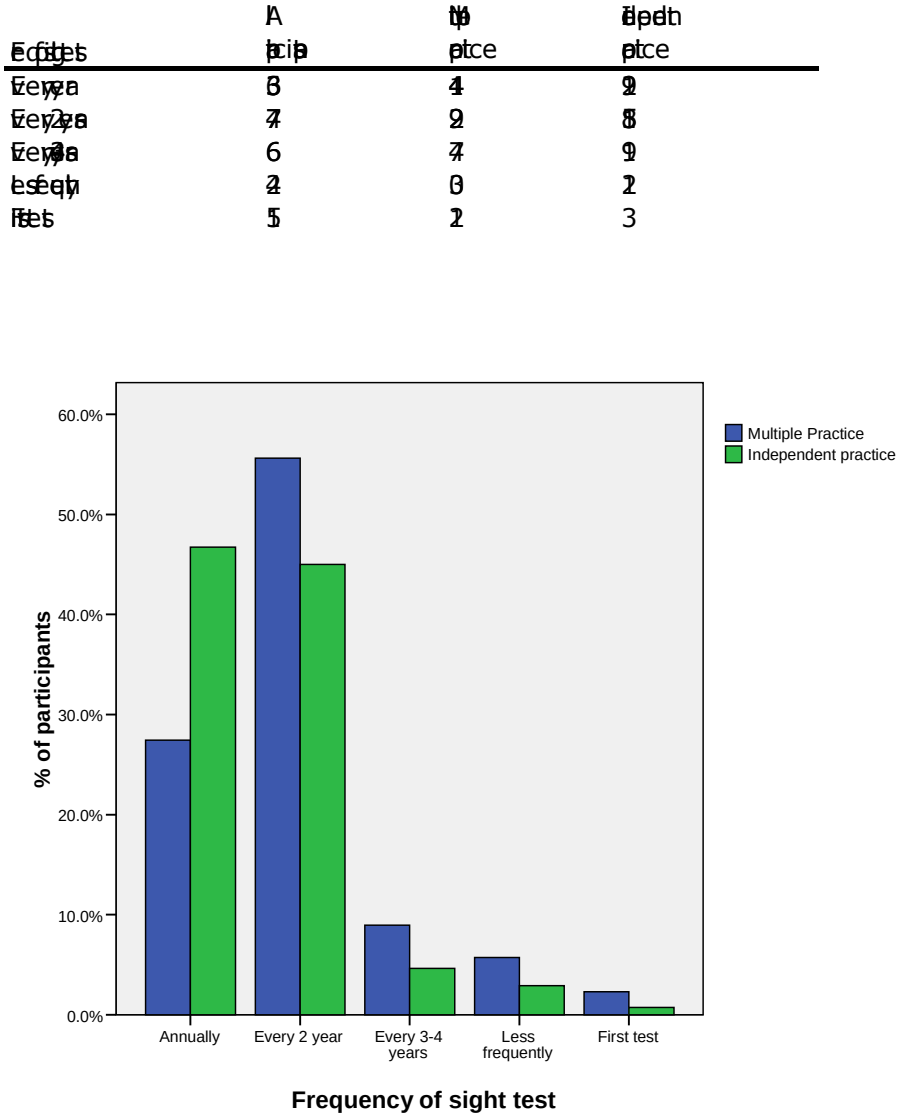
Figure 19 Demographic details of the participants, by practice, by gender and by practice type

	[illegible]	A	B	C	D	E
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible] (16.3)	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

6.2 Results

936 participants completed a questionnaire reporting the frequency which they attended for sight tests and whether they had been screened or tested for diabetes previously. 81.1% reported attending at least every two years. This is shown in figure 20. Independent practices (A, C and E) had a larger proportion of people attended for sight tests on yearly basis than the multiples (B and D). This may relate to the fact that the mean age of people attending independent practices was older than for those attending multiples. While most people who are eligible for a reimbursed NHS sight test can claim one every two years, those over 70 years of age are entitled to receive a reimbursed test every year.

Figure 20 Frequency of sight tests for all participants and by practice type



75% (698) reported that they had never been screened for diabetes previously. Figure 21 shows the self-reported occurrence of previous diabetes testing among the participants by gender, outcome of the rCBG test and the practice type the participants attended.

No significant difference was found in between males and females, with 75.5% of men and 74.7% of women reporting that they had not been screened previously. Similarly there was no significant difference

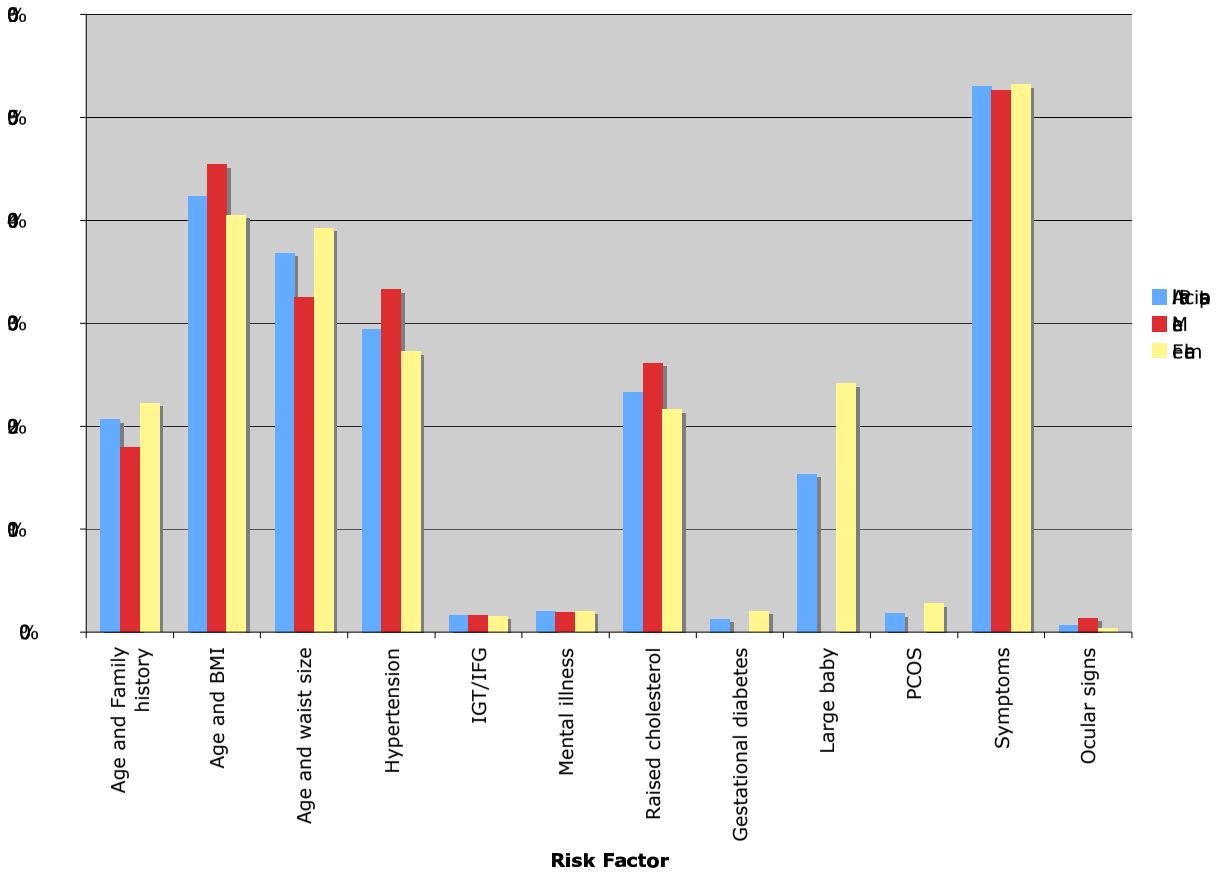
between the whether the rCBG measurement required further investigation or not and whether people had ever been screened previously. 76.4% of those who were found to have rCGB measurement of 6.0 or less had never been screened before compared with 71.9% of those with a rCBG of 6.1mmo.l or more. Slightly more people attending multiple practices (78.0%) reported that they had never been screened compared with 71.1% in independent practices.

Symptoms (53.0%), age and BMI (36.8%) and age and waist size (29.4%) were the most commonly reported risk factors. There was no significant difference for the prevalence of most risk factors between the genders. The exceptions to this were age and waist size which was reported slightly more frequently in women (39.3%) than men (32.5%) and hypertension which was reported more frequently by male (33.3%) participants than female (27.2%). This is shown in figures 21a and 21b. The mean number of risk factors reported was 2.28.

Figure 21a Self reported prevalence of the presence of risk factors

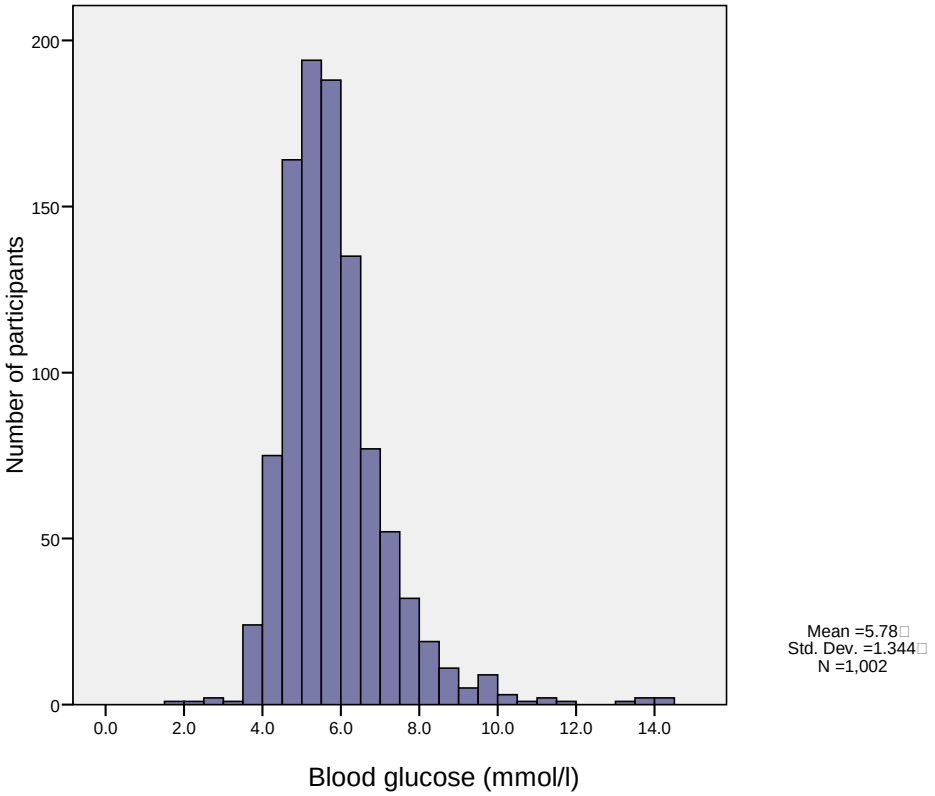
Risk factor	Participants		Men		Women		chi	p	
Age 45-54 years									
Hypertension	2	2%	6	3%	4	2%	3	0	
Age and BMI	4	4%	6	5%	9	5%	2	0	
Age and waist size	9	8%	8	4%	1	9%	7	0	*
Diabetes	1	2%	1	3%	4	2%	5	0	*
Stroke	6	6%	6	7%	0	6%	0	2	
Vascular disease	2	2%	7	3%	1	2%	0	9	
Raised cholesterol	3	2%	5	2%	8	4%	2	0	
Other risk factors	3	3%	-	-	3	2%	NA		
Family history	5	5%	-	-	5	2%	NA		
BMI	8	8%	-	-	8	2%	NA		
Symptoms	5	9%	1	2%	0	2%	2	6	
Other	7	7%	5	4%	2	0%			

Figure 21b Self reported prevalence of the presence of risk factors



The distribution of blood glucose measurements of all participants is shown in figure 22.

Figure 22 - Distribution of random capillary blood glucose measurements



The mean rCBG was 5.78mmol/l (95% CI 5.69-5.86 mmol/l). The minimum recorded was 1.9 mmol/l and the maximum 14.4mmol/l. Men were found to have a higher mean rCBG measurement (5.91mmo/l) when compared with women (5.70mmol/l). However, women tended to report more risk factors (2.37) than men (2.13). There was no difference between the genders in mean age (men 55.1 year, women 54.0years).

There was no significant difference between the mean blood glucose between the two practice types but the mean age in independent practice

(56.8 years) was significantly higher than that in multiple practices (52.5 years). Details are shown in figure 23.

Figure 23 - Age, blood glucose and risk factors by gender and practice type

	Male (n=363)		Female (n=639)				
	Mean	SD	Mean	SD	t	p	
Age (years)	55.1	16.3	54.0	16.3	1.06	0.29	
Blood Glucose (mmol/l)	5.91	1.47	5.70	1.26	2.32	0.02	*
No of risk factors	2.13	1.26	2.37	1.39	-2.80	0.005	*

	Multiple (n=559)		Independent (n=443)				
	Mean	SD	Mean	SD	t	p	
Age (years)	52.5	16.3	56.8	16.0	-4.20	<0.001	*
Blood Glucose (mmol/l)	5.77	1.30	5.78	1.40	-0.10	0.92	
No of risk factors	2.31	1.35	2.25	1.34	0.62	0.54	

363 (31.7%, 95% CI 28.8%- 34.7%) had a rCBG of 6.1 mmol/l or more.

There was no significant difference in the proportion of people with a rCBG of 6.1mmo/l or more in the two different type of practice, with 32.1% of those attending independent practices and 31.5% of those attending multiple practices requiring further investigation.

There was a significantly larger proportion of men (38.0%) than women (28.2%) who required further investigation following the rCBG test. This is shown in figure 24.

Figure 24 rCBG category by gender and practice type

	<6.1		≥6.1		chi-square	p	
Male	225	62.0%	138	38.0%			
Female	459	71.8%	180	28.2%	10.36	0.001	*
Independent	301	67.9%	142	32.1%			
Multiple	383	68.5%	176	31.5%	0.37	0.847	

Direct logistic regression was performed to see which risk factors had a significant impact on whether a participant had a rCBG of 6.1mmol/l or more and required further testing (250). All risk factors (A-L), age and gender were entered in a forward regression analysis. Age, gender, risk factor A (age and family history) and B (age and BMI) where statistically significant predictors of referral. Backward logistic regression was also performed and gave the same results. Presence of family history, BMI over 25kg/m^2 and increasing age increased the probability that someone had a rCBG measurement of 6.1mmol/l or more. Females were less likely to have a rCBG that required further investigation than men. The odds ratio for age indicates that, for each increased year of age, the likelihood of having a rCBG of 6.1mmol/l or more increased 1.01 times. Details are shown in figure 25.

Figure 25 Logistic regression predicting the likelihood of a rCBG measurement of 6.1mmol/l or more

							95% CI for odds ratio	
	B	S.E	Wald	df	p	Odds ratio	Lower	Upper
Family History	0.341	0.166	4.216	1	0.040	1.406	1.016	1.948
BMI	0.328	0.141	7.305	1	0.007	1.465	1.111	1.932
Gender	-0.441	0.142	9.672	1	0.002	0.643	0.487	0.849
Age	0.14	0.004	9.388	1	0.002	1.014	1.005	1.023
Constant	-1.495	0.273	29.935	1	0.000	0.224		

6.3 Discussion

31.7% of the participants had a rCBG of 6.1 mmol/l or more (5.6mol/l whole blood). This is a similar referral rate to a Danish stepwise screening programme, where high risk individuals were invited to have random blood glucose tests and continued to a fasting test if random whole blood glucose was greater then 5.5mmol/l. In this study, 30.1% required the fasting test (251). An Australian pharmacy study, also using 5.5mmol/l as the cut off point for further tests, found 38.8% were referred for further investigation (130).

The referral rate in this study was lower that that found in a UK pharmacy using the same RPSGB/Diabetes UK guidelines as used in our study (1). They found a prevalence of rCBG of 6.1mmol/l or more of 42.7% compared with 31.7% in our study. However, the populations differed in that our population was predominately white, whereas nearly 50% of the participants in the pharmacy study were South Asian. They reported the prevalence of rCBG of 6.1mmol/l or more of 42.7% for the South Asian participants compared with 18.3% among the white participants.

Chapter 7

Detection of diabetes in optometric practice: Part 3 – results of referral to GP following capillary blood glucose measurement

Chapter 7

Detection of diabetes in optometric practice: Part 3 – results of referral to GP following capillary blood glucose measurement

7.1 Participants

Questionnaires were sent to all 318 participants who had a blood glucose measurement of 6.1mmol/l or more between 4 and 8 weeks after the initial screening test. Further reminders were sent 4 weeks later to all those who had not replied or had replied to say they were waiting for results.

228 replies were received following 2 letters (response rate of 71.7%) Response rates from individual optometry practices varied from 62.4% to 81.5%. Response rate and details of respondents and non-respondents are shown in figure 26.

Figure 26 Response rate to follow-up questionnaire for each practice and characteristics of respondents

Practice	Participants with blood glucose ≥6.1mmol/l	Responses	Response rate
All	318	228	71.70%
A	34	27	79.40%
B	91	66	72.50%
C	65	53	81.50%
D	85	53	62.40%
E	43	29	67.40%

	Non-responders (n=90)		Responders (n=228)				
	Mean	SD	Mean	SD	t	p	
Age (Years)	49.0	15.7	60.7	14.7	-6.093	<0.001	*
Blood Glucose (mmol/l)	7.10	1.35	7.28	1.33	-1.09	0.28	
Risk factors	2.52	1.46	2.45	1.30	0.45	0.66	

Non-respondents (mean 49.0 years) were significantly younger than those responding (mean 60.7 years) to the questionnaire.

However, there was no significant difference in the mean rCBG between the two groups; non-responders 7.10mol/l, responders 7.28mmol/l. The mean number of risk factors was also not significant in whether participants returned the questionnaire; non-responders 2.52 risk factors, responders 2.45.

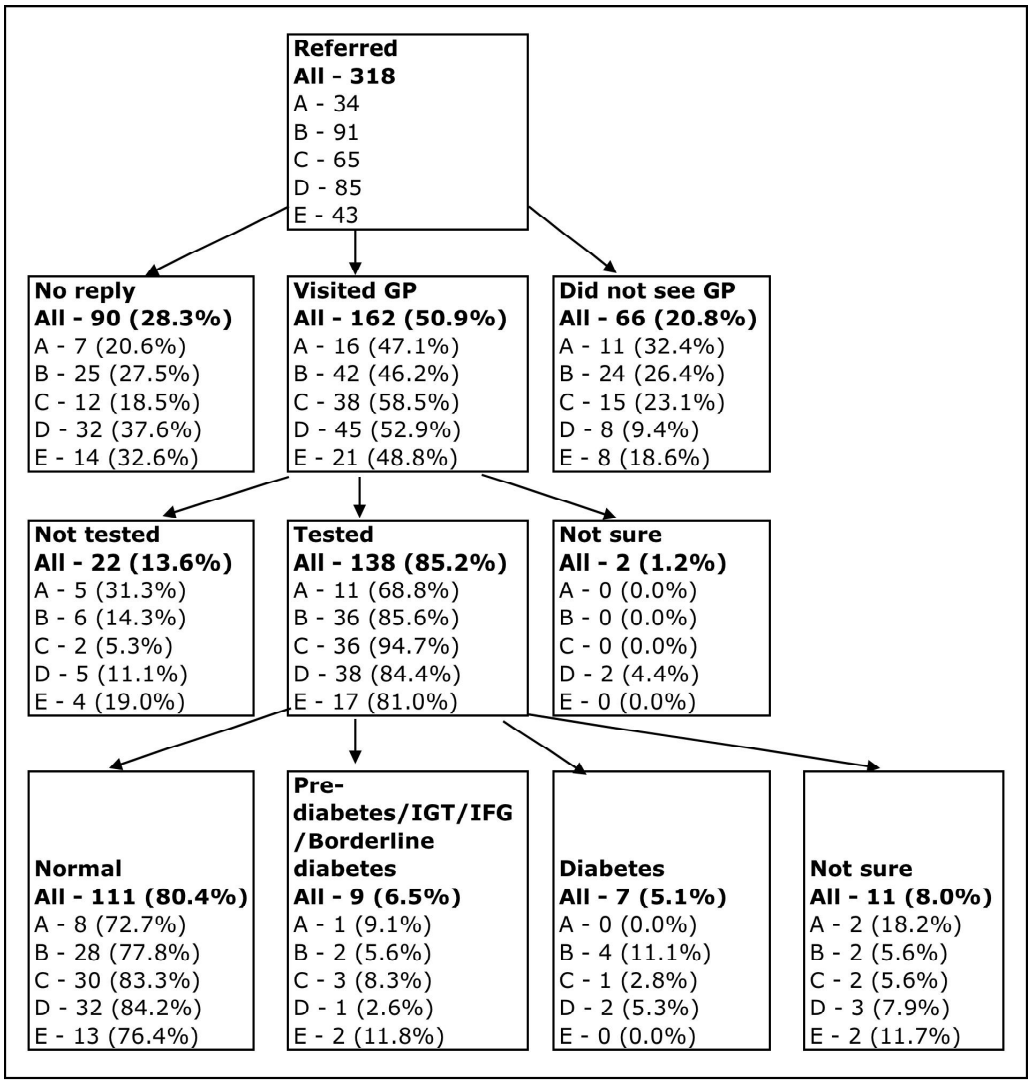
7.2 Results

Figure 27 show the summary of the participants who had a random capillary blood glucose level of 6.1mmol or above.

No response was received from 90 participants (28.3% 95% CI 23.4% - 33.6%).

66 of the 228 respondents (29.0% 95% CI 23.1%-35.3%) reported that they did not visit their GP. 71.1% (95% CI 64.7%-76.9%) of those responding reported that they did attend their GP. Of the 162 who did visit their GP, 85.2% (95% CI 78.8%-90.3%) reported that the GP carried out some form of further testing. 11.6% (95% CI 6.8%-18.1%) of those tested by a GP reported that they had been diagnosed with either diabetes, pre-diabetes, borderline-diabetes, IGT or IFG. Details are shown in figure 27.

Figure 27 - Summary of the participants who were referred following random capillary blood glucose test



Of the 318 participants who had a random capillary blood glucose level of 6.1mmol/l or more at the screening test, 43.4% reported attending their GP and undergoing further investigations. Just under one third (28.9%) of those who responded reported that they did not visit their GP.

While there was no significant difference in age of the participants who reported that they did attend the GP (60.5 years, 95% CI 58.3-62.7 years) and those who did not (61.0 years, 95% CI 57.2-64.8 years), there was a significant difference in mean blood glucose. Those who attended the GP had a higher mean rCBG (7.44mmol/l, 95% CI 7.21 - 7.68mmol/l), range 6.1 to 14.3mmol/l) than those who reported that they did not attend (6.88mmol/l, 95% CI 6.71 – 7.04mmol/l, range 6.1 to 9.3).

The mean number of risk factors reported did not make a significant difference as to whether participants made the decision to visit the GP (2.51, 95% CI 2.32-2.71) or not (2.29, 95% CI 1.95-2.63). Gender and practice type did not significantly affect whether participants made the decision to attend their GP for further investigation. Details are shown in figure 28.

Figure 28 Mean age, rCBG, risk factors, gender and practice type of participants who reported attendance or no attendance at their GP

	Attended GP (n=162)		Did not attend GP(n=66)				
	Mean	SD	Mean	SD	t	p	
Age (Years)	60.5	14.4	61.0	15.5	-0.231	0.818	
Blood Glucose (mmol/l)	7.44	1.48	6.88	0.67	3.96	<0.001	*
Number of risk factors	2.51	1.257	2.29	1.39	1.185	0.237	

	Attended GP		Did not attend GP			
	n	%	n	%	χ^2	p
Male	66	69.5%	29	30.5%	1.176	0.555
Female	96	72.2%	37	27.8%		
Multiple	87	73.1%	32	26.9%	3.757	0.153
Independent	75	68.8%	34	31.2%		

Not all of those who reported that they visited their GP received further tests. 22 (13.6%, 95% CI 8.7-19.8%) of the 162 who reported that they attended their GP, reported that no further investigations were carried out. A further two participants (1.2%, 95% CI 0.2-4.4%) were unsure as to whether any tests had been done. There was no significant difference between the mean blood glucose of those tested (7.49mmo/l, 95% CI 7.25 – 7.74mmol/l) or not tested (7.08mmol/l, 95% CI 6.38 – 7.78mmol/l). Those not tested had a range of rCBG from 6.1mmol/l to 13.6 mmol/l, compared with 6.1 to 14.3mmol/l for those reporting that they underwent further investigations. There was also no significant difference noted in the mean number of risk factors or mean age of those who were investigated further and those reporting that no tests were carried out. Details are shown in figure 29.

