Communicating Risk Information About Diabetic Retinopathy To People with type 2 Diabetes

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A thesis submitted in partial fulfilment of the
requirement s for the degree of Doctor of
Philosophy in Health sciences

University of Warwick
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February 2018

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Acknowledgements

All the praises and thanks be to Allah, the Lord of all mankind.

I could not have completed this thesis without the help and endless support of many people. In particular, I would like to thank my supervisors, Dr Alan Dolan, Professor Jackie Sturt, and Professor Peter Scanlon for their guidance and enthusiasm for this project. I would also like to thank Dr Antje Lindenmeyer and my previous supervisors at the University of Nottingham Dr Gary Adams and Dr Michael Watson for their guidance and support.

I would also like to thank University hospital Birmingham and Professor Peter Scanlon for their help and support with the university fees. Many thanks to my managers Abdulla Mahmood and the ophthalmology team at the University hospital Birmingham for their continuous support.

On a personal level, I am very grateful to my wife Ruba and my children Omar, Ahmed, Abdulrahman, and Mohammad for their patience and support during my study. I am also grateful to the FLURRI team and my friends who supported me at all times.

Lastly, I am particularly grateful to those who participated in the study.

Declaration

This declaration states that this thesis is my own work. This thesis has not been submitted for a degree at another university.

Abstract

A two-stage qualitative research strategy using semi-structured interviews was conducted with a convenience sample of 45 participants who lives with type 2 diabetes. In Stage One of the research, a qualitative study was conducted using semi-structured interviews with a purposive sample of 25 participants. Of these, 20 participants were diagnosed with type 2 diabetes, two participants were primary care physicians, two were ophthalmologists, and one was a retinal screener. People with diabetes were purposely recruited to fall into four groups with different grades of diabetic retinopathy. The aim of Stage One was to explore how people with type 2 diabetes perceive diabetic retinopathy risk, their understanding of risk information, and to appraise existing risk communication tools that have been used in other clinical settings. The data from Stage One was analysed and used to develop a risk communication tool designed to provide risk information about diabetic retinopathy and diabetic screening results to people with type 2 diabetes, which was then used in Stage Two.

In Stage Two of this research, a total of twenty people with type 2 diabetes were recruited. Participants were divided into two groups based on their grade of diabetic retinopathy. Group one: 10 participants with no diabetic retinopathy (R0); Group two: 10 participants who had background diabetic retinopathy (R1). The aim of Stage Two was to i) appraise a newly developed risk communication tool that was developed to communicate risk information about diabetic retinopathy to people with type 2 diabetes, ii) to explore the influence of the new developed risk tool on risk perception and on diabetes self-care management, and iii) to establish a method(s) by which risk information about diabetic retinopathy can be effectively communicated to people with type 2 diabetes. All interviews were audio recorded and transcribed using a digital recording machine. Data was analysed using constructivist grounded theory approach.

Results

In Stage One, people with type 2 diabetes appeared to lack knowledge about diabetes, diabetic retinopathy and its impact on their sight. Perception of risk appeared to be influenced by many factors, such as individual’s knowledge, beliefs, understanding and interpretation of risk information, type of diabetes,

presence of visible eye complications, and the individual’s past experience. There were also differences in risk perception between people with type 2 diabetes and Health Care Professionals. People with diabetes responded to being at risk in different ways, such as being optimistic, pessimistic, or underestimating diabetic retinopathy risk as well as having emotional responses such as denial, low mood, and depression.

In Stage Two, the new risk communication tool was reported as useful, easy to use, and described as a good visual representation that may improve the understanding and interpretation of risk. It was found to facilitate the presentation of risk for those who were illiterate or whose their first language was not English.

Conclusion

The lack of knowledge about diabetes and its complications points to the importance of designing educational material that address people with diabetes’s educational needs. This study also highlights the importance of how we frame the risk messages and that we need to take into consideration the differences in perception of risk between people with diabetes and their Health Care Professionals.

This study also demonstrates that risk information should be personalised and provided in a clear and attractive style based on level of understanding, particularly to the symptomless participants. Health Care Professionals should assess patients’ knowledge and understanding of risk when risk message is given. Risk communication tools could benefit participants to understand their own risk of developing diabetic retinopathy and reduces anxiety level. In addition, future quantitative studies should examine the effectiveness of risk tools.

Chapter 1. **Introduction**

1.1. Development of the research idea

This doctoral thesis is entitled “Communicating risk information about diabetic retinopathy to people with type 2 diabetes”. The researcher has been working for many years in the field of nursing. For the past seven years, he has worked in an ophthalmology department. In the course of his practice as a senior ophthalmic nurse, he has been engaged in the education of patients and the management of people with diabetes related eye complications. As a result of this work, the researcher noticed that a significant number of people with diabetes, in particular those from ethnic minority groups, who were invited for retinal photography did not always attend hospital appointments and diabetic retinopathy screening appointments, and as a result could be putting themselves at risk of future blindness (Gray *et al.*, 2009). For example, research has shown a relationship between non-attendance at screening and subsequent loss of vision (Gray *et al.*, 2009; Zoega *et al.*, 2005). Moreover, the lack of uptake in relation to diabetic retinopathy screening is of concern because only when the uptake is above eighty eight per cent will the screening service be eighty per cent sensitive to detect sight-threatening diabetic retinopathy (Gray *et al.*, 2009). This has been shown in a screening programme that investigated sight differences between attenders and non-attenders of screening programmes, which found that the non-attenders’ level of diabetic retinopathy was higher than those who attended regularly (Gray *et al.*, 2009).

Lay beliefs about the causes of health problems and the degree of risk people perceive they are subject to have long been a feature of research in the field of health (Smith *et al.*, 1999). Therefore, it was clear that non-attendance regarding diabetic screening could be due to a number of factors including people misunderstanding the risk message and their degree of personal risk, which could lead the person with diabetes to perceive their diabetes to be mild or at low risk of other associated problems. In turn, this may have a negative impact on their adherence to hospital and diabetic screening appointments as well as diabetes self-care management. For example, in relation to diabetes, research that has focused on population characteristics has shown that patients living in the most deprived areas are less likely to attend for screening and when they do present have worse retinopathy (Scanlon *et al.*, 2008).

At the time of conducting the research, people with diabetes were invited annually to have a digital photograph taken of the back of their eye (retinae). This is designed to detect problems at an early stage, so they can be treated to prevent further vision loss. The English NHS Diabetic Eye Screening Programme (NHS DESP) offers annual screening to over two million people, with over one and a half million being screened in 2012 (DH, 2014). If diabetic retinopathy is diagnosed early it can be effectively treated and the persons' sight can be saved or preserved (Bachmann and Nelson, 1996; Scanlon, 2008). Understandably, the maintenance of vision is associated with a better quality of life and independent living, particularly in older people (Chia *et al.*, 2004). The consequences of non-adherence regarding hospital appointments and diabetic screening appointments, as well as whether patients heeded Health Care Professionals' advice, motivated the researcher to explore people's understanding and decision-making processes as a means of ultimately preventing blindness within certain groups of patients, given that eighty per cent of blindness is preventable (IAPB, 2009). Therefore, the researcher commenced his PhD study at the University of Nottingham in 2009 and then transferred to the University of Warwick in 2011 where he joined a well-established research team, who were involved in a research project to identify factors leading to low uptake of diabetic retinopathy screening in primary care (FLURRI STUDY).

The original idea for this research (communicating risk information about diabetic retinopathy to people with type 2 diabetes) came whilst undertaking the FLURRI study. The team were aware of an ongoing discussion in the national screening programme about possible extended screening intervals for people at low risk of developing diabetic retinopathy. During the FLURRI fieldwork, when participants were asked about the views on extended screening intervals, many participants seemed concerned at the proposal. Additionally, the FLURRI study highlighted issues, such as a lack of communication, for non-concordance with diabetic eye screening (Lindenmeyer *et al.*, 2014; Hipwell *et al.*, 2014). However, the method regarding how risk information about diabetic retinopathy is communicated to people with diabetes may impact not only in their level of attendance at diabetic screening centres, but also may affect their decisions regarding their diabetes self-care management and their anxiety regarding the development of complications.

In addition, type 2 diabetes can be asymptomatic, and people are sometimes diagnosed with type 2 diabetes in retrospect when they present with diabetes complications such as renal problems or visual problems (Looker *et al.*, 2012). Diabetes is viewed as a serious condition leading to many severe complications, particularly in South Asian populations (Macaden and Clarke, 2006). This is despite the fact that a number of educational programmes (Ockleford *et al.*, 2008; Carey *et al.*, 2014; Sturt *et al.*, 2008; Davies *et al.*, 2008; Deakin *et al.*, 2006) have been designed to provide valuable information to people with diabetes. Furthermore, it was noticed that previous research on topics like perception of risk had been conducted mainly among western populations. As a result, there are very limited studies (Osal *et al.*, 2011; O'Sullivan *et al.*, 2009; Duncan *et al.*, 2010; Shrestha *et al.*, 2007; Macaden and Clarke, 2006; Macaden and Clarke, 2010) that have sought to address the perception of risk among the South Asian populations and among other minor ethnic groups living in western countries. Furthermore, the fact that research regarding risk perception about diabetic retinopathy and the communication of risk information about diabetic retinopathy has not taken place with people with diabetes is perhaps surprising given that this population is at risk of developing sight-threatening diabetic retinopathy. Issues relating to the perception of risk and the communication of risk information can be challenging topics, particularly when people with type 2 diabetes need to understand their risk before they make informed decisions about their care. Therefore, the researcher was interested in this subject area because of his academic and clinical background as well as personal interest and motivation to prevent avoidable blindness among people with type 2 diabetes.

1.2. Background of the researcher

The researcher is a senior ophthalmic nurse with Master's Degree in Advanced Nursing and has been involved in staff and patients' education and nursing practice for over twenty years in different Middle East and Western countries. As in the UK, Middle East countries such as United Arab Emirates and Saudi Arabia also have a considerable number of South Asian people with diabetes. Recently, the researcher has been working at hospital in the Midlands. This hospital has an international standing and reputation and has been a pioneer regarding nursing education and practice development within the United Kingdom.

1.3. Background of the research

Diabetes is a global problem affecting a significant number of people in the United Kingdom. Published data shows that 3.5 million people have diabetes in England (Diabetes UK, 2015). Of these, approximately 85 per cent have type 2 diabetes and 15 per cent have type 1 diabetes. Diabetes is costly, both in terms of resources and quality of life. People with diabetes are at high risk of developing a number of complications. One complication of diabetes is diabetic retinopathy, which occurs when diabetes damages the small blood vessels at the back of the eye (retinae). Diabetic retinopathy is also often symptomless to the patient until in its advanced stages and if left untreated this can result in loss of vision and blindness. Diabetic retinopathy was, until recently (Liew *et al.*, 2014), the leading cause of visual impairment in people of working age (Bunce *et al.*, 2010). However, the introduction of the national NHS diabetic eye screening programme in England and Wales (NHS choices, 2013) has resulted in more cases being detected at an earlier stage and treated before the diabetic retinopathy has progressed.

The risk of developing diabetic retinopathy and progressing can be reduced by maintaining blood glucose as near to normal as possible. In the UK, diabetic retinopathy affects nearly all people with type 1 diabetes and almost two thirds of people with type 2 diabetes within 20 years of diagnosis (Scanlon, 2008). People with diabetes may need to make major changes to their lifestyle, in terms of diet, exercise, and the need to take long term medications to bring their blood glucose levels into a target range for reducing diabetic retinopathy risk or progression (Garcia-Perez *et al.*, 2013). These changes in lifestyle can lead to decrease in quality of life, as people may feel deprived from their favourite foods, sweets, and drinks, in addition to having to endure regular finger prick checks to monitor their blood glucose level (Macaden and Clarke, 2010).

Knowledge about people, their values and culture facilitate the delivery of care as well as enabling Health Care Professionals to empower patients to make informed decisions and for them to feel valued (Pawa, 2003). However, there are several challenges in relation to diabetes awareness associated with culture and different ethnic groups (Iqbal *et al*., 2008; Osman and Curzio, 2012; Shrestha, *et al*., 2007; Zeh *et al.*, 2012) in addition to the high cost of delivering educational programmes (O'Hare *et al.*, 2004; Greenhalgh *et al.*, 2011). For example, a recent review conducted by Osman and Curzio (2012) concluded that cultural beliefs play a significant role in attitudes towards diabetes among people of South Asian origin and understanding their beliefs can improve the care provided to this community. Another systematic review conducted by Zeh *et al.*, (2012) reported that structured interventions that were tailored to people with diabetes from ethnic minority group and integrated elements of culture, language, religion, and health literacy skills, improved patient's outcomes such as HbA1c. However, O'Hare *et al*., estimated the annual cost per patient at £365 compared with £264 for treating type 2 diabetes, and Greenhalgh *et al*. (2011) estimated the cost of training a bilingual health care as a facilitator at £1500 and £345 to deliver the 12-week-sharing course per person. Ethnicity may impact on health care and access to the health services in many ways and at many levels such as: variation in service uptake, communication problems, culture and attitudes, socio-economic factors, and variations in disease prevalence. These variations influence access to services and may act as barriers to good health care (Szczepura, 2005). In summary, across diverse populations, the complications associated with type 2 diabetes could be prevented with better management that includes providing clear risk communication messages to people with diabetes. Therefore, this study aims 1) to explore how people with type 2 diabetes perceive and experience their diabetic retinopathy risk, 2) to develop or modify a risk communication tool and 3) develop a risk communication model to facilitate the presentation of risk messages about diabetic retinopathy to people with type 2 diabetes.

1.4. Definition of diabetes

The World Health Organization (WHO) defines diabetes as a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels (WHO, 2009).

1.5. Types of diabetes

Diabetes mellitus is divided into two main categories, type 1 diabetes and type 2 diabetes. There are differences in the causes and treatment for these two major forms of diabetes (Diabetes UK, 2014b). Type 1 Diabetes accounts for about 15% of all diabetic population; it is most often found in people less than 40 years of age. Type 2 diabetes accounts for about 85% of all people with diabetes. It is more common in over 40 years old in the White population and in over 25 years old of the Black and South Asian population (Diabetes UK, 2010). The symptoms with type 2 diabetes often appear very slowly and some people do not have any symptoms at all. Therefore, people can live with type 2 diabetes for up to 10 years before diagnosis (Diabetes UK, 2013).

1.6. Outline of the thesis

Chapter one of this thesis has outlined the development of the research idea, the researcher’s background, the origin and progression of the research project, and the definition and types of diabetes. It concludes with the aims and objectives of the study.

Chapter two provides a review of the literature on diabetes, diabetic retinopathy, prevalence of diabetes and diabetic retinopathy, cost of diabetes, and the main complications associated with diabetes. The chapter then considers diabetic retinopathy in more detail as the main diabetes related eye complication. It covers the modifiable and non-modifiable risk factors of developing diabetic retinopathy, its signs and symptoms, the diabetic retinopathy classification of progression to proliferative diabetic retinopathy, and how people with diabetes construct knowledge and make sense of their diabetes. Finally, the chapter provides details about the NHS diabetic eye screening programme, its effectiveness and a critique of diabetic eye screening as well as examining the screening pathway from invitation to communicating the screening results.

Chapter three examines the literature about perception of risk and risk communication among people with type 2 diabetes. The chapter begins by exploring the perception of risk before moving on to explore risk communication issues and the factors that have been found to influence the exchange of risk information about diabetes between Health Care Professionals and their patients. This includes a range of risk communication formats, numerical knowledge, the interaction between Health Care Professionals and their patient, the influence of visual risk communication tools, individual limitations, variations in risk interpretation, the use of fear and threatening messages, and framing bias. The chapter then considers other issues regarding risk communication such as the constraints around effective communication and other ethical issues related to risk communication.

Chapter four begins by stating the aims of the research and how these aims guided the research design and how the research was conducted. It discusses the philosophical position of the research and gives details of its theoretical and methodological perspectives. The chapter sets out the rationale for adopting the theoretical fundamentals drawn from social constructionism and interpretivism as a methodological and philosophical framework, with aspects of a constructivist grounded theory approach employed in relation to data analysis (Charmaz, 2006). This approach was adopted based on key issues, such as the methodological limitation of existing research regarding the communication of risk information about diabetic retinopathy to people with type 2 diabetes.

Chapter five discusses the methods used in this study. The chapter then proceeds to detail why the study has adopted a two-stage approach, followed by discussion regarding the recruitment process, data collection, and data analysis process.

Chapter six presents an analysis of the Stage One interview data and seeks to explore how the risks and benefits of diabetic retinopathy screening are understood and interpreted by people with diabetes and by Health Care Professionals. It also explores the perception of risk information about diabetic retinopathy by using numerical and textual formats and the influence of risk information on risk perception. It also appraises the existing risk communication tools from other clinical settings and develops a new diabetic retinopathy risk communication tool that can be used to communicate risk information about diabetic retinopathy to people with type 2 diabetes.

Chapter seven provides an analysis of the Stage Two interview data. This seeks to explore the views of people with diabetes regarding a newly developed diabetic retinopathy risk communication tool and explores the influence of the newly developed risk communication tool on risk perception and diabetes self-care management. The chapter also explores people’s preference regarding the most appropriate methods of communicating risk information about diabetic retinopathy and diabetic eye screening results to people with type 2 diabetes.

Chapter eight draws together the findings of this study that has the perception of risk and risk communication as its central concepts. The chapter discusses the main factors that have influenced risk perception and the model put forward for communicating risk information about diabetic retinopathy and diabetic retinopathy screening results.

Chapter nine provides the concluding comments of the thesis and makes recommendations for clinical practice, policy, and research.

Chapter 2. **Literature Review**

2.1. Introduction

This literature review aims to examine the research evidence regarding diabetes and diabetic retinopathy risk among people with type 2 diabetes. The literature reviewed in this chapter is primarily a scientific and medical review embedded within a medical context and includes limited work in the field of social sciences. This decision was informed by the researcher's clinical background and the pragmatic imperative to understand the evidence as it relates to, and impacts upon, clinical practice. Scoping reviews identified risk communication evidence in the behavioural sciences literature and the academic discipline of the primary supervisor as a behavioural scientist informed the directional decision of the evidence review. Firstly, the chapter explores the scientific and medical literature regarding diabetes, diabetic retinopathy, and prevalence of diabetes and diabetic retinopathy. It also explores the costs of diabetes and the different types and complications of diabetes. The chapter then considers diabetic retinopathy, the main cause of diabetes related eye complications, presentation of the modifiable and non-modifiable risk factors of developing diabetic retinopathy along with a critique of the modifiable factors, signs and symptoms, and the diabetic retinopathy classification of progression to proliferative diabetic retinopathy. Finally, the chapter provides details about the NHS diabetic eye screening programme. In so doing, it provides a critique of diabetic eye screening and explores the screening pathway from invitation to the communication of the screening results.

2.2. Source of the literature

The literature search for this study covers several areas because there were various components to the study. The main areas that were investigated were perception of risk among people with type 2 diabetes mellitus, risk communication, and risk communication tools. A broad search of the clinical and behavioural sciences evidence regarding issues related to perception of risk, risk communication tools, and risk communication and how these may be influenced by health beliefs, knowledge, education, and ethnicity. The literature search was performed by the researcher (NA) in October 2010 and updated at annual intervals with the final search conducted in December 2017, to identify literature on the perceptions and perspectives of people with diabetes on diabetes, diabetic retinopathy, risk, and risk communication tools. Boolean operators were used for combinations of the following keywords: “risk”, “risk communication”, “risk tools”, “risk communication tools”, “visual tools”, “diabetes”, diabetic retinopathy”, “diabetes self-care management”, and “qualitative research”. Equivalent terms in glossaries or MeSH browsers were used wherever possible. Searches were restricted to the English language only. A general literature search of the broad topic area was performed in the following journals: Diabetic Medicine, Practical Diabetes International, Journal of Diabetes Nursing, Health, Risk and Society, Risk Analysis, The Diabetes Educator, and Journal of Advanced Nursing. A number of bibliographic databases were accessed electronically including MEDLINE, EBSCO EJS, Cambridge University Press Journals, Blackwell Publishing of Synergy, Elsevier Journals, and Wiley. In addition, an electronic content alerts were set up and published journals were reviewed on a regular basis/as they were published in order to keep up to date with the current literature.

Due to the nature of the research and the fact that it has a number of different elements it was important to arrange the references in an easy way to facilitate the literature review process. Therefore, Endnote X7 was used to manage the referencing process. Endnote X7 is a bibliography manager that allows the access of bibliographic data from a range of resources such as journals, books, and electronic databases, search for entries by title, subject, keyword, or authors. Data were exported to bibliographic entries into a Microsoft word processor. Data was reformatted in word according to different bibliographic style such as author and date, Vancouver, APA 6th, or Harvard style directly from online resources (Endnote, 2014).

2.3. Prevalence of diabetes

Diabetes is a global problem affecting over 415 million people worldwide and causing about 5% of all deaths globally each year (Diabetes UK, 2015). The International Diabetes Federation (IDF) note that the prevalence of diabetes had risen to 285 million in 2010, representing 6.4% of the world's adult population, with a prediction that by 2040 the number of people with diabetes will have risen to 642 million (IDF, 2011). It was reported by the International Diabetes Federation (2011) that diabetes is accountable for 4.6 million deaths every year worldwide (one death due to diabetes occurs every 7 seconds) and that over 75 000 people with diabetes die every year in the UK. Of these, 24 000 people die earlier than would be expected for their age group (The Information Centre for Health and Social Care, 2011).

The number of people with diabetes in the UK in 1996 was 1.4 million, which had risen to 3.5 million by 2015, which equates to one in sixteen adults in the United Kingdom now having the condition (Diabetes UK, 2015). It is estimated that the prevalence of diabetes will rise to 5 million by 2025 (Diabetes UK, 2015). The evidence also shows that diabetes can affect certain ethnic groups to a far greater extent. For example, rates of diabetes are six times higher for individuals within the South Asian ethnic group and up to three times higher for individuals within the Afro-Caribbean ethnic group (Diabetes UK, 2014b).

2.4. Cost of diabetes

Long term conditions such as diabetes and its complications require a lot of planning to enable the NHS to deliver appropriate health care services, particularly when it involves people from different cultures and ethnic groups. Due to its long-term nature, diabetes is a costly condition. Not only for the particular individuals and their families in terms of quality of life, pain, anxiety, and complications (WHO, 2009), but also costly for the NHS (Diabetes UK, 2015). In the United Kingdom, diabetes accounts for around 10 per cent of the NHS budget and 80 per cent of these costs are because of complications (Diabetes UK, 2014a). It is estimated that diabetes costs the NHS approximately £23.7 billion each year (£9.8 billion in direct costs and £13.9

billion in indirect costs). The costs for type 1 diabetes mellitus was £1.9 billion and for type 2 diabetes was £21.8 billion. By 2035/2036 costs are estimated to rise to £39.8 billion (£16.9 billion in direct costs, which includes treatment, intervention, and complications and £22.9 in indirect costs, which includes those related to increased death and illness and work loss). The cost of type 1 diabetes is estimated to rise to £4.2 billion and the cost of type 2 diabetes is estimated to rise to £35.6 billion (Hex *et al.*, 2012). In addition to the financial costs, people with diabetes are twice as likely to be admitted to hospital compared with those without diabetes, and one in seven hospital beds is occupied by someone who has diabetes (Sampson *et al.*, 2007). Furthermore, diabetes leads to other conditions such as depression (Ali *et al.*, 2009), pain, anxiety, vision loss and amputations, which also impact on people’s quality of life (WHO, 2009).

2.5. Age of onset

Type 1 diabetes is more common in children and is sometimes known as Juvenile diabetes. It is prevalent in 98% of children with diabetes and 10% of adults with diabetes. In contrast, type 2 diabetes is more common in adults. It is prevalent in 90% of adults with diabetes and 2% of children with diabetes (HSCIC, 2013). Type 2 diabetes generally appears in middle age (Tuomilehto *et al.*, 2001). Despite the fact that type 1 diabetes is much more common in children, type 2 diabetes is the most common type of diabetes across all ages in the UK population (Tuomilehto *et al.*, 2001).

2.6. Complications of diabetes

Diabetes is a chronic long-life metabolic disorder marked by hyperglycaemia with disturbances of the body’s metabolism resulting from defects of insulin section, insulin action, or both (WHO, 2009). People with diabetes are at high risk of a number of complications. Diabetes can cause problem with other body functions, such as heart, kidneys, nerves, feet, bones, joint disorders, and eyes (Wu, 2010). There are also other long-term complications of diabetes include skin problems, digestive problems, sexual dysfunction, and problems with teeth and gums (Diabetes UK, 2014b; Wu, 2010).

Diabetes complications have negative consequences for patient’s quality of life, which may precipitate psychological, physiological and social burdens (Jeffcoate, 2004), and also results in increased economic costs for governments’ and the wider society (McCormack *et al.*, 2008). In this research, the researcher concentrates on issues related to diabetic retinopathy, which is one of the diabetes-related eye complications that confers a significant burden on patients’ quality of life (Jeffcoate, 2004).

2.7. Diabetes-Related Eye Complications

As the incidence of diabetes gradually increases there is the possibility that more individuals will suffer from eye complications, which if not properly managed may lead to permanent eye damage and blindness (Clarke, 2008). Sight-threatening diabetic retinopathy is one of the main diabetes related eye complication. If diabetes related eye complications are left untreated, they lead to the deterioration of vision and, ultimately, sight loss and blindness. Sight-threatening diabetic retinopathy was until recently (Liew *et al.*, 2014) the leading cause of visual impairment in people of working age in the UK and still is in most countries (Bunce and Wormald, 2006). As the incidence of diabetes gradually increases there is the possibility that more individuals will suffer from eye complications which, if not properly managed, may lead to permanent eye damage and blindness (Clarke, 2008). The most frequently recorded cause of certification for blindness are degeneration of the macula and posterior pole (58.6 %), which largely comprises age-related macular degeneration. Glaucoma (8.4 %), diabetic retinopathy (6.3 %), optic atrophy (4.2 %), hereditary retinal disorders (5.5 %), and cerebrovascular disease/accidents (1.5 %) are the next most frequently occurring causes of certification for blindness (Bunce and Wormald, 2006). These causes account for more than 80 % of blindness certifications and the percentage of severely sight impaired (blindness) registrations caused by diabetic retinopathy has increased from 5.9% in 2000 to 6.3% in 2008 (Bunce *et al.*, 2010).

2.8. Diabetic Retinopathy

Diabetic retinopathy is a complication of diabetes mellitus, which can eventually lead to blindness. It is an ocular manifestation of systemic disease which affects up to 80% of all patients who have had diabetes for 10 or more years (Kertes, 2005). Diabetic Retinopathy affects the blood vessels supplying the retina. Blood vessels in the retina of the eye can become blocked or leaky (Wu, 2010). Diabetes can also affect the big blood vessels of the head and neck, but pathology of the larger blood vessels does not come under the classification of diabetic retinopathy (Scanlon, 2010). Rates of diabetic retinopathy are also projected to increase exponentially due to an ageing populations and lifestyle changes (IAPB, 2009). People with diabetic retinopathy experience many socio-emotional problems in addition to sight-related problems (Fenwick *et al.*, 2012). It is also associated with incidence of mortality and cardiovascular disease. For example, there is almost twice the risk of ischaemic stroke when there is diabetic retinopathy and seventy one percent of patients registered blind from diabetic retinopathy died within 10 years of registration (Nagi *et al.*, 2009).

2.8.1 Signs and symptoms of diabetic retinopathy

Diabetic retinopathy can be a symptomless condition that may lead to irreversible eye damage (Wu, 2010). The dilemma that people with type 2 diabetes have is that they can live for up to 10 years before they are diagnosed with diabetes (Diabetes UK, 2010), They sometimes do not present themselves until they begin to lose their normal vision and are only seen by their ophthalmologist or optician when the disease progresses toward advanced or proliferative diabetic retinopathy. However, there are some early signs and symptoms of diabetic retinopathy. The most commonly reported signs and symptoms prior to treatment are blurred vision, short sightedness, difficulty with poor lighting, difficulty with night vision, flickering spots before eyes, distorted vision, difficulty identifying how close/far an object is (from them), and loss of contrast in vision (Scanlon *et al.*, 2006). There are also signs and symptoms of diabetic retinopathy that present at a later stage when the people with type 2 diabetes are referred to an ophthalmologist. This include retinal changes such as retinal swelling and blood vessels leaking fluids, floaters, spotty, blurry, or hazy vision, and difficulty in reading (Wu, 2010).

2.8.2 Diabetic Retinopathy Classification of Progression to Proliferative diabetic retinopathy

The English diabetic eye screening programme proposed the following Grading Classifications that should be used in any grading of diabetic retinopathy. The following Table (Table 2.1) shows diabetic retinopathy classification of progression to proliferative diabetic retinopathy in the first column that links to the features, symptoms, and grading criteria used in the English National Screening Programme as the management and screening criteria is affected by the progression of the lesion. For example, background diabetic retinopathy (R1), the least serious, is unlikely to be sight-threatening and requires no treatment other than annual monitoring through the screening programme. However, serious conditions such as preproliferative diabetic retinopathy (R2) and proliferative diabetic retinopathy (R3) require referral to the patient’s hospital ophthalmology team for closer monitoring (R2) or treatment (R3). This condition occurs when the retinal cells become stressed by oxygen deprivation, and new, weak, blood vessels grow. These blood vessels can leak, break off, or bleed, causing potentially sight-threatening damage to the retina (Wu, 2010). Most of these serious retinopathies are treated by a specialist, using a laser at a hospital outpatient clinic, with patients allowed to return home afterwards (Wu, 2010). A tiny laser beam is directed on to the abnormal part of the retina and then small bursts of laser light are used to seal leaking blood vessels or to treat areas of retina that are lacking oxygen. Laser treatment reduces the stimulus for the production of abnormal new blood vessels growing in the retina and those that have formed will often regress or fibrose after laser treatment. Whilst vision that has already been lost is not recoverable, laser treatment can prevent further damage from occurring. For some people, however, laser treatment is insufficient and surgical intervention may be required (Wu, 2010).

Table 2.1: Diabetic retinopathy classification of progression to proliferative diabetic retinopathy

NSC	International Term	Symptoms	Features	Action
R0	No Diabetic retinopathy	None	Normal retina. Grade 0 (US)	Aannual rescreen
RI	Mild non-proliferative (mild pre-proliferative)	None	Haemorrhages & microaneurysms, Grade 1 (US). Very minor IRMAs	Inform diabetes team
R2	Moderate non-proliferative, moderate pre-proliferative	None	Previously termed mild pre-proliferative. Extensive Microaneurysm, intraretinal haemorrhage, and hard exudates Grade 2 (US)	Refer HES
R2	Severe non-proliferative severe pre-proliferative	None	Previously termed severe pre-proliferative. Venous abnormalities, large blot haemorrhages, cotton wool spots (small infarcts), venous beading, venous loop, venous reduplication, IRMA, Grade 3 (US)	Urgent refer HES
R3	Proliferative retinopathy	Floaters, sudden visual loss	New Vessel formation either at the Disc (NVD) or New Vessel Elsewhere (NVE). Grade 4a (US)	Urgent refer HES
R3	Pre-retinal fibrosis+/- tractional retinal detachment	Floaters, central loss of vision	Extensive fibrovascular proliferation, retinal detachment, pre-retinal or vitreous haemorrhage, glaucoma. Grade 4b (US). Traction and Subhyaloid haemorrhage	Urgent refer HES
R3s	treated proliferative retinopathy (s = stable)		No haemorrhages or exudates or new vessels, laser ('P' added)	Annual rescreen

NSC: National screening Committee, IRMA: Intraretinal Microvascular Abnormalities, HES: Hospital Eye Services

2.8.3 Prevalence of Diabetic Retinopathy

In the United Kingdom, the prevalence of diabetic retinopathy in type 2 diabetes was present in 39% of men and 35% of women (Kohner *et al.*, 1998). In 2002, diabetic retinopathy was present in 45% of type 1 diabetes and 25.3% of type 2 diabetes (Younis *et al.*, 2002). Cormack *et al.* (2001) has estimated the prevalence and incidence of blindness due to diabetic retinopathy in Fife in Scotland where the prevalence of blindness was 0.21% of diabetic population and the incidence of blindness due to diabetes was 0.064% (SD: 0.024, 95%CI:

0.049-0.079). However, Scanlon (2008) argues that these figures reported by Cormack and colleagues are lower than European figures due to the voluntary nature of the certification and the criteria for registration in the UK, which is at a poorer visual acuity level than the World Health Organization (WHO) definition of blindness. Grauslund *et al.* (2009) reported the incidence of proliferative retinopathy among type 1 Danish diabetic patients was 42.9%. Two studies (Spijkerman *et al.*, 2003; Bek *et al.*, 2009) have found that, if one screens for Type 2 diabetes, the prevalence of diabetic retinopathy in screen positive patients (7.6% and 6.8%) is much lower than the prevalence in the known population of people with diabetes. The relatively small sample (n=195) in the first study may indicate false representation, while differences in health care systems could explain the low prevalence rate in the second study. However, the fact that these patients have a shorter duration of diabetes than those presenting symptomatically is the most likely explanation. The Wisconsin Epidemiological Study of Diabetic Retinopathy, a population-based incidence study that was conducted in an eleven county areas in Wisconsin, reported the prevalence of diabetic retinopathy in the United State of America (Klein *et al.*, 1992). Proliferative diabetic retinopathy (R3) was prevalent in 23% of people aged less than 30 years, and 10% in people older than 30 years. Proliferative diabetic retinopathy (R3) occurred in 67% in persons with type 1 diabetes for 35 or more years. However, the Wisconsin epidemiological study of diabetic retinopathy reported the cumulative rate of progression of proliferative diabetic retinopathy (R3) after twenty five years period to be 83% and the progression of to be 42% (Klein *et al.*, 2008). This reduction in the progression of proliferative diabetic retinopathy (R3) could be due to the early detection and treatment of diabetic retinopathy. One would therefore expect that nearly half of people with type 1 diabetes would need laser treatment for proliferative diabetic retinopathy during their lifetime. A recent study conducted by Yau *et al.* (2012) to examine the global prevalence of diabetic retinopathy reported that there are approximately 93 million people with diabetic retinopathy (34.6% of the overall people with diabetes). Of these, 17 million had proliferative diabetic retinopathy (6.96%).

2.8.4 Prevalence of diabetic retinopathy among South Asians

Patients from ethnic minorities have significantly higher rates of sight-threatening diabetic retinopathy than Caucasians. Raymond *et al.* (2009) conducted a cross-sectional study to compare prevalence and risk factors for diabetic retinopathy among UK residents of South Asian or White European ethnicity. One thousand and thirty five patients with type 2 diabetes were included. Of these, 421 (41%) were South Asians and 614 (59%) were white Europeans. Sight-threatening diabetic retinopathy was detected in 142 (14%) patients with more sight-threatening diabetic retinopathy in the South Asian group. Maculopathy was detected in 105 (10%) patients with a significant difference between ethnic groups: 55 South Asian patients (13%) versus 60 (9%) White European patients. Patients of South Asian ethnicity were significantly younger at the point of diagnosis of diabetes (mean age at diagnosis of diabetes 53 years vs. 58 years) and had shorter duration of diabetes (7.6 years vs. 8.8 years). Cardiovascular risk factors also were found to be significantly higher in South Asian patients; systolic blood pressure 144 vs. 137 mmHg, $P<0.0001$; diastolic blood pressure 84 vs. 74 mmHg, $P < 0.0001$; blood glucose level HbA1c 7.9 vs. 7.5%, $P< 0.0001$; and cholesterol level 4.5 vs. 4.2 mmol/l, $P< 0.0001$ (Raymond *et al.*, 2009). The above figures were similar to the prevalence of diabetic retinopathy among the population of people with diabetes living in India. A study conducted by Raman and colleagues in 2009 found that the prevalence of diabetic retinopathy among people with diabetes was 18% (Raman *et al.,* 2009). However, a more recent study (Gadkari, 2014) reported the prevalence of diabetic retinopathy in India was 21.7%.

2.8.5 Medical management of diabetic retinopathy

The medical management of diabetic retinopathy is based on the proven benefit of blood pressure control and blood sugar control (UKPDS, 1998; DCCT, 1993). The most effective treatment of diabetic retinopathy requires the management of diabetes and its risk factors as well as eye treatment to save vision, alongside effective communication between a multi-disciplinary team such as an ophthalmologist, diabetologist, GP, and diabetic nurse specialist (Al-Hussainy *et al.*, 2008). Recently, this is being facilitated within both the eye clinic and diabetic clinic by having access to retinal images in both sites (Al-Hussainy *et al.*, 2008). The Diabetes Control and Complications Trial in type 1 diabetes showed that achieving a 2% reduction in HbA1c resulted in a 76% reduction of developing diabetic retinopathy. The UKPDS study in type 2 diabetes showed a 37% reduction of microvascular complication for a 1% reduction in HbA1c level (DCCT, 1993).

2.9. Risk factors for developing diabetic retinopathy

A range of risk factors are associated with the development of diabetic retinopathy. These factors can be divided into two main categories; modifiable and non-modifiable risk factors (Matthews *et al.*, 2004).

2.10. Non-modifiable risk factors

There are a number of non-modifiable risk factors associated with the development of diabetic retinopathy, such as duration of diabetes (Stratton *et al.*, 2000), age of individual (Stratton *et al.*, 2000), type of diabetes (Stratton *et al.*, 2000), genetic disposition (Patel *et al.*, 2008), and ethnicity (Raymond *et al.*, 2009).

2.10.1 Duration of diabetes

Duration of diabetes is the most deterministic non-modifiable risk factor in the progression of diabetic retinopathy (Raman *et al.,* 2009). Over 80% of people with type 1 diabetes will develop some grade of diabetic retinopathy after 10 years of having diabetes (Klein *et al.*, 2008). Sixty seven per cent of people with type 2 diabetes who are treated with oral hypoglycaemic medication will develop some sort of diabetic retinopathy after 10 years of having diabetes. Nearly 80% of people with type 2 diabetes who are treated with insulin will develop diabetic retinopathy after 10 years of having diabetes (NHS, 2012). This has been well established in previous research (Klein *et al.*, 1984; Klein *et al.*, 1989; Kohner and Sleightholm, 1986; Stratton *et al.*, 2001; Simmons *et al.*, 2007).

Klein *et al.* (1989) investigated 271 patients with type 1 diabetes diagnosed before 30 years of age. After 4 years, 160 patients (59%) developed diabetic retinopathy. Stratton *et al.* (2001) reported the risk factors related to the incidence and progression of diabetic retinopathy over 6 years from diagnosis of Type 2 (non-insulin dependent) diabetes mellitus. One thousand nine hundred and nineteen patients were included in the study, of these, 1216 (63 %) had no retinopathy at diagnosis. After 6 years, 22 % of these had developed retinopathy. In the 703 (37 %) patients with retinopathy at diagnosis, 29 % worsened by two scale steps or more. Simmons *et al.* (2007) found that pre-proliferative diabetic retinopathy (R2) and proliferative diabetic retinopathy (R3) were associated with diabetes duration.

2.10.2 Age

Age was first reported as a risk factor in the Wisconsin Epidemiology Study of Diabetic Retinopathy (Klein *et al.*, 1984; Klein *et al.*, 2008). The study found that 3.6% patients who had Type 1 diabetes before the age of 30 years were legally blind compared with 1.6% of patients with Type 2 diabetes who had diabetes after the age of 30 (Klein *et al.*, 1984; Klein *et al.*, 2008). In the United Kingdom Prospective Diabetes Study (UKPDS), Stratton *et al.* (2001) reported that in patients with type 2 diabetes, who already had retinopathy, progression was associated with older age.

2.10.3 Genetic Predisposition

The Diabetic Control and Complication Trial (DCCT, 2008) suggested that the severity of diabetic retinopathy is influenced by familial factors and Patel *et al.*(2008) suggest a genetic contribution to disease development. In the Birinci *et al.* (2002) study, the differences in HLA antigen frequencies between people with diabetes with proliferative diabetic retinopathy suggest a genetic contribution to diabetic retinopathy. Birinci and colleagues argue that the inconsistency may be related to increasing homogeneity of retinopathy and diminishing power to detect small differences. It may also reflect the uncertain and inconsistent effects of HLA-DR3 or DR4 on the development and progression of diabetic retinopathy.

2.10.4 Ethnicity

Ethnicity and race were reported in many studies as a risk factor for the development of diabetic retinopathy (Fong *et al.*, 2004; Raymond *et al.*, 2009; Simmons *et al.*, 2007). Kempen *et al.* (2004) found that the differences in the prevalence of diabetic retinopathy between ethnic groups in the United States were larger than the differences among people with diabetes. Raymond *et al.* (2009) found that people with diabetes of South Asian ethnicity were diagnosed at a younger age had higher HbA1c, systolic and diastolic blood pressure, and total cholesterol and greater prevalence of diabetic retinopathy and maculopathy. Simmons *et al.* (2007) conducted a study to compare the prevalence of diabetic retinopathy in European, Maori and Pacific peoples with diabetes. In people with Type 2 diabetes, the prevalence of moderate or more severe retinopathy was 4.0% in Europeans, 12.9% in Maori and 15.8% in Pacific people (P = 0.003). There was no significant ethnic difference in the prevalence of retinopathy overall or in that of macular disease.