Figure 29 Mean age, rCBG and risk factors for those attending their GP who reported further investigations or no further investigations carried out

	Further investigations (n=138)		No further investigations (n=22)			
	Mean	SD	Mean	SD	t	p
Age (Years)	60.2	14.2	60.6	15.2	-0.140	0.888
Blood Glucose (mmol/l)	7.49	1.48	7.08	1.57	1.217	0.226
Number of risk factors	2.49	1.27	2.68	1.21	-0.675	0.5

Of the 138 who underwent further tests at their GP, 111 (80.4%, 95% CI 72.8 – 86.7%) reported that they were 'normal' or were given no diagnosis. 7 (5.1%, 95% CI 2.1-10.2%) were given the diagnosis of diabetes. 9 (6.5%, 95% CI 3.0 - 12.0%) reported a diagnosis of a non-diabetic hyperglycaemic condition (2 IGT, 2 IFG, 1 pre-diabetes and 4 borderline diabetes). 11 (8.0%, 95% CI 4.1 – 13.8%) were not sure of the results of the tests.

Those who were given a diagnosis of a hyperglycaemic conditions have a higher mean rCBG (8.90mol/l, 95% CI 7.62 – 10.18mmol/l) than those who were not (7.28mmol/l, 95% CI 7.06 – 7.51mmol/l). There was no significant difference between the mean age and the mean number of risk factors of those who were diagnosed as having normal glycaemic levels and those with diabetes or a pre-diabetic condition. Details are shown in figure 30.

Figure 30 Mean age, rCBG and number of risk factors of those diagnosed with hyperglycaemia and normal glycaemic levels

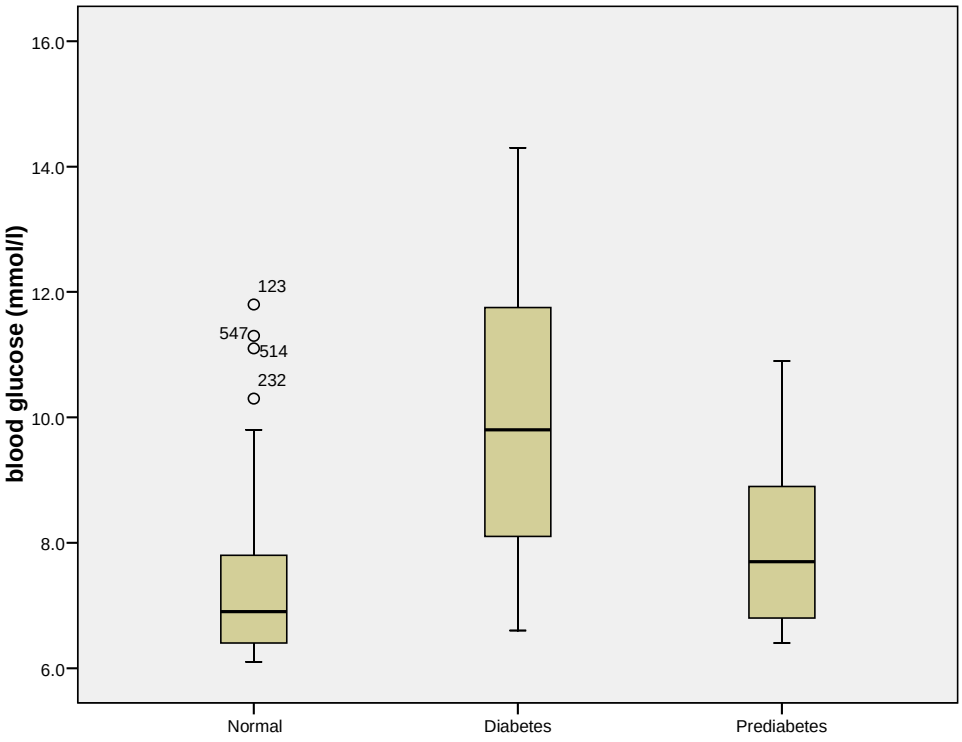
	Normal blood glucose (n=111)		Hyperglycaemia (n=16)				
	Mean	SD	Mean	SD	t	p	
Age (Years)	59.9	13.7	60.3	16.0	-0.110	0.931	
Blood Glucose (mmol/l)	7.28	1.21	8.90	2.39	-2.648	0.017	*
Number of risk factors	2.48	1.19	2.94	1.81	-0.988	0.337	

All participants with rCBG of 12.2mmol/l or more, who reported being tested by their GP, reported a diagnosis of diabetes.

The mean rCBG of those who were subsequently diagnosed with diabetes was 10.06mmol/l (95% CI 7.38-12.73 mmol/l). For those diagnosed with pre-diabetes the mean rCBG at screening was 8.00mmol/l (95% CI 6.81-9.19mmol/l). The mean rCBG of those who reported that they were normal or had been given no diagnosis was 7.29mmol/l (95% CI 7.06-7.51mmol/l). Figure 31 shows box plot of the blood glucose for those diagnosed as having diabetes, pre-diabetes and normal blood glucose.

Those participants diagnosed with diabetes had significantly higher mean rCBG(10.06mmol/l) than those who were given no diagnosis (7.29mmol/l). However, those diagnosed with a pre-diabetic hyperglycaemic condition did not have significantly increased mean rCBG when compared with the mean for those diagnosed as normal.

Figure 31 Box plot of rCBG measurements for those diagnosed as having diabetes, pre-diabetes or normal blood glucose



For this study we used a cut off point of 6.1mmol/l to decide whether a participant should be referred for further investigations. Other studies have used higher cut off limits (145) (144) (146). The effect on the number of cases of diabetes and pre-diabetes diagnosed if the cut off point for referral was increased is shown in figure 32.

Figure 32 Diabetes and Pre-diabetes for different cut off points

		Self report of test by GP (%	Diagnosis (% of pop. tested by GP)			
Blood glucose	n	of total)	Normal	Pre-diabetes	Diabetes	Unsure
≥6.1mmol/l	318	138 (43.4%)	111 (80.4%)	9 (6.5%)	7 (5.1%)	11 (8.0%)
≥7.1mmol/l	136	68 (50.0%)	52 (76.5%)	5 (7.4%)	6 (8.8%)	5 (7.4%)
≥8.1mmol/l	51	34 (66.7%)	21 (61.8%)	4 (11.8%)	5 (14.7%)	4 (11.8%)
≥9.1mmol/l	26	19 (73.1%)	11 (57.9%)	2 (10.5%)	4 (21.1%)	2 (10.5%)
≥10.1mmol/l	12	8 (66.7%)	4 (50%)	1 (12.5%)	3 (37.5%)	0 (0.0%)
≥11.1mmol/l	8	5 (62.5%)	3 (60.0%)	0 (0.0%)	2 (40%)	0 (0.0%)
≥12.1mmo/l	5	2 (40.0%)	0 (0.0%)	0 (0.0%)	2 (100%)	0 (0.0%)

If only participants who had a rCBG of 12.1mmol or more were referred for further investigation, only 5 would have been referred. We only know the outcome of further investigations for two of these participants, both were found to have diabetes. Increasing the cut of point by 1 mmol/l to 7.1mmol results in a reduction of the number of referrals by 43%, but also would have resulted in one case of diabetes and 4 pre-diabetes being missed. A rCBG of 12.1mmol/l or more has a positive predictive value (PPV) of 100% for diabetes and pre-diabetes. This is shown in figure 33.

Figure 33 - PPV of rCBG for pre-diabetes & diabetes and diabetes

Blood glucose	Self report of test by GP	Diagnosis Normal/not sure	Diagnosis Diabetes and Pre-diabetes	PPV
≥6.1mmol/l	138	122	16	11.6%
≥7.1mmol/l	68	57	11	16.2%
≥8.1mmol/l	34	25	9	26.5%
≥9.1mmol/l	19	13	6	31.6%
≥10.1mmol/l	8	4	4	50.0%
≥11.1mmol/l	5	3	2	40.0%
≥12.1mmo/l	2	0	2	100.0%

Blood glucose	Self report of test by GP	Diagnosis No diabetes	Diagnosis Diabetes	PPV
≥6.1mmol/l	138	131	7	5.1%
≥7.1mmol/l	68	62	6	8.8%
≥8.1mmol/l	34	29	5	14.7%
≥9.1mmol/l	19	15	4	21.1%
≥10.1mmol/l	8	5	3	37.5%
≥11.1mmol/l	5	3	2	40.0%
≥12.1mmo/l	2	0	2	100.0%

The characteristics of the individuals diagnosed with diabetes or a pre-diabetic condition are shown in figure 34.

Figure 34 - Characteristics of those diagnosed with diabetes, IGT, IFG, borderline diabetes or pre-diabetes

Age	Gender	Ethnicity	Risk factors reported	rCBG (mmol/l)	Diagnosis
67	Male	White	Family history, BMI, Waist size	6.4	Borderline diabetes
65	Male	White	Family history, BMI, Waist size, hypertension, cholesterol	7.7	Borderline diabetes
61	Female	White	Family history, BMI, hypertension, cholesterol	8.9	Borderline diabetes
70	Male	White	Family history, BMI, Waist size, hypertension, cholesterol, symptoms	9.3	Borderline diabetes
53	Female	White	BMI, Waist, Cholesterol	6.5	IFG
20	Female	White	Symptoms	6.8	IFG
82	Male	White	BMI, Waist size	6.8	IGT
66	Female	White	Hypertension, symptoms	10.9	IGT
47	Female	White	Family history, BMI, Waist size	8.7	Pre-diabetes
82	Female	White	Symptoms	7.3	Diabetes
76	Female	White	BMI	8.9	Diabetes
62	Male	White	Family history, BMI, Waist size, hypertension,symptoms	14.3	Diabetes
65	Female	White	Family history, hypertension, symptoms	9.8	Diabetes
35	Male	White	Ocular signs	13.4	Diabetes
61	Female	White	Symptoms	6.6	Diabetes
60	Female	White	Family history, BMI, Waist size, hypertension, cholesterol, symptoms	10.1	Diabetes

There were not enough participants subsequently diagnosed with diabetes or pre-diabetes to perform logistic regression analysis to determine which factors had a significant impact on whether a participant was diagnosed with a hyperglycaemic condition following the rCBG screening test.

Family history and BMI were both associated with increased likelihood of being referred following the rCBG test. 9 of the 16, who received a diagnosis, reported either family history, a BMI of 25 kg/m^2 or more or both factors. Increasing age was also associated with increased likelihood of referral. Only two people, one of whom was diagnosed as having diabetes and one who was diagnosed as having IFG, were are aged under 40 years. One of these reported symptoms, while the other reported no risk factors but was found by the optometrist to have ocular finding suspicious of diabetes.

Of the 1909 adults who attended the participating practices during the study period, 171 had previously been diagnosed with diabetes. 16 participants reported IFG or IGT as a risk factor. With these new case of diabetes and pre-diabetes discovered as a result of screening, 178 adults had diabetes and 25 pre-diabetes, 9.3% and 1.3% respectively of the total adults population attending the practices.

7.3 Discussion

Just under a third of those who responded to the questionnaire reported that they did not go the GP for further investigation. These tended to have lower rCBG than those who did attend their GP.

In this study 1.3% of all adults attending the optometry practices had some form of non-diabetic hyperglycaemia (IGT, IFG or pre-diabetes) and 9.3% diabetes, either previously diagnosed or newly diagnosed as a result of participating in the screening service. 16 (8%) of the 203 who had some form of hyperglycaemia were diagnosed as a result of the screening and represent a new hitherto undetected group. Reported prevalence of IGT is 15.8% in US adults aged between 40 and 65 years (95). The prevalence of diabetes (both type 1 and 2, diagnosed and undiagnosed) in the UK in 2001 was 4.41%(10).

The prevalence of diabetes among the adults attending the participating practices is higher than in the general population. People with diabetes are often made aware of the risk of ocular complications of diabetes and the need for frequent eye examinations. They are also entitled to a reimbursed NHS test yearly, whereas most other groups are only entitled to a test every two years.

Though the prevalence of diabetes was higher than among the general population, the prevalence of pre-diabetes was lower. 1.3% were found to have a non-diabetic hyperglycaemic condition, 0.8% previously diagnosed and 0.5% newly diagnosed. While we found that those diagnosed with diabetes had significantly higher mean rCBG results than those who were classified as normal, the mean rCBG results for those diagnosed with pre-diabetes was not significantly higher. Though there may be no significant difference, it may be that some people who had a pre-diabetic condition were classified as normal causing more overlap between the two groups. It may be that this is a factor of using random blood glucose measurements instead of fasting. However, it is possible that the lack of a significant difference is due to some participants who do have some form of pre-diabetic hyperglycaemia have been described as normal. This may be due to GPs not diagnosing these conditions, or to the participants' interpretation of the result. If the participant interprets the result of having pre-diabetes as meaning they do not have diabetes and so it is a normal result for present, they may report the incorrect diagnosis on the questionnaire.

In this study, we did not specify what further investigations should be carried out. Letters sent to the GPs suggested that further tests should be carried out. However, we did not prompt them to consider IGT or IFG when carrying out the tests. We do not know what tests were carried out and what the results were. If we had carried out fasting blood glucose and OGTT on all participants we could have ensured that pre-diabetic conditions were considered as well as diabetes. An investigation of

attitudes of GPs in the North East toward IGT found that awareness of the condition was low and there is some reluctance to screen for the condition (252). Similar attitudes were found among GPs and practice nurses in Wales. (253). Concerns about medicalisation of people with non-diabetic hyperglycaemia and reluctance to divert overstretched resources to this area have been reported. This may lead to the low prevalence of pre-diabetic hyperglycaemia found in this study, with people with IGT and IFG not being diagnosed as such.

Retrospective analysis of patients attending a district hospital over a one month period, who were found to have a random plasma glucose levels between 6.0 and 11.1mmol/l, found that only 95 out of the 518 patients received formal investigations for diabetes, with 92 receiving fasting tests and 3 OGTT. Of the 95 investigated 18 (18.9%) were found to have IGT or IFG, and 3 (3.1%) diabetes (254). We found that around 5% of those who received further investigations where diagnosed with diabetes compared with 3.1% in the hospital study. However, we found a much smaller proportion diagnosed with a pre-diabetic condition, 6.5% compared with 18.9%. It may be that there was a lower proportion of IGT and IFG in our population, as a hospital population may have multiple co-morbidities compared with a population attending screening in the community. Hospital populations may also be more likely to be prescribed drugs that are known to increase the risk of diabetes compared with our population. However, we relied on patients reporting the outcome, whereas Doyle et al. (254) had access to the patients' records and had the results of the blood tests and were able to report diagnosis from those results. We do not know what tests were carried out and what the blood glucose measurements were in those who reported a diagnosis of normal. We cannot differentiate between those who considered the outcome normal as they did not have diabetes, but may have had some form of impaired glucose regulation and those who did not have any form of hyperglycaemia.

We do not know who initiated the appointment for further investigations. Participants were told that further investigation was recommended and the GP was sent a copy of the results, recommending that fasting tests should be carried out. The GP appointment could then have been initiated either by the participant contacting the GP for follow up or by the GPs' practice inviting the participant to attend for follow up. We know that around half the people who had rCBG of 6.1mmol or more visited their GP and a further 20% did not. The 66 who reported that they did not attend for any further investigation received verbal and written instructions that they should visit their GP for further investigation at the time of participating in the study. They also received the questionnaire about the outcomes of any investigations, which prompted them that they should seek further investigation. It would be interesting to know if they also received a invitation from the GPs' surgery to attend. It may be that more people attended for further follow up if the GP issued an invitation. Previous qualitative investigations into people experience of screening for diabetes has shown that, while participants feel it a good thing that people are screened and can be diagnosed and treated earlier, they do not feel that they are likely to have the disease themselves (142). This feeling among participants that they won't have diabetes themselves may be reinforced if, though they screen positive, the GP does not invite the participant for further tests. It may be that, as participants were aware that the GP had been notified of the results, if the GP did not initiate any further tests, the participant felt that the rCBG results were not serious enough to warrant further investigation. If they felt that the GP did not act on it, then there was no need for them to. A qualitative study of people newly diagnosed with diabetes showed that if there was a long wait between the initial GP contact and hospital appointment for investigation of diabetes, the patient believed that the diagnosis could not be serious (255). However, we did not collect any information on who initiated the appointment with the GP.

There were a number of people who reported that they did attend the GP but no tests were carried out. This would suggest that this group initiated the appointment without a prompt from the GP.

For screening in optometry practices to be effective, communication between the health care professions needs to be seen to be consistent. If a person is told by one profession that they may have a health issue and then told no further tests are required by the next, this will send conflicting information to the patients. In our study, there was no significant difference in the mean rCBG measurement between those who were tested by the GP and those who were not. The range of rCBG of those who attended the GP and were not investigated further was from 6.1mmol/l to 13.6mmol/l. It would be interesting to see why the GP made the decision not to investigate further these patients, despite them attending.

5 participants in the study had a rCBG measurement of 12.2mmol/l or more and were told that they should see a GP urgently. We received responses from three of these participants, 2 received a diagnosis of diabetes and the third reported that GP did not carry out any investigations.

If it is assumed that all the people who did not respond to questionnaire did not attend their GP, around half the participants who we suggested should consider further investigations did not act on that suggestion, and so are not receiving benefit from participating in the screening.

The links that optometrists have with other professionals are vital in the effective running of any shared care or screening service. In the previous qualitative work in chapter 4, optometrists felt that the relationship they had with GPs varied. While some think of optometrists as clinical professionals, others think of optometrists as primarily business people.

The views of GPs on the role and knowledge of optometrists may have an effect on the way they treat referrals from them.

7.3.1 Limitations and strengths

By using a postal questionnaire to contact the participants we risked a high non-response rate which is a common issue with postal surveys.

By sending the questionnaire to the participants, we relied on them going the GP and reporting the results of any investigations. We do not know how accurately the participants are reporting the outcomes.

We could have sent to questionnaires to the GPs to complete. However the GP named by the patient may not be the GP the patient sees so the response rate may have suffered. We referred participants to the GP on the basis that they were at risk of diabetes or pre-diabetes. The prevalence of diagnosed pre-diabetes, borderline diabetes, IGT and IFG was lower than we would have expected, suggesting that GPs are either not diagnosing these conditions or not communicating it to patients, or that the patients are not understanding these conditions. If we had sent equivalent questionnaires to GPs giving the option of these non-diabetic hyperglycaemic states, we may have prompted them to consider them when carrying out further testing. If a screening service in optometry practices was implemented and run in a way similar to pharmacy screening, the GPs would not have to report results to anyone except the patient.

To determine whether the extent of diabetes and pre-diabetes was accurate, we could have arranged to carry out the fasting blood glucose investigations ourselves. This would have required the participants to come to a central location for the further tests, thereby negating the convenience of them attending their local optometry and GPs practice. Unlike with GP practices, people do not have to register with a local optometry practice. They may attend a practice that is distant from their

home, but convenient for that particular time, whether they are working away from home or on holiday. For these people it would be more convenient to visit their own GP when they returned home than attending a location in the North East for further fasting tests.

Had we carried out the follow up testing ourselves and used a constant test procedure and diagnosis protocol we would have got a more accurate determination of the rates of pre-diabetes and diabetes among the population we tested. The method we have used to determine the outcomes of further testing does not give us the most accurate prevalence, however, it does show how the participants interpret the results they are given. The strength of using this method is that it reflects real life and demonstrates how a screening service would run if implemented in high street practices. We know that lifestyle changes can slow the progression of pre-diabetic conditions to diabetes (99) (98) (256). As diabetes is a condition that is affected by lifestyle choices, people need to be aware of diagnosis of diabetes and pre-diabetes so they can consider making changes they need to.

We could consider following up all those who reported that they did not attend their GP or had no investigations done to invited them to have fasting blood glucose tests.

There were a large number of participants who either did not attend their GP, attended but were not investigated or did not reply to the questionnaire. We do not know whether any of these may still have undiagnosed disease even through they have participated in screening.

Chapter 8

Acceptability of capillary blood glucose tests to users in high street opticians practices

Chapter 8

Acceptability of capillary blood glucose tests to users in high street opticians practices

Abstract

Background

A screening service offering people with risk factors or symptoms of diabetes random capillary blood glucose (rCBG) tests was piloted in high street opticians' practices in North East England.

Aim

To determine acceptability to the users of a screening service using rCBG tests to detects raised blood glucose levels in the "at risk" populations attending optometry practices

Methods

1002 people used the screening service in 5 practices. Each was given a questionnaire to complete and return following a screening finger-prick test.

Results

939 questionnaires were returned (return rate 93.7%). The mean age of respondents was 54.5 years; 63.3% were female.

99.1% agreed or strongly agreed that the location was convenient for them. 95.1% disagreed that the test procedure was uncomfortable. 98.0% would recommend others to use the screening service. 82.9% felt that optometrists should be able to detect health problems. 83.8% of the participants would not have gone elsewhere to have any tests done. 148 (15.7%) responded that they would have sought a test elsewhere; of these 91.5% would have sought tests at their GP, 4.7% at a pharmacy and 3.5% elsewhere.

Conclusions

Opticians' practices provide an acceptable and convenient place to provide screening services to the general public who may not access services elsewhere. This provides an opportunity to identify people at risk of diabetes in a hitherto unutilised setting.

8.1 Introduction

To be suitable for screening a disease must be common, have a suitable test, and have an effective treatment or management. However, screening cannot be effective unless the target population takes up the screening test. For a screening programme to be successful, it needs to be accessible and acceptable to the population who are at risk of the disease.

A screening programme was implemented in high street optometry practices in North East England, offering random capillary blood glucose (rCBG) tests to those reporting risk factors for developing Type 2 diabetes.

Previous studies, such as the ADDITION study, have used rCBG tests as the initial part of a screening procedure to identify those who would benefit from further fasting test. People who were identified as high risk of developing diabetes were invited to participate. Uptake of rCBG testing was between 44% in the Danish arm of the study (257) up to around three quarters in the UK arm (258) (259). The psychological impact of screening in these studies was assessed qualitatively and quantitatively and the authors concluded that there was limited negative psychological impact of screening, both short and long term (142) (218).

8.2 Methods

Adults aged 18 years and over attending one of 5 high street opticians practices in North East England were offered a rCBG test if they self reported on a questionnaire the presence of risk factors or symptoms of diabetes. 1303 adults were offered the opportunity to participate, with 1002 (77.9%) consenting to take part. After participants took part in the screening procedure described in the previous chapter, they were given a written questionnaire to complete. The screening procedure is described in chapter 5.

8.2.1 Choice of Method

A written questionnaire was chosen. Written questionnaires have the advantage that they are simple method of gaining information from a large population. They are simpler in terms of scheduling and time commitment when compared with face-to-face interviews. There are issues in terms of poor response rate and control over who completes the questionnaire, particularly with postal questionnaires (188). This can be overcome by using face-to-face interviews. However, this creates issues in terms of cost and time. Due to time constraints we were aware that we would not be able to interview all participants in the screening programme. A written questionnaire could be administered immediately after the test procedure by the researcher. As the participant could take the questionnaire away, they could complete it without the researcher who undertook the blood glucose tests seeing the results. This would enable a more independent response.

8.2.2 Questionnaire Development

The questionnaire aimed to investigate how acceptable the service was to users. The initial questions determined demographic data about the participants; how frequently they attended for sight tests and whether they knew they had been screened or tested previously.

Previous qualitative research indicated that optometrists believed that the public would accept screening in opticians' practices if it was convenient, and they felt that the there was a difference in expectations between people attending an independent practice and those attending a multiple practice. Questions on convenience and expectations of optometrists' ability to detect health problems were included to investigate those concepts and constructs developed in chapter 4.

The questions were piloted with 15 adults who were not involved in the project design and had no background in optometry or diabetes. They

were asked to provide their views on completing the questionnaire and changes were made to the wording and layout as a result.

Participants were asked to report the frequency with which they attended opticians' practices, whether they had been screened previously, and whether they would have gone elsewhere to be screened. They were also asked to rate how convenient they found the location, how uncomfortable the procedure was, whether they would recommend it and whether they expected opticians to detect general health care problems, using a 5 point Likert scale. They were also asked if they would have considered going elsewhere for a test and if so, where. They were also given the opportunity to write free text comments. The questionnaire is included in appendix H. The final questionnaire was approved by the School of Medicine and Health Ethics Committee.

8.2.3 Sample size

Every participant in the screening study (n=1002) received the questionnaire immediately after being given the results of the blood glucose test.

Participants were given a stamped, addressed envelope, or given the opportunity to return it to either the research assistant or practice staff member if they wished to complete it while they waited for their sight test appointment.

Each questionnaire was labelled with the participants ID number so responses could be linked with the details of their blood glucose tests, and the practice where the screening occurred.

The results were entered into a database and analysed in SPSS 15.0.

8.3 Results

1909 adults attended optician practices during the study period. 1303 self reported the presence of risk factors or symptoms of diabetes in response to a questionnaire. 1002 (77.9% of those eligible) consented to receive the rCBG test. Demographic details of participants are described in chapter 6.

939 questionnaires were returned from all the study locations (overall return rate 93.7%). Return rate for individual study locations ranged from 91.8% to 95.2% (A 93.3%, B 95.2%, C 91.8%, D 93.3%, E 93.9%)

8.3.1 Demographics

The mean age of respondents was 54.5 years (54.4 years for the participants in the screening study). 36.7% were male; 98.9% were white. The average blood glucose of respondents was 5.79 mol/l. There was no significant difference between the mean rCBG measurements of those who completed the questionnaire (5.79 mmol/l) and those who did not (5.51mmol/l). 32.4% were referred for further tests compared with 31.7% in the screening as a whole. Details are shown in figure 35.

Figure 35 Demographic details for participants returning questionnaire and all participants in the screening

	Screening (n=1002)	Questionnaire returns (n=939)	Questionnaire not returned (n=63)	
Mean Age (SD)	54.40 (16.31)	54.50 (16.36)	53.0 (15.8)	t=0.71, p=0.47
Male (%)	363 (36.2%)	345 (36.7%)	18 (28.6%)	
Female(%)	639 (63.8%)	594 (63.3%)	45 (71.4%)	
White(%)	992 (99.0%)	929 (98.9%)	63 (100%)	
Mixed (%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	
Asian/British Asian(%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	
Black/Black British(%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	
Chinese or other(%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	
Blood glucose - mean	5.78 (1.34)	5.79 (1.36)	5.51(1.04)	t=1.6, p=0.11
<6.1mmol/l	684 (68.3%)	635 (67.6%)	49 (77.8%)	
≥6.1mmol/l	318 (31.7%)	304 (32.4%)	14 (22.2%)	
Multiple practice	559 (55.8%)	527 (56.1%)	32 (50.8%)	
Independent practice	443 (44.2%)	412 (43.9%)	31 (49.2%)	

Figure 36 show the responses to the 4 questions about convenience, comfort, recommendation and expectations of optometrists with regards to general healthcare.

Figure 36 Table of participants’ responses

	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Only 2 respondents (0.2%) disagreed or strongly disagreed with the idea that the opticians’ practice was a convenient location. The majority felt that the location was convenient for them. 99.4% of male and 99.0% of female participants agreed or strongly agreed that the practice was convenient. Likewise, there was no significant difference between responses from the different practice types, with only 0.2% of those attending independent and multiple practices disagreeing or strongly disagreeing that the location was convenient

Thirty participants, from the 926 who responded to the statement, reported that the test was uncomfortable (24 strongly agreed, 6 agreed). However, only one of these reported that they would not recommend the test to family and friends. Over 95% reported that they would recommend participation to other people. 13 disagreed or strongly disagreed that they would recommend it to others. The scores were not related to whether a person was referred or not following the rCBG test. Again there was no difference in responses between the genders, with 2.7% of males agreeing or strongly agreeing that the tests were uncomfortable compared with 3.6% of female participants.

When asked if they would recommend the test to others, 98% agreed that they would. Again, this did not significantly vary when the genders were considered (male 97.4%, female 98.3%). Similarly, whether a person was referred for further investigation following the tests did not influence whether they would recommend other to participate in screening, with 98.2% of those who were not referred and 97.4% of those who were referred, agreeing or strongly agreeing that they would recommend screening to others.

Over three quarters of participants agreed that opticians should be able to detect health problems. Around 4% disagreed with this statement. Again, as with the other statements, gender (male 80.5%; female 84.3%), practice type (multiple 82.8%; independent 82.8%) and whether someone was referred following rCBG tests (not referred 83.4%; referred 82.5%) made no significant difference as to the proportion of people who indicated that they agreed and strongly agreed with the statement.

148 respondents reported that they would have considered going elsewhere for a diabetes screening test, while 768 would not. Of the 148 who would have considered going somewhere else, 77 had never been tested previously and 69 reported that they had undergone screening for diabetes prior to participating in the study (no details on previous test status for 2 participants).

Nearly two thirds of the population that participated in the screening reported that they had never been tested previously and that they would not have gone on to seek out screening (n=609). Details of whether a participant reported that they would have considered going elsewhere for a screening test shown in figure 37.

Figure 37 – Responses by gender, previous test, blood glucose levels and practice type

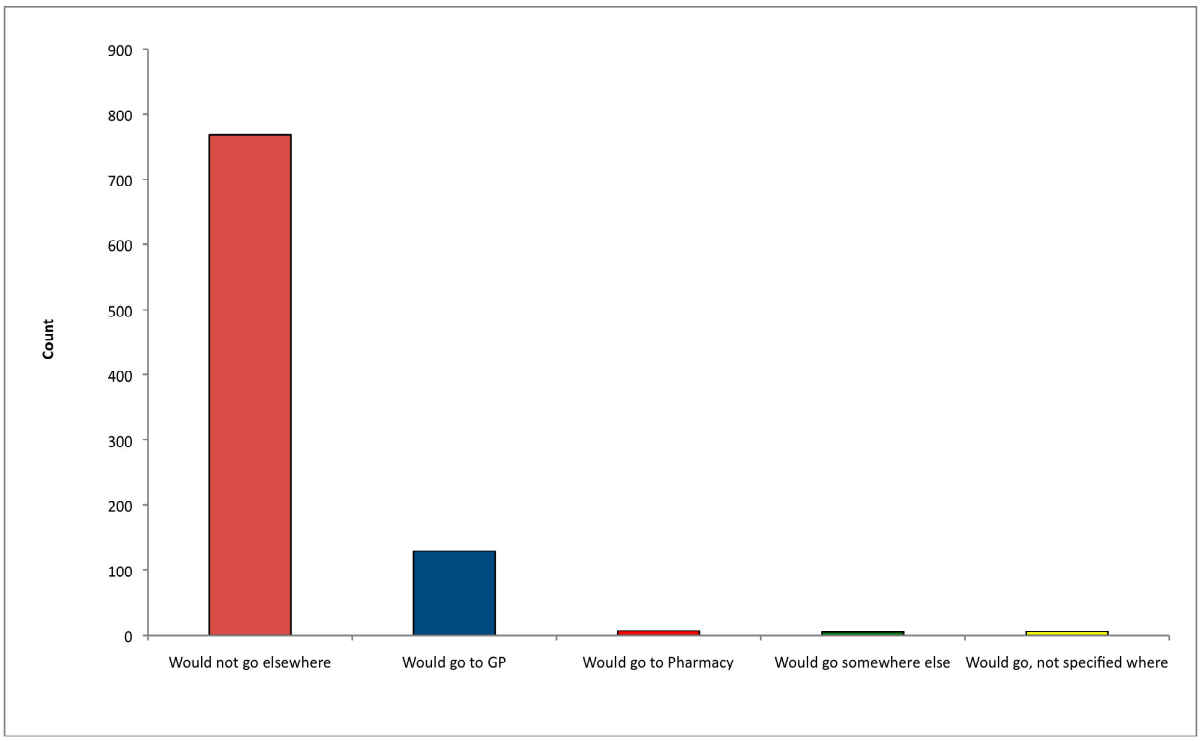
	Would you go elsewhere? No		Yes		chi-square	p	
Male	276	81.4%	63	18.6%			
Female	492	85.3%	85	14.7%	2.34	0.126	
Not tested previously	609	88.8%	77	11.2%			
Tested previously	153	68.9%	69	31.1%	49.01	<0.001	*
Blood glucose <6.1mmol/l	523	84.6%	95	15.4%			
Blood glucose ≥6.1 mmol/l	245	82.2%	53	17.8%	0.86	0.535	
Multiple practice	440	85.4%	75	14.6%			
Independent practice	328	81.8%	73	18.2%	2.207	0.137	

There was no significant difference in gender, with only 18.6% of women and 14.7% of men reporting that they would consider going elsewhere to be tested for diabetes. Likewise, whether a person was referred following the screening test or the practice type attended did not significantly influence whether they reported that they would have gone elsewhere to seek out testing if they had not participated in this study. There was a significant difference in relation to whether people had been previously tested for diabetes. Those who reported that they had been screened in the past were more likely report that they would consider going elsewhere to ask for a test, with 31% reporting they would go somewhere else compared with 11.2% of those who had never been screened previously.

Of the 148 people who reported that they would have gone elsewhere to request a screening test, most (87.8%) reported that they would have gone to see their GP or practice nurse. 7 (4.7%) would have gone to a pharmacy. 5 (3.4%) said they would have gone somewhere else, these

included shopping mall (n=1), self testing with friends or family member's machine (n=2), hospital (n=1) or with the off-shore medic at work (n=1). 6 respondents who reported they would go elsewhere did not specify where they would go. Figure 38 shows the responses of whether people would seek to be screened if they had not participated in the study and where they would have gone.

Figure 38 - Where respondents would seek screening if they had not participated in the screening study



Space was given for participants to make any additional comments. Around one third (326) made some comment.

The comments fell in to a few broad categories; convenience and location, ease and comfort of test, reassurance, raising awareness and testing people not previously tested or considering tests, and recommendation to other.

There were several comments that it was convenient to have the test done at the opticians practice.

'It was good to have the test done without making an appointment at the doctors, especially as I work out of town and it was a Saturday' MI ≥6.1

'Very convenient to have test when come to opticians regularly (annually) to have eyes tested, Less likely to seek a specific test even if at a pharmacy' FI <6.1

Several people felt that the opticians practice was a friendly atmosphere, which made the tests less stressful. Several compared the experience to attending GPs surgery, both in terms of convenience and atmosphere.

'Quick and comfortable, and not stressed out by waiting at a doctors surgery' FI ≥6.1

'Convenient, comfortable atmosphere and friendly staff all helped keep the experience trauma free' FI ≥6.1

Several people liked the idea of a 'one-stop shop' for health care, combining different tests into one appointment.

'*I visit my optician every year. It's a brilliant idea to have this test at the same time. I had the test done while I waited for the optician. It's a great offer, buy one get one free.*' FM <6.1

'I think it's a good idea to have a 'one stop shop' for health issues' FM <6.1

'A very sensible and worthwhile idea to have the test done along with optometric test' FM <6.1

Ease and comfort of the test was commented on by many of the participants.

'Pain free and very informative' FI <6.1

'It was quick and painless, Thank you' MM ≥6.1

Some people found that the procedure was reassuring, and even if they were referred for further investigations, felt that others would find that the test could give peace of mind.

'I agree fully with these tests as they can give peace of mind and think they should be made compulsory.' MI ≥6.1

'Very convenient and having results straight away was reassuring – thank you' MI <6.1

Some people reported that while they were aware of diabetes they would not have considered being tested if it had not been offered. Others reported that being asked to participate had raised their awareness of the disease, and encouraged them to take part, even if they did not feel they had symptoms that were worth taking to the GP.

'Test at optician seem to me to be a good idea. Even though mother had Type 2 diabetes I would not have bothered to get tested until symptoms showed. I did not know about slow healing of wounds, it is this that encouraged me to take part' FI ≥6.1

'Very convenient and helpful, I would not have booked an appointment with my GP just to see about any symptoms unless they were very severe' FM ≥6.1

‘*Pleased the test was available otherwise I wouldn’t have thought about having it done.’* FM ≥6.1

Some participants commented that they would recommend the test to others.

‘*Felt it was vey convenient, quick and easy. Would recommend to family and friends’* FM <6.1

‘It was completely painless and only took a few minutes. I would therefore recommend everyone to have it done’ FM <6.1

8.4 Discussion

Some participants voiced concerns over how painful the test would be prior to taking part, and reported a dislike of needles. When the equipment was demonstrated and they could see that no needle was visible they were happy to take part. Around 3% reported that the test was uncomfortable. Only one of those who reported discomfort would not have recommended others to have the screening test done. This may reflect the fact that the participants believe that the test is worthwhile even if it does cause some discomfort. However, it is also possible that some participants may not have fully read the statements and ticked the same agreement level for all four statements. This was true in just over half of the thirty cases where they either agreed or strongly agreed that the test was uncomfortable (14 strongly agreed with all statements, 3 agreed with all statements).

The setting of high street optometry practices appears to be convenient for this population. This may not be surprising, as people are not tied to a specific practice as they would be with a GP, and so can chose a practice that is convenient to them at that particular time. Several people commented that they liked the convenience of being able to have different tests done at the same time and location instead of attending

two different places. The Danish arm of the ADDITION study found that employed people were less likely to attend screening than other groups who were not in employment. They suggested that this may be due to the fact that, as they did not feel unwell, the employed did not prioritise screening over other demands on their time (257). If attendance at screening requires an individual to take time off work, this may affect their willingness to take up screening. We did not investigate the employment status of participants in this study. All the practices that took part in the screening were open 6 days a week, some with early morning or late night opening and one testing 7 days a week, in an attempt to provide a service to those who were employed and found it difficult to attend in normal office hours. Some participants did report that the ability to attend on a Saturday was convenient as they were working and were not able to attend during the week.

The responses show that offering screening in conjunction with the sight test may result in people taking up screening when they would not go out and actively seek it. Nearly two thirds of the people who took part reported that they had not been screened previously and that they would not have considered going elsewhere to be tested. It had been suggested by optometrists that the people most likely to accept the offer of screening in optometry practices would be those who would have sought healthcare from other locations (chapter 4). However, from this data we can see that, while some would have been screened before and would consider going to the GP or pharmacist for a test, there is a significant number of people attending optometry practices who have not considered taking part in any form of screening test. Although pharmacies in the UK have been offering screening for several years, very few people in this study (4.7% of those who reported that they would somewhere else for a test, 0.7% of all respondents) considered going to a pharmacist to request a test.

In previous qualitative work in chapter 4, optometrists expressed concerns that the public viewed multiple and independent practices

differently, treating the large multiple chains more like retail outlet, while viewing the smaller independent practices as health care providers. Over three quarters of people who participated in the screening believed that optometrists should be able to detect health problems. There was no difference between the proportion of people agreeing or strongly agreeing with the statement between those attending multiple practices and independent practices.

It was also felt that people attending independent practices would be those who would take up the offer of screening more willingly, but would also be the people most likely to attend elsewhere for screening. There was a small difference between the proportion of people screened previously between the practice types, 22.0% screened previously in those attending multiple practices and 28.9% in independent practices. Even though there is a statistically significant difference between the two practices type, over 70% of people who were screened in either practice type reported that they were not aware of being tested previously, which indicates that there is a large population attending both types of practice who have risk factors, but have not been screened previously or are not aware that they have been tested. Whether people attended a multiple or independent practice had no significant effect on whether they would have considered going else where for a screening test if they had not been tested as part of the screening study.

Though the optometrists felt that there were differences between independent and multiple practices in terms of how the public viewed them, and how those attending the different practice types accessed health care, this was not reflected in the responses to these questionnaire to a great extent. The participants in our study showed little difference in responses between those who attended multiples and those attending independents.

8.4.1 Limitations and Strengths

This survey was only carried out among people who consented to take part in the screening procedure, so is self-selecting toward those who are more willing to accept screening. However, only 22% of those eligible chose not to participate indicating a generally good acceptance among the population attending high street practices. We were unable to record details of people who did not wish to participate due to ethical considerations, so cannot see how they differ from those who did participate. Though we did not ask people why they did not wish to have the blood test, people often gave a reason. The two most common were that they had been tested recently by their GP or that they did not want to know if they had a problem. Some of those who said they had been tested recently said they thought it was a good thing to offer screening to those who were not accessing it elsewhere so were not refusing it because it was not acceptable to them, but felt it was unnecessary for them to participate. Other studies have found between 44% and 77% attendance after receiving an invitation to attend for rCBG screening (257) (259). These studies differed from this in that the invitation was delivered by post and required the participants to make a trip to the test centre to participate. In our study the invitation was made while the person was already at the location were the test would take place and a research assistant was on hand to answer any questions they may have had.

Though the sample was biased towards those who would accept screening, by asking the participants to complete the questionnaire after the screening test had been carried out and the results given we could explore whether a negative or positive screening result affected the views of the participant. No significant differences were found in the attitudes of the participants who were advised that they should seek out further tests, to those who screened negative.

No respondent validation of the results was carried out. We did not ascertain whether the scores reported in the questionnaire corresponded with the participants' views. It is not possible to ascertain how strongly agree and agree differ from each other.

Further qualitative research would help explore the relationship between peoples' expectations of optometrists' and different practice types. Ascertaining reasons behind non-participation in the blood glucose testing service should be considered.

There were a number of people who had never been tested who reported that they would consider going elsewhere for a test. Ascertaining why these people said they would go for a screening test, but did not, would provide an insight to how to target screening willing people. There is likely to be a small group of people who recognise the value of screening and but do not avail themselves of a service anywhere.

Chapter 9

Detection of diabetes in optometric practice: Resource implications and economics

Chapter 9

Detection of diabetes in optometric practice: Resource implications and economics

9.1 Costs of Screening: a ready reckoner

The cost of carrying out a single blood glucose has three aspects; cost of the equipment to carry out the test, the cost of the time taken to administer the test and cost of training.

Equipment and time costs are fixed for each test no matter how many are carried out. The fixed costs per test are shown in figure 39.

Figure 39 - Fixed costs for rCBG screening test

Equipment			
	Cost per unit	**No of tests provided in unit**	**Cost per test**
Bayer Contour® Meter	£10.29 (260)	1000	£0.01
Contour test strips	£14.74 (260)	50	£0.29
Cotton wool	£5.31 (260)	500	£0.01
Hand wash gel, 1000ml (3ml per use)	£7.00	333	£0.02
Unistix lancet	£12.20 (260)	200	£0.06
Referral letter to GP	£0.40	If 33% referral - 0.33	£0.13
Information leaflet + results information	£0.10	1	£0.10
		Total	**£0.63**
Consultation with optometrist			
15 minutes	£36 a hour	**Total**	**£9**
Total fixed costs per screening tests			**£9.63**

Training costs will vary depending in how many professionals are attending training and how many rCBG tests each can perform between reaccreditation points.

1002 tests were carried out over the 20 weeks period. Blood glucose testing was carried out on 120 days. The mean number of tests carried

out per day was 8.35. Between 1 and 3 optometrists were in a practice carrying out sight tests each day. During the study period, the equivalent of 212 days of single optometrists sight tests were carried out. The mean number of tests carried out each day per optometrist was 4.72.

If it is assumed that an optometrist works 240 days a year, 1133 rCBG tests would be carried out by one person during the course of one year. If a one-day training course is required to validate an individual for 2 years, training one person will allow 2266 tests to be carried out over a 2 year period. If 10 optometrists attend one one-day training session, the cost of developing the course materials and running the course will be shared between 22656 rCBG tests. A summary of training costs is shown in figure 40.

Figure 40 - Cost of training courses assuming 4.72 tests per day

		No of tests	Cost per test
Cost of developing and running one one-day course for 10 optometrists	£1000	22656	£0.04
Cost of optometrist cover for one day	£500	2265.6	£0.22
		Total	**£0.26**

The estimated total cost for carrying out a rCBG test would be £9.90. By far the most important cost component is the optometrists time, costing is not sensitive to the other variables in the other cost components.

We carried out 1002 rCBG, which subsequently led to 318 people being discovered who would benefit from further investigations as the had a rCBG of ≥6.1mmol/l. This results in a cost of case requiring further investigation detected of £32. 17 people where then subsequently diagnosed with diabetes or pre-diabetes after visiting the GP. This results in a cost per case of hyperglycaemia detected of £620.

9.2 Different screening strategies

A range of different strategies to identify those at risk who would benefit from screening have been explored.

9.2.1 55-75 years with hypertension

Hoerger et al. suggested that the most cost effective strategy would be to screen only hypertensive people aged between 55 and 75 years (120). Among the 1002 people who participated in our study, 295 reported hypertension. 163 were aged between 55 and 75 at the time of participating. Had we used this criteria we would have reduced the number of rCBG tests carried out by around 6 times and resulted in a cost per case of rCBG of ≥6.1mmol/l detected of £27.

67 (41.1% of the people aged between 55 and 75years with hypertension) had a rCBG results of 6.1mmol/l or more. 3 of these had a blood glucose measurement of 12.1mmol/l or more, so by just testing this group we would have identified 3 out of the 5 who fell in to the urgent referral category. There was a higher rate of referral among this group than the population who participated as a whole (31.7%).

Of the 16 people who subsequently received a diagnosis following the screening, six were aged between 55 and 75 years and were diagnosed with hypertension. Two of this group were diagnosed as having diabetes, one with IGT and three with borderline diabetes. If this screening strategy had been adopted, 163 people would have been tested, and 6 (3.7%) subsequently diagnosed with hyperglycaemia. 27 tests would be carried out for every case of hyperglycaemia discovered.

Using these criteria to identify people to be screened, fewer tests would have been carried out with the average per optometrist per day being 0.77. Over 2 years, one optometrist would carry out 370 rCBG tests. This result in an increase in the training cost per test from £0.26 to £1.57, and

a total cost per test to £11.20. However, while the cost per test is increased using this strategy, the cost per case of hyperglycaemia detected is reduced from £620 to £304.

Though the cost per case detected is less using this strategy, we would have missed 10 cases of hyperglycaemia. Only screening people with hypertension may be an effective and cost effective screening strategy, it relies on reliable diagnosis of hypertension. If they are aware of the diagnosis, it is likely that they are accessing healthcare via their GP.

Screening in optometry practices would be an ideal opportunity to find the 'hard to reach at risk' population who would not access other forms of health care. If we only screen those with pre-existing medical diagnoses, we would miss hard to detect disease which may be still considered to be cost-effective care.

9.2.2 Age, Family History and BMI

Logistic regression analysis of the risk factors showed that age, family history and BMI increased the likelihood of having a rCBG measurement of 6.1mmol/l or more, while female gender reduced the likelihood of referral for further investigations.

If we chose a strategy of screening only those aged 40 and over with either a family history of diabetes, a BMI of 25kg/m^2 or both, we would have tested 507 of the participants (2.4 tests per optometrist per day). 193 were subsequently referred (38.1%), three urgently as they had a rCBG measurement of 12.2mmol/l or more. Eleven of those aged over 40 and reporting family history or BMI over 25kg/m^2 responded that they had been given a diagnosis of hyperglycaemia (4 borderline diabetes, 1 IFG, 1 IGT, 1 pre-diabetes and 4 with diabetes).

This method results in a cost per test of £10.14, cost per case of rCBG ≥6.1mmol/l detected of £26 and cost per case of diagnosed hyperglycaemia detected of £467.

9.2.3 Age, Family History, BMI and symptoms

It is often suggested that screening asymptomatic people for diabetes has not been shown to be worthwhile (261). A large number of participants reported symptoms, some of who did not report having any other risk factors. Many of them reported not having been screened earlier. If we propose to use optometrists' practices in order to find those 'hard to reach' people who have not presented to other providers, then screening those who report having symptoms may be an obvious step.