2.11. Modifiable risk factors

Diabetic retinopathy is also associated with a number of modifiable factors including hyperglycaemia (UKPDS, 1998), hypertension (Matthews *et al.*, 2004; UKPDS, 1998), serum lipid level (Cusick *et al.*, 2003), smoking (Muhlhauser *et al.*, 1996), non-adherence to diabetic retinopathy screening (Gray *et al.*, 2009; Zoega *et al.*, 2005) and knowledge about diabetes and complications (Boren *et al.*, 2007). Although hyperglycaemia is often deemed as the most important modifiable risk factor in diabetes mellitus, in relation to the progression of diabetic retinopathy (Yau et al, 2012), hypertension and hyperlipidaemia are also very common and can have a significant impact on patient’s vision. Furthermore, due to time limitations during outpatient consultations, risk factors such as hypertension and hyperlipidaemia are often given less attention than hyperglycaemia (Nirmalan *et al.*, 2004). These modifiable risk factors are presented and critiqued individually below. Non-attendance at diabetic screening is also considered as a modifiable risk factor and is discussed in the section on diabetic retinopathy screening (see section 2.12.5).

2.11.1 Blood glucose

People with diabetes have higher risk of developing diabetic retinopathy if their level of blood glucose is high. Blood glucose levels are measured with the HbA1c test. HbA1c is a type of haemoglobin which holds the oxygen substance that is found in red blood cells and has glucose attached to it (NHS, 2012). The Diabetes Control and Complications Trial (DCCT, 1993) was a randomised controlled clinical trial conducted to assess the relationship between glycaemic control and the development and progression of early vascular complications in people with insulin dependent diabetes mellitus. The DCCT consisted of two similar studies: a primary prevention, which tested whether improvement of abnormal metabolic status led to prevention of the complications, and a secondary intervention study, where people with type 1 diabetes received intensive insulin therapy. Intensive treatment is the means to get glucose control to as near normal as possible. The primary outcome in the primary prevention was the first appearance and subsequent development of background diabetic retinopathy. In the secondary intervention study, the primary outcome was the development of pre-existent minimal retinopathy. The Diabetes Control and Complications Trial (DCCT, 1993) showed in the primary prevention cohort, that the intensive therapy reduced the adjustment mean risk for the development of retinopathy in insulin dependent diabetes mellitus by 76% (95 CI, 62 to 85%) as compared with conventional therapy. In the secondary intervention cohort, intensive therapy showed the progression of diabetic retinopathy by 54% (95 CI, 39-66%) and reduced the development of proliferative or severe non-proliferative diabetic retinopathy by 47% (95 CI, 14 to 67%). The United Kingdom Perspective Diabetes Study (UKPDS, 1998) found that intensive blood glucose control either by sulphonylureas or insulin substantially decreased the risk of microvascular complications, but not macrovascular disease in patients with type 2 diabetes. The Diabetes Control and Complications Trial (Zhang *et al.*, 2001) reported the progress (after 9-year follow-up) of a study designed to determine whether improved glucose control in patients with newly diagnosed non-insulin dependent diabetes mellitus (NIDDM) is effective in reducing the incidence of clinical complications. Among the 153 patients within target metabolic control (mean HbA1c≤6.87%), 138 (90%) remained free of retinopathy. On the other hand, among the 166 patients within out of target metabolic control (mean HbA1c ≥9.49%), the complication did not develop in 71 (43%) and did develop in 95 (57%).

The Diabetes Control and Complications Trial confirmed that retinopathy develops in nearly 10% of patients with type 1 diabetes within target metabolic control, whereas more than 40% of patients with type 1 diabetes remain free of retinopathy despite out of target metabolic control. Whilst these findings confirm that HbA1c is the most significant risk factor for developing diabetic retinopathy that can be modified, the process of modifying HbA1c for people with diabetes, supported by Health Care Professionals, is far from straightforward.

Taking insulin and oral hypoglycaemic agents is the first line of treatment for lowering blood glucose. However, many studies reported that people with diabetes are generally not compliant with diabetes medication (Bailey, *et al.*, 2011, Karter, *et al.*, 2010, Karter, *et al.*, 2009). For example, Bailey and colleagues (2011) found less than fifty per cent of people with diabetes adhere to the prescribed diabetes medications (Bailey *at al.,* 2011). Adherence to prescribed medication is generally regarded as the proportion of patients taking at least 80% of their prescribed medication (Caro *et al.,* 2004). A systematic review of adherence with oral hypoglycaemic medication reported that only between 61% and 85% of diabetes medications prescribed, are taken, whereas 25.5% level of non-adherence to insulin as people with diabetes never obtained a refill (Cramer, 2004). Adverse reactions and side effects can also lead to non-adherence. For example, some of the current treatments for diabetes are associated with weight gain and hypoglycaemia (Yurgin *et al*., 2008; Donnelly *et al*., 2008). The evidence suggests that resistance to diabetes medication is linked to many factors including the number of oral hypoglycaemic medications (Thayer *et al*., 2010), the combination of insulin and oral hypoglycaemic medication (Yurgin *et al*., 2008), age and perception of glycaemic control (Donnelly *et al*., 2008), duration of the disease (Garcia-Perez, *et al.*, 2013), side effects (Curtis *et al.,* 2009; Dilla et al., 2008; Donnelly *et al*., 2009), knowledge (Boren *et al*., 2007), psychological burden (Garcia-Perez, *et al.*, 2013), complexity of dosing regimen (Garcia-Perez, *et al.*, 2013), and interactions/relationships with Health Care Providers (Ciechanowski *et al.,* 2001). It is clear from this evidence that controlling glycaemia with medication is not straightforward. Diabetes self-management education and psychological intervention both aim to reduce blood glucose and yet systematic reviews of both show only marginal gains in HbA1c (Royle *et al*., 2009; Allam *et a*l 2009; Ismail, Winkley, Rabe-Hesketh, 2004; Sturt *et al.,* 2015). The evidence for interventions to consistently modify (lower) blood glucose levels over the periods of time required to reduce diabetic retinopathy progression is low.

Whilst individual's may wish to engage with the life style modifications necessary for the management of diabetes, the evidence suggests that it is often difficult to achieve these changes, particularly for those who live with a partner with high expressed emotion, or that people have periods of relapse (Lister *et al*., 2016). Therefore, it is important that the individual is supported during relapse and supported to understand that occasional outside of target diabetes control is inevitable with this complex metabolic condition and does not indicate permanent failure. Macaden and Clarke (2006) suggest that individuals can be supported to cope with relapses through a number of strategies such as providing relevant information, access to guidance when needed, and modifying health related behaviours through social support. According to Listers and colleagues (2014), greater consideration should be given to using family-based approaches rather than individual based approaches for diabetes management.

2.11.2 Blood Pressure

High Blood Pressure is damaging to each aspect of diabetic retinopathy and a tight blood pressure control policy of achieving blood pressure of less than 140 mm Hg systolic and less than 90 mm Hg diastolic (NICE, 2009), using the angiotensin converting enzyme inhibitor captopril, 25 mg twice daily increasing to 50 mg twice daily (NICE, 2009), has been found to reduce the risk of clinical complications from diabetic eye disease (UKPDS, 1998). Control of blood pressure can minimise the risk of new onset diabetic retinopathy and can slow the progression of the existing diabetic retinopathy (Chase *et al.*, 1990). A study carried out by Matthews *et al.* (2004) sought to establish the relationship between blood pressure control and the different aspects of diabetic retinopathy in patients with type 2 diabetes mellitus. The study found that there was a highly significant difference in microaneurysm count, with 23.3% in the tight blood pressure control group and 33.5% in the less tight blood pressure control group (relative risk [RR], 0.70; *P*=.003). Hard exudates, largely made up of extracellular lipid which has leaked from abnormal retinal capillaries, increased from a prevalence of 11.2% to 18.3% at 7.5 years after randomization with fewer lesions found in the tight blood pressure control group (RR, 0.53; *P*<.001). Cotton-wool spots increased in both groups, but less so in the tight blood pressure control group which had fewer cotton-wool spots at 7.5 years (RR, 0.53; *P*<.001). The study also found that patients allocated to tight blood pressure control were less likely to undergo photocoagulation (RR, 0.65; *P*=.03). The cumulative incidence of the end point of blindness (Snellen visual acuity, ≥6/60) in one eye was 18/758 for the tight blood pressure control group compared with 12/390 for less tight blood pressure control group. Chase *et al.* (1990) found that the existence of high normal blood pressure resulted in a prospectively higher occurrence of retinopathy and of progression of pre-existing retinopathy. A randomised controlled trial (UKPDS, 1998) conducted to determine whether tight control of blood pressure prevents macrovascular and microvascular complications in people with type 2 diabetes found that tight blood pressure control achieves a significant reduction in the risk of death related to diabetes, complications related to diabetes, progression of diabetic retinopathy, and deterioration in visual acuity. The study included 1148 hypertensive people with type 2 diabetes. Of these, 758 individuals were allocated to achievement of tight control of blood pressure using medication and 390 individuals were allocated to less tight control with a median follow up of 8.4 years. Mean blood pressure in the tight blood pressure control was 144/82 mg Hg compared with the group assigned less tight blood pressure 154/87 mm Hg. After nine years of follow-up the group assigned tight blood pressure control had a 47% reduction in risk of diabetic retinopathy.

Prevention of diabetes-related complications commonly includes medications for the control of blood pressure (Garcia-Perez, 2013). As mentioned in the previous section, adherence to blood pressure treatment also remain low. Analysis of data from previous study (Bramley *et al.,* 2006) which included 840 individuals reported that 629 individuals (75%) had high adherence to blood pressure monotherapy and these individuals were 45% more likely to attain blood pressure control than those who were less compliant. Type 2 diabetes is a progressive condition (Garcia-Perez, 2013) which means that once diabetes is diagnosed people will have to take medication for life and the complexity of the medication regimen is likely to increase over time. For instance, a lot of people with diabetes may require not only oral hypoglycaemic agents, but also insulin and medication to lower their blood pressure and lipids level (NICE, 2009). This complex treatment for diabetes and related complications can involve up to ten different tablets every day (Gaede, et al, 2003), and it is this complexity of treatment that may lead to non-adherence (Mateo *et al*., 2006).

2.11.3 Lipid Levels

Data from the Early Treatment Diabetic Retinopathy Study show that high levels of serum lipid are associated with an increased risk of retinal hard exudate in people with diabetic retinopathy. The data suggest that lipid lowering may also decrease the risk of hard exudate formation and associated vision loss in patients with diabetic retinopathy (Chew *et al.*, 1996). Cusick *et al.* (2003) conducted a study to describe a regression of retinal hard exudates in 2 patients with diabetic maculopathy. Both patients showed a dramatic regression of retinal hard exudates after correction of dyslipidaemia. Recent Indian data also showed significant correlation between high levels of serum lipids and severity of diabetic retinopathy (Agroviya *et al*., 2013). However, patients' adherence to statin therapy to control lipids is also reported to be poor (Donnelly *et al*., 2008).

2.11.4 Smoking

Smoking may be a risk factor in the progression of diabetic retinopathy in type 1 diabetes. Muhlhauser *et al.* (1996) conducted a study to analyse the association between cigarette smoking and progression of retinopathy and nephropathy, respectively. Six hundred and thirty six people with Type 1 diabetes were included: 81% of the original cohort of consecutively referred patients, aged 15 to 40 years, and free of severe late diabetic complications. All patients had participated in a 5-day in-patient group treatment and teaching programme for intensification of insulin therapy. Patients were examined at recruitment and reviewed after 1, 2, 3 and 6 years including assessment of smoking status, blood pressure, metabolic control, and degree of nephropathy. The degree of diabetic retinopathy was assessed by ophthalmoscopy or fundus photography at baseline and after 6 years. Although significant associations between smoking and retinopathy were found, the relations were variable depending on the statistical model used. The results suggest that the factual associations between smoking and retinopathy are complex and that more research is needed. Karamanos *et al.* (2000) found that smoking is associated with early development of, and late protection from, microvascular complications in people with Type I diabetes. In contrast, the UKPDS suggested that smoking may be protective for diabetic retinopathy although mortality risks are higher (Adler *et al.*, 2002).

In the UK, the government has funded country-wide programmes and specialist clinics that provide help to smokers and most of these services have been found to be effective (McAlpine *et al*., 2015). A systematic review conducted by Stead and Lancaster (2016) assessed the effect of combining behavioural support and medication to help smoking cessation. The authors reported that interventions that combine medications and behavioural support enhance smoking cessation achievement compared to a minimal intervention or usual care. Another recent systematic review was carried out by Ussher, Taylor, and Faulkner (2014) to determine the effect of exercise-based intervention on smoking cessation. The authors reported significant benefits for a combined exercise and smoking cessation programme compared with brief smoking cessation advice. Han *et al*., (2014) reported a significant improvement in smoking behaviours at one month post brief physician counselling sessions. However, the effect was not sustained at three month post intervention. Whilst there is strong evidence for the effectiveness of intervention for smoking cessation, the behavioural requirements to initiate and complete treatment are significant and remain a barrier to the modification of smoking in relation to improving vision retention in diabetes.

2.11.5 Knowledge about diabetes and complications

People’s knowledge about their diabetes and its complications is an important part of managing diabetes and avoiding complications (Boren *et al.*, 2007). A number of previous studies (Iqbal *et al.*, 2008; Bowyer *et al.*, 2011; Pace *et al.*, 2006) have reported a lack of knowledge regarding diabetes. For example, Pace *et al.* (2006) conducted a study of 84 participants in Brazil to assess patients' knowledge of diabetes mellitus, and its causes, and complications. Only 28% gave correct answers as to “what is diabetes?” and “what are its causes?” The authors pointed to aspects that made the learning process more difficult, including little knowledge about diabetes, its causes, and symptoms. For example, only 8.6% knew the correct answer about the normal blood glucose level and just 28% gave the correct answer about the causes of diabetes. In the study by Pace and colleagues (2006) 59% of participants had not finished their basic education and 74% were retired or defined as housewives. Iqbal *et al.* (2008) conducted a quantitative study of 111 participants using a questionnaire to examine the impact of improving patient’s understanding of HbA1c values and the relevance to their self-care management. Of these, 60% were found to be unfamiliar with the term HbA1c and people’s knowledge was poor among those who had poor glycaemic control.

Although previous studies suggest that people with diabetes can improve their knowledge by attending diabetes education programmes (Hansen and Drivsholm, 2002; Iqbal *et al.*, 2008; Sturt *et al*., 2008), Ockleford *et al.* (2008) argue that education programmes are unlikely to suit all people with diabetes. However, they also reported that education programmes can be improved by taking the preferences of people with diabetes into account (Ockleford *et al.*, 2008). Sturt *et al.* (2008) conducted a study to determine the effect of the Diabetes Manual on glycaemic control, diabetes related distress, and confidence of self-care management of patients with type 2 diabetes. The Diabetes Manual is a one-to-one structured education tool designed for delivery by a practice nurse. The study found no significant difference in HbA1c measures (difference -0.08%, 95% Confidence Intervals (CI) -0.28. 0.11). However, there was slightly lower scores in terms of diabetes-related distress (difference -4.5; 95% CI -8.1, -1.0) and higher score of confidence to self-care management (11.2 points higher; 95% CI 4.4, 18.0). Reporting on qualitative findings, Lindenmeyer *et al.* (2010) sought to explore how people with type 2 diabetes self-manage their condition in daily life and how they viewed the impact of the Diabetes Manual programme on their self-care management. Although the study was unable to identify differences between how the control group and intervention group participants talked about their knowledge and habits regarding diet, exercise, and medication, the participant’s experiences suggests that the Diabetes Manual programme needs close communication to improve individual’s confidence for diabetes self-care management. For example, it was not possible for the researchers to verify whether all participants from the intervention group received phone calls from nurses (Lindenmeyer *et al.*, 2010). In addition to lacking knowledge of diabetes, previous studies (Rosal *et al.*, 2011; O'Sullivan *et al.*, 2009; Duncan *et al.*, 2010; Shrestha *et al.*, 2007) show that people with diabetes lacked knowledge about diabetes complications such as diabetic retinopathy. A quantitative study in Ireland conducted by O'Sullivan *et al.* (2009) to assess the awareness of diabetes complications among people with diabetes found that only 12% of the participants were aware of diabetic retinopathy as a complication of diabetes. Less than half of the participants were aware that improvements in diet and exercise could potentially cut their cardiovascular risk. Duncan *et al.* (2010) carried out a standardized survey in the United States for adult ophthalmology diabetic patients to investigate basic knowledge of the “recommended levels ABCs of Diabetes”. The recommended levels were as follows: HbA1c less than 7.0%; blood pressure, lower than 130/80 mm Hg; and LDL-C levels, less than 100 mg/dL. One hundred and sixty one participants were included. Of these, only 7 participants (4%) reported that they knew the recommendations for all the three items (HbA1c, blood pressure, and LDL level). This rate increased to 38 participants (23%) who knew about 2 of the 3 recommendations. A cross sectional study was conducted in Nepal by Shrestha *et al.* (2007) with the aim to establish the knowledge of diabetic retinopathy among people with diabetes. Three hundred and sixteen participants were included. The authors reported that 50% of participants were not aware of diabetic retinopathy.

2.12. Diabetic Eye Screening Programmes

Only a few countries in Europe undertake systematic screening for retinopathy. For example, Scotland, Wales, Northern Ireland, Ireland, and Iceland have systematic screening programmes (Scanlon 2011, personal communication, 29th September). Denmark screens people with diabetes in regions covering the whole country whilst Sweden covers a number of regions, but not the whole country. There is some screening in relation to certain indigenous communities, such as North American Indians in the USA and Aboriginals in parts of Australia. Any other systematic screening that is undertaken is only in small areas around the world. According to Scanlon (2011) many of the programmes do not have good population coverage and hence are not systematic in the sense that they are unaware of the number of people with diabetes in their areas.

2.12.1 The NHS Diabetic Eye Screening Programme (NHS DESP)

Diabetic retinopathy screening as a procedure has been available in some areas of the UK since late 1980s. However, the English National Screening Programme for Diabetic Retinopathy (ENSPDR), which brought screening to all areas of England, was not established until 2003 (Scanlon, 2008). The National Screening Committee (NSC, 2011) defines screening as:

> *“Screening is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complication, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications.” (http://www.nsc.nhs.uk)*

Up until 2003, diabetic retinopathy screening had been opportunistic and *ad hoc*, with people being screened when they attend the diabetic or eye clinic or by optometrists and GP’s in the community. The NHS diabetic eye screening programme aims to cut the risk of sight loss among people with diabetes, by the timely identification, efficient communication, and successful treatment, if required, of sight-threatening diabetic retinopathy, at the right stage of the diabetic retinopathy process. All people with diabetes are at risk of developing diabetic retinopathy, whether the individual is controlling his/her diabetes with insulin, tablets, or diet. At the time of the research, the NHS diabetic eye screening programme offers annual diabetic retinopathy screening to 2.4 million people with diabetes (type 1 and type 2) from the age of 12 years old. In England, 84 local programmes screened 1.9 million people with diabetes between February 2012 and February 2013 (NHS England, 2013). Figure 2.1 (Lindenmeyer *et al.*, 2014) shows details of the NHS DESP process. Patients are systematically invited to have their retinae digitally photographed at their GP surgery, high street optician, or local hospital, depending on which part of the country they live. In some areas of the UK, screening is carried out at high-street optometrists. For the photograph to be taken properly, mydriasis eye drops to dilate the pupils are put into patients' eyes, affecting their ability to drive for a short while afterwards. People who do not attend their screening are followed up by letter or telephone call, up to three times, by the regional screening teams. Additional screening sessions are held to maximize attendance, including at weekends in some areas. The photographs are sent to a trained and accredited regional NHS retinal grading teams, who perform a two or three-stage image grading process. This identifies any changes that could indicate sight-threatening diabetic retinopathy that requires monitoring or treatment. The grading teams notify any such indicators and communicate it to the patient and the medical team.