If we use those risk factors that were shown to be significant and also include those aged over 40 years and reporting symptoms, we would have tested 675 people, 237 (35.1%) of who had a rCBG of 6.1mmol/l or more.

14 of the 16 people who received a diagnosis were aged over 40, with at least one of family history, BMI over 25 kg/m^2 and symptoms. This strategy would have identified all of the participants who were diagnosed with pre-diabetes, IGT or borderline diabetes and six out of the seven who were discovered to have diabetes and one of the two who reported a diagnosis of IFG.

The mean number of tests carried out per optometrist per day using this strategy would be 3.18, resulting in training costs per test of £0.51. The total cost per test would be £10.02, cost per case of rCBG ≥6.1mmol/l detected of £28.06 and the cost per case diagnosed would be £483.11.

A summary of the outcomes and costs of different strategies for identifying those to be screened is shown in figure 41.

Figure 41 - Comparison of 4 strategies for identifying people at risk to undergo screening

	Strategy for identifying those to be screened			
	All Participants	55-75yrs and hypertension	≥40years with BMI of ≥25kg/m^2 and/or Family history of diabetes	≥40years with at least one of BMI of ≥25kg/m^2, Family history of diabetes, or symptoms
Number of tests	1002	163	507	675
Tests per optometrist per day	4.73	0.77	2.39	3.18
rCBG ≥6.1mmol/l (% of those tested)	318 (31.7%)	67 (41.1%)	193 (38.1%)	237 (35.1%)
Diagnosed with a hyperglycaemic condition (% of all participants diagnosed)	16	6 (37.5%)	11 (68.8%)	14 (87.5%)
Diabetes	7	2 (28.6%)	4 (57.1%)	6 (85.7%)
Borderline diabetes	4	3 (75.0%)	4 (100%)	4 (100%)
IFG	2	0 (0.0%)	1 (50.0%)	1 (50.0%)
IGT	2	1 (50.0%)	1 (50.0%)	2 (100%)
Pre-diabetes	1	0 (0.0%)	1 (100%)	1 (100%)
Number of screening tests per case of rCBG ≥6.1mmol/l detected	3.2	2.4	2.6	2.8
Number of screening tests per case of hyperglycaemia diagnosed	62.6	27.2	46.1	48.2
Cost per test	£9.90	£11.20	£10.14	£10.02
Cost per case of rCBG ≥6.1mmol/l detected	£31.68	£26.88	£26.36	£28.06
Cost per case of diabetes/prediabetes diagnosed	£619.99	£304.27	£467.36	£483.11

9.3 Resource and economic implications of screening

Screening those aged 40 years or over with a BMI of 25kg/m^2 and over or a family history of diabetes or both appears to be a cost effective method of screening for diabetes in optometric practices. If we had used this method, the number of tests carried out in the 20 week period would have been reduced from 1002 costing £9,920 to 507 costing £5,140.

Using this strategy to indentify those who would benefit from screening resulted in 25 screening tests each week. We used several different sized practices, with different numbers of optometrists testing and with different opening times. We did not include any of the very large city centre practices with 5 or more optometrists practicing. We also did not choose any of the smaller practices where optometrists may only test 2 or 3 days a week. However, neither of these type of practice are the norm. For the purposes of this analysis, it is assumed that the participating practices are typical. If, on average, 25 screening tests are carried out in a practice each week, with a practice testing for 50 weeks of the year, a single practice would carry out 1250 tests costing £12,675. If a new case of diabetes or pre-diabetes was detected, on average, every 46 tests, a single practice would potentially discover 27 new cases each year

We used practices located in three different Primary Care Trusts (PCTs), County Durham, Redcar & Cleveland and Hartlepool. Hartlepool PCT has a population base of 91,000 (246), Redcar & Cleveland a population of 139,500 (245) and County Durham 504,900 (247). There are 9 optometry practices in Hartlepool, 11 in Redcar & Cleveland and 54 in County Durham. There is approximately 1 practice for every 10,000 people. Figure 42 shows the potential number of screening tests and cost to the PCT if every practice in the PCT offers screening. The approximate costs for extending the service to the whole of England has been estimated assuming a population of 51 million and one practice serving 10,000 people. If the cost per test is £10.14 and 1,250 tests are carried out per year by each practice, there is the potential to carry out 6,375,000

screening tests in England costing £64,642,500. If, on average one new case of diabetes or pre-diabetes are found for every 46 cases, around 138,000 new case could be found in a year.

Figure 42 Costs to PCT and England of screening those aged 40 years or over with or BMI of 25kg/m2 and over and/or a family history of diabetes

	Hartlepool	Redcar & Cleveland	County Durham	England
Population	91,000	139,500	504,900	51,000,000
Number of optometry practices	9	11	54	5,100
Population per practice	10,111	12,681	9,350	10,000
No of screening tests each year (1250 per practice per year)	11,250	13,750	67,500	6,375,000
Cost to PCT for screening in all practices for 1 year	£114,075	£139,425	£684,450	£64,642,500
Potential new diagnosis of diabetes/pre-diabetes per year	243	297	1,458	138,586

These estimates assume all practices will offer the screening tests. However, this is unlikely to be case. If only half the practices in England take up the screening programme offering screening to those aged 40 years and over with either family history of diabetes or a BMI of 25kg/m^2

or more, the total cost for one year of screening would be just over £32 million, with nearly 70,000 new cases of diabetes or pre-diabetes discovered.

The cost of £64 million also assumes that the whole procedure would be carried out by an optometrist. When calculating the cost, it has been assumed that the optometrist will administer all parts of the test, as this is the most expensive option. It should be possible for optical assistants to carry out some of the paperwork prior to the test. Currently optical assistants collect information from the patients and carry out some routine screening tests for optometrists. If the 15 minutes taken for the test is broken down into 10 minutes with the optical assistant and 5 minutes with the optometrist, the cost of time is reduced to £6 (assuming £18 per hour for optical assistants) and the overall fixed cost of time and equipment to £6.63, compared with £9.63; a reduction of £3 per test. If the screening strategy of offering tests to only those who are over 40 years with either a family history of diabetes or a BMI of 25kg/m^2 and it is assumed that the training costs are unchanged, the cost per test would be reduced to £7.14. This reduces the cost per cast detected from £467 to £329.

The costs to the PCTs are shown in figure 43, assuming 50% of practices participating and optical assistants and optometrists perform the tests.

Figure 43 - Costs to PCT and England of screening those aged 40 years or over with one of the following risk factors: BMI of 25kg/m2 and over, a family history of diabetes if 50% take up and optical assistants and optometrists carry out tests

	Hartlepool	Redcar & Cleveland	County Durham	England
Population	91,000	139,500	504,900	51,000,000
Number of optometry practices	9	11	54	5,100
Number of practices offering screening (assume 50%)	4	5	27	2,550
No of screening tests each year (1250 per practice per year)	5,000	6,250	33,750	3,187,500
Cost to PCT for screening in all practices for 1 year	£35,700	£44,625	£240,975	£22,758,750
Potential new diagnosis of diabetes/pre-diabetes per year	108	136	732	69,143

The cost of the time taken to administer the screening tests is the most significant factor affecting the total cost of screening. One way sensitivity analysis, adjusting who is to carry out the tests, while keeping the strategy for identifying those to be screened and the number of practices participating shows that the cost of implementing a scheme in 50% of the

practices in England could range from £18 million to £32 million. Figure 44 shows details, assuming a take up of 50% and screening those aged 40 years and over with a BMI of 25kg/m^2 or more or a family history of diabetes.

Figure 44 – Costs of screening if tests are carried out by different people within optometry practices

	Testing by optometrists	Testing by optometrists and optical assistant	Testing by optical assistants
Cost of time	£9.00	£6.00	£4.50
Cost per test	£10.14	£7.14	£5.64
Cost per case of rCBG ≥6.1mmol/l detected	£26.36	£18.56	£11.70
Cost per case of diabetes/prediabetes diagnosed	£467.36	£329.15	£260.00
Cost of screening in England	£32,321,250	£22,758.750	£17,977,500

9.4 Discussion

An Australian pharmacy study, using similar methods and equipment estimated the price per test to be Aus$11.83 (£7.18) (130). An analysis of the use of rCBG as a method of opportunistic screening at US physicians offices calculated the cost per test to be $32.68 (£21.85) (262). As yet the cost of screening for diabetes in the UK as part of the National Health checks has not been determined. When this data are available it would be possible to compare the costs of screening using these different methods.

The pharmacy estimated the cost of the consumables for the test to be Aus$5.00 (£3.03) and the cost of time to be Aus$6.41 (£3.89), with further

fixed costs assuming 5 tests a day over one year to be Aus$0.43 (£0.26). The time was broken down into 10 minutes with a pharmacy assistant and 5 minutes with the pharmacist.

The cost to the practice in carrying out the test would be around £10 a test with most of this being the cost of the time used to carry out the testing. The equipment to carry out the testing costs less than £1 per test, and does not require a large initial investment. It also does not require a great deal of space to be stored, when compared with other equipment that optometry practices often used for other screening services, such as field machines for glaucoma screening and fundus cameras. Time would be the major consideration for the practices, both the time for carrying out the testing and time involved in training. The training time would involved could be covered in an initial one day training session followed by ½ day re-accreditation after 2 years. We have considered the costs involved in the initial 2 years of screening. Further evaluation of the cost of reaccreditation and re-screening strategies will have to be considered in future work to determine long-term strategies and costs.

In our study, we used a large number of inclusion criteria compared with some other methods of screening. Had we used fewer inclusion criteria and been more selective about who we included in the screening we could have reduced the number of screening tests carried out. This increases the overall cost per test, but decreases the cost per case detected and may mean that some of those who were diagnosed would not have participated in the study and have been missed

The National Screening Committee does not recommend universal screening. They do, however, suggest that targeting ‘at risk’ groups’ is justified (117). Different strategies have been suggested at identifying ‘risk groups’.

The strategy of screening those aged 55 to 75 years with hypertension has been suggested to be an cost effective method of identifying those who would benefit from screening (120). In our study population, using this strategy would have resulted in far few tests being carried out, and reduction of half in the cost per case detected. However, only 6 people would have been identified as having a hyperglycaemic condition compared with 16, and 5 people with diabetes would have remained undiagnosed.

Using optometrists' practices as a location for screening, instead of a GPs practices, may allow people who are not accessing their GP to participate in screening. Using medical diagnosis as a sole inclusion criteria results in only those people who have attended other healthcare providers, usually GPs, being able to participate in screening. While this method of deciding who to screen may be cost-effective in medical practices, if we are to find those hard to reach people who are not regularly accessing other services, this would not be an effective strategy to use in optometrists practices.

If we are to fully utilise this location for screening, using criteria that does not rely on a previous medical diagnosis would be preferable. Logistic regression showed the BMI of 25kg/m^2 or more, family history of diabetes and increased age increased the likelihood of having a rCBG of 6.1mmol/l or more. None of these risk factors require the participants to have previously attended a GP. Though people may misreport their weight and height (238) (241), resulting in underreporting of obesity levels, over 40% of participants in our study reported that they had a BMI of 25kg/m^2 or more, suggesting that people are willing to report this as a risk factor. Only screening those aged 40 years or more with either a family history of diabetes or self reported BMI of 25kg/m^2 or more would have halved the number of tests carried out, and identified around two thirds of those who were diagnosed with hyperglycaemia following participation in the study.

An argument made against screening is that there is insufficient evidence that testing asymptomatic people is worthwhile (261). This assumes that people with symptoms will seek out medical attention, however over half the participants reported symptoms in response to a questionnaire and only a quarter of participants reported that they had been tested for diabetes previously. People with mild symptoms may not be attending their GP as they do not realise that their symptoms my be indicative of diabetes, or that they do not perceive their symptoms as being serious enough to warrant medical attention. Including symptoms in the strategy to identify those at risk, along with age, BMI and family history is more cost effective than the method we used. However, it is more expensive than the other strategies (age and hypertension and age, BMI and family history), but it identifies more people who have diabetes or pre-diabetes.

The cost per case of diabetes or pre-diabetes diagnosed using the four strategies considered ranged from £304 to £620, while the cost per case of rCBG of 6.1mmol/l or more detected, as recommended by Diabetes UK (244), ranged from £26.40 to £31.70.

It was assumed that all those who did not reply to the postal questionnaire did not visit their GP, and so did not receive any diagnosis. It may be that some of the non-respondents did receive the diagnosis, but did not communicate the information to us. If more people who participated in the screening attended the GP for further tests, more cases may be diagnosed and thereby reducing the cost per case detected and increasing the number of new cases diagnosis. Two factors could improve the cost effectiveness of these screening methods: firstly, to encourage the diagnosis of pre-diabetic hyperglycaemia which currently appears to be under-diagnosed: and secondly, both professions, optometrists and GPs, must be working together for the same goals. We know that some people attended the GP, but were not investigated further. These people are potentially missing out on receiving a diagnosis. If these people, who were willing to undergo further tests but were not

given the opportunity, were investigated further, this may have resulted in more cases being detected and therefore a decrease in the cost per case detected, while not changing the overall cost of the service.

Chapter 10

Discussion and conclusions

Chapter 10

Discussion and conclusions

Diabetes is known to be a common problem affecting around 4.4% of the population of England (15) and the prevalence is set to increase. Impaired glucose tolerance and impaired fasting glucose, precursors to diabetes, are also becoming increasingly common, with an estimated 11.2% and 6.9% prevalence respectively in USA (95) (96). Large numbers of these are undiagnosed.

Despite these high rates of disease and the introduction of screening services outwith general practitioner surgeries, such as in high street pharmacies, there are people who fail to present to any of the available services. This may be due to lack of knowledge on their part, unwillingness to be diagnosed with a disease, or lack of access or unwillingness to present to the current providers.

Current literature describes screening services provided by a number of healthcare providers, using different methods and with different outcomes. The role of optometrists in these services has not been previously considered.

Firstly, the willingness of optometrists to undertake such a task must be considered, and the barriers concerns addressed. Secondly, the feasibility of running a service evaluated. Screening in optometry practices can only be effective if there is a population presenting in that location willing to be screened and would benefit from screening, and may not be presenting elsewhere.

10.1 Attitudes of optometrists and professional roles and relationships

The focus groups and interviews described in chapter 3 and 4, as well as considering optometrist knowledge and understanding of diabetes and

screening, also raises questions about the role and position of the optometry profession in UK healthcare.

From this study it is clear that optometrists have some uncertainty about their professional role. While they seemed to feel that their role was primarily clinical, they were also aware of the business aspects of the profession and the conflict between the two roles. This conflict affected their ability to take on extended care roles. Some reported that they would like to offer services, but felt that the business pressures would prevent them from being able to do so. This conflict between healthcare and business leads to optometrists being unsure how others perceive them.

During the interviews and focus groups, some optometrists reported good relationships between themselves and GPs. However, others felt that the GPs did not appreciate optometrists' clinical training and viewed them as businessmen in high street shops. There is a feeling among optometrists that they are over-trained for simply carrying out sight tests. However, they also felt that other healthcare professionals did not appreciate the clinical knowledge and training they have and they feel they are sometime excluded from proposed schemes.

Relationships between optometrists and other health care professionals are critical for the evolution of any shared care scheme. Current perceptions of optometrists are that, while some GPs work well with optometrists, not all understand the role of optometrists. It is felt that there was a lack of communication between the professions when it comes to routine referrals. For screening programme to be effective, we need to ensure as many people who would benefit from further testing receive that care. Optometrists can only suggest to the patients that they should go to the GP and contact the GP with the results if the patient consents. However, they cannot coerce the patient to attend for further tests, or make the GP carry them out. If the GPs are not involved with the

implementation of screening service, they may not be as willing to follow up results that they see as borderline.

This is particularly true of those with the lower levels of rCBG levels who, while it is unlikely that they have diabetes, may have IGT or IFG. If GPs are not routinely diagnosing these conditions, they may not feel that is worth investigating people who report a rCBG level of under 7.0mmol/l. Most of the people who did attend the GP, but were not investigated further, had blood glucose measure measurements at these levels. However, there was one with a rCBG falling in to the category of 12.2mmol/l or more who was not investigated. If GPs are not investigating people who are referred for further investigation, we need to know why, and how the communication between the two professions could be improved so that the people who are screened benefit from the service.

Screening can only benefit the individuals who participate if the initial screening test result is acted on by that individual, and if the medical professional they go to also acts on that result in an appropriate way.

10.2 Attitudes and acceptance of the public

99.1% of participants agreed that the location was convenient for them. 98.0% would recommend the screening service to others. Only 3.2% agreed that the test was uncomfortable. 82.9% felt that optometrists should be able to detect health problems. 15.7% said they would have considered going elsewhere to be screened, either at the GPs, pharmacists or elsewhere.

This study achieved a take-up rate of around three-quarters of eligible adults, with around 300 (23.1%) people turning down the opportunity to participate. While in some cases this was because people had recently undergone tests with their GP others refused to participate as they did not want to know if they had a medical condition. This was not always through lack of knowledge as some were aware of the risks, but they

preferred not to know. However, others, while aware of the disease, were not aware of the risks until they participated in the study.

Optometrists thought that the views of the public varied, with a divide of opinion between those in independent and multiple practices. They felt there was a clear distinction between the expectations and characteristics of people attending different practice types. When carrying out the screening, we found that those attending independent practices were more likely to attend yearly compared with two yearly as in multiple practices, but they were also slightly older than participants from multiple practices. As those aged over 70 years are entitled to a reimbursed NHS test every year, unlike most other groups who are entitled to a two yearly test, the increase in age will be reflected in an increase in people attending on a yearly basis.

Optometrists felt that those attending independent practices would be more likely to take up the offer of screening, but would be more likely to have been tested elsewhere before. We found that the take up rate of screening was similar in all practices. There were slightly more people attending multiples who reported that they had never been screened before, but over 70% of participants from either practice type had never been screened before. The optometrists also believed that those attending multiple practices viewed optometrists' as shops, whereas those attending independent practices would view the optometrist as a health care provider. Our questions to participants about whether they thought optometrists should be able to detect health problems showed no great difference between participants from the different practices. However, while we based our study in several different practices, including independent practices with one optometrist to larger multiples with up to three optometrists testing at one time, we did not include any of the very large city centre practices where they may be seven or more optometrists testing at one time.

Some members of the public are aware of diabetes screening and of diabetes itself, but don't always take up opportunities unless confronted directly. There was a significant minority of participants who said that they had never been tested before, but also said they would consider going elsewhere for tests. Whilst they knew about diabetes, were aware that they were at risk and that screening would be available if they asked for it at a pharmacist or GP, they did not actually participate in a screening programme until asked directly

10.3 Findings of the screening study

During the 20 weeks of the screening study, 1909 adults attended the practices. The prevalence of self-reported diagnosed diabetes in this population was 9% (171 people with type 1 or 2 diabetes). 1303 (68.3% of adults attending practices) reported risk factors making them eligible to participate in the study. 1002 (77.9% of those eligible) agreed to participate. 75% of participants had never been screened before. 318 (31.7%) were found to have a rCBG measurement of 6.1mmol/l or more. 5 (0.5%) were found to be at high risk of having diabetes, with a rCBG measurement of 12.2mmol/l or more. This is similar to referral rates found in a Danish programme (247) and an Australian pharmacy programme (129). However, there was a lower prevalence of raised rCBG than found in an UK pharmacy based study, though this may be due to a higher number of South Asian participants in the pharmacy study (1).

Of the 318 people who we suggested should visit their GP for further investigation, 162 (50.9%) reported that they visited their GP and 66 (20.8%) did not. No response was received from the remaining 90 (28.3%). 138 (43.4% of those referred) were tested by their GP. 9 (0.9% of all participants) were subsequently diagnosed with pre-diabetes and 7 (0.7% of all participants) with diabetes. 22 participants (6.9% of those referred) reported that they attended their GP, but were not investigated further. This may reflect the difficulties in relationships and communication between optometrists and some medical practitioners.

Though optometrists can suggest that the participants may benefit from further investigation, it is then up to the GP to decided whether they feel it is appropriate to act on that information.

10.4 Cost consequences of screening and organisational challenges

The screening strategy we used resulted in a cost of £9.90 to carry out each rCBG test when costs of the equipments, time and training costs are considered. This results in a cost of £31.70 per case of rCBG of 6.1mmol/l or more found. Altering the strategy to offer screening tests to only those aged 40 years or more and with either a BMI of 25kg/m^2 or more pr a family history of diabetes increases the cost of each test to £10.14, but reduces the cost per case of rCBG of 6.1mmol/l or more to £26.36. If the strategy to identify those at risk who would benefit from screening was simplified to the risk factors of age, family history of disease and BMI, the cost of screening in the 20 weeks that the study ran for would have been reduced from £9,220 to £5,141.

The most significant factor in the cost of screening is the cost of time involved. If optical assistants were to carry out the majority of the preparation for the tests, the cost would be reduced by £3 for each rCBG resulting in a cost per case of RCBG of 6.1mmol/l or more detected of £18.69 if the reduced number of risk factors are used to identify those at risk. This would have reduced the screening costs for the 20 weeks to £3,620. The cost of carrying out the screening using optometrist and optical assistants is comparable to screening using other locations, such as pharmacies (129).

If a screening programme was to be implemented on a wider scale, organisation challenges occur at three levels; in the practice, PCT and finally nationally.

The equipment involved in screening in not extensive, and will not require significant space when compared with other equipment used for screening for glaucoma and retinopathy. The main considerations on the practice level would be determining who would carry out the tests and how this would fit in to the current practice procedures. In most practices optical assistants are trained to carry out screening tests, such as intra-ocular pressures and field tests for glaucoma screening. Diabetes screening tests could be offered alongside the other screening procedures that are currently offered. Using trained assistants would be more cost-effective and would fit in with many practices current procedures.

Financial barriers to screening in optometric practices would need to be overcome on a PCT level. Currently, most extended care roles are implemented initially on a local level. The Association of Optometrists provides guidance on the commissioning of enhanced services and advice on how local optical associations can work with their local PCT to develop contracts to provide these services (263). This would be the next stage in developing the service. If a PCT based service is successful, the protocols and procedures can then be shared on a national basis.

10.5 Feasibility

For a screening service to be feasible, we must be able to identify a population to target, ensure that the test is accessible and acceptable to that target population and that the service is cost-effective and can identify people who would benefit from further testing.

We have shown that the location is feasible, with around two-thirds of adults attending the practices having at least one risk factor for developing diabetes, and nearly 80% of those at risk taking up the offer of screening. Those participating in the screening service found it acceptable and accessible. Almost one-third of those participating had a rCBG level that required further investigation. Three-quarters of those

who participated had never been screened previously. Optometry practices are a feasible location for providing a screening service to those who may not be accessing other services.

We found a lower prevalence of pre-diabetes than may have been expected, 1.3% prevalence of non-diabetic hyperglycaemia (self-reported diagnosis of IFG, IGT, pre-diabetes or borderline diabetes) in this study compared with reported prevalence of IGT of 11.2% in US adults (96) and a prevalence of IFG of 6.9% in adults over 20 years (95). Though it is known that lifestyle changes can slow the progression to diabetes in people with non-diabetic hyperglycaemia, these changes are unlikely to be made if a person is unaware of the condition.

An argument against the use of screening for diabetes is the apparent lack of evidence showing benefit of screening asymptomatic people (261). This assumes that people with symptoms will seek out health care themselves. We found that just over half the participants reported that they had some symptoms of diabetes, but only one quarter had been screened before. Of the 531 people (53% of participants) who reported symptoms less than a quarter had been screened previously and only 71 (13.8%) reported that they would have considered asking for a test if they had not participated in the study. Some participants commented that they were not aware of all the symptoms of diabetes until they read the information provided in the study, or that, while they were aware of the symptoms, they would not have gone to the GP unless the symptoms were very severe.

There are a number of ways that have been suggested to identify people at risk of diabetes who would benefit from screening. We used a large number of risk factors, but it may be that the criteria for inclusion in a screening programme can be refined. Though performing fewer tests increases the cost per test slightly in terms of training costs, it will reduce

the overall cost by the virtue of fewer tests and decreases the cost per case detected.

Utilising medical conditions as method of identifying people who would benefit from screening, while useful in a GPs surgery, may be of less use in the optometrists practice. Using known hypertension as an indicator of who should be screened may be a cost effective strategy, but will only benefit those who have already accessed health services. This reduces the value of testing in optometry practices; the new approach is partly designed to reach people who have not been tested elsewhere.