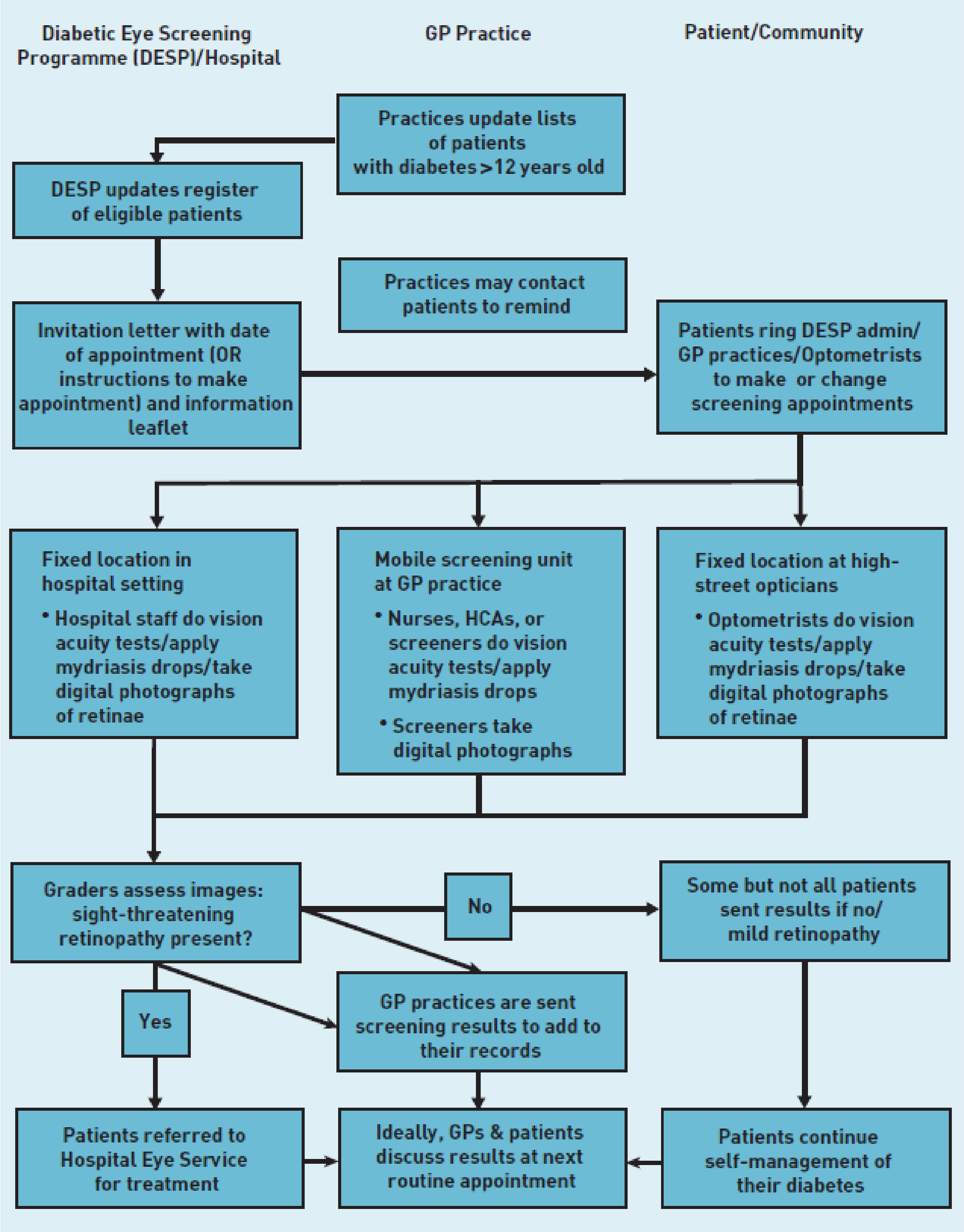


Figure 2.1 Process of diabetic eye screening, source: Lindenmeyer et al., 2014)

2.12.2 Effectiveness and cost-effectiveness of diabetic retinopathy screening

Screening and early treatment of diabetic retinopathy can stop deterioration and loss of sight (Bachmann and Nelson, 1998). The effectiveness of systematic screening for diabetic retinopathy, in terms of sight years preserved compared with no screening has been considered in a number of studies (Vijan *et al.*, 2000; Fong *et al.*, 2001; Jones and Edwards, 2010). Bachmann and Nelson (1998) used data from previous screening studies and found that retinal photography screening was the most effective form of screening. A systematic review conducted by Hutchinson *et al.* (2000) to determine the most effective screening and monitoring tests for diabetic retinopathy concluded that the use of mydriatic retinal photography with further use of ophthalmoscopy for cases where photographs are ungradable were most effective.

In terms of cost effectiveness, diabetic retinopathy screening has been assessed by the UK National Screening Committee and was the subject of a report from the Centre for Health Planning and Management at the University of Keele (James *et al.*, 2000). This report concluded that diabetic retinopathy screening is a cost-effective strategy for the UK compared with opportunistic screening. The report also recommended that the establishment of a diabetic register that has high population coverage is a key factor in the implementation of a successful screening strategy. A study carried out in the United States (Moss *et al.*, 1994) reported rates of ten-year incidences of blindness were 1.8% in the younger-onset diabetes (diagnosed before age of 30), 4.0% in older-onset (diagnosed after age of 30) taking insulin, and 4.8% in older-onset persons not taking insulin. Improvements in the incidence of blindness have been found to be impressive where organized screening programmes have been introduced. The best reduction of blindness was documented in Iceland (Stefansson *et al.*, 2000; Zoega *et al.*, 2005) where the prevalence of diabetic retinopathy has dropped from 2.4% in 1980 to 0.5 in 2005.

2.12.3 Critiques of screening

Screening may create a dilemma between patients and their doctor as it is the latter who normally seeks out the patient that is deemed to need help and support. Therefore, it is important that the NHS DESP can offer some sort of effective support and intervention. The main principles of the NHS DESP were derived from the public health paper which is proposed by Wilson and Jungner

(1968) as general principles of establishment a screening programme. These principles are as follows:

- The condition for screening is required should be an important health problem.
- There should be an acceptable treatment for the cases identified.
- Facilities for diagnosis and treatment should be available.
- There should be a recognized latent or early symptomatic stage.
- There should be a suitable test or examination.
- The test should be acceptable to the population.
- The natural history of the condition should be understood.
- There should be an agreed policy on whom to treat as patients.
- The cost of case findings should be economically balanced in relationship to expenditure on medical care as a whole.
- Case-finding should be a continuing process and not a one-time event.

Due to the high prevalence of diabetic retinopathy that is reported by the UK prospective Diabetes Study (UKPDS) (39% of diabetic male and 35% of diabetic female), it is evident that diabetic retinopathy is a significant public health problem and that diabetic retinopathy screening is a good fit with the above criteria. However, whilst support screening programmes may have the potential to reduce sight-threatening diabetic retinopathy (Younis *et al.*, 2002) others criticize screening programme in general as a possible misuse of limited resources (Weltermann *et al.*, 2013) and as a cause of unnecessary anxiety (Landstra *et al.*, 2013; Tinmouth *et al.*, 2011; Park *et al.*, 2008). Screening appears to have certain psychological costs, mainly for those who receive bad news or false positive results (Eborall *et al.*, 2007; Hafslund *et al.*, 2011). Although the provision of individualized risk information can encourage and promote health, the perception of increased personal risk may also cause or increase anxiety levels, particularly if the level of the risk is very high (Roach and Marrero, 2005). A positive result can also result in negative feelings and depression (Michie *et al.*, 2004). High levels of anxiety have been reported in patients participating in screening programmes, including breast cancer screening, cervical screening (Marteau *et al.*, 2001b), and anal cancer screening (Tinmouth *et al.*, 2011). A study carried out by Marteau *et al.* (2001b) shows that patients who were falsely diagnosed on routine screening, continued to be overwhelmed by questions and uncertainties about their health although they knew that the results of subsequent testing were negative. This also resulted in people being more likely to attended future screening (Michie *et al.*, 2004). In addition to the unnecessary stress and anxiety there is also risk when communicating information either when risk messages are misunderstood (Marteau *et al.*, 2001b) or when false-negative results are communicated (Petticrew *et al.*, 2001). Other disadvantages to the diabetic retinopathy screening programme as highlighted by Taylor (2007) includes: 1) Poor at detecting macular oedema by using photographic screening; 2) Less flexible due to constraints of centralized recall system as patients with diabetes are not able to be screened if not registered on the database or not referred by their general practitioner to diabetic retinopathy screening services; 3) The complexity associated with managing large numbers of screening locations in an optometrist based scheme; 4) Large number of graders makes quality assurance difficult and; 5) Screening is relatively expensive for Primary Care Trust to use an optometric model, a diabetic retinopathy screening that carried out by optometrists, using slit-lamb biomicroscopy. In addition, Taylor (2007) added that poor performance by a screener can cause problems for the patients, the screener, and the screening services as missing sight-threatening diabetic retinopathy that can lead to loss of visual function or blindness. Also, it could lead to legal action and financial loss against the screener and the screening services for the damage due to missed sight-threatening diabetic retinopathy or anxiety and stress. Furthermore, it could lead to a lack of confidence in the service if the problem is exposed to the public.

There have been reductions in the progression rate of diabetic retinopathy and severe visual loss in the past thirty years, probably reflecting improvements in diabetes care, screening and early detection of diabetic retinopathy (Klein *et al.*, 2008; Wang *et al.*, 2009). Therefore, annual screening may not be required for all people with diabetes, which can mean that unnecessary consequences, such as anxiety are eliminated.

2.12.4 How results are communicated

The standard of the NHS DESP is that results are communicated to all patients in writing within 3 weeks after the screening as well as to the Health Care Professionals providing their care, such as GPs and Diabetologists (NSC, 2003). This delay is because the photographs require careful grading, which requires time and suitable equipment and lighting, and these are normally not available in the screening environment. Furthermore, the images should go through a process of internal quality assurance involving more than one grader. Images can be seen by patients if they wish to view them and general information can be provided about the retina and diabetic retinopathy. The screeners must take great care when providing such information not to mislead the patients about the outcome of the grading process as it may increase their anxiety level or diminish trust (UK NSC, 2009). Individuals are also more likely to turn the risk information they receive from their Health Care Providers into appropriate behavioural change when they understand their health condition and have engaged in treatment decisions (Jacob and Serrano-Gil, 2010).

2.12.5 Non-adherence to diabetic retinopathy screening

Early detection and early treatment is key for reducing diabetic retinopathy blindness and visual impairment (Bachmann and Nelson, 1996). Unfortunately, many people in the at risk population do not have regular and timely eye examinations to ensure early diagnosis and treatment (Gray *et al.*, 2009). Non-adherence to diabetic retinopathy screening is not only a waste of resources, but it could have a significant effect on a patient’s sight and is a risk factor for poor visual outcome (Zoega *et al.*, 2005). Data from the Insulin Dependent Diabetes Trust (IDDT) shows that screening rates consistently fall far below recommended levels (IDDT, 2009). Twenty eight per cent of people aged 12 and over did not receive eye screening between October 2007 and September 2008, and 13 of the total of 152 Primary Care Trusts failed to screen half of their diabetic population (IDDT, 2009). Almost 66% of service providers were failing to meet the government's 2003 target of screening 80% of the diabetic population (IDDT, 2009). The great variation in the provision of diabetic retinopathy screening services throughout the UK is believed to be due to the variation in screening methods and population coverage and organized systematic screening in some units (Grimshaw *et al.*, 1999). Many studies have been conducted in the past decade that are designed to improve uptake to diabetic screening programmes. A systematic review was conducted by Zhang and colleagues in 2007 to assess the effectiveness of interventions intended to increase retinal screening among people with diabetes. The review found a range of interventions focused on one of the following: people with diabetes, Health Care Providers, and health care system infrastructure and processes. Zhang *et al.* (2007) suggested that increasing patients' awareness of diabetic retinopathy can significantly improve diabetic retinopathy screening attendance, particularly among diverse and disadvantaged population.

A recent qualitative study aimed to identify factors contributing to high or low patient uptake of diabetic retinopathy screening (Lindenmeyer *et al.*, 2014). A purposive sample of nine GP practices in three regional screening programme areas were recruited. Practices were sampled to achieve a variety of backgrounds according to location, level of deprivation that was identified from Index of Multiple Deprivation data (IMD), and screening uptake level from the Diabetes Eye Screening Programme. A range of professionals and people with diabetes were interviewed in each GP practice, to ensure a broad spectrum of views and experiences. Semi-structured interviews were conducted, in a place of participants' choice, to gather information about the diabetic retinopathy screening from the perspective of people with diabetes and their Health Care Professionals. Lindenmeyer and Colleagues used a comparative case study design to identify factors leading to high or low screening uptake. The study highlighted many modifiable factors, related to service and staff interactions. These include communication issues between General Practice and screening programme, people with diabetes and Health Care Professional's perception, contacting and motivating patients, diversity and ethnicity, and language. Lindenmeyer *et al.*, (2014) found that practice's uptake was positively linked to communication levels between practice staff and screening services. Practices with higher uptake had identified their patients who did not attend and called them to attend again for diabetic eye screening. Practices with lower levels of communication between the practice, the screening service and the patient had lower levels of screening uptake. The study also highlighted that good communication on the day of mobile in-practice screening, resulted to practice staff sharing their knowledge of their patients with screening staff. The study also reported the importance of contacting people with diabetes to motivate them and to encourage them to attend diabetic screening later in the day or provide them with alternative dates. The study also reported staff perception of non-attenders, as they described them as a “hard core of difficult to engage” (p: 488) patients, as they would only attend when symptoms appear to start. This has led to a sense of frustration among Health Care Professionals, despite the hard efforts and time they spent to motivate people with diabetes.

2.13. Implications of diabetes

The prevalence of type 2 diabetes has been affected by changes in patterns of living, changes in diet and food consumption, level of physical activities, and stress (Naemiratch and Manderson, 2008). Once contracted, it is a chronic condition that requires changes in people’s daily living, which are constructed around symptom management (Macaden and Clarke, 2006). It also represents a loss of reliability when part of the body does not function properly. These disruptions to people’s daily activities have social, financial, and medical implications as well as symbolic meaning for the person affected, including a significant impact on their feelings of self-worth (Bury, 1982). Diabetes is a particular problem within the South Asian community as they have higher rates of diabetes and greater risk of developing complications (Raymond *et al.* 2009). Bellary *et al.* (2008) conducted cluster randomised study to investigate the effectiveness of a culturally sensitive approach to ease risk factors in diabetes among a range of South Asian communities. The authors used an enhanced care model with extra time from practice nurses/diabetes nurse specialists and support link worker to provide culturally sensitive care and compared this with standard care. Bellary *et al.* (2008) found that the culturally tailored care produced significant improvements in diastolic blood pressure and main arterial blood pressure. Previous studies conducted by Choudhury *et.al*. (2009) and Greenhalgh *et al.* (1998) among Bangladeshi community found that most participants were lacking in knowledge about the cause, prevention, and management of their diabetes. For example, the participants in Choudhury *et al.*, study (2009) often defined their diabetes as being acquired during a visit to Bangladesh. Other Bangladeshi participants believed that sugar and western diet were the cause of diabetes together with increased physical and psychological stress (Greenhalgh, 1998). In contrast, some Bangladeshi participants appeared to have better knowledge, which was gleaned from their experiences of living with diabetes for longer periods. In other words, it appeared that their experience of having diabetes for longer duration thus having more contact with Health Care Professionals and others may have shaped their knowledge and improved their diabetes management. Lawton *et al.* (2007) argued that people with diabetes from South Asian background repeatedly refer to external factors when seeking to explain their diabetes. Choudhury *et al.* (2009) reported that many Bangladeshi participants showed awareness about the importance of healthy food and exercise together with a cultural concept of body weight. They associated small body sizes with poor health while medium or large body sizes with good health, which impacts on their decisions regarding diabetes (Choudhury *et al.* 2009).

Diabetes has also been found to have negative implications for other family members. A recent global study conducted across four continents and within seventeen countries including the UK (Joensen *et al.*, 2016) sought to explore the effect of household composition on the psychological health of adults with diabetes by comparing those who living with other adults including a partner with those living with neither. The study surveyed one hundred and twenty two family members, five hundred people with diabetes, and two hundred and eighty one Health Care Professionals such as nurses, dieticians, general practitioners and specialists. The UK results show that fifty four per cent of family members were anxious about the likelihood that a family member would develop severe complications related to their diabetes. This study also found that twenty five per cent of family members reported a negative financial impact on them because of their loved ones diabetes. Furthermore, the study also reported that seventy nine percent of family members had not attended an educational programme about diabetes and so lacked knowledge regarding the condition. Whilst Health Care Professionals provided a lot of information about diabetes management through healthy diet and healthy lifestyles, the study found that this information was not be absorbed and understood by people with diabetes or those around them (Choudhury et al 2009). Thus, in the light of such evidence, Joensen *et.al* (2016) argue that whilst Health Care Professionals must prioritise the needs of people with diabetes they also need to understand the concerns of those close to them such as their family members and friends, particularly as they are often left worried and uncertain about the implication of diabetes.

Taking the incidence, prevalence, and diabetes related complications into account, a number of organisations including the Department of Health, Diabetes UK, the British Heart Foundation, and the South Asian Health Foundation have identified objectives and scheduled strategic plans to tackle these challenges (Barnett *et al*., 2006). These include increasing awareness of diabetes and its complications through greater community-based activities; providing and promoting more culturally specific risk information for groups at higher risk; more partnership with relevant community organisations; and funding of community and research projects (Barnett *et al.,* 2006). Barnett and colleagues (2006) also highlight the significance to address specific cultural structures such as customs, religion, lifestyle, food, and languages. This requires a lot of educational interventions to ensure that people with diabetes benefit and therefore reduce the risk of diabetes complications.

2.14. Meanings of diabetes to people with diabetes, their family, and professionals

The ways in which diabetes is constructed by individuals is important to consider because it inevitably has different meanings to different people. For example, for people with diabetes it can mean a devastating long-term condition that imposes disruption causing interruption in social relations and self-identity – what is known as ‘biographical disruption’ (Macaden and Clarke, 2006). People with diabetes need to make lifestyle changes in order to successfully manage their diabetes. For the family, the daily life of people with diabetes can become disrupted. Diabetes also has an emotional impact upon individuals, families, and friends, particularly on those with a close relationship to those with diabetes. According to Conrad and Baker (2010), some illnesses are embedded with cultural meanings — which is not directly derived from the nature of the medical condition — that outlines how society reacts to those distressed and influences the experience of that illness. People experience an illness not as isolated situation, but in the ways it is developed through interactions in a social context. Thus, the same condition may hold quite different meanings in different times and contexts and for different groups of people (Davey and Seale, 2002). For example, eating a diet not appropriate for a condition may make it worse, and diet is a factor controlled by society, as certain people eat certain food in a certain way of preparing, cooking, and storing. Dietary habits and drinking are also influenced by religious beliefs, as well as area of origin (Barnett *et al.*, 2006). Furthermore, changes in society have led to more inactive lifestyles and many occupations necessitating less energy expenditure. These reduced levels of physical activity may affect certain populations and ethnicities more than others, such as the South Asians groups. For, example, a systematic review conducted by Fischbacher, Hunt, and Alexander (2004) included 17 studies to assess the level of physical activities among the South Asians population in the UK. All the seventeen studies reported lower levels of activities among South Asians compared with the general population. This mainly because people of South Asian ethnic groups were uncertain what type and level of activity was appropriate and safe for them, more difficult to attend gyms, fear of walking in public spaces, and lack of appropriate facilities (Fischbacher, Hunt, and Alexander, 2004; Sriskantharajah & Kai, 2007).

In summation, society and culture does not cause diabetes, but may worsen a physical illness that already exists. In this sense, the condition and the meanings attached to it are, in part, socially constructed and culturally relative, and the nature of this construction can profoundly alter the experience of the condition for everyone who is affected by it (Davey and Seale, 2002). The next section discusses how people may construct their knowledge around diabetes through their social interactions.

2.15. How knowledge is constructed

People actively construct their social words and their constructions of selfhood, through continuing social interaction with other people (Blumer, 1969). Social constructivism refers to the concept that individuals form or construct knowledge as they interact with others to share, relate, and dispute their interpretations of their social worlds (Applefied *et al.*, 2011). Thus, individuals build their knowledge as they participate in a range of social activities (Woolfolk, 2011) with people developing their own understandings through collaboration and interactions with those around them (Applefield, *et al*., 2011). Personal knowledge and development or construction of understanding is therefore based upon personal actions and interactions within daily life (Carmichael, 1990). The ways in which knowledge is created and understood within a social constructionist framework is at odds with a more ‘scientific’ or medical model of understanding. Within the medical model, for example, diseases are universal and invariant to time or place, whereas a more social model of health, the meaning and experience of illness is key and is formed by cultural and social factors (Conrad and Barker, 2010). Put another way, illness does not simply exist in nature, waiting to be discovered by Health Care Professionals. Rather knowledge and understanding about illness is key and is constructed when individuals interact and interpret their signs and symptoms (Driver *et al*., 1994). Woolfolk (2011) states that the construction of knowledge by individuals is based on two main concepts. First, individuals are active in constructing their own knowledge through personal experiences. Second, social interactions are essential for understanding the construction of knowledge. People with diabetes construct their own understanding and knowledge of diabetes through experiencing signs and symptoms and reflecting on those experiences. This shift in understanding begins to recognise the importance of experience in relation to conditions such as diabetes (Macaden and Clarke, 2010)

2.16. Conclusion

Diabetes is a global problem affecting over 415 million people worldwide and is increasing. The number of people with diabetes in the UK in year 2000 was 1.8

million and has risen to 3.5 million in 2015 and expected to rise to 5 million by 2025. Diabetes mellitus is divided into type 1 diabetes, which accounts for about 15% of all diabetic population, and type 2 diabetes, which accounts for about 85% of all people with diabetes. Diabetes can cause problem with major organs and systems such as heart, kidneys, nerves, feet, bones, joint disorders, and eyes.