10.6 Reflections

Prior to beginning this study, I felt that, in day-to-day routine practice, optometrists' skills and training was underutilised and that practices were ideally located to provide more services that currently undertaken. The educational role that an optometrist can provide seemed to be underestimated. During the course of routine sight tests, I have seen numerous people who did not believe that they were at risk of diabetes, despite having a family history of diabetes among other risk factors. It was often believed that as the family member had diabetes that was diagnosed in later life and was controlled by diet or medication, it would not be significant, unlike having diabetes from childhood and needing insulin. These were often people who reported that they did not go to their GP, and were often coming to optometrist as they had started to notice visual problems, usually with reading. Diabetes seemed to be an ideal disease for optometrists to have a role in detecting as is a condition about which they receive training and the public is aware of the link between diabetes and eye disease to some extent. The risk of developing diabetes increases with age, with screening recommended for those aged 40 years and over. Presbyopia begins to affect near vision from this age and so people may see an optometrist when they may not have any other problems that they would see other healthcare providers for and so

optometrists may be effective in reaching those who are not accessing other services.

The focus groups and interviews with optometrists confirmed that there are optometrists who would like to develop their underused skills, but that some feel that they are prevented from doing so by the attitudes of other professionals towards them. As a profession, optometrists can be isolated from other health care providers and interaction can be limited. Optometry has developed in a relatively short time, and while the public seem to have accepted changing roles, other heath professionals do not always accept or understand the developments. Optometrists sometime miss out on the opportunity to take on extended care roles as other professionals do not appreciate how optometrists can participate. However, optometrists may sometimes be the ones preventing themselves from taking on roles as they expect opposition from others, so do not wish to make the first steps themselves. During the course of this study, I have felt that some optometrists would be willing to take on schemes, and have been interested in the outcomes of this study to see if it is something they can look towards developing if it proved to be feasible. However, due to their perceptions of the sometime poor relationships with some other health professions, they would be reluctant to take on the initial work in setting up protocols and determining cost-effectiveness as they feel that the idea may be rejected by others.

Although some optometrists were concerned that a screening service would only be accepted by people who would have already accessed screening at other locations, we have shown that the offering services in unconventional settings can successfully reach people who are missing out on services currently offered by medical practitioners. Having determined that the public will accept new services in optometry practices, this can open the door to offering other services, such as smoking cessation and hypertension monitoring.

10.7 Future work

From this work we have begun to uncover how the optometrists view themselves and how they believe others, both the public and other professionals, view them. We have begun to investigate how the public views the optometry profession, but it would be interesting to know more about the publics' expectations of optometrists. GPs' views and attitudes towards optometrists could also be investigated. We know that not all those who presented to the GP following participating in screening were investigated further. It would be interesting to know why GPs chose not to investigate these people, as this has implications for the success of screening programmes.

We have shown that some optometrists are willing to carry out screening and that there is a population at risk of developing diabetes not being screened elsewhere but are willing to be screened at the optometry practice. The next step would be to begin a larger scale, PCT wide study, with optometry practice staff carrying out the screening themselves, as a possible precursor to implementation of a national policy. Following the results of the regression analysis, the inclusion criteria for this larger study could be reduced to those aged 40 years and over, who have a BMI of 25kg/m^2 or more or a family history of diabetes.

10.8 Limitations

We did not demonstrate any significant difference between the practice types, either in screening take up or participants' attitudes to optometrists' role in general health problems. However, while we based our screening study in several different practices, including independent practices with one optometrist to larger multiples with up to three optometrists testing at one time, we did not include any of the very large city centre practices where they may be seven or more optometrists testing at one time.

We demonstrated that the service was acceptable to those who participated. However, just under one-quarter of eligible adults chose not

to participate. We were not able to gain detailed reasons for their unwillingness to participate or to determine whether there was any difference in the demographics of those not participating. A large number of the people who participated in the screening services had never been screened before and it is likely that some of those who declined to participate had never been screened either. If we could understand why some people do not wish to be screened even when the opportunity is made convenient, we could target these people more effectively. However, the role of personal choice in health care must be considered. Some people do not wish to participate in screening despite being given information about potential long-term benefits of early detection of a disease. It has been suggested that informed choice can reduce the take up of breast cancer screening among those who are ‘present orientated’ (215), an attitude often associated with deprivation. This can lead to a reduced take up in the highest risk groups. Though public health as whole may benefit from screening, the rights of the individual to refuse to participate should be respected, even though some participants in our study did comment that screening should be made compulsory. However, we have shown that there are a large number of people attending optometry practices who have never been screened, but are willing to participate. While we must respect peoples wish not to participate in screening schemes, even if we believe the potential long-term benefits outweigh the potential short-term risk, we must also make screening available to those who would like to participate but do not want to go and request it. Though diabetes screening is currently available, it is not accessed by all those who be screened if it was offered to them directly.

We know that some did not participate as they reported that they had previously been tested by their GP. Some of those who participated also reported that they had been tested previously, but we did not ask how recently they were screened. Screening is recommended every three years by American Diabetes Association (ADA) (112) and has been shown to be a cost effective strategy (121).

When following up the participant who had a rCBG level of 6.1mmol/l or more, around half reported that they had been to see their GP. It has been assumed that those who did not respond did not visit their GP, and so did not benefit from screening. This included 2 people who had a rCBG level of 12.2mmol/l or above, who were at high risk of having diabetes.

We could have potentially increased the cases of diabetes and pre-diabetes diagnosed by carrying out the further testing ourselves, and ensuring that investigation and diagnosis was carried out in a standard way for all participants. If more cases of pre-diabetes were diagnosed, the cost per case detected would be lower than we calculated. This would ensure that all those with pre-diabetes would be diagnosed using the same criteria and it would not rely on participants to report the results to us. However, this would not be how a screening service would work if implemented in a larger scale. In this situation GPs would have to shoulder the responsibility of carrying out the further investigations and participants the responsibility of attending for those tests.

In calculating the economic implications of screening, the costs were considered for the initial two years of a screening programme. The majority of participants attended for sight tests either yearly or every two years. After running the service for 2 years, a large proportion of those at risk will have been screened, however, there will be new cohorts of people entering the ‘at risk’ group and people who would benefit from re-screening. 3 yearly retesting has been suggested by ADA, though for most people attending optometry practices, screening would have to occur on a two yearly or four yearly basis. The time frame for rescreening and the implications this has for cost needs to be considered.

Analysis of the results suggests that screening those aged 40 years and over with BMI of 25kg/m^2 or more or a family history of diabetes is an

effective strategy in our population. However, our participants were almost exclusively white (99%). The small numbers of Asian and black participants means that these results may not be applicable to those populations. It is known that the South Asian population has higher prevalence of diabetes, often with a younger onset (32) than the white population. We took account of this in our inclusion criteria by offering screening to those aged 25 years or more with high BMI, increased waist size or family history instead of 40 years for the white population. The lack of participants from black or South Asian populations was due to nature of the populations attending the participating practices, which was predominantly white, rather than an unwillingness to take up the offer of screening.

10.9 Conclusions

Optometrists are willing to take on new roles and some are keen to advance their clinical roles, but there are barriers to overcome in doing so. There is some uncertainty of their role within the health system and in how others professionals perceive them. This can make some reluctant to take on roles that they would otherwise like to be involved in. Financial barriers are a significant concern to optometrists, and have implications on how they take on new roles.

Screening in optometry practices would give those hard to reach ‘at risk’ individuals, who do not routinely visit their GP, the opportunity to participate. Age, family history of diabetes and increased BMI were all shown to be significant indicators of whether an individual was likely to have a rCBG of 6.1mmol/l or more. These factors do not require an individual to have visited their GP, unlike other conditions we asked about such as polycystic ovary syndrome and hypertension.

There are a large number of people attending optometry practices who have never been screened before and are at risk of developing diabetes. Some are unaware of the risks, while others know that they have risk

factors, but have not been tested before. Screening is available to them currently; all participants were registered with a GP and local pharmacies have free screening available if requested, but they had not availed themselves of these services.

Screening in optometry practices would seem to be very appropriate to target at those who may not be using other services. This may not provide the highest yield of new cases of diabetes or pre-diabetes at the lowest cost, but it will start to reach those who are not accessing other services that are currently in place, such as the NHS Health Checks. Screening in optometric practice would not be designed to replace other programmes, but would be complementary to these services.

This research has shown that screening is feasible in optometric practice, that substantial new numbers of people with pre-diabetes and diabetes can be detected. The next question is whether this could be applied to a larger set of practices, for example, an entire PCT, and the results more reasonably extrapolated for the rest of the UK. This could have significant national health policy implications for diabetes and screening.

Appendices

Appendix A
Invitation letter and consent form for focus groups and interviews

A qualitative evaluation of optometrists' perceptions, attitudes and beliefs towards screening and diagnosing diabetes.

Information Letter

Dear Colleague,

I am an optometrist based at Durham University and I am currently involved in a research project that aims to explore the optometrists' perceptions, beliefs and attitudes towards screening and diagnosing diabetes.

Diabetes is an increasing problem that may go undiagnosed for up to 7 years. It is estimated that the prevalence of all types of diabetes, both diagnosed and undiagnosed, is 4.73% in the North East of England. Around one third are undiagnosed Type 2 diabetics. Many patients will have developed complications by the time they are diagnosed as diabetic, leading to a reduction in quality of life.

I would like to find out local optometrists' views on screening for diabetes by holding some group discussions. It will last between 60 and 90 minutes. It will involve between 6 and 12 other optometrists and will be held at Durham University, Queen's Campus in Stockton-on-Tees on xxx at xxx. There is no payment for taking part.

The discussions will be tape recorded and transcribed to produce an anonymised written document that can be used for the purpose of the study. Thought it is not envisaged that any situation would occur where this would be the case, you should be aware that information given in confidence may not enjoy legal privilege and may be liable to sub poena by a court. Tape recordings of the discussions will be held securely for 6 months and the written document for three years before they are destroyed. You will also be asked to complete a short questionnaire before the start of the discussion. This information in this will be used anonymously. If you are willing to take part you will be asked to sign a consent form. You may withdraw at any point if you wish. The study is covered by the University public liability policy and has been approved by the School of Health Ethics committee.

You will have the opportunity to see and comment on a brief summary of the discussions.

I would be very grateful if you would consider being involved in these discussions. Please could you read this information letter and then complete and return the attached consent form as soon as possible.

If you have any questions or would like further information, please contact myself at Durham University on 0191 3340689 or email j.h.howse@dur.ac.uk

Thank you very much for your time and I look forward to hearing from you.

Yours sincerely

Jenny Howse

A qualitative evaluation of optometrists perceptions, attitudes and beliefs towards screening and diagnosing diabetes.

Please delete as appropriate

I have read the information letter	YES / NO
Have you had the opportunity to ask questions and discuss the study if you wish to?	YES / NO
Were you given enough time to consider whether you want to participate?	YES / NO
Have you received enough information about the study?	YES / NO
Do you consent to participate in the study?	YES / NO
Do you understand that you are free to withdraw from the study at any point, and without giving a reason?	YES / NO
Do you understand that the discussions will be tape recorded?	YES / NO

Signed……

Name……..

Address……

…….

…….

Telephone Number (Day)……

(Evening)…….

Email Address ……

Appendix B

Inclusion Criteria

Can I take part in this study?

You are eligible to take part in this study if you can answer YES to any of these questions. If you cannot answer a question, or don't understand it, just answer NO.

Are you White, aged over 40 years, or Black, Asian or from a minority ethnic group and aged over 25 years and:

A. have a close family member (parent, brother, sister) with type 2 diabetes? YES/NO

B. have a body mass index of 25kg/m^2 or more (if you're not sure, have a look on the chart)? YES/NO

C. have a waist measurement of:
more than 94cm (37 inches) for white and black men
more than 90cm (35 inches) for Asian men
more than 80cm (31.5 inches) for women YES/NO

For people of any age and ethnicity:
D. Do you have high blood pressure (or taking medication for high blood pressure) or have you had a heart attack or a stroke? YES/NO

E. Have you been told you have impaired glucose tolerance or impaired fasting glycaemia? YES/NO

F. Do you have a history of severe mental health problems? YES/NO

G. Do you have raised cholesterol? YES/NO

For women only:
H. Have you ever developed diabetes while pregnant (gestational diabetes)? YES/NO

I. Have you ever given birth to a baby weighing more than 4kg (8lb 8oz)? YES/NO

J. Do you have polycystic ovary syndrome? YES/NO

For everyone:
K. Do you experience any of the following symptoms of diabetes?
Increased thirst
Going to the toilet all the time, especially at night
Extreme tiredness
Weight loss YES/NO
Genital itching or regular episodes of thrush
Slow healing of wounds
Blurred vision

If you answer YES to any of these questions you are at risk of developing diabetes. The more risk factors that apply to you, the greater your risk of having diabetes.

Appendix C

Information leaflet and consent form

Information Sheet

Part 1

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you.
Please take time to read the following information carefully. Talk to others about the study if you wish.
(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).
Ask us if there is anything that is not clear or if you would like more information.
Take time to decide whether or not you wish to take part.

What is the purpose of the study?

This test is part of a study with Durham University looking at the role optometrists (opticians) can play in helping in the early diagnosis of type 2 diabetes. We hope to see if it is worthwhile using opticians as a setting for carrying out screening tests.
Diabetes Mellitus is a condition where the amount of sugar (glucose) in the blood is too high. Insulin is a hormone produced by the pancreas that helps the body use glucose.
There are two main types of diabetes, Type 1 and Type 2. Type 2 is the most common type of diabetes. It develops when the body does not produce enough insulin or if the insulin does not work properly.
There are around 2.3 million people with diabetes in the UK and around half a million people have diabetes but do not know it. Most of these people will have Type 2 diabetes.

Why have I been invited?

You have been invited to take part in this study as you have reported that you have a risk factor for diabetes.
The risk of type 2 diabetes increases with age. You are at risk if you are white and over 40. If you are African-Caribbean or South Asian you are at risk if you are over 25 years.
If you have diabetes in the family you are at risk. The risk is greater the closer the relative is, so you are more likely to develop diabetes if your parents or siblings have the condition than if aunts or uncles do.
Many people who are diagnosed with diabetes are overweight, the more overweight you are, the greater the risk.
If you have any problems with your circulation, or have a heart attack or a stroke you may have an increased risk. Also if you have high blood pressure or are taking medication to control your blood pressure you are at risk of developing diabetes.

Other conditions such as raised triglycerides, history of diabetes while pregnant (gestational diabetes) and severe mental health problems also increase the risk of developing the condition.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part and what do I have to do?

We will ask you to read the whole of this information sheet and then sign a consent form to say you are happy to take part. If you have any questions please ask. We will ask you to indicate which risk factors you have that put you at risk of developing diabetes. If you are at risk, we will then give you the opportunity to have the finger-prick test.
We will measure your blood glucose levels using a small machine like the ones people with diabetes sometime use to measure their own blood levels.
It involves a small pinprick on one finger to produce a small drop of blood. A test strip is touched against the drop of blood. The machine tells you the blood glucose level in a few seconds.
If your result is above a certain level, there is a risk that you may have diabetes or conditions know as Impaired Fasting Glucose (IFG) or Impaired Glucose Tolerance (IGT) and we would recommend that you have further tests carried out at your doctors. We will let your GP know the results of the test.
If the result is below this level it is unlikely that you have diabetes at the moment. However, you may still be at risk and you may go on to develop it in the future.
We will also give you a short questionnaire to take home with you and complete in your own time and return in a stamped addressed envelope.
If we do suggest that you should see your GP for further tests we will also write to you and ask you to complete another short questionnaire about the results.

What are the possible disadvantages and risks?

The test will involve taking a very small drop of blood from one finger. It will not interfere with normal activities. There is a small risk of infection from the test, however this test is routinely used in hospitals and by some people with diabetes to monitor their condition.

What are the possible benefits?

Type 2 diabetes develops slowly and people can have the condition for up to 12 years before it is diagnosed and they are treated. Often complications have developed by the time someone is diagnosed. If it can be diagnosed and treated earlier, complications may be reduced. Diabetes increases the risk of having a stroke, heart disease, kidney disease and nerve damage. It can also cause damage to the eyes (retinopathy). Good control of blood glucose is important in reducing these complications. The test can also identify IGT and IFG, which are conditions that increase the risk of progression to diabetes. There is some evidence that if you have these conditions, you can delay the development of diabetes by taking simple actions such as losing weight if you overweight or increasing your exercise.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision

Part 2

What will happen if I don't want to carry on with the study?

The study consists of three actions at the most. The blood test, a questionnaire, which we will give you when you have the test done, and a further questionnaire if you are referred to your GP. If at any point you do not wish to continue with the study you can withdraw without giving any reason. We will keep the results of the tests you have already completed. Withdrawal will not affect any other part of the service you receive from your optician.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the School of Medicine and Health, Durham University. The address is shown at the end of part 2.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential, and any information about you that leaves the opticians will have your name and address removed so that you cannot be recognised.

Involvement of the General Practitioner/Family doctor (GP)

If your blood glucose level is above a certain level we will advise you to visit your GP. We will also send them a copy of the results.

What will happen to any samples I give?

We will be collecting a tiny drop of blood on to a test strip. As soon as the machine reads the glucose levels in the blood, we will dispose of the test strip. No samples will be kept.

What will happen to the results of the research study?

The results will be written up as part of a thesis. We will also be publishing the results in medical journals. We will produce a short report on the results which we can send you if you would like.

Who is organising and funding the research?

The research is organised and funded by Durham University School of Medicine and Health. One of the researchers tuition fees are paid by the Francis J Bell fund.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Durham University School of Medicine and Health Research Ethics Committee.

Contact details

For further information regarding this research contact:
Jenny Howse
School of Medicine and Health
Wolfson Research Institute
Queens Campus
Stockton on Tees
TS17 6BH
j.h.howse@dur.ac.uk

Participant number……..

CONSENT FORM

Please initial box

I confirm I have read and understood the information sheet dated 23/1/09 version no. 2 for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my eye care or legal rights being affected. ☐

I understand that a high blood glucose reading will need further investigation and does not mean I necessarily have diabetes. ☐

I am happy for a copy of the test result to be forwarded to my GP and for us to contact you to follow up the results if I have a raised blood glucose reading. ☐

I agree to take part in this study ☐

Name (please print)……

Signature…… Date……..

Name of person taking consent……

Signature…… Date…….

Time of consent……..

Time of blood glucose test……

When completed, 1 copy for patient, 1 copy for researcher file.

Appendix D

Participant results forms

Your blood glucose (sugar) level today was……..mmol/l

This indicates that you are unlikely to have diabetes at the moment.
It does not mean you will never develop diabetes. You were offered the test today because you said you had at least one factor that puts you at increased risk of developing diabetes.

Some risk factors you cannot change, such as family history of diabetes. However, there are some that you can change, for example reducing your weight if you are overweight.

If you develop any of the symptoms described in the information leaflet you should contact you GP.

If you require any further information about diabetes you can visit www.diabetes.org.uk or talk to staff at your GPs surgery.

0. Results less than 6.1 mmol/l

Your blood glucose (sugar) level today was……mmol/l

These results show that your blood glucose is a little higher than normal. This does not indicate that you definitely have diabetes, but you are at risk of having impaired fasting glucose or impaired glucose tolerance, which are conditions sometimes referred to as ‘pre-diabetes’ or diabetes. It is not possible to say whether or not you have these conditions without having further tests. Your GP will be able to carry out these tests for you

People with IFG or IGT are more likely to develop diabetes than people without.
However it has been shown that if you have either of these conditions you can reduce the risk or delay the development of diabetes by ensuring you have a healthy lifestyle.

We are sending a copy of the results to your GP. We suggest that you arrange to see your GP routinely.

We would suggest that you see your GP in the next few weeks to discuss these results. You should not change your diet or current medication until you have seen your GP.

If you require any further information about diabetes you can visit www.diabetes.org.uk or talk to staff at your GPs surgery.

1. Results 6.1-12.1mmol/l

Your blood glucose (sugar) level today was ……..mmol/l

This indicates that you are at high risk of having diabetes. It does not mean you definitely have diabetes. Further tests need to be carried out to see whether you have diabetes or not. Your GP will be able to do this for you.

We advise that you contact your GP soon so they can investigate to see whether you do have diabetes. You should not change your diet or current medication until you have seen your GP.

We will send a copy of the results to your GP.

If you require any further information about diabetes you can visit www.diabetes.org.uk or talk to staff at your GPs surgery.

2. Results 12.2mmol and above

Appendix E

GP information letter and results form

Durham University Feasibility and acceptability of offering finger-prick blood glucose testing in optometric practice

Dear Colleague

I am an optometrist based at Durham University. I am currently involved in a research project that aims to look at the feasibility of optometrists carrying out screening for diabetes.

The research will be carried out in your area. I am proposing to carry out random capillary blood glucose tests on people attending opticians practices for routine sight tests who are found to be at risk of diabetes using the Diabetes UK risk questionnaire.

The protocols for referring will be similar to those set out by Diabetes UK and the Royal Pharmaceutical Society of Great Britain for screening using random blood glucose levels.

Diabetes UK recommend that anyone with risk factors who has a random capillary blood glucose whole blood level greater than 5.6mmol/l or plasma level greater than 6.1 mmol/l should be retested using a fasting test [1] and suggest that this should ideally be done by the GP. People with a random blood levels of 11.1 mmol/l and above (12.2mmol/l plasma equivalent) have a high probability of having diabetes and they suggest that these individuals should be referred urgently[2].

We will be offering the test to anyone who attends a practice for a sight test who reports risk factors for diabetes as determined using the Diabetes UK risk questionnaire. We will give the patients a copy of the results of the test with instructions to visit your practice if necessary. We will also send you a copy of the results if it is found to be 6.1mmol/l or greater.

We will be contacting the patient again around month after the test to determine the outcome of the referral. Other than the referral letter, we will have no other contact with you and we will not expect you to report any results to us.

If you would like any further information, please contact me on j.h.howse@durham.ac.uk or 0191 33408689.

I would like to thank you in advance for your help.

Yours sincerely

Jenny Howse

1. Diabetes UK (2007) Measure Up Campaign. Information for health care professionals: who should be screened for diabetes and how?
2. RPSGB (2004) Practice guidance on the care of people with diabetes (incorporating ‘Early Identification” guidance)

To Dr Date

Surgery

Patients Name

Address

DOB

This patient presented with risk factors of diabetes and was found to have a random blood glucose level of …… on testing.

Diabetes UK guidelines recommend the following action.