Diabetes is a costly condition for the individuals, their families, and the Health Services. Furthermore, diabetes leads to other complaints such as depression, pain, anxiety, vision loss, and amputations. Diabetic retinopathy is a complication of diabetes mellitus, a potential cause of irreversible vision loss, and which can cause a decrease in workplace productivity and a loss of income and productivity. There are a number of non-modifiable risk factors associated with the development of diabetic retinopathy, such as duration of diabetes, age of individual, type of diabetes, genetic disposition, and ethnicity. Diabetic retinopathy is also associated with a number of modifiable factors including hyperglycaemia, hypertension, serum lipid level, smoking, knowledge about diabetes and complications, and non-adherence to diabetic retinopathy screening. The NHS diabetic eye screening programme aims to reduce the risk of sight loss amongst people with diabetes. It is evident that annual diabetic retinopathy screening programmes are effective in terms of screening compared with no screening and cost effective at detecting and treating diabetic retinopathy. Screening and early treatment of diabetic retinopathy can stop considerable disability. The impact of awareness raising of diabetic retinopathy and communication between GP practice, the screening service and the person with diabetes have been shown to be an important factor related to screening uptake.

Diabetes has also negative implications for other family members. Therefore, the ways in which diabetes is constructed by individuals is important to consider because it inevitably has different meanings to different people. Some illnesses are embedded with cultural meanings, which is not directly consequent from the nature of the medical condition. People experience an illness not as isolated situation, but in the way it is developed through interactions in a social context. People construct their social words and selfhood through continuing social interaction with other people. In the next chapter, the researcher will explore the literature regarding risk perception, the risk communication process and how people with diabetes understand, interact, make sense of knowledge, and respond to risk communication messages.

Chapter 3. **Literature Review-Risk perception and Communication**

3.1. Introduction

Chapter 2 (section 2.11.5) highlighted that people with diabetes lacked knowledge about the risk of diabetes and its complications. Previous studies (Boren, 2007; Iqbal *et al.*, 2008; Bowyer et *al*., 2011; Barnett *et al.*, 2006; Lindenmeyer et al, 2014) suggest that this can be improved by good communication, patient education about their condition, and through good Health Care Professional - Patient interaction. This chapter examines the literature regarding perception of risk and risk communication issues among people with type 2 diabetes. As with chapter 2, the literature reviewed in this chapter is primarily a scientific and medical review embedded within a medical context and includes limited work in the field of social sciences. This decision was informed by the researcher's clinical background and the pragmatic imperative to understand the evidence as it relates to, and impacts upon, clinical practice. The chapter explores the factors that influence the exchange of risk information about diabetes between Health Care Professionals and their patients. This includes perception of risk, risk communication and informed decision-making, professional-patient interactions, various risk communication formats, numerical knowledge, the effect of visual risk communication tools, individual’s limitations, variations in risk interpretation, fear messages, and framing bias. The chapter then considers other issues regarding risk communication, such as constraints to effective communications and ethical issues related to risk communication.

3.2. Definitions of risk

Many terms have been used in relation to communicating risk information to people. These include risk, relative risk, residual risk, and absolute risk. The word risk was first cited in Oxford English Dictionary (spelled as risque) in 1621 and was changed to the current spelling as risk in 1655 (Oxford English Dictionary). Risk is defined as: *"A situation involving exposure to danger."*

In statistics, the meaning of risk is defined as the expected value of unwanted outcome (Lundgren and McMakin, 2009). While risk in a mathematical formula is risk = (probability of the accident) x (expected loss). Relative Risk is defined as: *"The ratio of risk in the exposed and unexposed groups" (Sistrom and Garvan, 2004; P: 16).* In statistics, relative risk is the ratio of the probability of an event occurring or developing a disease in an exposed group to the probability of the event occurring in a comparison, non-exposed group. For example, a risk of 10 per cent in the control group and a risk of six per cent in the intervention group means that the relative risk reduction would be sixty per cent. Therefore, one can provide the risk in the control group along with the relative risk reduction (e.g. 60% relative risk reduction from a baseline of 10%). The absolute risk reduction or risk difference is the difference in risk of a given activity or treatment in relation to a control activity or treatment (Sistrom and Garvan, 2004). For example, for a risk of ten per cent in the control group and a risk of five per cent in the intervention group, the absolute risk reduction would be five per cent.

3.3. Perception of risk

Risk has become a significant topic in many areas of life including economics, medicine, and engineering, and is well studied by social scientists (Macaden and Clarke, 2006; French *et al.*, 2013; Schapira *et al.*, 2006). This section focuses on the understanding of risk in relation to certain health problems. There are many synonyms and meanings to risk such as danger, hazard, and threat. Such meanings of risk are generally negative and are associated with some kind of threat or loss to the person concerned (Macaden and Clarke, 2006). The physical outcomes of risk or hazard, such as death or loss of vision are very real. However, perceptions of risk are subjective because they are based on people's attitudes, culture, religion, age, and gender and are dependent upon human decisions as well as people's life experiences (Macaden and Clarke, 2006).

Within the social sciences, the notion of risk is best understood within particular social and cultural contexts. For example, Ogden (1995) argues that risk should understood as a social construct that is contextualised within the realities of people's lives; i.e. people's perceptions, interactions, and experiences of risk are generated through the ways in which people construct their social world. Social constructionism seeks to make sense of the individual in society through the meanings individuals assign to phenomena and events via their interpretations of their experiences and their interactions with others (Charmaz, 2006). Therefore, understanding how people construct risk based upon their perceptions and experiences can offer a useful means for designing health promotion and risk prevention strategies (Adams and Smith, 2001). Given that risk is socially constructed based upon interpretation, it then follows that people with diabetes and Health Care Professionals may have varied understandings and interpretation of diabetes and diabetic retinopathy and the risks related to those illnesses. For example, in broader terms, Macaden and Clarke (2006) found that Health Care Professionals tend to understand risk mainly in terms of probability and occurrence of a related complication, which may also be associated with individual's non-compliance to medical advice. In contrast, individuals' understandings of risk have been associated with personal beliefs, past experiences, spirituality, and interactions with family members, friends, and other social groups. The evidence also suggests that variations in people's perception and experience of risk as well as their interpretation of risk can lead to different reactions (Tate *et al.*, 2003). For example, people have been found to underestimate their risk when they associated it with individual behaviour as opposed to when risks are associated with external sources (Macaden and Clarke, 2006). For example, smoking may be considered by an individual to be risky, but individuals can also be as or more worried or anxious about natural disasters that they perceive may happen within their environment (Tate *et al.*, 2003; Shepperd *et al.*, 2002). In terms of Health Care Professionals, Edwards *et al.* (1998b) suggest a standardisation of the language of risk in order to make

Health Care Professionals consistent in their perceptions of risk, particularly when conveying risk messages to patients.

Research has also revealed differences in risk perception between men and women (Homko et al., 2010). Differences in risk perception have also been found in relation to ethnicity and other social divisions. For example, Buster *et al.* (2012) conducted a quantitative study to evaluate skin cancer risk perception across race and other demographic factors. Buster and colleagues (2012) reported that the black population, the elderly, and people with less education perceived themselves as lower risk of developing skin cancer. In terms of diabetes, Macaden and Clarke (2006) conducted a qualitative study to report perception of risk among older South Asian people in the UK with type 2 diabetes. Data was collected via focus group interviews with ethnic health development workers together with seven individual interviews with Health Care Professionals and twenty interviews with participants with type 2 diabetes from a South Asian background. The study found that risk perception was influenced by a number of issues such as the belief about the cause of diabetes, perceived severity of diabetes, food and its social function, religion and beliefs about external control, and diabetes management. The study reported that individuals were required to make decisions by weighing up different risks. For example, participants weighed up the risk when making decisions about dietary management where the risk of causing social offence to others had to be taken into account together with the risk of less than perfect diabetes management. The study only recruited participants of South Asian origin. The author conducted more than one interview with each participant in order to cover specific issues in detail. Whilst interpreters were involved, the transcripts were not reinterpreted or verified by language experts due to financial constraints (Macaden and Clarke, 2006).

3.4. Risk communication and informed decision-making

Within clinical environments, counselling patients regarding risk involves the presentation of appropriate risk information. For example, the patients' charter states that patients have a right to be given a clear explanation of the potential risks associated with conditions and procedures; i.e. that they are able to make informed decisions regarding their health. Marteau *et al.* (2001a) defines informed choice as:

"One that is based on relevant knowledge, consistent with the decision-makers' values and behaviourally implemented" (P: 99).

The evidence from within primarily medical perspectives suggests that better informed patients have been found to make decisions that are deemed to be in their best interest, which is usually defined in terms of adherence to treatment regimens (Epstein *et al.*, 2004). Conversely, patients who are less well informed about the risks associated with certain behaviours and procedures are deemed as being more likely to make less appropriate decisions (Epstein *et al.*, 2004). Inevitably, when making decisions much depends on a person's level of understanding of the relevant risks presented to them, but also how this information corresponds with other beliefs and values they may hold (Michie *et al.*, 2005). In order words, whilst people with diabetes have the right to be presented with risk information regarding their illness, prognosis, and complications this may not correspond with them behaving in ways that are deemed to be in their best interests, but in them making decisions they believe to be best for them (Sullivan, 2003). Thus, in terms of diabetic screening, presenting evidence to patients on the benefits of diabetic eye screening when they are defined as low risk may lead people with diabetes to also believe they are doing well regarding their diabetes management and for that reason may not see the value in attending for annual diabetic eye screening. This in turn may lead them to underestimate the importance of controlling their diabetes when the evidence suggests that adherence to diabetic eye screening is one important factor in the risk of developing sight-threatening diabetic retinopathy.

The effectiveness of communicating risk information also appears to depend not only on people's understanding and contextualisation of the information given to them, but also on the form in which the risk information is presented that may influence decision-making processes (Lipkus, 2007; Epstein *et al.*, 2004). For example, factors that can influence the risk communication process include understanding and interpretation of numerical information (Schillinger *et al.*, 2002; Paasche-Orlow *et al.*, 2005) as well as probabilities and percentages (Lipkus, 2007). Other factors include low health literacy and the ability to fully engage and be involved in decision-making process about their own health (Schillinger *et al.*, 2002; Paasche-Orlow *et al.*, 2005). The evidence also demonstrates that Health Care Professionals' skills and abilities regarding the provision of information to also be important (Cokely et al., 2012; Anderson and Schulkin, 2014). Furthermore, the risk communication process may also be influenced by the amount of information that patients receive form their Health Care Providers to provide them with the opportunity to participate in decision-making around their own health (Heisler *et al.*, 2002; Kinnersley *et al.*, 2008; Edwards *et al.*, 2002) as well as the interaction between Health Care Professionals and their patients (Epstein *et al.*, 2004). These significant factors are discussed in the following sections.

3.5. Doctor-Patient interaction

Clearly, interactions between patients and their Health Care Providers are central when patients have to make complex decisions about their health care (Evans *et al.*, 2004). The interaction between Health Care Providers and their patients has been shown to influence the nature of the information that is both presented and retained by each of the parties involved (Evans *et al.*, 2004). Therefore, Epstein *et al* (2004) recommended that Health Care Providers build strong relationships with their patients in order to build trust and facilitate the transfer of risk information, which also take account of patient's perspectives. According to Epstein *et al.* (2004) trust building between Health Care Providers and patients can be done by the expression of empathy (e.g. "*You might feel uneasy*"); acknowledgment of the complexity or difficulty of the issue and an expression of mutual understanding (e.g. *"I think I understand*…"); increasing patient/ family involvement (e.g. "*I would like to help you understand...*"); and promoting and encouraging partnership (e.g. "*We need to make this decision together*") (Epstein et al., 2004; P:2364).

Building trusting relationships between Health Care Professionals and their patients also requires good understanding of the patient's and family members' experience and expectations:

> *"Even if the clinician has inquired about the patient's perspective earlier in the visit, it is helpful to delineate the patient's specific needs, fears, expectations, and context specific to this issue. Also, this is the time to invite family members to participate when appropriate." (Epstein et al., 2004; P: 2363).*

Poor interactions between people with diabetes and their Health Care Professionals has also been shown to have a negative impact on the level of adherence to oral hypoglycaemic medications, blood glucose monitoring, and found to be associated with higher level of HbA1c (Ciechanowski *et al.*, 2001). Sinclair *et al.*, (2016) found that patients identified Health Care Professionals' ability to build a relationship with their patients as a core element of doctor-patient relationships. Most participants stressed the need for Health Care Professionals to receive training in the development of interpersonal skills to improve communications and patient care. The majority of patients felt that understanding the patient as "a fellow human being" (P: 6) was a vital feature of patient care. The participants felt that the emphasis within medical education on the condition rather than the relationship caused Health Care Professionals "to view the patients as a body or disease, rather than a person" (P: 6). Although participants recognized that developing biomedical knowledge was important, they also pointed out that greater attempt needed to be made in educating Health Care Professionals about the holistic needs of their patients, including their social, emotional, and spiritual needs. According to Sinclair *et al*, (2016) most participants believed that compassionate care implicated addressing people's medical needs within the larger setting of person, including the systematic effect that their illness had on other fields of life.

However, it is also clear that other factors can influence the nature of the doctor-patient relationship. For example, the evidence suggests that many South Asian people have grown up in a culture with hierarchical relationships based upon class variations in which the physician is often higher placed within the social hierarchy (Macaden and Clarke, 2010). In these cases, such patients have often been found to listen more to their doctor, which results in more dependent behaviour, less independent thinking and higher reliance on others (Macaden and Clarke, 2010). Such groups of people tend to perceive Health Care Professionals as being in control of their medical condition and so often absolve themselves of responsibility for managing their diabetes (Macaden and Clarke, 2010). In a similar vein, South Asian patients have expectations that their physician will be experts in their condition, be able to answer all of their queries, and make decisions for them (Kannayiram, 2006; Macaden and Clarke, 2010). South Asian patients have also been found to assume more of a passive role health care instead of participating in the decision-making process (Macaden and Clarke, 2010). Therefore, it appears that many South Asian people prefer to be told what to do, and consider the Health Care Professionals as incompetent if they did not control and take charge of the medical consultation (Kannayiram, 2006). For these reasons, Health Care Professionals are required to use different techniques when conveying risk messages to patients as well as the amount of information that people with diabetes can understand and absorb during a relatively short period of consultation.

3.6. Amount of risk information required by patients during medical consultation

As mentioned earlier, Health Care Professionals may face challenges when providing risk information to people with low numeracy skills or low health literacy (Elwyn *et al.*, 2012). In such cases, Health Care Professionals are required to use their expertise to provide appropriate levels of information to enable their patients to provide informed decisions. However, previous research shows that patients frequently do not receive sufficient information from their Health Care Professionals to allow them to understand their personal health risk and to give them the opportunity to fully participate in the decision-making process (Heisler *et al.*, 2002; Kinnersley *et al.*, 2008; Edwards *et al.*, 2002):

“Patients often desire more information than currently provided” (Edwards et al. 2002; P: 827).

The amount of information that patients receive from their Health Care Provider about their medical condition has also been shown to be critical in shaping the level of concordance to medical treatment and treatment outcomes. The evidence suggests that most patients understand and remember less than half of what they are told during the consultation process (Roter, 2000). Another problem that patients may face is that many patients may not know what questions to ask or how to ask questions during consultations (Epstein *et al.*, 2004). Therefore, Health Care Professionals should anticipate important unasked questions and should discuss them with patients. Epstein et al (2004) suggest a balanced discussion of uncertainties:

“Balance is achieved by explaining the limitations of what is known while maintaining confidence that this represents the imperfections of medical science rather than lack of competence of the practitioner”. (P: 2364).

Welschen *et al.* (2012) conducted a randomized control study to investigate the effect of a six-step cardio vascular risk communication tool regarding the ten-year risk of developing cardio vascular disease among people with type 2 diabetes. The primary outcome measure was the appropriateness of risk perception (the difference between the actual cardio vascular disease risk calculated by the United Kingdom Perspective Diabetes Study risk engine and individuals’ risk perception). The study shows that absolute risk perception improved after two weeks of risk communication. However, the effect of risk communication disappeared after twelve weeks as patients were not able to recall their risk after a few months. Therefore, Welschen *et al.* (2012) suggested that patients should be reminded with the risk information at all patient interactions as single risk communications may not be sufficient and should be seen as the initial step in a range of additional interventions. Heisler *et al.* (2002) conducted a cross-sectional survey of two thousand patients to assess patients’ evaluations of their physicians’ decision-making style and to report understanding of diabetes self-care management. The study found that those who understood more had better diabetes self-care management. According to Heisler *et al.* (2002), the cross-sectional design of the study was a limitation and that more longitudinal studies are needed to establish the causal relations between decision-making and outcomes. The second issue is that all measures in the study were self-reported by people with diabetes.

In addition to the amount of information that patients require in order to make informed decisions, the format that Health Care Professionals use to present risk information can also influence patients' understanding of risk. However, Health Care Professionals may adopt a particular form of risk communication by using simple words or changing the order of the risk information that may cause framing bias (Edwards *et al.*, 2002; Paling, 2003; Quick and Bates, 2010). As such, they may consider a range of risk communication methods in order to facilitate the communication of risk information. These methods are covered in the following sections.

3.7. The use of words and numbers to communicate the risk

Health Care Providers may use different methods to present risk information to their patient, which includes the use of words or numbers (Brainerd and Reyna, 2007). However, patients and Health Care Professionals have been found to have differing views and preferences regarding the use of words and numbers during medical consultations (Kinnersley *et al.*, 2008). For example, patients were found to prefer risk expressed as numbers rather than words during genetic counselling for breast and ovarian cancer (Hallowell *et al.*, 1997). In contrast, doctors have been found to prefer words rather than numbers in their communication, on the basis that words were perceived as easier to process (Marteau *et al.*, 2000; Paling, 2003). This is despite the fact that using numbers in risk communication has been found to raise awareness of individual risk among patients; e.g. pregnant women (Marteau *et al.*, 2000). In addition, Marteau *et al.* (2001b) found that the use of an additional verbal probability words such as "low risk" improved patients' understanding from 52% to 70%, which was not found when adding an absolute or relative risk number. In addition, Paling (2003) suggests that Health Care Professionals should avoid explaining risk by using pure descriptive words such as “low risk” or “high risk”. He preferred the use of estimated numbers and the use of standardized descriptive words to minimize any miscommunication. Research has also shown that when medical materials are written in plain language this increases people’s understanding of the materials (Clement *et al.*, 2009).

When numbers are used, Paling (2003) found that using a consistent denominator minimized the chances of the misinterpretation of probability. For example, it is suggested that Health Care Professionals use “two out of ten” and “one out of ten” instead of “one in five” and “one in ten”. This is because patients were sometimes confused by which is the higher risk as they may interpret “one in one hundred” as a greater risk than “one in fifty” (Grimes and Snively, 1999). However, the main problem with numbers is that there may be a lack of mathematical knowledge, both among patients and Health Care Professionals (Gigerenzer and Edwards, 2003).

3.8. Numerical knowledge

The use of numerical information in relation to health is very common when risk information is communicated to patients (Reyna *et al.*, 2009). Two recent developments in health care have exacerbated the use of numerical information. First, medical decision-making has changed from being led by primarily Health Providers to a shared or patient centred model of decision-making (Apter *et al.*, 2008). This shift has increased the emphasis on people to understand health related information, so they can make informed choices about their care. Second, there has been an increased use of research results to inform evidence-based practice (Nelson *et al.*, 2008). Thus, people are increasingly exposed to research findings in relation to health as Health Care Professionals are expected to communicate these findings to their patients, frequently using numerical information (Brainerd and Reyna, 2007). Many statistical formats have been used to present risk communication and risk reduction (Gigerenzer and Edwards, 2003). These formats consist of frequencies (one in ten or five in a thousand) and percentages (ten per cent or twenty per cent). A study conducted by Gigerenzer and Edwards (2003) found that there is a lack of statistical understanding among both Health Care Professionals and patients. Therefore, people are required to have fundamental numerical skills to enable them to make informed decisions (Reyna *et al.*, 2009).

A study conducted by Hoffrage and Gigerenzer (1998) sought to examine whether doctors' diagnostic inferences can be improved by communicating information using natural frequencies instead of probabilities. A natural frequency is the joint frequency of two or more events such as 1) the frequency by which a disease occurs 2) the frequency by which a false positive occurs and 3) the frequency with which a false positive occurs in diagnosing a disease. In contrast to using probabilities communicated in percentages to calculate disease prevalence and true/false positives, natural frequencies take 1000 women and say 10 of these women have will breast cancer, of these 10 women 9 will test positive in mammography. Of the 990 with no breast cancer, 89 will nevertheless test positive to breast cancer in mammography screening. Hoffrage and Gigerenzer's (1998) study involved forty eight doctors with an average of 14 years' experience. The doctors were given the following information; the prevalence of cancer was 0.3, the sensitivity of the test was 50% and the false positive rate was 3.0%. The doctors were then asked to assess the probability of whether a person who tested positive for cancer did in fact have cancer. Only 10% of the doctors were able to provide accurate responses when information about cancer was communicated in probabilities. However, 46% of the same group of doctors were able to provide accurate responses when the information was communicated in natural frequencies. These results suggest that natural frequencies, can serve as an effective tool in risk communication by increasing the likelihood that people will understand the risks (Gigerenzer and Edwards 2003; Gigerenzer 2011).

Akl *et al.* (2011) conducted a systematic review to assess the use of different statistical presentations of risk and risk reduction in relation to understanding, perception, persuasiveness and behaviours amongst patients, Health Care Professionals, and policy makers. The review examined 35 studies and reported 83 comparisons. The main results were that patients and Health Care Professionals understood natural frequencies better than percentages in the context of screening tests. The interventions were perceived by patients to be more effective and more persuasive to accept the interventions when exposed to Relative Risk Reduction compared to Absolute Risk Reduction and Number Needed to Treat. Relative Risk Reduction suggested better understanding than Number Needed to Treat. However, Akl *et al.* (2011) were unsure whether presenting relative risk reduction is likely to help patients make decisions consistent with their values as the studies reviewed did not evaluate actual behaviour in relation to risk communication message regarding patient's real life. In addition to the lack of mathematical skills, studies reported massive variation in risk interpretation as well as interpretation of statistical and mathematical information (Epstein *et al.*, 2004; Gigerenzer and Edwards, 2003). The next section considers variation in risk and numbers interpretation.

3.9. Variation in interpretation

This chapter has highlighted that interactions between Health Care Providers and people with diabetes influence the process of risk communication (Epstein *et al.*, 2004). As mentioned earlier, Health Care Professionals and people with diabetes may have different preferences in terms of their preferred risk communication format. Other issues can also affect and influence the exchange of information, such as variations in the interpretation of risk information or mathematical information between Health Care Professionals and patients, who themselves are not a homogeneous group (Epstein *et al.*, 2004; Gigerenzer and Edwards, 2003). For example, Epstein *et al.* (2004) reported that Health Care Professionals did not process probability information in the same way as it was processed by patients. It was also found that both patients and Health Care Professionals interpreted numbers differently (Epstein *et al.*, 2004; Gigerenzer and Edwards, 2003). It has also been found that people with low health literacy were unable to fully engage and be involved in decision-making about their own health (Schillinger *et al.*, 2002; Paasche-Orlow *et al.*, 2005). Health literacy is defined by Roach and Marrero (2005) as: "*The degree to which individuals have the capacity to obtain, process, and understand basic health information* *needed to make appropriate health decisions.*” This sort of misunderstanding was more likely to happen when the patient and the Health Care Providers were not of the same ethnic group (Fiscella *et al.*, 2000; Balsa and McGuire, 2003).

A potential problem of communicating risk information by using probability words is the high level of variability in interpretation. For example, Health Care Professionals may use terms such as “likely” to represent sixty per cent risk while patients may interpret “likely” as eighty per cent (Lipkus, 2007). There were also other problems among patients regarding the interpretation of numbers. For example, patients believed that a death rate of 1286 in 10,000 was a greater risk than a death rate of 24.14 in 100 (Yamagishi, 1997). Furthermore, such misinterpretation was not exclusively related to the use of percentages but also to probability words and numbers. Different groups of people have been associated with different meanings when probabilities were used (Lipkus, 2007). For example, some people understood “likely” as representing a chance of “one in five” while other people interpreted ‘likely’ as representing a chance of “one in two” (Lipkus, 2007).

In addition, the magnitude of risk, which is the approximate measure of the size, severity, or quantity of the risk, may differ between patients and their Health Care Professionals. The evidence suggests that Health Care Professionals and patients approach risks from different viewpoints and even when the two groups agree on the magnitude of the risk, patients may still resist risk management due to personal values, beliefs, and experiences. This is the case even when Health Care Professionals provide more technical information about the risk (Lundgren and McMakin, 2009).

3.10. Individual’s understanding

Risk information may be interpreted differently by people with diabetes due to differences in age, gender, ethnicity and so forth (Schillinger *et al.*, 2002; Paasche-Orlow *et al.*, 2005). Studies show, for example, that patients with lower levels of health literacy were less likely to be fully involved in decision-making about their own health (Schillinger *et al.*, 2002; Paasche-Orlow *et al.*, 2005).

Furthermore, they were more likely not to adhere to prescribed treatment and more likely to have poor diabetic control compared with patients with higher levels of health literacy (Schillinger *et al.*, 2002; Paasche-Orlow *et al.*, 2005).

Even when information is given, not all patients may interpret such information in the same way because of other factors that impact on these decision-making processes, which can be linked to past experiences, perceived levels of complexity and urgency together with patients' tacit and explicit knowledge in relation to the topic (Gigerenzer and Edwards, 2003). These interpretations apply not only in terms of literacy but also in terms of numeracy, which is also related to individuals' ability to process complex information. These kinds of issues affect risk communication efforts and can be a significant challenge to Health Care Professionals. Alongside this, there are patients whose cultural traditions make it more likely that they lack experience in relation to autonomous decisions and so tend to base their decisions on the views of their Health Care Professionals (Elwyn *et al.*, 2012). Health Care Professionals, therefore, increasingly acknowledge that patients base their interpretations of the information provided on a wide range of factors and it is this variation within patient interpretation that results in Health Care Professionals not supporting the principle of having a standard risk message (Edwards *et al.*, 1998a).

For example, Edwards *et al.* (1998a) conducted a qualitative study using six semi-structured focus groups to explore current practice regarding the communication about risk. Thirty six Primary Care Professionals were recruited including general practitioners, practice nurses, district nurses, community psychiatric nurses, and health visitors. The sample structure was designed to enable a comparison to be made between professionals and to ascertain whether there were any differences in their attitudes to risk communication. Edwards *et al.* (1998a) found that although Health Care Professionals supported the idea of using standardized communication techniques, because they felt it had benefits in making professionals consistent, they did not support the idea of standardizing the language of communication because of discrepancy in the interpretation of risk data by patients.

It is also important to note that the ways in which individuals interpret the information provided is also related to the ways in which Health Care Professionals adequately explain health information and not simply the ways in which patients interpret or understand such information. A number of studies have examined the ways in which variances in the ways in which numeracy is used by physicians can impact on this process. For instance, Cokely *et al*., (2012) reported that many physicians did not understand relevant numerical information, which decreases their ability to accurately interpret and inform their patients about their risk. A systematic review conducted by Anderson and Schulkin (2014) shows that 53-75% of physicians' samples are not able to appropriately answer questions about basic probabilities, which limited their ability to convert probabilities into frequencies and percentages for their patients. In addition, a randomised control trial conducted by Garcia-Retamero and colleagues assessed numeracy and risk literacy in a diverse group of practicing surgeons, to investigate whether using transparent visual aids improved surgeons' risk comprehension and to investigate changes in surgeons' risk comprehension process. Surgeons were asked to complete a two-part computer-based questionnaire. In the first part, they provided demographic information. They also completed the Berlin Numeracy Test, a validated, psychometric research instrument designed to measure numeracy and predict risk literacy in educated samples from diverse countries. In the second part of the questionnaire, surgeons were presented with a scenario describing the results of a randomised controlled trial testing side effects of new type of anaesthesia in patients who underwent surgery. The task involved realistic risk information taken from a published study (Davis, *et al.*, 1989) that was selected to be representative of the type of information that practicing surgeons would routinely encounter and evaluate in due course of continuing medical education and professional development. The results show that 50% of the surgeons were classified in the first (lowest) level of numeracy, 20% were classified in the second level, 14% were classified in the third level, and 16% were classified in the fourth (highest) level of numeracy. Despite the fact that surgeons from developed countries had higher levels of numeracy, compared with surgeons from developing countries, the results showed that 37% of surgeons from developed countries had limited numerical skills. Surgeons with limited numeracy skills were unable to correctly interpret the risk without additional help. However, visual tools made risks more clearer and eliminated differences in understanding between surgeons who had high levels on numeracy and those with low levels of numeracy. Therefore, risk tools can be an effective tool in improving risk understanding among Health Care Professionals with mixed numeracy abilities.

3.11. Visual risk communication tools

It is important for Health Care Professionals to design and use different methods that facilitate patients' understanding of risk. Roach and Marrero (2005) suggest the use of simple pictures and broadly familiar images to help patients understand the disease process and to make it easier for them to absorb their degree of risk:

> *"For example, a plumbing pipe becoming progressively occluded with rust and mineral deposits alongside a diagram of a narrowed blood vessel provides a relevant, familiar, and easily understood analogy to describe the process that leads to heart attack and stroke" (Roach and Marrero, 2005; P: 303).*

Such images can strengthen the message about the causes of disease and incorporate graphic and symbolic modes of communication to illustrate how the patients' individual characteristics increase their cardiovascular or heart attack risk. After providing such important information to patients it is recommended that Health Care Professional check patients understanding of the provided risk information (Epstein *et al.*, 2004).

Risk information has also been presented using visual risk communication tools (Schapira *et al.*, 2006; Chiu *et al.*, 2009; Schapira *et al.*, 2001; Hawley *et al.*, 2008). These visual risk communication tools are designed to help convey complex risk information and to improve informed decision-making (Fagerlin *et al.*, 2011; Edwards *et al.*, 2006b; Chiu *et al.*, 2009). Using a written or visual format for discussing risk probabilities was found to be effective and increased the knowledge of Health Care Professionals (Garcia-Retamero *et al.*, 2016) and patients and was found to reduce their levels of fear and anxiety (Lee *et al.*, 2003). Edwards *et al.* (2002) suggests that the visual presentation of risk information is favoured by patients and that the graphical format of information boosts the efficiency of risk communication, particularly when visual aids are used for probabilities. Visual tools are especially important when communicating risk with people who have language barriers or who are not familiar with numbers (Edwards *et al.*, 2002). Paling (2003) advocates the use of visual aids not only to facilitate the presentation of risk, but also to inform a shared "doctor-patient partnership" and increase patient satisfaction. The presentation of risk using simple bar charts was found to be favoured by patients over the representation of faces or stick figures as a means of presenting risk (Paling, 2003). Comparing medical risk with everyday risk was also seen as valuable by Edwards *et al*. (2002); e.g. comparing the risk of stroke in atrial fibrillation with the risk associated with road traffic accidents. According to Waldron (2007) presenting cardiovascular risk information in percentages or frequencies using visual representation was found to be better for achieving risk reduction through behaviour change.

Schapira *et al.* (2001) conducted a qualitative study using focus groups to evaluate the response of women aged 40 to 65 years to various formats used for presenting risk information. Participants were randomly recruited from two Wisconsin communities. Segmented samples were used to achieve homogeneity in relation to age, educational level, and community of residence, but they were heterogeneous with respect to race. Each of the focus groups met for two hours and were audiotaped and videotaped. Visual aids were used to illustrate various graphic formats of risk presentation (Schapira et al, 2001, P: 462-463). This study used a graphic of a human figure to demonstrate the frequency of numeric format. Figure 3.1 illustrates how highlighted human figures were used to present a lifetime risk of breast cancer for a 50 year old woman. The lifetime risk of 9% is portrayed in a frequency format with a denominator of ten. This tool was presented to explore individual's perception of visual tools. Numeric values (such as 0.9/10 or 9%) were used to tag the human figure graphics:

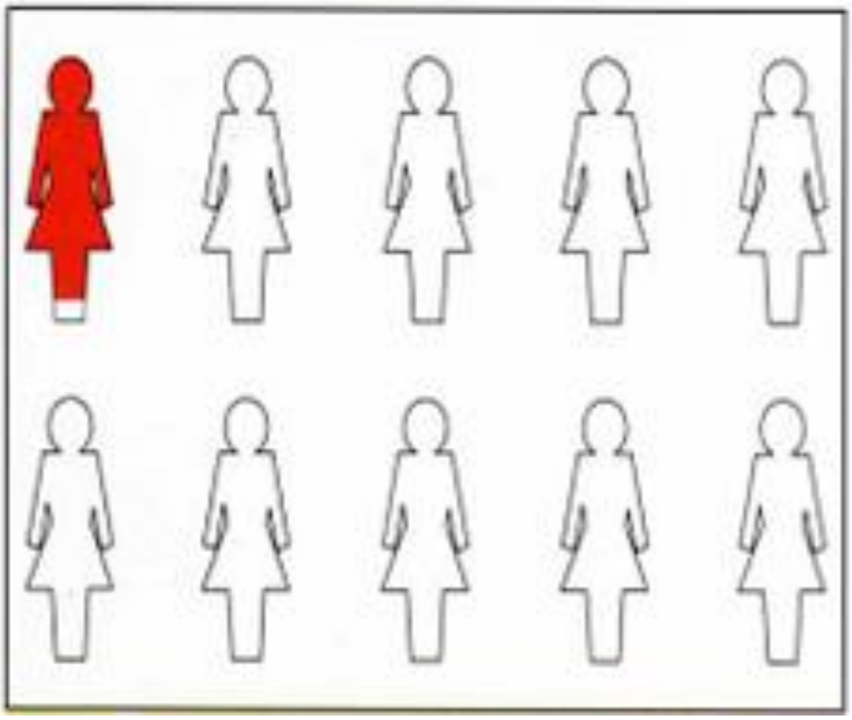


Figure 3.1 represents highlighted human figures(Schapira *et al.*, 2001)

A bar graph (Figure 3.2) was also used to demonstrate in a numeric format the probability of the lifetime risk of breast cancer for a 50 year old woman. They used numeric values such as nine per cent or nine out of ten to mark the bar graph.

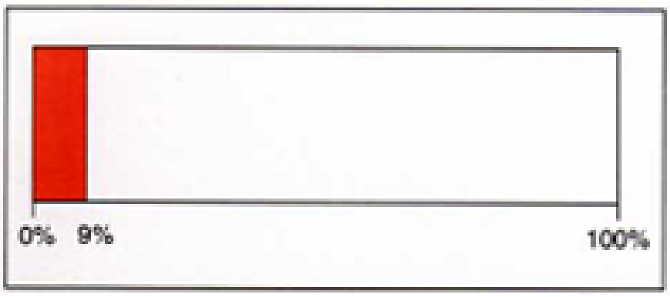


Figure 3.2 represents bar graph format (Schapira *et al.*, 2001)

Figure 3.3 represents a vertical bar graph format that was also used to communicate comparative lifetime risks for a 50 year old woman including the risk of heart disease, osteoporosis, stroke, breast cancer, and endometrial cancer:

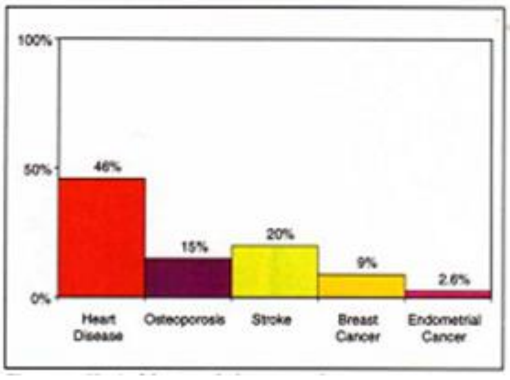


Figure 3.3 represents vertical bar graph format represents lifetime risks of heart disease, osteoporosis, stroke, breast cancer, and endometrial cancer (Schapira *et al*., 2001)

Figure 3.4 represents a highlighted human figure format that was also used to communicate lifetime risk of breast cancer for a 50 year old woman using a denominator of 1000 and consecutive highlighting of figures (Schapira *et al.*, 2001):

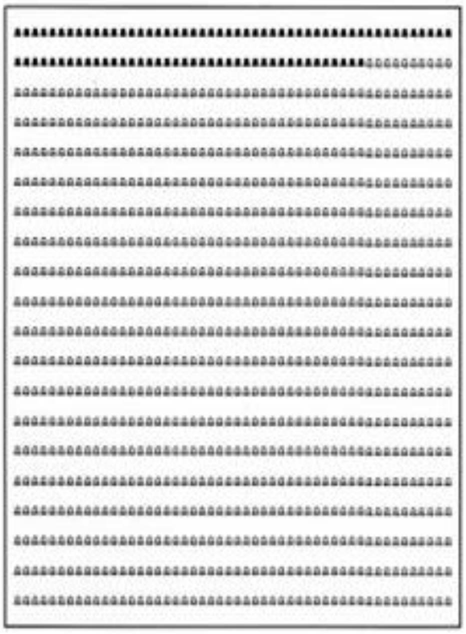


Figure 3.4 represents a thousand-consecutive highlighted human figure format (Schapira *et al*., 2001)

Figure 3.5 represents the use of human figures to communicate the lifetime risk of breast cancer for a 50 year old woman using a denominator of 1000 and randomly highlighting of figures:

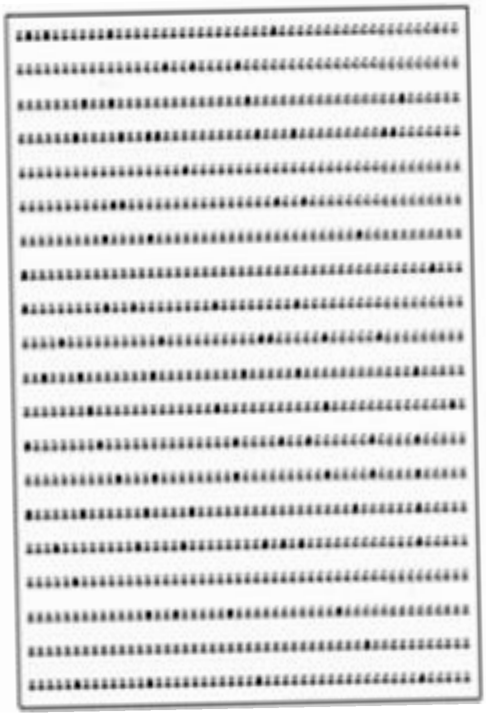


Figure 3.5 represents a thousand-randomly highlighted human figure formats (Schapira *et al*., 2001)

Schapira *et al.* (2001) performed a content analysis to develop themes from the data that informed the findings. Positive characteristics associated with the frequency format included simplicity of interpretation and the ability to provide a human contextual quality in the graphics. Positive characteristics associated with the percentage format included connection with personal risk estimation. The study found that human figures were easy to identify with, were clear, and provided a meaningful message. The human figures added meaning to the numeric information presented because of the illustration of a person, and particularly a woman, in the graphics. In contrast, bar graphs were viewed as “analytical”, not easy to understand, and as not having such impact. The magnitude of risk was viewed to be higher when communicated with human figures compared to a bar graph. Graphics with a larger denominator were perceived as demonstrating risk of a lower magnitude (Figures 3.1 and 3.4) as more figures were presented without illness (i.e. a thousand figures compared to ten figures). However, graphics with a lower denominator had positive features associated with "*simplicity, directness, and ease of interpretation*" (Schapira *et al*., 2001; P: 461).

A second study conducted by Schapira and colleagues in 2006 examined the same graphic formats (Figure 3.1-3.5) used in the first study (Schapira *et al.*, 2001) in relation to perceptions of risk magnitude and perceived accuracy using a vignette of a hypothetical case. Invitation letters were sent to 1,409 participants, with a response rate of 26% (254 participants responded). A written survey was administered face-to-face with a research assistant available to answer questions. The survey ascertained socio-demographic factors, breast cancer risk factors, numeracy, and perceptions and preferences regarding graphic formats. Participants viewed a series of hypothetical risk communications regarding the lifetime risk of breast cancer. Identical numeric risk information was presented using graphic formats (Figure 3.1-3.5). Risk was perceived to be of a lower magnitude when communicated with a bar graph as compared with a pictorial display ($p < 0.0001$). It was also found to be lower with consecutively highlighted human figures versus randomly highlighted human figures in a pictorial display (p ¼ 0.0001). Data were perceived to be more precise when presented as random versus consecutive highlights in a pictorial display ($p < 0.01$). A pictorial display was preferred to a bar graph format for the presentation of breast cancer risk estimates alone (p ¼ 0.001). However, when considering breast cancer risk in comparison to heart disease, stroke, and osteoporosis, bar graphs were preferred to pictorial displays ($p < 0.001$).

Other forms of visual risk communication tools used to personalise risk have also been found (Chiu *et al.*, 2009; Cates, 2009). For example, Chiu *et al.* (2009) used participatory action research to investigate how the risks and benefits of breast and cervical cancer screening programmes are understood by Health Care Professionals along with black and minority ethnic groups and low income groups. Two hundred and twenty-eight participants evaluated a risk communication tool (Figure 3.6) that was designed to present risk information for breast and cervical cancer screening programme that personalizes the risk. The efficiency of the risk communication tool was tested against the NHS cancer screening programme leaflet “*Breast Screening: The Facts*”. Chiu *et al.* (2009) reported that the risk tool was found to be more effective than the leaflet for passing on knowledge about the main risk factors for breast and cervical cancer and cancer screening risks. The risk tool was particularly helpful for those participants whose English was not good and who did not gain knowledge from the leaflet.