……. Retested using fasting test (results between 6.1-12.1mmol/l)

……. High risk of diabetes, further investigation required (≥12.2mmol/l)

I have asked them to see you for further investigation

Signed (Optometrist/researcher)

Practice Details

Appendix F

Quality control of blood glucose meters

Practice A

Meter 33771032

Date	Test Solution	Strip lot	Result	Expected range	Tester
18/5/09	1597 Low	8KC3A07	2.3	1.8-2.7	JH
	1553 Normal	8KC3A07	7.7	5.8-8.1	JH
	1615 High	8KC3A07	21.7	16.8-23.3	JH
19/5/09	1597 Low	8KC3A07	2.4	1.8-2.7	JH
	1553 Normal	8KC3A07	7.6	5.8-8.1	JH
	1615 High	8KC3A07	21.9	16.8-23.3	JH
20/5/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.3	5.8-8.1	TL
	1615 High	8KC3A07	20.9	16.8-23.3	TL
21/5/09	1597 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.3	5.8-8.1	SB
	1615 High	8KC3A07	20.6	16.8-23.3	SB
22/5/09	1597 Low	8KC3A07	2.4	1.8-2.7	JH
	1553 Normal	8KC3A07	7.6	5.8-8.1	JH
	1615 High	8KC3A07	22.1	16.8-23.3	JH
23/5/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	8.1	5.8-8.1	TL
	1615 High	8KC3A07	21.3	16.8-23.3	TL
26/5/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.2	5.8-8.1	TL
	1615 High	8KC3A07	21.3	16.8-23.3	TL
27/5/09	1597 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.3	5.8-8.1	SB
	1615 High	8KC3A07	21.0	16.8-23.3	SB
28/5/09	1597 Low	8KC3A07	2.4	1.8-2.7	JH
	1553 Normal	8KC3A07	7.8	5.8-8.1	JH
	1615 High	8KC3A07	22.6	16.8-23.3	JH
29/5/09	1597 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.7	5.8-8.1	SB
	1615 High	8KC3A07	21.7	16.8-23.3	SB
1/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.4	5.8-8.1	TL
	1615 High	8KC3A07	21.2	16.8-23.3	TL
2/6/09	1597 Low	8KC3A07	2.5	1.8-2.7	SB

	1553 Normal	8KC3A07	7.8	5.8-8.1	SB
	1615 High	8KC3A07	22.8	16.8-23.3	SB
3/6/09	1597 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.6	5.8-8.1	TL
	1615 High	8KC3A07	21.6	16.8-23.3	TL
4/6/09	1597 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.0	5.8-8.1	TL
	1615 High	8KC3A07	20.3	16.8-23.3	TL
5/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	JH
	1553 Normal	8KC3A07	7.4	5.8-8.1	JH
	1615 High	8KC3A07	22.1	16.8-23.3	JH
6/6/09	1597 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.2	5.8-8.1	SB
	1615 High	8KC3A07	21.4	16.8-23.3	SB
8/6/09	1597 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.2	5.8-8.1	SB
	1615 High	8KC3A07	21.4	16.8-23.3	SB
9/6/09	1597 Low	8KC3A07	2.2	1.8-2.7	TL
	1553 Normal	8KC3A07	7.3	5.8-8.1	TL
	1615 High	8KC3A07	21.0	16.8-23.3	TL
10/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	JH
	1553 Normal	8KC3A07	7.5	5.8-8.1	JH
	1615 High	8KC3A07	21.3	16.8-23.3	JH
11/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.3	5.8-8.1	SB
	1615 High	8KC3A07	21.6	16.8-23.3	SB
12/6/09	1597 Low	8KC3A07	2.5	1.8-2.7	TL
	1553 Normal	8KC3A07	7.8	5.8-8.1	TL
	1615 High	8KC3A07	23.1	16.8-23.3	TL

Practice B

Meter 3771040

Date	Test Solution	Strip lot	Result	Expected range	Tester
15/6/09	1597 Low	8KC3A07	2.3	1.8-2.7	JH
	1553 Normal	8KC3A07	7.2	5.8-8.1	JH

	1568 High	8KC3A07	21.9	16.8-23.3	JH
16/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	JH
	1553 Normal	8KC3A07	7.2	5.8-8.1	JH
	1615 High	8KC3A07	21.9	16.8-23.3	JH
17/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.1	5.8-8.1	SB
	1615 High	8KC3A07	21.0	16.8-23.3	SB
18/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.3	5.8-8.1	TL
	1615 High	8KC3A07	20.6	16.8-23.3	TL
19/6/09	1597 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.2	5.8-8.1	SB
	1615 High	8KC3A07	21.1	16.8-23.3	SB
20/6/09	1597 Low	8KC3A07	2.5	1.8-2.7	TL
	1553 Normal	8KC3A07	7.3	5.8-8.1	TL
	1615 High	8KC3A07	21.8	16.8-23.3	TL
21/6/09	1597 Low	8KC3A07	2.6	1.8-2.7	SB
	1553 Normal	8KC3A07	7.7	5.8-8.1	SB
	1615 High	8KC3A07	22.6	16.8-23.3	SB
22/6/09	1597 Low	8KC3A07	2.6	1.8-2.7	JH
	1553 Normal	8KC3A07	7.9	5.8-8.1	JH
	1615 High	8KC3A07	22.6	16.8-23.3	JH
23/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	DH
	1553 Normal	8KC3A07	8.1	5.8-8.1	DH
	1615 High	8KC3A07	23.2	16.8-23.3	DH
24/6/09	1597 Low	8KC3A07	2.6	1.8-2.7	SB
	1553 Normal	8KC3A07	7.7	5.8-8.1	SB
	1615 High	8KC3A07	22.8	16.8-23.3	SB
25/6/09	1597 Low	8KC3A07	2.5	1.8-2.7	TL
	1553 Normal	8KC3A07	7.8	5.8-8.1	TL
	1615 High	8KC3A07	22.4	16.8-23.3	TL
26/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.7	5.8-8.1	SB
	1615 High	8KC3A07	21.6	16.8-23.3	SB
27/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	8.1	5.8-8.1	TL
	1615 High	8KC3A07	21.7	16.8-23.3	TL
28/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	RM
	1553 Normal	8KC3A07	7.9	5.8-8.1	RM

	1615 High	8KC3A07	22.9	16.8-23.3	RM
29/6/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.6	5.8-8.1	SB
	1615 High	8KC3A07	22.3	16.8-23.3	SB
30/6/09	1597 Low	8KC3A07	2.6	1.8-2.7	SB
	1553 Normal	8KC3A07	8.1	5.8-8.1	SB
	1615 High	8KC3A07	23.0	16.8-23.3	SB
1/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.4	5.8-8.1	TL
	1615 High	8KC3A07	20.4	16.8-23.3	TL
2/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.6	5.8-8.1	SB
	1615 High	8KC3A07	21.1	16.8-23.3	SB
3/7/09	1597 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.5	5.8-8.1	TL
	1615 High	8KC3A07	21.4	16.8-23.3	TL
4/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	8.0	5.8-8.1	SB
	1615 High	8KC3A07	23.2	16.8-23.3	SB
5/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.8	5.8-8.1	TL
	1615 High	8KC3A07	22.3	16.8-23.3	TL
6/7/09	1597 Low	8KC3A07	2.6	1.8-2.7	TL
	1553 Normal	8KC3A07	8.1	5.8-8.1	TL
	1615 High	8KC3A07	22.9	16.8-23.3	TL
7/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.9	5.8-8.1	SB
	1615 High	8KC3A07	22.3	16.8-23.3	SB
8/7/09	1597 Low	8KC3A07	2.5	1.8-2.7	JH
	1553 Normal	8KC3A07	8.0	5.8-8.1	JH
	1615 High	8KC3A07	22.4	16.8-23.3	JH
9/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.3	5.8-8.1	TL
	1615 High	8KC3A07	21.8	16.8-23.3	TL
10/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.3	5.8-8.1	SB
	1615 High	8KC3A07	21.7	16.8-23.3	SB
11/7/09	1597 Low	8KC3A07	2.4	1.8-2.7	TL
	1553 Normal	8KC3A07	7.4	5.8-8.1	TL

	1615 High	8KC3A07	21.6	16.8-23.3	TL
12/7/09	1597 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.5	5.8-8.1	TL
	1615 High	8KC3A07	21.9	16.8-23.3	TL

Practice C

Meter 3771137

Date	Test Solution	Strip lot	Result	Expected range	Tester
6/7/09	1549 Low	8KC3A07	2.5	1.8-2.7	JH
	1553 Normal	8KC3A07	7.9	5.8-8.1	JH
	1610 High	8KC3A07	21.6	16.8-23.3	JH
7/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	SB
	1553 Normal	8KC3A07	7.7	5.8-8.1	SB
	1610 High	8KC3A07	20.8	16.8-23.3	SB
9/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.5	5.8-8.1	SB
	1610 High	8KC3A07	21.1	16.8-23.3	SB
10/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.1	5.8-8.1	TL
	1610 High	8KC3A07	21.6	16.8-23.3	TL
11/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.6	5.8-8.1	SB
	1610 High	8KC3A07	22.7	16.8-23.3	SB
13/7/09	1549 Low	8KC3A07	2.5	1.8-2.7	JB
	1553 Normal	8KC3A07	7.7	5.8-8.1	JB
	1610 High	8KC3A07	21.2	16.8-23.3	JB
14/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	DH
	1553 Normal	8KC3A07	7.9	5.8-8.1	DH
	1610 High	8KC3A07	22.4	16.8-23.3	DH
15/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.4	5.8-8.1	SB
	1610 High	8KC3A07	21.1	16.8-23.3	SB
16/7/09	1549 Low	8KC3A07	2.5	1.8-2.7	TL
	1553 Normal	8KC3A07	7.6	5.8-8.1	TL
	1610 High	8KC3A07	22.3	16.8-23.3	TL

17/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	JB
	1553 Normal	8KC3A07	7.7	5.8-8.1	JB
	1610 High	8KC3A07	21.9	16.8-23.3	JB
18/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	RM
	1553 Normal	8KC3A07	7.6	5.8-8.1	RM
	1610 High	8KC3A07	23.1	16.8-23.3	RM
20/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.7	5.8-8.1	SB
	1610 High	8KC3A07	21.6	16.8-23.3	SB
21/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	DH
	1553 Normal	8KC3A07	8.0	5.8-8.1	DH
	1610 High	8KC3A07	22.4	16.8-23.3	DH
22/7/09	1549 Low	8KC3A07	2.6	1.8-2.7	JB
	1553 Normal	8KC3A07	8.1	5.8-8.1	JB
	1610 High	8KC3A07	22.1	16.8-23.3	JB
23/7/09	1549 Low	8KC3A07	2.6	1.8-2.7	DH
	1553 Normal	8KC3A07	7.8	5.8-8.1	DH
	1610 High	8KC3A07	21.7	16.8-23.3	DH
24/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.5	5.8-8.1	SB
	1610 High	8KC3A07	22.0	16.8-23.3	SB
25/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	JH
	1553 Normal	8KC3A07	7.6	5.8-8.1	JH
	1610 High	8KC3A07	21.3	16.8-23.3	JH
27/7/09	1549 Low	8KC3A07	2.6	1.8-2.7	DH
	1553 Normal	8KC3A07	7.7	5.8-8.1	DH
	1610 High	8KC3A07	22.5	16.8-23.3	DH
28/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	JB
	1553 Normal	8KC3A07	7.2	5.8-8.1	JB
	1610 High	8KC3A07	21.5	16.8-23.3	JB
28/7/09	1549 Low	9CC3B31	2.4	1.9-2.7	JB
	1553 Normal	9CC3B31	7.8	6.0-8.3	JB
	1610 High	9CC3B31	22.8	17.3-23.9	JB
29/7/09	1549 Low	9CC3B31	2.5	1.9-2.7	TL
	1553 Normal	9CC3B31	7.7	6.0-8.3	TL
	1610 High	9CC3B31	21.8	17.3-23.9	TL
30/7/09	1597 Low	9CC3B31	2.4	1.9-2.7	JB
	1553 Normal	9CC3B31	7.5	6.0-8.3	JB
	1615 High	9CC3B31	22.2	17.3-23.9	JB

31/7/09	1597 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.3	6.0-8.3	TL
	1615 High	9CC3B31	21.6	17.3-23.9	TL
1/8/09	1597 Low	9CC3B31	2.4	1.9-2.7	JH
	1553 Normal	9CC3B31	7.5	6.0-8.3	JH
	1615 High	9CC3B31	22.3	17.3-23.9	JH

Practice D

Meter 3771044

Date	Test Solution	Strip lot	Result	Expected range	Tester
20/7/09	1549 Low	8KC3A07	2.7	1.8-2.7	JH
	1553 Normal	8KC3A07	8.1	5.8-8.1	JH
	1615 High	8KC3A07	23.2	16.8-23.3	JH
21/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	SB
	1553 Normal	8KC3A07	7.6	5.8-8.1	SB
	1615 High	8KC3A07	23.3	16.8-23.3	SB
22/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.4	5.8-8.1	TL
	1615 High	8KC3A07	21.0	16.8-23.3	TL
23/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	JB
	1553 Normal	8KC3A07	6.9	5.8-8.1	JB
	1615 High	8KC3A07	21.1	16.8-23.3	JB
24/7/09	1549 Low	8KC3A07	2.3	1.8-2.7	TL
	1553 Normal	8KC3A07	7.6	5.8-8.1	TL
	1615 High	8KC3A07	20.9	16.8-23.3	TL
25/7/09	1549 Low	8KC3A07	2.4	1.8-2.7	RM
	1553 Normal	8KC3A07	7.8	5.8-8.1	RM
	1615 High	8KC3A07	21.9	16.8-23.3	RM
28/7/09	1549 Low	9CC3B31	2.5	1.9-2.7	SB
	1553 Normal	9CC3B31	7.9	6.0-8.3	SB
	1615 High	9CC3B31	21.8	17.3-23.9	SB
29/7/09	1549 Low	9CC3B31	2.4	1.9-2.7	JB
	1553 Normal	9CC3B31	7.8	6.0-8.3	JB
	1615 High	9CC3B31	21.78	17.3-23.9	JB
30/7/09	1549 Low	9CC3B31	2.4	1.9-2.7	SB

	1553 Normal	9CC3B31	7.6	6.0-8.3	SB
	1615 High	9CC3B31	21.0	17.3-23.9	SB
31/7/09	1549 Low	9CC3B31	2.4	1.9-2.7	JH
	1553 Normal	9CC3B31	7.5	6.0-8.3	JH
	1615 High	9CC3B31	22.3	17.3-23.9	JH
1/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	RM
	1553 Normal	9CC3B31	7.8	6.0-8.3	RM
	1615 High	9CC3B31	22.3	17.3-23.9	RM
3/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	SB
	1553 Normal	9CC3B31	8.1	6.0-8.3	SB
	1615 High	9CC3B31	21.4	17.3-23.9	SB
4/8/09	1549 Low	9CC3B31	2.3	1.9-2.7	SB
	1553 Normal	9CC3B31	7.8	6.0-8.3	SB
	1615 High	9CC3B31	21.6	17.3-23.9	SB
5/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	SB
	1553 Normal	9CC3B31	7.7	6.0-8.3	SB
	1615 High	9CC3B31	21.7	17.3-23.9	SB
6/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.4	6.0-8.3	TL
	1615 High	9CC3B31	22.1	17.3-23.9	TL
7/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	JH
	1553 Normal	9CC3B31	7.7	6.0-8.3	JH
	1615 High	9CC3B31	21.9	17.3-23.9	JH
8/8/09	1549 Low	9CC3B31	2.6	1.9-2.7	RM
	1553 Normal	9CC3B31	7.8	6.0-8.3	RM
	1615 High	9CC3B31	22.3	17.3-23.9	RM
10/8/09	1549 Low	9CC3B31	2.6	1.9-2.7	TL
	1553 Normal	9CC3B31	8.1	6.0-8.3	TL
	1615 High	9CC3B31	23.5	17.3-23.9	TL
11/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	SB
	1553 Normal	9CC3B31	7.7	6.0-8.3	SB
	1615 High	9CC3B31	22.1	17.3-23.9	SB
12/8/09	1549 Low	9CC3B31	2.3	1.9-2.7	SB
	1553 Normal	9CC3B31	7.5	6.0-8.3	SB
	1610 High	9CC3B31	21.3	17.3-23.9	SB
13/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.9	6.0-8.3	TL
	1615 High	9CC3B31	21.6	17.3-23.9	TL
14/8/09	1549 Low	9CC3B31	2.6	1.9-2.7	SB

	1553 Normal	9CC3B31	8.1	6.0-8.3	SB
	1615 High	9CC3B31	21.8	17.3-23.9	SB
15/8/09	1597 Low	9CC3B31	2.3	1.9-2.7	JH
	1553 Normal	9CC3B31	7.2	6.0-8.3	JH
	1615 High	9CC3B31	21.6	17.3-23.9	JH

Practice E

Meter 3771133

Date	Test Solution	Strip lot	Result	Expected range	Tester
17/8/09	1549 Low	9CC3B31	2.6	1.9-2.7	JH
	1553 Normal	9CC3B31	8.1	6.0-8.3	JH
	1615 High	9CC3B31	22.6	17.3-23.9	JH
18/8/09	1549 Low	9CC3B31	2.6	1.9-2.7	TL
	1553 Normal	9CC3B31	7.9	6.0-8.3	TL
	1615 High	9CC3B31	22.7	17.3-23.9	TL
19/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	JB
	1553 Normal	9CC3B31	7.7	6.0-8.3	JB
	1615 High	9CC3B31	22.6	17.3-23.9	JB
20/8/09	1549 Low	9CC3B31	2.6	1.9-2.7	SB
	1553 Normal	9CC3B31	7.8	6.0-8.3	SB
	1615 High	9CC3B31	22.7	17.3-23.9	SB
21/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.3	6.0-8.3	TL
	1615 High	9CC3B31	21.1	17.3-23.9	TL
22/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	RM
	1553 Normal	9CC3B31	7.8	6.0-8.3	RM
	1615 High	9CC3B31	22.2	17.3-23.9	RM
24/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	JB
	1553 Normal	9CC3B31	8.3	6.0-8.3	JB
	1615 High	9CC3B31	22.8	17.3-23.9	JB
25/8/09	1549 Low	9CC3B31	2.7	1.9-2.7	JH
	1553 Normal	9CC3B31	7.9	6.0-8.3	JH
	1615 High	9CC3B31	23.0	17.3-23.9	JH
26/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.2	6.0-8.3	TL
	1615 High	9CC3B31	21.6	17.3-23.9	TL

27/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	SB
	1553 Normal	9CC3B31	7.4	6.0-8.3	SB
	1615 High	9CC3B31	21.7	17.3-23.9	SB
28/8/09	1549 Low	9CC3B31	2.5	1.9-2.7	SB
	1553 Normal	9CC3B31	7.6	6.0-8.3	SB
	1615 High	9CC3B31	21.7	17.3-23.9	SB
29/8/09	1549 Low	9CC3B31	2.4	1.9-2.7	SB
	1553 Normal	9CC3B31	7.4	6.0-8.3	SB
	1615 High	9CC3B31	21.8	17.3-23.9	SB
1/9/09	1549 Low	9CC3B31	2.6	1.9-2.7	JH
	1553 Normal	9CC3B31	7.9	6.0-8.3	JH
	1615 High	9CC3B31	23.3	17.3-23.9	JH
2/9/09	1549 Low	9CC3B31	2.4	1.9-2.7	SB
	1553 Normal	9CC3B31	7.6	6.0-8.3	SB
	1615 High	9CC3B31	21.9	17.3-23.9	SB
3/9/09	1549 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.6	6.0-8.3	TL
	1615 High	9CC3B31	21.8	17.3-23.9	TL
4/9/09	1549 Low	9CC3B31	2.6	1.9-2.7	JB
	1553 Normal	9CC3B31	7.6	6.0-8.3	JB
	1615 High	9CC3B31	22.5	17.3-23.9	JB
5/9/09	1549 Low	9CC3B31	2.5	1.9-2.7	RM
	1553 Normal	9CC3B31	8.1	6.0-8.3	RM
	1615 High	9CC3B31	23.2	17.3-23.9	RM
7/9/09	1549 Low	9CC3B31	2.5	1.9-2.7	TL
	1553 Normal	9CC3B31	7.7	6.0-8.3	TL
	1615 High	9CC3B31	23.1	17.3-23.9	TL
8/9/09	1549 Low	9CC3B31	2.7	1.9-2.7	JB
	1553 Normal	9CC3B31	8.2	6.0-8.3	JB
	1615 High	9CC3B31	22.7	17.3-23.9	JB
9/9/09	1549 Low	9CC3B31	2.4	1.9-2.7	JH
	1553 Normal	9CC3B31	7.4	6.0-8.3	JH
	1615 High	9CC3B31	21.8	17.3-23.9	JH
10/9/09	1549 Low	9CC3B31	2.4	1.9-2.7	TL
	1553 Normal	9CC3B31	7.2	6.0-8.3	TL
	1615 High	9CC3B31	21.7	17.3-23.9	TL
11/9/09	1549 Low	9CC3B31	2.5	1.9-2.7	JB
	1553 Normal	9CC3B31	8.1	6.0-8.3	JB
	1615 High	9CC3B31	22.0	17.3-23.9	JB

Appendix G

Follow up questionnaire for participants with rCBG of 6.1mmol/l or more

Participant number xxx 2009

You recently attended your opticians and had your blood sugar levels checked. Based on the information you gave us, and the results of the blood test, we suggested that you should visit your GP. We also sent the results of your blood test to your GP.

As we explained when you attended your opticians, we are following up on the referral. I have enclosed a short questionnaire. I would be very grateful if you could complete it as fully as you can and return it in the stamped addressed envelope supplied.

Please tick the appropriate statement

1. Did you visit your GPs practice about the results of the blood test you had at the opticians?

……YES – please go to question 2

…….NO – Thank you for your help. Your do not need to answer any further questions

2. Did your GP or Nurse carry out any further tests to see if you had diabetes?

……YES – please go to question 3

…….NO – Thank you for your help. Your do not need to answer any further questions

……UNSURE – please go to question 3

3. Did your GP or nurse give you a diagnosis or tell you that you had any of the following?

…… Diabetes

…… Pre-diabetes

…… Impaired Fasting Glucose

…… Impaired Glucose tolerance

…… Borderline diabetes

…… No diagnosis/Normal

…… Unsure of diagnosis

Thank you very much for your help

Appendix H

Acceptability questionnaire

Durham University Feasibility and acceptability of offering finger-prick blood glucose testing in optometric practice

Participant ID ……..

Thank you for taking part in the study today.
We would be very grateful if you could complete following questions as fully as possible. The questionnaires are anonymous. The researcher who will look at the responses will not have access to your personal details and we will not report individual responses to your optician.

1. How often do you usually visit an optician? Please tick one response

…… Every year

…… Every 2 years

…… Every 3-4 years

…… Less frequently

…… This was my first sight test

2. Have you ever been screened or tested for diabetes before the test that was carried out at the opticians? Please tick one response.

…… Yes

…… No

3. Please think about the diabetes test you had done at the opticians (not the sight test) and circle the response that you feel most accurately describes your response

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
The opticians practice was convenient for the screening test	1	2	3	4	5
The screening test was uncomfortable	1	2	3	4	5
I would recommend friends/family to have the test	1	2	3	4	5
I expect opticians to be able to detect health problems	1	2	3	4	5

4. If you had not had the diabetes test done at the opticians, would you have gone anywhere else and asked for a screening test?

……. NO – please go to question 6

……. YES – please go to question 5

5. Where would you have gone for the diabetes test?

……. GP/practice nurse

……. Pharmacy

……. Other - Please indicate where……..

6. If you have any comments about the diabetes screening test you had at the opticians, please write below.

Thank you for help.

Please return the form in the stamped addressed envelope provided.

References

References

1. Lawal AG, Patel MG, Wong ICK, Chrystyn H. Opportunistic screening for type 2 diabetes within inner city community pharmacies. International Journal of Pharmacy Practice. 2003;11:R10.

2. National Health Check Programme. Putting Prevention First – NHS Health Check: Vascular Risk Assessment and Management Best Practice Guidance Department Of Health 2009.

3. Sight test volume and workforce survey 2005/06. The Information Centre; 2006.

4. Scheme for Registration Handbook 2009: College of Optometry; 2009.

5. Hurcomb PG, Wolffsohn JS. The management of systemic hypertension in optometric practice. Ophthalmic and Physiological Optics. 2005 Nov;25(6):523-33.

6. MacFarlane IA, Bliss M, Jackson JGL, Williams G. The history of diabetes mellitus. In: Pickup JC, Williams G, editors. Textbook of diabetes. Oxford: Blackwell; 1997. p. 1.-.21.

7. Part 1: Diagnosis and classification of diabetes mellitus: World Health Organisation1999.

8. WHO expert committee on diabetes mellitus. Second Report. Geneva: WHO1980 Contract No.: 646.

9. Diabetes Mellitus: report of a WHO study group. Geneva: WHO1985.

10. Forouhi NG, Merrick D, Goyder E, Ferguson BA, Abbas J, Lachowycz K, et al. Diabetes prevalence in England, 2001 - estimates from an epidemiological model. Diabetic Medicine. 2005;23:189-97.

11. Bingley PJ, Gale EJ. Incidence of insulin dependent diabetes in England: a study in the Oxford region, 1985-1986. British Medical Journal. 1989;298:558-60.

12. Connolly V, Unwin N, Sherriff P, Bilous R, Kelly W. Diabetes prevalence and socioeconomic status: a poulation based study showing increased prevalence of type 2 diabetes mellitus in deprived areas. Journal of Epidemiology and Community Health. 2000;54:173-7.

13. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes - Estimates for the year 2000 and projections for 2030. Diabetes Care. 2004;27:1047-53.

14. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025. Prevalence, numerical estimates, and projections. Diabetes Care. 1998;21:1414-31.

15. Mainous III AG, Baker R, Koopman RJ, Saxena S, Diaz VA, Everett CJ, Majeed A. Impact of the population at risk of diabetes on projections of diabetes burden in the United States: an epidemic on the way. Diabetologia. 2007;50:934-40.

16. Boyle JP, Honeycutt AA, Narayan KMV, Hoerger TJ, Geiss LS, Chen H, Thompson TJ. Projection of diabetes burden through 2050 - Impact of changing demography and disease prevalence in the US. Diabetes Care. 2001;24:1936-40.

17. Narayan KMV, Saaddine JB, Boyle JP, Thompson TJ, Geiss LS. Impact of recent increases in incidence on future diabetes burden. Diabetes Care. 2006;29:2113-6.

18. Thomas MC, Walker MK, Emberson JR, Thomson AG, Lawlor DA, Ebrahim S, Whincup PH. Prevalence of undiagnosed Type 2 diabetes and impaired fasting glucose in older British men and women. Diabetes Medicine. 2005;22:789-93.

19. Gatling W, Guzder RN, Turnbull JC, Budd S, Mullee MA. The Poole Diabetes Study: how many cases of Type 2 diabetes are diagnosed each year during normal health care in a defined community? Diabetes Research and Clinical Practice. 2001 Aug;53(2):107-12.

20. Haines L, Wan KC, Lynn R, Barrett TG, Shield JPH. Rising Incidence of Type 2 Diabetes in Children in the U.K. Diabetes Care. 2007;30:1097-101.

21. Feltbower RG, McKinney PA, Campbell FM, Stephenson CR, Bodansky HJ. Type 2 and other forms of diabetes in 0-30 year olds: a hospital based study in Leeds, UK. Archives of Disease in Childhood. 2003;88:676-9.

22. Ehtisham S, Barrett TG, Shaw NJ. Type 2 diabetes mellitus in UK children - an emerging problem. Diabetic Medicine. 2000;17:867-71.

23. Koopman RJ, Mainous III AG, Diaz VA, Geesey ME. Changes in age at diagnosis of type 2 diabetes mellitus in the United States, 1988 to 2000. Annals of Family Medicine. 2005;3:60-3.

24. King H, Rewers M. Global Estimates for Prevalence of Diabetes-Mellitus and Impaired Glucose-Tolerance in Adults. Diabetes Care. 1993;16(1):157-77.

25. Hitman GA, Sudagani J. Searching for genes in diabetes and the metabolic syndrome. International Journal of Clinical Practice. 2004;58:3-8.

26. Busch CP, Hegele RA. Genetic determinants of type 2 diabetes melitus. Clinical Genetics. 2001;60:243-54.

27. McCarthy MI, Zeggini E. Genome-wide association scans for Type 2 diabetes: new insights into biology and therapy. Trends in Pharmacological Sciences. 2007;28:598-601.

28. Rich SS. Mapping genes in diabetes - Genetic epidemiologic perspective. Diabetes. 1990;39:1315-9.

29. Molyneaux L, Constantino M, Yue D. Strong family history predicts a younger age of onset for subjects diagnosed with type 2 diabetes. Diabetes Obesity & Metabolism. 2004;6(3):187-94.

30. Bo S, Cavallo-Perin P, Gentile L, Repetti E, Pagano G. Influence of a familial history of diabetes on the clinical characteristics of patients with Type 2 diabetes mellitus. Diabetic Medicine. [Article]. 2000 Jul;17(7):538-42.

31. Simmons D, Williams DRR, Powell MJ. Prevalence of diabetes in a predominantly Asian community: preliminary findings of he Coventry diabetes study British Medical Journal. 1989;298:18-21.

32. Mather HM, Keen H. The Southall Diabetes Survey: prevalence of known diabetes in Asians and Europeans. British Medical Journal. 1985;291:1081-4.

33. Jenum AK, Holme I, Graff-Iverson S, Birkeland KI. Ethnicity and sex are strong determinants of diabetes in an urban western society: implications for prevention. Diabetologia. 2005;48:435-9.

34. Riste L, Khan F, Cruickshank K. High prevalence of type 2 diabetes in all ethnic groups, including Europeans in a British inner city. Diabetes Care. 2001;24:1377-83.

35. Oldroyd J, Banerjee M, Heald A, Cruickshank K. Diabetes and ethnic minorities. Postgraduate Medical Journal. 2005;81:486-90.

36. Pearson S, Brolos EJ, Herner EB, Hansen B, Olsen BS. Screening Copenhagen school children at risk of type 2 diabetes mellitus using random capillary blood glucose. Acta Paediatrica. 2007;96:885-9.

37. Mayer-Davis EJ. Type 2 diabetes in youth: Epidemiology and current research towards prevention and treatment. Journal of the American Dietetic Association. 2008;108:S45-S51.

38. Jinlin F, Binyou W, Terry C. A new approach to the study of diet and risk of type 2 diabetes. Journal of Postgraduate Medicine. 2007;53:139-43.

39. Simmons RK, Harding A-H, Wareham NJ, Griffin SJ. Do simple questions about diet and physical activity help to identify those at risk of Type 2 diabetes? Diabetic Medicine. 2007;24:830-5.

40. Borodulin K, Tuomilehto J, Peltonen M, Lakka TA, Sundvall J, Jousilahti P. Association of leisure time physical activity and abdominal obesity with fasting serum insulin and 2-h postchallenge plasma glucose levels. Diabetic Medicine. 2006;23(9):1025-8.

41. Salmasi AM, Alimo A, Dancy M. Prevalence of unrecognized abnormal glucose tolerance in patients attending a hospital hypertension clinic. American Journal of Hypertension. 2004 Jun;17(6):483-8.

42. Bakris G, Stockert J, Molitch M, Zhou Q, Champion A, Bacher P, Sowers J. Risk factor assessment for new onset diabetes: literature review. Diabetes Obesity & Metabolism. 2009;11(3):177-87.

43. Chang J, Azziz R, Legro R, Dewailly D, Franks S, Tarlatzis R, et al. Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome. Fertility and Sterility. 2004;81:19-25.

44. Ehrmann DA, Kasza K, Azziz R, Legro RS, Ghazzi MN. Effects of race and family history of type 2 diabetes on metabolic status of women with polycystic ovary syndrome. Journal of Clinical Endocrinology and Metabolism. 2005;90(1):66-71.

45. Ehrmann DA, Barnes RB, Rosenfield RL, Cavaghan MK, Imperial J. Prevalence of impaired glucose tolerance and diabetes in women with polycystic ovary syndrome. Diabetes Care. 1999 Jan;22(1):141-6.

46. Dunaif A. Insulin resistance and the polycystic ovary syndrome: Mechanism and implications for pathogenesis. Endocrine Reviews. 1997;18(6):774-800.

47. Ford ES. Prevalence of the metabolic syndrome defined by the International Diabetes Federation among adults in the U.S. Diabetes Care. 2005;28(11):2745-9.

48. Meigs JB, Williams K, Sullivan LM, Hunt KJ, Haffner SM, Stern MP, Villalpando CG, Perhandidis JS, Nathan DM, D'Agostino RB, Wilson PWF. Using metabolic syndrome traits for efficient detection of impaired glucose tolerance. Diabetes Care. 2004 Jun;27(6):1417-26.

49. Kim C, Herman WH, Vijan S. Efficacy and cost of postpartum screening strategies for diabetes among women with histories of gestational diabetes mellitus. Diabetes Care. 2007 May;30(5):1102-6.

50. Kim C, Newton KM, Knopp RH. Gestational diabetes and the incidence of type 2 diabetes - A systematic review. Diabetes Care. 2002;25(10):1862-8.

51. Ratner RE, Christophi CA, Metzger BE, Dabelea D, Bennett PH, Pi-Sunyer X, Fowler S, Kahn SE. Prevention of Diabetes in Women with a History of Gestational Diabetes: Effects of Metformin and Lifestyle Interventions. Journal of Clinical Endocrinology & Metabolism. 2008;93(12):4774-9.

52. Zhao W, Chen Y, Lin M, Sigal RJ. Association between diabetes and depression: Sex and age differences. Public Health. 2006;120(8):696-704.

53. Singh R, Zimmet P, Shaw J. Mental health, antipsychotics and hyperglycaemia. Diabetes and Metabolic Syndrome: Clinical Research and Reviews. 2007;1(3):209-24.

54. Rubin RR, Ma Y, Marrero DG, Peyrot M, Barrett-Connor EL, Kahn SE, Haffner SM, Price DW, Knowler WC. Elevated Depression Symptoms, Antidepressant Medicine Use, and Risk of Developing Diabetes During the Diabetes Prevention Program. Diabetes Care. 2008;31:420-6.

55. Golden SH, Williams JE, Ford DE, Yeh H-C, Sanford CP, Nieto FJ, Brancati FL. Depressive Symptoms and the Risk of Type 2 Diabetes. Diabetes Care. 2004;27:429-35.

56. Basu A, Meltzer HY. Differential trends in prevalence of diabetes and unrelated general medical illness for schizophrenia patients before and after the atypical antipsychotic era. Schizophrenia Research. 2006 Sep;86(1-3):99-109.

57. Meisinger C, Lowel H, Thorand B, Doring A. Leisure time physical activity and the risk of type 2 diabetes in men and women from the general population. Diabetologia. 2005 Jan;48(1):27-34.

58. Hulme SA, Tin-U A, Hardy KJ, Joyce PW. Evaluation of a district-wide screening programme for diabetic retinopathy utilizing trained optometrists using slit-lamp and Volk lenses. Diabetic Medicine. 2002 Sep;19(9):741-5.

59. Chien KL, Chen MF, Hsu HC, Su TC, Lee YT. Sports activity and risk of type 2 diabetes in Chinese. Diabetes Research and Clinical Practice. 2009 Jun;84(3):311-8.

60. Laaksonen DE, Lindstrom J, Lakka TA, Eriksson JG, Niskanen L, Wikstrom K, et al. Physical activity in the prevention of type 2 diabetes - The Finnish Diabetes Prevention Study. Diabetes. 2005 Jan;54(1):158-65.

61. Jeon CY, Lokken RP, Hu FB, van Dam RM. Physical activity of moderate intensity and risk of type 2 diabetes. Diabetes Care. 2007 Mar;30(3):744-52.

62. Genuth S, Alberti K, Bennett P, Buse J, DeFronzo R, Kahn R, et al. Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care. 2003;26(11):3160-7.

63. Chew SL, Leslie D. Clinical endocrinology and diabetes : an illustrated colour text. New York: Churchill Livingstone; 2006.

64. Clark NG, Fox KM, Grandy S. Symptoms of diabetes and their association with the risk and presence of diabetes. Diabetes Care. 2007;30:2868-73.

65. Drivsholm T, Olivarius ND, Nielsen ABS, Siersma V. Symptoms, signs and complications in newly diagnosed type 2 diabetic patients, and their relationship to glycaemia, blood pressure and weight. Diabetologia. 2005 Feb;48(2):210-4.

66. Chew SL, Leslie D. Clinical Endocrinology and Diabetes: Churchill Livingston; 2005.

67. Chaturvedi N. The burden of diabetes and its complications: Trends and implications for intervention. Diabetes Research and Clinical Practice. 2007;76S:S3-S12.

68. Gu K, Cowie C, Harris MI. Diabetes and decline in heart disease mortality in US adults. Journal of the American Medical Association. 1999;281(14):1291-7.

69. Donnan PT, Boyle DIR, Broomhall J, Hunter K, Macdonald TM, Newton RW, Morris AD. Prognosis following first acute myocardial infarction in Type 2 diabetes: a comparitive population study Diabetic Medicine. 2002;19(6):448-55.

70. Resnikoff S, Pascolini D, Etya'ale D, Kocur I, Pararajasegaram R, Pokharel GP, Mariotti SP. Global data on visual impairment in the year 2002. Bulletin of the World Health Organisation. 2004;82(11).

71. Ghafour IM, Allan D, Foulds WS. Common causes of blidness and visual handicap in the west of Scotland. British Journal of Ophthalmology. 1983;67:209-13.

72. Kocur I, Resnikoff S. Visual impairment and blindness in Europe and their prevention. British Journal of Ophthalmology. 2002;86:716-22.

73. Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. British Medical Journal. 2000 Aug;321(7258):405-12.

74. Olivarius ND, Nielsen NV, Andreasen AH. Diabetic retinopathy in newly diagnosed middle-aged and elderly diabetic patients. Prevalence and interrelationship with microalbuminuria and triglycerides. Graefes Archive for Clinical and Experimental Ophthalmology. 2001 Sep;239(9):664-72.

75. Stratton IM, Kohner EM, Aldington SJ, Turner RC, Holman RR, Manley SE, Matthews DR. UKPDS 50: Risk factors for incidence and progression of retinopathy in Type II diabetes over 6 years from diagnosis. Diabetologia. 2001 Feb;44(2):156-63.

76. Mitchell P, Smith W, Wang JJ, Attebo K. Prevalence of diabetic retinopathy in an older community - The Blue Mountains Eye Study. Ophthalmology. 1998 Mar;105(3):406-11.

77. Litwin AS, Clover A, Hodgkins PR, Luff AJ. Affluence is not related to delay in diagnosis of Type 2 diabetes as judged by the development of diabetic retinopathy. Diabetic Medicine. 2002 Oct;19(10):843-6.

78. Rema M, Deepa R, Mohan V. Prevalence of retinopathy at diagnosis among type 2 diabetic patients attending a diabetic centre in south India. British Journal of Ophthalmology. 2000 Sep;84(9):1058-60.

79. Ramachandran A, Snehalatha C, Vijay V, Viswanathan M. Diabetic retinopathy at the time of diagnosis of NIDDM in south Indian subjects. Diabetes Research and Clinical Practice. 1996 Apr;32(1-2):111-4.

80. Royal College of Ophthalmologosts. Guidelines for diabetic retinopathy. 2005 [cited 2009 8th Dec 2008]; Available from: http://www.rcophth.ac.uk/docs/publications/published-guidelines/DiabeticRetinopathyGuidelines2005.pdf.

81. Fong DS, Cavallerano JD, Aiello L, Ferris FL, Gardner TW, Klein R, King GL, Blankenship G. Diabetic retinopathy. Diabetes Care. 2003;26(1):226-9.

82. Okamoto F, Sone H, Nonoyama T, Hommura S. Refractive changes in diabetic patients during intensive glycaemic control. British Journal of Ophthalmology. 2000 Oct;84(10):1097-102.

83. Eva PR, Pascoe PT, Vaughan DG. Refractive change in hyperglycemia - hyperopia not myopia. British Journal of Ophthalmology. 1982;66(8):500-5.

84. Saito Y, Ohmi G, Kinoshita S, Nakamura Y, Ogawa K, Harino S, Okada M. Transient hyperopia with lens swelling at initial therapy in diabetes. British Journal of Ophthalmology. 1993;77(3):145-8.

85. Chen S-J, Liu J-H, Shih H-C, Chou P, Tsai C-Y, Tung T-H. Prevalence and associated factors of lens opacities among Chinese type 2 diabetics in Kinmen, Taiwan. Acta Diabetolgica. 2008;45(1):7-13.

86. Leske MC, Chylack LT, Wu SY. The lens opacities case-control study - risk-factors for cataract. Archives of Ophthalmology. 1991;109:244-51.

87. West SK, Valmadrid CT. Epidemiology of risk factors for age-related cataract. Survey of Ophthalmolgy. 1995;39:323-34.

88. Sharma P, Vasavada AR. Acute transient bilateral diabetic posterior subcapsular cataracts. Journal of Cataract and Refractive Surgery. 2001;27(5):789-94.

89. North RV. Early ocular and non-ocular indications of diabetes mellitus. Ophthalmic and Physiological Optics. 1998 Mar;18(2):167-72.

90. Klein R, Klein BEK. Diabetic eye disease. Lancet. 1997 Jul;350(9072):197-204.

91. Alberti KGMM. Screening and diagnosis of prediabetes: where are we headed? Diabetes, Obesity and Metabolism. 2007;9(Suppl. 1):12-6.

92. Faerch K, Borch-Johnsen K, Holst JJ, Vaag A. Pathophysiology and aetiology of impaired fasting glycaemia and impaired glucose tolerance: does it matter for prevention and treatment of type 2 diabetes? Diabetologia. 2009;52(9):1714-23.

93. Colagiuri S, Borch-Johnsen K, Wareham NJ. Back to the future - Do IGT and IFG have value as clinical entities? Diabetes Research and Clinical Practice. 2008;81(2):131-3.

94. Alberti KGMM. The clinical implications of impaired glucose tolerance. Diabetic Medicine. 1996;13:927-37.

95. Harris MI, Flegal KM, Cowie CC, Eberhardt MS, Goldstein DE, Little RR, Wiedmeyer HM, Byrd-Holt DD. Prevalence of diabetes, impaired fasting glucose, and impaired glucose tolerance in US adults - The Third National Health and Nutrition Examination Survey, 1988-1994. Diabetes Care. 1998;21(4):518-24.

96. Harris MI, Hadden WC, Knowler WC, Bennett PH. Prevalence of Diabetes and Impaired Glucose-Tolerance and Plasma-Glucose Levels in United-States Population Aged 20-74 Yr. Diabetes. 1987;36(4):523-34.

97. Forouhi NG, Luan J, Hennings S, Wareham NJ. Incidence of Type 2 diabetes in England and its association with baseline impaired fasting glucose: The Ely study 1990-2000. Diabetic Medicine. 2007;24(2):200-7.

98. Edelstein SL, Knowler WC, Bain RP, Andres R, Barrett-Connor EL, Dowse GK, et al. Predictors of progression from impaired glucose tolerance to NIDDM: An analysis of six prospective studies. Diabetes. 1997;46:701-10.

99. Rasmussen SS, Glumer C, Sandbaek A, Lauritzen T, Borch-Johnsen K. Determinants of progression from impaired fasting glucose and impaired glucose tolerance to diabetes in a high-risk screened population: 3 year follow-up in the ADDITION study, Denmark. Diabetologia. 2008 Feb;51(2):249-57.

100. Gerstein HC, Yusuf S, Holman RR, Bosch J, Anand S, Avezum A, et al. Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial. Lancet. 2006 Sep;368(9541):1096-105.

101. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine. 2002;346(6):393-403.

102. Pan XR, Li GW, Hu YH, Wang JX, Yang WY, An ZX, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance - The Da Qing IGT and diabetes study. Diabetes Care. 1997;20(4):537-44.

103. Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. New England Journal of Medicine. 2001;344(18):1343-50.

104. Penn L, White M, Oldroyd J, Walker M, Alberti K, Mathers JC. Prevention of type 2 diabetes in adults with impaired glucose tolerance: the European Diabetes Prevention RCT in Newcastle upon Tyne, UK. BMC Public Health. 2009;9.

105. Borch-Johnsen K. IGT and IFG. Time for revision? Diabetic Medicine. 2002;19(9):707-.

106. Balkau B, Hu G, Qiao Q, Tuomilehto J, Borch-Johnsen K, Pyorala K. Prediction of the risk of cardiovascular mortality using a score that includes glucose as a risk factor. The DECODE Study. Diabetologia. [Article]. 2004 Dec;47(12):2118-28.

107. Coutinho M, Gerstein HC, Wang Y, Yusuf S. The relationship between glucose and incident cardiovascular events. Diabetes Care. [Article]. 1999 Feb;22(2):233-40.

108. de Vegt F, Dekker JM, Ruhe HG, Stehouwer CDA, Nijpels G, Bouter LM, Heine RJ. Hyperglycaemia is associated with all-cause and cardiovascular mortality in the Hoorn population: the Hoorn Study. Diabetologia. 1999 Aug;42(8):926-31.

109. Ceriello A. Impaired glucose tolerance and cardiovascular disease: The possible role of post-prandial hyperglycemia. American Heart Journal. 2004 May;147(5):803-7.

110. Tominaga M, Eguchi H, Manaka H, Igarashi K, Kato T, Sekikawa A. Impaired glucose tolerance is a risk factor per cardiovascular disease, but not impaired fasting glucose - The Funagata diabetes study. Diabetes Care. 1999;22(6):920-4.

111. Morabia A, Zhang FF. History of medical screening: from concepts to action. Postgraduate Medical Journal. 2004;80(946):463-9.

112. Engelgau MM, Narayan KMV, Herman WH. Screening for type 2 diabetes. Diabetes Care. 2000;23:1563-80.

113. Clarke P, Gray A, Legood R, Briggs A, Holman R. THe impact of diabetes-related complications on healthcare costs: results from the United Kingdom Prospective Diabetes Study (UKPDS study no. 65). Diabetes Medicine. 2003;20:442-50.

114. Ray NF, Thamer M, Gardner E, Chan JK, Kahn R. Economic consequences of diabetes mellitus in the U.S. in 1997. Diabetes Care. 1998;21:296-309.

115. Harris MI, Klein R, Welborn TA, Knuiman MW. Onset of NIDDM occurs at least 4-7 years before clinical diagnosis. Diabetes Care. 1992;15:815-9.

116. Saum SL, Thomas E, Lewis AM, Croft PR. The effect of diabetic control on the incidence of, and changes in, retinopathy in type 2 non-insulin dependent diabetic patients. British Journal of General Practice. 2002 Mar;52(476):214-6.

117. Wareham NJ. Evaluation of Type 2 diabetes mellitus screening against the NSC handbook criteria. National Screening Committee.2006.

118. Glumer C, Yuyun M, Griffin S, Farewell D, Spiegelhalter D, Kinmouth AL, Wareham NJ. What determines the cost-effectiveness of diabetes screening? Diabetologia. 2006;49:1536-44.

119. Wareham NJ, Griffin SJ. Should we screen for type 2 diabetes? Evaluation against National Screening Committee criteria. British Medical Journal. 2001;322:986-8.

120. Hoerger TJ, Harris R, Hicks KA, Donahue K, Sorensen S, Engelgau M. Screening for type 2 diabetes mellitus: A cost-effectiveness analysis. Annals of Internal Medicine. 2004;140:689-99.

121. Johnson SL, Tabaei BP, Herman WH. The efficacy and cost of alternative strategies for systematic screening for type 2 diabetes in the U.S. population 45-74 years of age. Diabetes Care. 2005;28:307-11.

122. Dillon EL, Janghorbani M, Angel JA, Casperson SL, Grady JJ, Urban RJ, Volpi E, Sheffield-Moore M. Novel Noninvasive Breath Test Method for Screening Individuals at Risk for Diabetes. Diabetes Care. 2009;32(3):430-5.

123. Gill GV, Lishman M, Kaczmarczyk E, Tesfaye S. Targeted screening for diabetes in community chiropody clinics. Monthly Journal of the Assosciation of Physicians. 1996;89:229-32.

124. Davies MJ, Ammari F, Sherriff C, Burden ML, Gujral J, Burden AC. Screening for type 2 diabetes mellitus in the UK Indo-Asian population. Diabetic Medicine. 1999;16:131-7.

125. Davies MJ, Alban-Davies H, Cook C, Day J. Self testing for diabetes. British Medical Journal. 1991;303:696-8.

126. Bullimore SP, Keyworth C. Finding diabetics - A method of screening in general practice. British Journal of General Practice. 1997 Jun;47(419):371-3.

127. Rolka DB, Nayayan KMV, Thompson TJ, Goldman D, Lindenmayer J, Alich K, et al. Performance of recommended screening tests for undiagnosed diabetes and dysglycemia. Diabetes Care. 2001;24:1899-903.

128. Boltri JM, Seale JP, Okosun IS, Ouzts A, Cornelius M, Davis-Smith M. The effects of a patient-based risk assessment prompt on diabetes screening. Diabetes Research and Clinical Practice. 2007;78:102-7.

129. Lindstrom J, Tuomilehto J. The diabetes risk score. a practical tool to predict type 2 diabetes risk. Diabetes Care. 2005;26:725-31.

130. Krass I, Mitchell B, Clarke P, Brillant M, Dienaar R, Hughes J, et al. Pharmacy diabetes care program: Analysis of two screening methods for undiagnosed type 2 diabetes in Australian community pharmacy. Diabetes Research and Clinical Practice. 2007;75:339-47.