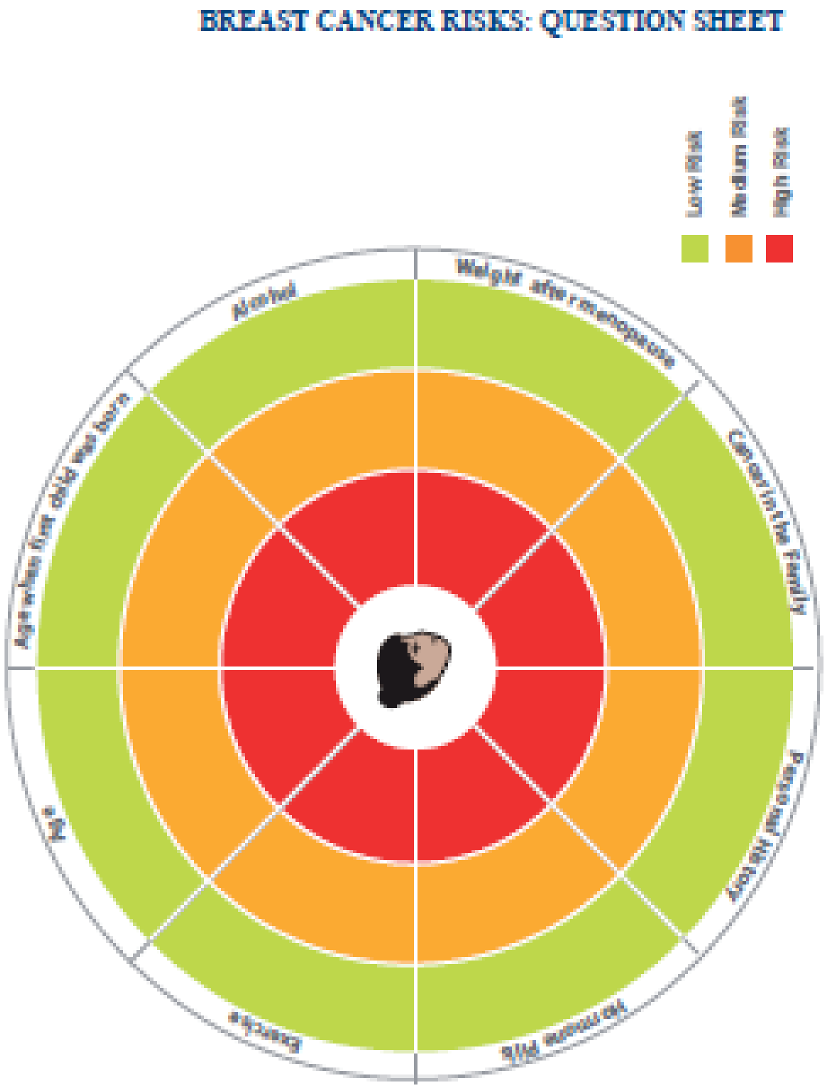


Figure 3.6 represents a breast cancer self-assessment risk tool (Chiu *et. al*, 2009)

Another visual tool used to communicate risk information has been developed in relation to Statin tablets (Cates, 2009) (see Figure 3.7) This tool uses emoji’s to demonstrate levels of cardiovascular risk. Thus, 20 patients (red and yellow faces) out of 100 patients (green faces) are predicted to have cardiovascular event in the next 10 years. However, if each of the same 100 patients takes a statin tablet for the next 10 years, five patients would not have suffered a vascular event due to taking a statin tablet (the yellow faces). Eighty patients (green faces) would not have had a cardiovascular event, but this group would not have had a cardiovascular event even if they had not taken statin tablet. Fifteen patients will still have cardiovascular event (red faces) even though they had taken statin tablet:

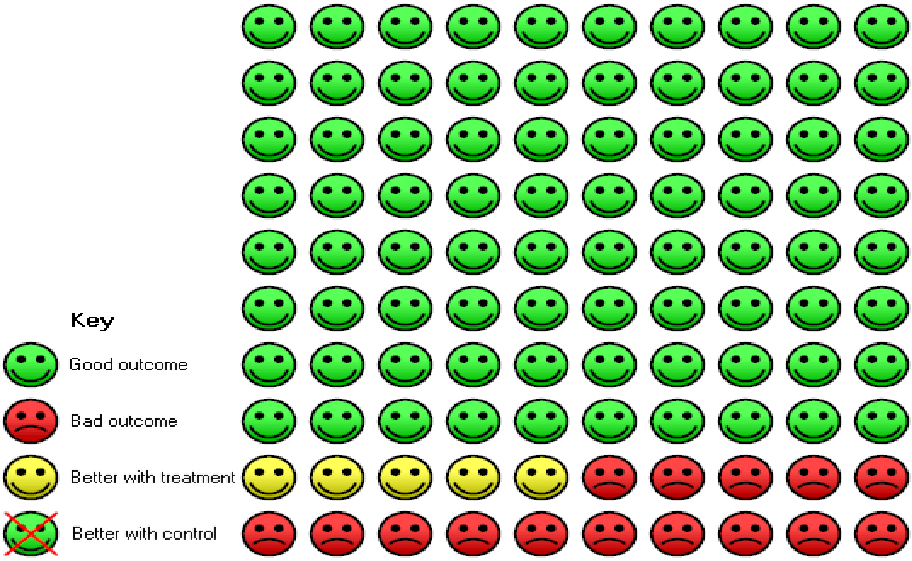


Figure 3.7 represents the advantages of taking statin tablet for 10 years, five patients would be saved and would not have cardiovascular event (yellow faces) (Cates, 2009)

Hawley *et al.* (2008) conducted a randomized control study to evaluate the ability of graph formats to impart knowledge about treatment risks/benefits to people with low and high numeracy. Participants were randomized to receive numerical information about risks and benefits of a hypothetical medical treatment using one of the six visual formats. All visual formats were perceived positively and associated with higher knowledge. The visual formats were more effective with those individuals with low numeracy skills.

3.12. Effective visual display

Weinstein and Sandman (1993) have proposed a seven point criteria for use in evaluating communications designed to explain the magnitude of a risk. These points are:

1. Comprehension: do patients understand the message of the communication content?
2. Agreement: do patients agree with the interpretations and recommended action?
3. Dose-response consistency: do people who are exposed to a higher level of hazard show a higher level of readiness than people who are exposed to a lower level of hazard?
4. Hazard-response consistency: do people perceive a high level of hazard as high risk and take extra caution and perceive a low level of hazard as low risk and take less precaution?
5. Uniformity: do patients have the same reaction when exposed to the same risk?
6. Audience evaluation: do patients evaluate the tool as clear, helpful, and effective?
7. Communication failures: when patients interpret the tool in different way than it is intended, is it because these failures are generally of the more acceptable?

These points can be used as a potential guidance to researchers or clinical teams in designing a risk communication tool and then may be used as evaluation criteria to test the validity and efficiency of the tool in a research study or clinical evaluation.

3.13. Individualized risk information

The availability of interactive technology presents an opportunity to generate individualized risk communications for patients with diabetes, either by video, graphics, animation, or text. The presentation of risk information in these formats has been shown to increase involvement in the process of understanding when compared with traditional methods (Aspelund *et al.*, 2011). It also appears that relevant personal risk data is more valuable to patients than providing average population data (Edwards, 2000). Risk can be calculated for individuals using data on risk factors such as smoking, age, cholesterol level and blood pressure (Wood et al 1999). Many 'risk calculators' have been used and have been shown to be effective (Hippisley-Cox *et al.*, 2010; Kshirsagar *et al.*, 2010; Hippisley-Cox *et al.*, 2009). A risk calculator is an algorithm that has been developed by Health Care Professionals and academics and is based on regularly collected data from several thousands of GPs (Collins and Altman, 2010). Risk calculators can be used to work out the risk of having a specific condition, such as cardiovascular event or stroke over a given period of time such as five or ten years. Most risk calculators have been developed to detect and facilitate the risk of cardiovascular disease and diabetes. A study conducted by Imms *et al.* (2010) showed that most general practitioners had used a risk calculator and had used it appropriately as a decision-making tool to guide their management of cardiovascular disease. Ninety three per cent of the general practitioners in Imms study had used a risk calculator to motivate lifestyle change and for educational purposes. Sixty six per cent of GPs had used them to assist the patient managing their medical condition (Imms *et al.*, 2010). In contrast, another study conducted by Holmberg *et al.* (2011), to assess the use of a web-based tool to calculate the five-year risk of developing type 2 diabetes, reported that forty per cent of people did not know important values that were required to assess their risk such as waist circumference.

Only one risk calculator has been developed to present risk information about diabetic retinopathy (Aspelund *et al.*, 2011). The risk factors for the development and progression in diabetic retinopathy are well documented in the literature (as mentioned in Chapter 2). These risk factors include age, duration of diabetes, type of diabetes, mean blood glucose or HbA1c and blood pressure. Based on these risk factors, Aspelund *et al.* (2011) developed an individual risk calculator to provide risk information about diabetic retinopathy. This provided information regarding different time periods; twelve months, five years, or ten years. The aim of the study was to optimize diabetic screening, while maintaining patient safety, by using information technology and an individualized risk assessment to establish screening frequency. This risk calculator used a quantitative calculation based on six variables; individual's age, type of diabetes, duration of diabetes, medication, blood pressure, HbA1c, and previous diabetic retinopathy screening result. The choice of variables was generated by epidemiological data for the prevalence of diabetic retinopathy from the Icelandic eye screening database (Kristinsson *et al.*, 1994), and from studies on risk factors (Kohner *et al.*, 2001).This makes communicating risk information quick and it is easy for patients to understand their risk, which may also make screening programmes more efficient.

The following Table (Table 3.1) shows the differences in diabetic eye screening intervals based on risk margin rather than having a standard interval for all people with diabetes. For example, Mr. X is 40 years old and has had type 2 diabetes mellitus for the last 5 years. He has no previous retinopathy (R0), his blood pressure is well controlled (120/80 mmHg) and his HbA1c is 7%. He is therefore at low risk of developing diabetic retinopathy in the next five years. The risk would be medium if blood pressure rose to 150/100 mmHg, with HbA1c 7%. Mr. X would be high risk of developing diabetic retinopathy within the next five years if his with blood pressure was 150/100 mmHg, and his HbA1c 10%.

Aspelund (2011) did not include smoking as a risk factor because of the effect of smoking in terms of lung cancer and cardiovascular diseases, which was felt to be more important than the retinopathy risk reduction in terms of morbidity. In addition, and due to the nature of the Danish population, ethnicity was not included. This may raise questions about the efficacy and accuracy of the individualised risk calculator in cities with a diverse population as the prevalence rate of diabetes and diabetic retinopathy is higher than in White Europeans (Raymond *et al.*, 2009). McGee *et al*. (2012) argue that the generalisability of this risk calculator remains unclear. Furthermore, countries such as Iceland, where the risk calculator was developed, have a relatively small population, just over 330,000 people (Worldometer, 2017) and a high level of adherence (77%) with diabetic eye screening (Zoega et. al, 2005) compared to the England where the rate of non-adherence can vary between practices from 5% to 45% (Scanlon, 2008).

Table 3.1 Diabetic retinopathy risk calculation based on patient individualised risk factors

Name	Age	Type of diabetes	Duration of diabetes	HbA1c	Systolic blood pressure	Diastolic blood pressure	Previous diabetic retinopathy	Calculated risk of developing STDR every year	Calculated risk of developing STDR in 5 years	Level of Risk
Mr. X	40	T2DM	5 years	7%	120	80	No	0.4%	2.2 %	Low
				7%	150	100	No	1.5%	7.7%	Medium
				10%	150	100	No	4.6%	22.2%	High

T2DM: type 2 diabetes mellitus, STDR: sight-threatening diabetic retinopathy, DR: diabetic retinopathy

3.14. Understanding and Agreement

Regardless of the format used to provide risk information to people with diabetes, Health Care Providers need also to ensure that patients understand the provided information (Epstein *et al.*, 2004). Checking patients understanding is relatively straightforward and can be used to check whether Health Care Professionals continue with their strategy and recommendations. For example, it is useful to request that patients summarize what they understand, and the reason for that understanding, which may be reflected in the level of adherence to Health Care Professionals' advice. Misunderstanding or lack of understanding may also underlie patient's mistaken belief that their diabetes is controlled, and they are doing well and therefore no longer need eye screening. Levels of understanding are influenced by many factors including whether the Health Care Professional has checked people's understanding during consultation (Campion *et al.*, 2002; Baker *et al.*, 2007), the amount of information communicated to people with diabetes (Edwards *et al.*, 2002; Roter, 2000; Roach and Marrero, 2005), and risk communication formats. Therefore, checking patients understanding is an important task during medical consultations and a relatively easy way to ensure that people with diabetes have understood the information provided (Baker *et al.*, 2007). According to Baker *et al.* (2007), this is a routine aspect of medical consultations. Similar findings are also reported by Campion *et al.* (2002) who found that Health Care Professionals do not frequently assess patients' understanding after medical consultation. Campion *et al* (2002) carried out an analysis of 2094 videos of trainee GPs. This found that only 0.3% of these GPs checked patients' understanding across five consultations and 45% did not check their understanding in any consultation.

3.15. Framing bias

The previous sections have highlighted that many different factors can influence risk communication such as personal factors, doctor-patient interaction, and the way that risk information is delivered and interpreted. Edwards *et al.* (2002) highlights a "framing effect" problem where the manipulation of various framing factors could affect patients' decision. Framing means the way that risk messages are constructed and communicated to individuals. Framing manipulation is an example of bias in which people react to risk information in a particular way depending on how it is presented. For example, the use of "loss" framing influences screening uptake more than "gain" framing:

"The potential losses from not having a mammogram" (Edwards, 2002; P: 324).

Similar findings were also reported by Yu *et al.* (2010) who investigated the combined effects of messages framed in terms of loss and gain on foetal alcohol spectrum disorder. Yu *et al.* (2010) found that the "gain" frame demonstrates an advantage in encouraging perceived efficacy toward foetal alcohol spectrum disorder whereas the "loss" frame shows an advantage in increasing prevention intention, perceived severity and perceived fear towards foetal alcohol spectrum disorder. Another quantitative study supports the use of "loss" frame messages that were found to be more effective for heavy drinkers and underage drinkers, whereas those people who perceived health risk to be low would benefit from "gain" frame messages (Quick and Bates, 2010). Another form of framing bias is when Health Care Professionals provide positive and negative outcomes, with the provision of positive outcomes being more acceptable psychologically (Paling, 2003). For example, individuals may feel better when Health Care

Professionals provide information such as the chances of preserving vision are 98 out 100, which is perceived to be better than the chances to losing vision are 2 in 100.

Although framing bias may be justifiable in screening programmes in terms of improving public health, Edwards *et al*. (2002) argues that presenting information with an incomplete picture is not consistent with informed decision-making. The following section considers other types of framing effects when communicating risk messages by using other forms of risk messages, such as fear and threatening messages.

Different forms of framing effects may influence people's understanding of risk and risk information, such as the effect of ways in which risk information has been portrayed by the media (Sandell *et al.*, 2013). For example, in general, immunization rates are similar in Australia and Sweden. However, during the H1N1 pandemic in 2009, the immunization uptake was 60% in Sweden and 18% in Australia, despite the fact the risk information regarding the H1N1 pandemic was communicated in the same way in Australia and Sweden. Sandell and colleagues found that the perception of risk was largely influenced by media, which was reflected in people's response. Thus, major differences in how the media in both countries framed the pandemic risk information was defined in terms of "responsibility, self-efficacy, and uncertainty". For example, the Australian media reported responsibility mainly in a negative way, holding a range of organizations responsible for a lack of information, whereas Swedish media was more transparent in relation to the uncertainties of the pandemic and placed responsibility on the community to help protect public health (Sandell *et al.*, 2013).

3.16. The use of fear messages

The evidence also demonstrates that concentrating on patient's fears and increasing their anxieties have been used as a strategy to attempt to reduce certain behaviours (Albarracin *et al.*, 2005; Cohen *et al.*, 2007). In such cases, patients must feel adequate worry about the risk to take action, whereas risks that are common and perceived to be low are less likely to prompt that concern (Lundgren and McMakin, 2009). However, according to Brown and Smith (2007), the frequent use of fear and messages designed to increase anxieties can lead to defensive reactions from people that are activated by distress associated with perceptions of personal vulnerability (Brown and Locker, 2009; Brown and Smith, 2007). Although such messages resulted in defensive reaction among smokers (Brown and Smith, 2007) and people with alcohol dependency (Brown and Locker, 2009), the use of these messages were reported to be well accepted by individuals and Health Care Professionals (Albarracin *et al.*, 2005; Cohen *et al.*, 2007). Stephenson and Witte (1998) conducted a study to test the effectiveness of fear messages in promoting skin cancer. College students received either a plain text message or a text message with a graphic photograph. Participants who received the text with a graphic photograph reported that they were more likely to take preventative measure than those who received the plain message. The results also showed that fear messages appear to be effective in prompting people’s behaviours. The higher level of threat was more effective as people were more concerned when exposed to stronger messages. Therefore, individuals appear to demand more information about their condition when the risk information is more threatening (French *et al.*, 2006).

3.17. Constraints to effective risk communication

Many factors have been found to limit the effectiveness of communicating risk information. Therefore, it is vital that Health Care Professionals identify such factors in order that they can provide effective risk communication. Lundgren and McMakin (2009) have done significant and well-respected work on the subject of risk perception within their field. The following sections highlight some of their work. Lundgren and McMakin (2009) have divided the potential constraints to effective communications into three main domains; organizational constraints, emotional constraints, and population constraints. The following sections provide an overview of these domains.

3.17.1 Organizational constraints

Despite the fact that it is in the best interest of the organization, such as the NHS, that the risk message should be presented and communicated effectively, the organization itself may present certain barriers (Lundgren and McMakin, 2009). These include:

- Insufficient resources, such as lack of time, funding, and staff to communicate the risk information to people effectively.
- “Management Apathy” or lack of interest. Even when resources are available, Health Care Professionals may fail to do their job and fail to provide effective risk information due to lack of support from managers and stake holders.
- Possible role division, as there may be other demands not simply risk communication, particularly when the organization perception of this role is to adhere to the policies, guidelines, and community expectations. To manage role division, Lundgren and McMakin suggest that the Health Care Professionals identify the organizational role before the process of risk communication starts.
- Difficult review and agreement procedures, in particular, when the risk communication process is inappropriate or requires a lengthy time to review the process of risk communication and approve it.
- Inadequate information to effectively plan and set schedules. In order to establish a strategy for risk communication, a considerable amount of information is needed to plan and create this strategy.

In order to communicate risk information appropriately, Health Care Professionals should identify the organizational constraints before the process of risk communication starts. Insufficient resources, lack of management support, inappropriate consultation time, conflicting organizational policies and regulations, and inadequate information could lead to incorrect risk communication.

3.17.2 Emotional constraints

The second type of constraint regarding effective communication is emotional constraints. There are three types of emotional constraints highlighted by

Lundgren and McMakin (2009). The first constraint is the reluctance in most cases to see the community as an equal partner in risk decision-making; i.e. decisions about risk should be based on scientific evidence and by Health Care Providers who understand the situation, rather than involving the emotions and beliefs of the lay population. The second constraint is differences in values; e.g. different cultures have different values and may therefore view risk in different ways. This can lead the risk communicator to focus their attention on matters they feel important without giving attention to the issues that are of importance to patients. Health Care Providers must understand their patients thoroughly in order to avoid biases in how they frame risk communication messages, as well as for the message to be an effective message. Finally, the last emotional constraint is the belief that patients cannot understand science. The evidence suggests that many Health Care Professionals believe that patients cannot understand or absorb scientific terms and information (Lundgren and McMakin, 2009).

3.17.3 From patients

Patients can also bring a whole range of interpretive factors when risk is communicated to them. These include hostility, anger, panic, denial, lack of concern, mistrust of risk assessment, variation regarding the magnitude of risk, lack of confidence in science and institutions, and learning difficulties (Lundgren and McMakin, 2009). More details are provided below about these issues.

3.17.4 Hostility and Anger

Many patients may interpret risk information with a degree of anger, anxiety, and uncertainty about the future. This can particularly be the case when patients receive bad news or are involved in ‘crisis’ communications (Eborall *et al.*, 2007; Hafslund *et al.*, 2011). In such circumstances, Lundgren and McMakin (2009) stress that Health Care Professionals must be aware of these issues as the higher the level of anger, the less chance that patients will give attention to the risk message and the less chance of effective risk communication. One reason that patients may feel angry is when they feel that the risk communicator has no credibility; hence, anything the risk communicator says will be viewed with great doubt. Also, patients may feel angry if they perceive their concerns regarding a risk have been ignored. Misunderstanding of the risk or misunderstanding the process of risk communication may also cause anger among patients, especially when technical terms, medical words, or acronyms are used (Lundgren and McMakin, 2009).

3.17.5 Panic and Denial

Panic happens because patients perceive themselves or those they care for to be in imminent, often life-threatening danger that they cannot control (Lundgren and McMakin, 2009). Panic is defined as an unexpected overwhelming dread, with or without reason, that generates hysterical or unreasonable behaviour, and that often extends quickly throughout a group of people (Dictionary.com, 2012). Panic tends to distort cognitive processing, potentially blocking risk messages from being heard, which can make problems worse (Lundgren and McMakin, 2009). Denial occurs when the perceived consequence of a risk is so shocking that other coping mechanisms break down. Humans tend towards denial when they cannot admit the fact that something terrible has happened or about to happen (Branstrom *et al.*, 2006). Panic and denial are difficult to deal with by most of Health Care Professionals and need skilful and expert risk communicators to manage such occasions. Lundgren and McMakin, (2009) argue that Health Care Professionals who communicate risk information must realize that panic and denial are important part of people’s response to risk information, and therefore, a thorough understanding of people’s needs may help prevent the introduction of unwanted risk message responses.