131. Early identification of diabetes for community pharmacists: Diabetes UK & Royal Pharmaceutical Society of Great Britain2006 11 Sept 2006.

132. Hersberger KE, Botomino A, Mancini M, Bruppacher R. Sequential screening for diabetes - evaluation of a campaign in Swiss community pharmacies. Pharmacy World and Science. 2006;28:171-9.

133. Park PJ, Sargeant L, Griffin SJ, Wareham NJ. The performance of a risk score in predicting undiagnosed hyperglycemia. Diabetes Care. 2002;25:984-8.

134. Spijkerman AMW, Yuyun MF, Griffin SJ, Dekker JM, Nijpels G, Wareham NJ. The performance of a risk score as a screening test for undiagnosed hyperglycemia in ethnic minority groups. Diabetes Care. 2004;27:116-22.

135. Kahn HS, Cheng YJ, Thompson TJ, Imperatore G, Gregg EW. Two Risk-Scoring Systems for Predicting Incident Diabetes Mellitus in US Adults Age 45 to 64 Years. Annals of Internal Medicine. 2009;150(11):741-W134.

136. Heikes KE, Arondekar B, Eddy DM, Schlessinger L. Diabetes Risk Calculator. A simple tool for detecting undiagnosed diabetes and pre-diabetes. Diabetes Care. 2008;31:1040-5.

137. Glumer C, Vistisen D, Borch-Johnsen K, Colagiuri S. Risk scores for type 2 diabetes can be applied in some populations but not all. Diabetes Care. 2006;29:410-4.

138. Al-Lawati JA, Tuomilehto J. Diabetes risk score in Oman: A tool to identify prevalent type 2 diabetes among Arabs of the Middle East. Diabetes Research and Clinical Practice. 2007;77(3):438-44.

139. Kruijshoop M, Feskens EJM, Blaak EE, de Bruin TWA. Validation of capillary glucose measurements to detect glucose intolerance or type 2

diabetes mellitus in the general population. Clinica Chimica Acta. 2004;341:33-40.

140. Sandbaek A, Lauritzen T, Borch-Johnsen K, Mai K, Christiansen JS. The comparison of venous plasma glucose and whole blood capillary glucose in diagnoses of Type 2 diabetes: a population-based screening study. Diabetic Medicine. 2005;22:1173-7.

141. Engelgau MM, Thompson TJ, Smith PJ, Herman WH, Aubert RE, Gunter EW, et al. Screening for diabetes mellitus in adults. The utility of random capillary blood glucose measurements. Diabetes Care. 1995;18:463-6.

142. Eborall H, Davies R, Kinmouth A-L, Griffin S, Lawton J. Patients' experience of sceening for type 2 diabetes: prospective qualititative study embedded in the ADDITION (Cambridge) randomised controlled trial. British Medical Journal. 2007;335:490-3.

143. Moses RG, Colagiuri S, Shannon AG. Effectiveness of mass screening for diabetes mellitus using random capillary blood glucose measurements. The Medical Journal of Australia 1985;143:544-6.

144. George PM, Valabhji J, Dawood M, Henry JA. Screening for Type 2 diabetes in the accident and emergency department. Diabetic Medicine. 2005 Dec;22(12):1766-9.

145. Andersson DK, Lundblad E, Svardsudd K. A model for early diagnosis of type 2 diabetes mellitus in primary health care Diabetes Care. 1993;10:167-73.

146. Lidfeldt J, Nerbrand C, Samsioe G, Schersten B, Agardh C-D. A screening procedure detecting high-yield candidates for OGTT. The Women's Health in the Lund Area (WHILA) srudy: A population based study of middle-aged Swedish women. European Journal of Epidemiology. 2001;17:943-51.

147. Leiter LA, Ross SA, Barr A, Tildesley HD, Belanger A, Fontaine N, et al. Diabetes Screening in Canada (DIASCAN) Study - Prevalence of undiagnosed diabetes and glucose intolerance in family phy. Diabetes Care. 2001;24(6):1038-43.

148. Mann E, Prevost AT, Griffin S, Kellar I, Sutton S, Parker M, et al. Impact of an informed choice invitation on uptake of screening for diabetes in primary care (DICISION): trial protocol. Bmc Public Health. 2009;9.

149. Zhang P, Cadwell B, Engelgau MM, Benjamin SM, Valdez R, V. NKM. Efficient cutoff points for three screening tests for detecting undiagnosed diabetes and pre-diabetes - An economic analysis. Diabetes Care. 2005;28:1321-5.

150. Puavilai G, Kheesukapan P, Chanprasertyotin S, Chantraraprasert S, Suwanvilaikorn S, Nitiyanant W, et al. Random capillary plasma glucose measurement in the screening of diabetes mellitus in high-risk subjects in Thailand. Diabetes Research and Clinical Practice. 2001;51:125-31.

151. Greaves CJ, Stead JW, Hattersley AT, Ewings P, Brown P, Evans PH. A simple pragmatic system for detecting new cases of type 2 diabetes and impaired fasting glycaemia in primary care. Family Practice. 2004;21:57-62.

152. Lawrence JM, Bennett P, Young A, Robinson AM. Screening for diabetes in general practice: cross sectional population study. British Medical Journal. 2001 Sep;323(7312):548-51.

153. Ealovega MW, Tabaei BP, Brandle M, Burke R, Herman WH. Opportunistic screening for diabetes in routine clinical practice. Diabetes Care. 2004;27:9-12.

154. Borrell LN, Kunzel C, Lamster I, Lalla E. Diabetes in the dental office: using NHANES III to estimate the probability of undiagnosed disease. Journal of Periodontal Research. 2007;42:559-65.

155. Georgievski Z, Koklanis K, Fenton A, Koukouras I. Victorian orthoptists' performance in the photo evaluation of diabetic retinopathy. Clinical & Experimental Ophthalmology. 2007;35:733-8.

156. de Sonnaville JJJ, Colly LP, Wijkel D, Heine RJ. The prevalence and determinants of foot ulceration in type II diabetic patients in a primary health care setting. Diabetes Research and Clinical Practice. 1997;35:149-56.

157. Mealey BL, Ocampo GL. Diabetes mellitus and periodontal disease. Periodontology 2000. 2007;44:127-53.

158. Nuttal NM, Bradnock G, White D, Morris J, Nunn J. Dental attendance in 1998 and implications for the future. British Dental Journal. 2001;190:177-82.

159. Muller HP, Behbehani E. Methods for measuring agreement: glucose levels in gingival crevice blood. Clinical Oral Investigations. 2005;9:65-9.

160. Beikler T, Kuczek A, Petersilka G, Flemming TF. In-dental-office screening for diabetes mellitus using gingival crevicular blood. Journal of Clinical Periodontology. 2002;29:216-8.

161. Parker RC, Rapley JW, Isley W, Spencer P, Killoy WJ. Gingival crevicular blood for assessment of blood-glucose in diabetic-patients. Journal of Periodontology. 1993;64:666-72.

162. Simoens S, Foulon E, Dethier M, Mathieu C, Laekeman G. Promoting targeted screening for type 2 diabetes mellitus:the contribution of community pharmacists. Diabetic Medicine. 2005;22:812-3.

163. Sight test volume and workforce survey 2001-2002: Optometrists & ophthalmic medical practitioners. Department of Health; 2002.

164. Opticians Act, (1989).

165. HC11 - Help with health costs. Department of Health.2004.

166. Barnard NAS, Allen RJ, Field AF. Referrals for vasular hypertension in a group of 45-64-year-old paients. Ophthalmic and Physiological Optics. 1991;11:201-5.

167. Schmid KL, Swann PG, Pedersen C, Scmid LM. The detection of diabetic retinopathy by Australian optometrists. Clin Exp Optom. 2002;85(4):211-88.

168. McCarty CA, McKay R, Keeffe JE. Management of diabetic retinopathy by Australian optometrists. Australian and New Zealand Journal of Ophthalmology. 1999 Dec;27(6):404-9.

169. Warburton TJ, Hale PJ, Dewhurst JA. Evaluation of a local optometric diabetic retinopathy screening service. Diabetic Medicine. 2004 Jun;21(6):632-5.

170. Scanlon PH, Carter S, Foy C, Ratiram D, Harney B. An evaluation of the change in activity and workload arising from diabetic ophthalmology referrals following the introduction of a community based digital retinal photographic screening programme. British Journal of Ophthalmology. 2005 Aug;89(8):971-5.

171. Hobley AJ, Woodward EG, Port MJA. Retrospective study of optometric referrals. Ophthalmic and Physiological Optics. 1992;12:395-9.

172. Lash SC. Assessment of information included on the GOS 18 referral form used by optometrists. Ophthalmic and Physiological Optics. 2003 Jan;23(1):21-3.

173. Pooley JE, Frost EC. Optometrists' referrals to the Hospital Eye Service. Ophthalmic and Physiological Optics. 1999 Mar;19:S16-S24.

174. Perkins P. Outcome of referrals by optometrists to general practitioner: an 18 month study in one practice. British Journal of General Practice. 1990;40:59-61.

175. Menon GJ, Faridi UA, Gray RH. Direct referral of posterior capsular opacification by optometrists. Ophthalmic and Physiological Optics. 2004;24:106-10.

176. Bosanquet N. Developing a new partnership contract for community eye care in England. London: Imperial College Feb 2006.

177. Taylor SP. The Opticians Act 1989 and UK Optometry. Ophthalmic and Physiological Optics. 1991;11(2):185-90.

178. Wild SH, Forouhi NG. What is the scale of the futures diabetes epidemic, and how certain are we about it? Diabetologia. 2007;50:903-5.

179. National Service Framework for diabetes: delivery strategy. Department of Health. 2003.

180. Kato S, Shiokawa A, Fukushima H, Numaga J, Kitano S, Hori S. Glycemic control and lens transparency in patients with type 1 diabetes mellitus. American Journal of Ophthalmology. 2001;131:301-4.

181. Stoutenbeek R, Jansonius NM. Glaucoma screening during regular optician visits: can the population at risk of developing glaucoma be reached? British Journal of Ophthalmology. 2006;90(10):1242-12-44.

182. Meng X, Heft MW, Bradley MM, Lang PJ. Effect of fear on dental utilization behaviors and oral health outcome. Community dentistry and oral epidemiology. 2007;35(4):292-301.

183. Doerr PA, Lang WP, Nyquist LV, Ronis DL. Factors associated with dental anxiety. Journal of the American dental association 1998;129:1111-9.

184. Margrain TH, Greenland K, Anderson J. Evaluating anxiety in patients attending optometric practice. Ophthalmic and Physiological Optics. 2003;23:287-93.

185. Taylor SP. Effect of the Health and Social-Security Bill 1984 on the Profession of Optometry in the United-Kingdom. American Journal of Optometry and Physiological Optics. 1986;63(5):377-81.

186. Mason A, Mason J. Optometrists prescribing of therapeutic agents: findings of the AESOP survey. Health Policy. 2002;60:185-97.

187. Pope C, Mays N. Qualitative Research: Researching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. British Medical Journal. 1995;311:42-5.

188. Eaden J, Mayberry MK, Mayberry JF. Questionnaires: the use and abuse of social survey methods in medical research. Postgraduate Medical Journal. 1999;75:397-400.

189. Britten N. Qualitative research: Qualitative interviews in medical research. British Medical Journal. 1995;311:251-3.

190. Marvasti AB. Interviews. In: Qualitative research in sociology. London: Sage Publications Ltd; 2004. p14-33

191. Mays N. Qualitative research: observational methods in health care settings. British Medical Journal. 1995;311:182-4.

192. Gale EAM. The Hawthorne studies - a fable for our times. Q J Med. 2004;97:439-49.

193. Morgan DL. Deciding on group size. In: Planning focus groups. Krueger RA, Morgan DL, editors: SAGE Publications; 1998. pg 71-75

194. Kitzinger J. Qualitative Research: Introducing focus groups. British Medical Journal. 1995;311:299-302.

195. Wilkinson CE, Rees CE, Knight LV. "From the heart of my bottom": negotiating humor in focus group discussions. Qualitative health research. 2007;17:411-22.

196. Kitzinger J. The methodology of focus groups: the importance of interaction between research participants. Sociology of Health & Illness. 1994;16:103-21.

197. Morgan DL. Focus groups as a qualitative method; Compared to individual interviews. In: Focus groups as qualitative research. 2nd ed. London: Sage Publications; 1997. p 10-13

198. Wight D. Boys' thoughts and talk about sex in a working class locality of Glasgow. Sociological Review. 1994;42:702-37.

199. Krueger RA. Analysis consideration for focus group research. In: Analyzing & reporting focus group results. Krueger RA, Morgan DL, editors: SAGE publications Inc.; 1998. p31-38

200. Marshall MN. Sampling for qualitative research. Family Practice. 1996;13:522-5.

201. Patton MQ. Designing qualitative studies. In: Qualitative evaluation and research methods. Newbury Park: Sage; 1990. p. 145-98.

202. Powell RA, Single HM. Focus groups. International Journal for Quality in Health Care. 1996;8:499-504.

203. Glaser BG, Strauss AL. Generating theory by comparative analysis. In: The discovery of grounded theory: strategies for qualitative research. Chicago: Aldine; 1967. pg 21-62

204. Kitzinger J, Barbour RS. Introduction: the challenge and promise of focus groups. In: Barbour RS, Kitzinger J, editors. Developing focus group research: politics, theory and practice. London: Sage; 1999 pg 1-20.

205. Melia KM. Producing 'plausible stories': Interviewing student nurses. In: Miller G, Dingwall R, editors. Context and method in qualitative research. London: Sage; 1997. p26-36

206. Strauss AL, Corbin J. Introduction. In:Basics of qualitative research: techniques and procedures for developing grounded theory. 2nd ed. London: Sage; 1998. pg 3-15

207. Green J. Commentary: Grounded therory and the constant comparitive method. British Medical Journal. 1998;316:1064-5.

208. Charmaz K. Reflecting on the research process. In: Constructing grounded theory: A practical guide through qualitative analysis. London: Sage; 2006. pg 177-183

209. Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? British Medical Journal. 2001;322:1115-7.

210. Bloor M. Techniques of validation in qualitative research: a critical commentary. In: Miller G, Dingwall R, editors. Context and method in qualitative research. London: Sage; 1997. p37-50

211. Mays N, Pope C. Qualitative research in health care: Assessing quality in qualitative research. British Medical Journal. 2000;320:50-2.

212. Adriaanse MC, Twisk JWR, Dekker JM, Spijkerman AMW, Nijpels G, Heine RJ, et al. Perceptions of risk in adults with a low or high risk profile of developing type 2 diabetes; a cross-sectional population-based study. Patient Education and Counseling. 2008 Nov;73(2):307-12.

213. Morrison MK, Collins CC, Lowe JM. Perceived risk of type 2 diabetes in Australian women with a recent history of gestational diabetes mellitus. Diabetologia. 2008 Sep;51:222.

214. Sutton S, Rutherford C. Sociodemographic and attitudinal correlates of cervical screening uptake in a national sample of women in Britain. Social Science & Medicine. 2005;61:2460-5.

215. Crockett R, Wilkinson TM, Marteau TM. Social patterning of screening uptake and the impact of facilitating informed choices: psychological and ethical analyses. Health Care Analysis. 2008;16:17-30.

216. Park P, Simmons RK, Prevost AT, Griffin SJ. Screening for type 2 diabetes is feasible, acceptable, but associated with increased short-term anxiety: A randomised controlled trial in British general practice. Bmc Public Health. 2008 Oct;8:9.

217. Farmer AJ, Doll H, Levy JC, Salkovskis PM. The impact of screening for Type 2 diabetes in siblings of patients with established diabetes. Diabetic Medicine. 2003 Dec;20(12):996-1004.

218. Eborall HC, Griffin SJ, Prevost AT, Kinmouth A-L, French DP, Sutton S. Psychological impact of screening for type 2 diabetes: controlled trial and comparitive study embedded in the ADDITION (Cambridge) randomised control trial. British Medical Journal. 2007;335:486.

219. Skinner TC, Davies MJ, Farooq AM, Jarvis J, Tringham JR, Khunti K. Diabetes screening anxiety and beliefs. Diabetic Medicine. 2005;22:1497-502.

220. Whittaker KW, Ikram K, Anderson DF, Kiel AW, Luff AJ. Non-communication between ophthalmologists and optometrists. Journal of the Royal Society of Medicine. 1997;92:247-8.

221. Evans BJW, Harle DE, Cocco B. Optometric referrals: towards a two way flow of information. British Journal of Ophthalmology. 2005;12:1663.

222. Ingram DV, Culham LE. Ophthalmologists and optometrists - interesting time? British Journal of Ophthalmology. 2001;85:769-70.

223. Needle JJ, Petchey R, Lawrenson JG. A survey of the scope of therapuetic practice by UK optometrists and their attitudes to an extended presribing role. Ophthalmic and Physiological Optics. 2008;28:193-203.

224. Pointer JS, Baranyovits P, O'Malley BP. The Kettering Diabetic Monitoring Programme: twelve months experience of an optometric practice-based scheme. Ophthalmic and Physiological Optics. 1998 Sep;18(5):401-7.

225. Sagan W, Schwader K. Non-contact tonometry by assistants. American Journal of Optometry and Phsiological Optics. 1975;52:288-90.

226. Thompson C, Harrison RA, Wilkinson SC, Scott-Samuel A, Hemmerdinger G, Kelly SP. Attitudes of community optometrists to smoking cessation: an untapped opportunity overlooked. Ophthalmic and Physiological Optics. 2007;27:389-93.

227. Schwartz SH. THe optometrist's role in the management of clinical depressive disorders. Optometry. 2007;78:469-73.

228. Balliet P. Professionalism and ethical practice in optometry. Journal of the American Optometric Association. 1987;58(2):128-30.

229. Thistlethwaite J, Spencer J. Professionalism in medicine. Oxford: Radcliffe Publishing; 2008.

230. Hafferty FW. Definitions of professionalism - A search for meaning and identity. Clinical Orthopaedics and Related Research. 2006(449):193-204.

231. Begun JW, Lippincott RC. The politics of professional control: the case of optometry. In: Roth JA, editor. Research in the Sociology of Health Care. Greenwich, Connecticut: JAI Press Inc; 1980. p. 55-103.

232. Gray SF, Spry PGD, Brookes ST, Peters TJ, Spencer IC, Baker IA, et al. The Bristol shared care glaucoma study: outcome at follow up at 2 years. British Journal of Ophthalmology. 2000;84(5):456-63.

233. NYCRIS. Cancer Registry and Information Service Middlesbrough PCT 2009 [cited 2009 26/8/09]; Available from: http://www.nycris.nhs.uk/uploads/doc576_109_PCT%20Factsheet%20NECN%20-%2009%205KM%20Middlesbrough%20PCT.pdf.

234. DiabetesUK. Our 2 minute test. http://www.diabetes.org.uk/measure%2Dup/. [12 Nov 2008].

235. ADA. http://www.diabetes.org/risk-test.jsp. 2008 [12 Nov 2008].

236. Tuomilehto J, Lindstrom J. http://www.diabetes.fi/english/risktest/. 2001 [12 Nov 2008].

237. Nijhof N, ter Hoeven CL, de Jong MDT. Determinants of the use of a diabetes risk-screening test. Journal of Community Health. 2008;33(5):313-7.

238. Danubio ME, Miranda G, Vinciguerra MG, Vecchi E, Rufo F. Comparison of self-reported and measured height and weight: implications for obesity research among young adults. Economics and human biology. 2008;6:181-90.

239. Gunnell D, Berney L, Holland P, Maynard M, Blane D, Frankel S, et al. How accurately are height, weight and leg length reported by the elderly, and how closely are the related to measurements recorded in childhood. International Journal of Epidemiology. 2000;29:456-64.

240. Shields M, Gorber S, Tremblay M. Estimates of obesity based on self report versus direct measure. Health Report 2008;19:61-76.

241. Kuczmarski MF, Kuczmarski RJ, Najjar M. Effects of age on validity of self reported height, weight, and body mass index: Findings from the third National Health and Nutrition Examination Survey, 1988-1994 Journal of the American dietetic association. 2001;101:28-34.

242. Johnson L, Cooke L, Croker H, Wardle J. Changing perceptions of weight in Great Britain: comparison of two population surveys. British Medical Journal. 2008;337:a494.

243. Oldroyd JC, Unwin NC, White M, Mathers JC, Alberti KGMM. Randomised controlled trial evaluating lifestyle interventions in people with impaired glucose tolerance. Diabetes Research and Clinical Practice. 2006;72:117-27.

244. Practice guidance on the care of people with diabetes: Royal Pharmaceutical Society of Great Britain. Nov 2004.

245. APHO. Health Profile. Redcar and Cleveland. 2009 [cited 2009 26/8/09]; Available from: http://www.apho.org.uk/default.aspx?QN=P_HEALTH_PROFILES.

246. APHO Health Profile. Hartlepool. 2009 [cited 2009 26/8/09]; Available from: http://www.apho.org.uk/default.aspx?QN=P_HEALTH_PROFILES.

247. APHO. Health Profile. County Durham. 2009 [cited 2009 26/8/09]; Available from: http://www.apho.org.uk/default.aspx?QN=P_HEALTH_PROFILES.

248. Whitley E, Ball J. Statistics review 5: comparison of means. Critical Care. 2002;6(5):424-8.

249. Driscoll P, Lecky F. Article 8: An Introduction to hypothesis testing. Non-parametric comparison of two groups - 1. Emergency Medincine Journal. 2001;18:276-82.

250. Altman D. Relation between several variables. in: Practical Statistics for medical research. London: Chapman & Hall; 1991. p. 325-64.

251. Christensen J, Sandbaek A, Lauritzen T, Borch-Johnsen K. Population-based stepwise screening for unrecognised Type 2 diabetes

is ineffective in general practice despite reliable algorithms. Diabetologia. 2004;47(9):1566-73.

252. Wylie G, Hungin APS, Neely J. Impaired glucose tolerance: qualitative and quantitative study of general practitioners' knowledge and perceptions. British Medical Journal. 2002;324(7347):1190-2.

253. Williams R, Rapport F, Elwyn G, Lloyd B, Rance J, Belcher S. The prevention of type 2 diabetes: general practitioner and practice nurse opinions. British Journal of General Practice. 2004;54(504):531-5.

254. Doyle A, Desilva P, Koduah D, Birdi J, Sabah M, King R. An insight into undiagnosed impaired glucose regulation. Prim Care Diabetes. 2007;1(3):155-8.

255. Parry O, Peel E, Douglas M, Lawton J. Patients in waiting: a qualititative study of type 2 diabetes patients' perceptions of diagnosis. Family Practice. 2004;21:131-6.

256. Fonseca VA. Identification and treatment of prediabetes to prevent progression to type 2 diabetes. Clin Cornerstone. 2008;9(2):51-9; discussion 60-1.

257. Dalsgaard EM, Lauritzen T, Christiansen T, Mai KS, Borch-Johnsen K, Sandbaek A. Socioeconomic factors related to attendance at a Type 2 diabetes screening programme. Diabetic Medicine. 2009;26(5):518-25.

258. Van den Donk M, Sandbaek A, Borch-Johnsen K, Lauritzen T, Simmons RK, Wareham NJ, et al. Population-based screening for type 2 diabetes in Denmark, the Netherlands and the United Kingdom: uptake and prevalence in the ADDITION study. Diabetologia. 2009;52:840.

259. Sargeant LA, Kinmonth A, Wareham NJ, Griffin SJ. Feasibility and uptake of screening for type 2 diabetes in primary care. Diabetologia. 2006;49:0324.

260. British National Fourmulary (BNF) 58. London: BMA, RPSGB; 2009.

261. Herman WH. Predicting Risk for Diabetes: Choosing (or Building) the Right Model. Annals of Internal Medicine. 2009;150(11):812-4.

262. Hoerger TJ, Ratner RE, Hicks KA, Ackermann RT, Sorensen SW, Zhang P, et al. Cost-effectiveness of screening for prediabetes among overweight and obese U.S. adults. Diabetes Care. 2007;30:2874-9.

263. Association of Optometrists. Enhanced services and commissioning guidance. http://www.assoc-optometrists.org/primary/primary_clinicalcoman.html [18 Mar 2010]