3.18. Ethical issues in risk communication

Communicating any form of risk information can result in certain ethical dilemmas (Johnson, 1999). One of the main reasons for this is that each individual has his/her own ethical values that have been shaped by their personal experience and beliefs (Lundgren and McMakin, 2009). This individual ethical code formulates ethical issues in subjective ways; i.e. what is true for one may not be for another and/or what is acceptable for one person may not acceptable for others. In this section, some of the ethical issues faced by those who are communicating risk information are discussed. There are many important questions in relation to risk communication such as how much information should be released, to whom it should be communicated, who should provide or communicate this information, and when is the best time to do it? Lundgren and McMakin, (2009) highlight additional potential ethical issues, such as whether the use of persuasion is acceptable and the relationship between public dangers compared with private interests. Lundgren and McMakin, (2009) divided the ethical issues in relation to risk communication into three main areas: social, organizational, and personal. Social ethics include the code of conduct by which society judge certain behaviour and can vary between countries and between cultures within same country:

> *"Each country and population group may have its own characteristics that affect how people perceive and communicate risks. These characteristics may include religious beliefs, health and environmental regulations, and community traditions, all of which can affect how people perceive and respond to risk information." (Lundgren and McMakin, 2009; P: 330).*

A study in Hong Kong showed that people in Western countries are more likely to evaluate unfamiliar or less controllable threats as more frightening than others. While Hong Kong Chinese generally evaluate lesser known threats as less worrying and something that can be considered with 'sensible coolness' (Lai and Tao 2003). Another social ethical issue that has been highlighted by Lundgren and McMakin (2009) is whether the risk is being explained in the same way to all individuals regardless of their ethnic origin. In addition, it was also important as to whether the message was clear enough and understandable to formulate an informed decision:

> *"In any given situation, any message can be misunderstood. No matter how much we analyse our audience, there will always be someone within it who misinterprets the risk message" (Lundgren and McMakin, 2009; P: 63).*

The second ethical issue relates to organizational issues. Lundgren and McMakin (2009) refer to organizational ethical issues in terms of how an organisation’s code of ethics deals with concerns such as the release of information. Health Care Professionals may be more or less restricted in line with their organization’s policies and regulations in terms of what kind of risk information can be released and to whom should it be communicated.

The third ethical issue is personal ethics. Although Lundgren and McMakin insisted that the risk communicator should consider one’s own personal ethics and be aware one’s own beliefs and role as a risk communicator, this may create a dilemma due to the massive variation in risk interpretation. In other words, risk information may not be processed by all people in the same way as it was processed by Health Care Professionals or risk communicators (Epstein *et al.*, 2004; Gigerenzer and Edwards, 2003). This highlights the use of persuasion, which is one way to communicate and present the risk information with the plan of forcing a view on the patient. A convincing method may be used to warn the patients and motivate them to action for fear of loss life or loss of vision. This is viewed to be justified when time is limited, and risk is high. Therefore, risk communicators argue that every effort should be made to influence people’s action and get them to do what is good for them (Cohen et. al, 2007). However, Edwards *et al*. (2002) argues that providing information with an inaccurate picture is not consistent with informed decision-making. Lundgren and McMakin (2009) highlight situations in which persuasion has been justified. For example, when a patient is in immediate danger of death or when the individual at risk are not the same as individual engaged in the behaviour, such as the unborn babies of alcoholic mothers. Another example when persuasion is justified is when an individual has specifically asked to be persuaded such as when a speaker is involved in lively debate.

3.19. Conclusion

Understanding people’s behaviours is vital to the management of their diabetes and diabetes complications. Therefore, it becomes crucial to understand the various perceptions of risk related to type 2 diabetes and understand perceived susceptibility (or risk) as it is influential in encouraging changes in behaviour. Risk is a social construct that is contextualised within the realities of people's lives and experiences and generated through interaction. Previous research shows that making an informed decision depends on a persons' level of understanding and interpretation of the evidence of the relevant risks that are given to them and the form in which the risk information is presented. Whilst, the interactive decision-making approach between patients and their Health Care Providers help patients to make complex decisions about their health care, poor interactions have shown to have negative impact on people's adherence to medical treatment. Previous studies show that patients prefer risk expressed as numbers rather than words. In contrast, doctors prefer to use words rather than numbers in their communication, as words are easier to process. Although Health Care Professionals are increasingly using numerical information there appears to be a lack of numerical understanding among patients and Health Care Professionals. Additionally, there are also variations in interpreting the risk information and mathematical information between patients and their Health Care Professionals. There are also other issues that limit the effectiveness of risk communication, such as perception of risk, variation in interpretations of medical information, and personal factors such as gender and ethnicity. Furthermore, previous studies have highlighted many aspects that influenced risk communication, such as framing effect, the way that risk messages are constructed and communicated to individuals, and how the manipulation of various framing could affect patients' decision. Framing risk messages were found to be effective in terms of increasing prevention intention and perceived fear. Concentrating on individual's fears as a means of reducing certain health-reducing behaviours has also been found to be accepted by individuals and Health Care Professionals.

This literature review suggests that research about diabetic retinopathy risk has tended to focus on potential causal risk factors rather than understanding individuals' perceptions and experiences of risk. Visual risk communication tools used in other clinical settings were found to be effective and improved patient's knowledge. None were found that specifically communicate the risk of diabetic retinopathy, and previous studies did not explain how visual aids help patients to understand the risk. Evidence suggests that risk has socially constructed elements that people with diabetes and Health Care Professionals have varied understandings of diabetes and diabetic retinopathy and the risks related to those illnesses, and that an explanatory model of risk perception of diabetic retinopathy among people with diabetes was not available. Consequently, an exploration of how people with type 2 diabetes perceive and understand diabetic retinopathy risk is warranted. This study sought to develop a risk communication tool to facilitate the presentation of risk messages about diabetic retinopathy, and how the risk messages about diabetic retinopathy and diabetic retinopathy screening results should be communicated.

Chapter 4. Methodology

4.1. Introduction

The purpose of this chapter is to provide the theoretical underpinnings of the research. The chapter discusses the philosophical position of the research and explains its theoretical and methodological perspectives. The chapter sets out the rationale for adopting a social constructivism approach that draws upon the theoretical fundamentals of interpretivism, as a methodological and philosophical framework, along with key aspects of social constructionist grounded theory in relation to data analysis (Charmaz, 2006). This choice of this approach was based on key issues that included the methodological limitations of existing work regarding communicating risk information about diabetic retinopathy to people with type 2 diabetes. This decision was also based upon the wish to access individual's meanings and perceptions regarding diabetic retinopathy risk, and their experiences and views about retinal screening so as to achieve a richer and deeper understanding about diabetes complications and how the risks and benefits of diabetic retinopathy screening are understood by people with diabetes and by Health Care Professionals. The chapter starts by restating the aims of the research and how these aims influenced the research methods.

4.2. Aims of the research:

The research question to be explored in this thesis is: "How to communicate risk information about diabetic retinopathy to people with type 2 diabetes?" The aims of the research are to explore how the risks and benefits of diabetic retinopathy screening are understood by people with diabetes and Health Care Professionals, and then to establish the most appropriate methods by which risk information about diabetic retinopathy can be effectively communicated to people with type 2 diabetes.

4.3. Research objectives:

1. To explore how the risks and benefits of diabetic retinopathy screening are understood by people with type 2 diabetes and Health Care Professionals
2. To explore how people with type 2 diabetes perceive risk information about diabetic retinopathy by using numerical and textual format
3. To explore the influence of risk information on risk perception
4. To appraise existing risk communication tools from other clinical settings by participants
5. To develop a new diabetic retinopathy risk communication tool that can be used to communicate risk information about diabetic retinopathy to people with type 2 diabetes
6. To appraise the views of people with diabetes regarding a newly developed diabetic retinopathy risk communication tool
7. To explore the influence of the new developed risk communication tool on i) risk perception, ii) diabetes self-care management
8. To establish a method(s) by which risk information about diabetic retinopathy can be effectively communicated to people with type 2 diabetes to enable informed choice
9. To establish a method by which diabetic retinopathy screening result can be effectively communicated to people with type 2 diabetes

4.4. Quantitative and qualitative research

The aim of any research is to create new knowledge through systematic enquiry governed by scientific principles that vary from one discipline to another (Silverman, 2001). Within this context, it is essential to distinguish between the terms ‘methodology’ and ‘methods’ (Parahoo, 1997). Research methodology is the process of understanding the alternative ways of answering the proposed research question/s. Once the relative strengths and weaknesses of the different methods are appraised, it results in a defensible decision regarding the proposed research design. Research methods are techniques used to gather information relevant to the research questions (Polit, 2001; Parahoo, 1997), resulting in a plan that describes how, when and where data are to be collected and analysed (Parahoo, 1997). Our understandings of what represents knowledge (epistemology), and the nature of being and the way is the world viewed (ontology) influence the theoretical position, methods, and methodology applied to a study (Schwandt, 2001). Research methodology can be located within two main dominant paradigms: qualitative and quantitative methods. Qualitative research is defined by Holloway and Wheeler (2013, P: 3) as:

> *"A form of social inquiry that focuses on the way people make sense of their experiences and the world in which they live. A number of different approaches exist within the wider framework of this type of research, and many of these share the same aim - to understand, describe and interpret social phenomena as perceived by individuals, groups and cultures. Researchers use qualitative approaches to explore the behaviour, feelings, and experiences of people and what lies at the core of their lives."*

Thus, qualitative research is associated with naturalistic inquiry and emphasizes understanding the human experience as it is lived by collecting and analysing narrative and subjective data (Polit *et al*, 2001; Porter and Carter, 2000; Creswell, 2003). In contrast, quantitative research tends to understand the social world and knowledge as objective that can be accessed and measured (Denzin, 2000). The particular approach adopted by the researcher depends largely on the nature of the issue investigated and the type of data to be generated. In addition, the researcher's personal philosophy also plays a role in choosing the research paradigm, as it is this that informs the research problem (McNeill and Chapman, 2005; Polit *et al*, 2001; Porter and Carter, 2000; Cormack, 2000). It is also the case that research studies are increasingly combining both quantitative and qualitative approaches on the basis that this may yield a more complete analysis, as each research method can access different features of the social world and are seen to complement each other (Creswell *et al.*, 2004). In selecting a particular research methodology, it is also worth bearing in mind that the chosen approach will inevitably have some limitations. It is also the case that members of different disciplines or even within the same discipline may approach their research in distinctive ways. As a result, they may focus on research questions or research aims and go about answering those questions or aims in different ways (Porter, 2000). Therefore, careful consideration of research methodology informed the selection of the most appropriate methods for this particular study (Porter, 2000).

4.5. Quantitative research

Quantitative research is associated with a positivist tradition, which is generally portrayed as an objective and systematic process used to collect numeric information that is analysed using statistical procedures (Porter and Carter, 2000; Carter, 2000a; Polit *et al*, 2001). Quantitative research can be divided into experimental and non-experimental designs. Experimental designs tend to examine and establish causal links between variables (Parahoo, 1997). Polit *et al* (2001) explain that experiments are the most powerful designs for testing hypothesis of cause and effect relationships by using manipulation to control and consciously vary the independent variable and then observe its effect on the dependent variable. However, experimental designs have some limitations that make them difficult to apply. For example, some variables, such as culture, are not amenable to manipulation (Polgar and Thomas, 2001; Polit *et al*, 2001). On the other hand, non-experimental designs do not attempt to manipulate the independent variable and are mainly descriptive in their nature (Polit *et al*, 2001). They can be divided into two kinds of research. The first is correlation (ex post facto) research in which the relationships among variables can be studied. This type of research is often an efficient and effective means of collecting a large amount of data. The second broad class of non-experimental research is descriptive research (Carter, 2000a). The aim of descriptive research is to discover new facts about people, activities, situations, and events or the frequency with which certain events occur (Carter, 2000b). This new knowledge can be achieved through systematic collection of information about the phenomenon of interest. The data obtained can be used to assess and justify current situations and to make plans for improvement (Carter, 2000b).

However, the major disadvantage of non-experimental research is its inability to conclusively reveal causal relationships. The research question of this particular study does not fit into the positivism paradigm of research that focuses on theory testing, establishing cause-effect relationship, predicting, controlling variables, and generalization (Polit, 2003).

4.6. Qualitative research

The central premise of qualitative research is that people actively construct their social worlds through on-going social interaction with other people (Blumer, 1969). Social constructivism refers to the concept that individuals form or construct knowledge as they interact with others to share, relate, and dispute their interpretations of their social worlds (Applefied *et al.*, 2011). The ontological viewpoint of social constructionism is therefore relativist and the epistemological viewpoint is subjectivist; i.e. this research methodology denies the existence of an objective reality and instead asserts that realities are social constructions and, as such, it recognises that a multiplicity of perspectives and 'truths' exist (Charmaz 2006). Thus, individuals build their knowledge as they participate in a range of social activities (Woolfolk, 2011) with people developing their own understandings through collaboration and interactions with those around them (Applefield, *et al*., 2011). Personal knowledge and development or construction of understanding is therefore based upon personal actions and interactions within daily life (Carmichael, 1990).

The ways in which knowledge is created and understood within a social constructionist framework is at odds with a more 'scientific' or medical model of understanding. Within the medical model, for example, diseases are universal and invariant to time or place, whereas a more social model of health, the meaning and experience of illness is key and is formed by cultural and social factors (Conrad and Barker, 2010). Put another way, illness does not simply exist in nature, waiting to be discovered by Health Care Professionals. Rather knowledge and understanding about illness is key and is constructed when individuals interact and interpret their signs and symptoms (Driver *et al.*, 1994). Woolfolk (2011) states that the construction of knowledge by individuals is based on two main concepts. First, individuals are active in constructing their own knowledge through personal experiences. Second, social interactions are essential for understanding the construction of knowledge.

Therefore, one of the main purposes of qualitative research is for the researcher to provide detailed descriptions of the social settings and social interactions that they investigate (Bryman, 1988). In other words, the qualitative researcher’s concern is to reflect the reality of certain aspects of people’s everyday lives (Bryman, 1988). This emphasis on description entails attending to details and encourages the researcher to explore issues in depth (Lacy *et al.*, 2004). Therefore, qualitative research is acknowledged as a method to collect important insights into the meanings and motivations ascribed by individuals to social phenomena and for developing knowledge about such phenomena that cannot be accessed by quantitative research (Denzin, 2000). Qualitative approaches are more concerned with ‘how’ and ‘why’ things happen. Before considering the most appropriate research paradigm to choose, the researcher should consider the aim of the study and the type of knowledge needed to answer the research question.

At the beginning of the current research the qualitative research paradigm was considered most relevant given the research questions and taking into account the existing knowledge and research gaps that have been identified in the literature review. Defining risk as socially constructed means that understanding risk and perceptions of risk requires the researcher to access individual beliefs, values and attitudes, as well as their experiences. The researcher is also interested in the motivations and capabilities of individuals when making choices, which also need to be located within particular cultural and social contexts. Therefore, as Sjöberg (2000) argues, risk perception is more thoroughly related to the subjective aspects of the social world it is better understood using the qualitative approach.

Field (1985) suggests that there are two main considerations that are central for researchers when choosing a research approach. The first element is the nature of the phenomenon being explored. The aim of this study is to explore how people with type 2 diabetes and Health Care Professionals perceive and experience the risks and benefits of diabetic retinopathy screening. The second element is the “maturity” of the concept; this refers to an appraisal of the degree to which the concept is identified and understood. There have been many studies that have used qualitative methods to explore lived experiences among people with diabetes (Macaden and Clarke, 2006; Macaden and Clarke, 2010). However, the area of diabetic retinopathy is relatively new, and the perception of diabetic retinopathy risk has not been explored via qualitative methods. Thus, the use of qualitative methods can achieve insight and depth regarding how people understand risk in relation to diabetic retinopathy and can enable us to gain more in-depth information about the ways that risk is communicated to people with type 2 diabetes. Furthermore, evaluating and appraising the existing risk communication tools and exploring patient’s perceptions and experiences of other potential tools requires the use of in-depth qualitative methods.

In wider terms, the importance of a qualitative study in this field is evident in main two ways, Firstly, many researchers have noted the need for more exploration into the health beliefs of people with diabetes and the factors that influence their ability to make lifestyle alterations (Macaden and Clarke, 2010; Anderson and Robins, 1998). This study is clearly concerned with exploring the broader dimensions of participant’s lives. Secondly, it is suggested that Health Care Professionals and people with diabetes have different understanding of health, illness and the associated risks and benefits related with non-adherence (Macaden and Clarke, 2010). For example, Health Care Professionals tend to explain risk generally as the probability of incidence of a related adverse event that linked with non-adherence to health advice or if safety measures are not taken as requested. However, people’s perceptions of risk are influenced by their previous experiences, communications with family members, friends, peers, and other colleagues. This is also can be influenced by people’s culture, values, and beliefs. Therefore, individuals can overestimate or underestimate risks and their decisions as to whether to avoid potential risks or not can be conceived as rational decisions associated with perceived individual losses or gains (Reyna *et al.*, 2009). Given that the main aim of this study is to understand risk perception and it is effect on communicating risk information about diabetic retinopathy to people with type 2 diabetes, and then to develop a model of risk communication, it was essential to explore how people with type 2 diabetes perceive and experience their risk; to identify the meanings they hold regarding diabetes and its complications; to explore how their experiences, values and beliefs inform their perceived risk, and the ways in which they handle and interpret risk. This study is therefore well positioned to provide better understanding of such differences in understanding between Health Care Professionals and people with diabetes.

4.7. Consideration of potential qualitative methods

In considering the most appropriate methodological approach the researcher considered the applicability of implementing either ethnography or phenomenology as a research methodology because both are informed by social constructionism and the notion that individuals interpret the social worlds in which they live (Creswell, 1994).

4.7.1 Ethnography

In ethnography, the researcher studies a particular group within their everyday setting over a period of time mainly by collecting observational and interview data (Creswell, 2003). The goal of ethnography is to provide a deeper, richer understanding of the perceptions, social interactions, and behaviours that take place within groups, teams, organisations, and communities (Creswell, 2008). The primary method of ethnography is fieldwork, which consists of intense periods of observing the people who are the focus of the study. Observation is important as it enables researchers to both observe and potentially participate in daily activities over a period of time (Creswell, 2003). Ethnographers also use in-depth conversational interviews alongside the observations during their studies to enable them to investigate emerging themes or issues, or to ask questions regarding certain behaviours or interactions (Creswell, 2008). As such, ethnographers are able to employ methods of triangulation; e.g. check out aspects of their observation data, to enable them to offer more comprehensive insights into the phenomenon under study. Developing an understanding of different cultures in term of social rules, values and interaction approaches can assist Health Care Professionals to work more effectively with different groups of people, including people with diabetes from different ethnic and cultural backgrounds (Chesnay, 2016). For example, it is increasingly recognised that Health Care Professionals should understand different cultures and patterns of living as a means of improving patients' experiences during treatments (Chesnay, 2016).

Thus, ethnography was considered as a potential methodology given that culture is one of the main aspects that may influence risk perception. Ethnographic research can also lead to a deeper understanding than can be achieved by interviews alone, because it provides knowledge of the context in which events occur (Hoepfl, 1997). However, as the main aim of the research was not to study the culture of this group of participants, but rather to understand the different ways of communicating risk information to people with diabetes, ethnography was not considered appropriate. There is not a defined setting for the researcher to explore; e.g. observing patients in the waiting area would not provide valuable information or rich data regarding their views or understand of risk.

4.7.2 Phenomenology

Phenomenology seeks to explore experiences in relation to a specific phenomenon and aims to generate a description of a phenomenon through the lived experiences of participants via extensive and prolonged engagement that enables the researcher to develop guides and relationships of meaning (Creswell, 2003). For some phenomenological research concentrates on describing what individuals have in common as they experience a phenomenon such as anger, grief, or loss of appetite (Holloway, 2013). However, for others, such as Van Manen (1990), phenomenology is not just a description of lived experience, but it is also considered as an interpretive process in which the researcher makes an interpretation of the meaning of the lived experience. Phenomenological philosophy is informed by epistemological questions relating to "how we know" and the connection between the individual who knows and what can be known (McLeod, 2001). It is also related to the ontological question:

"what is being" and is concerned with the nature of reality and our knowledge about it, "how things really are" (Holloway, 2013).

The phenomenological inquiry starts when the researcher identifies an area of interest, concern, or a gap in knowledge about a phenomenon such as non-attendance to diabetic screening or non-adherence to diabetes medications. Data collection starts with the specific and proceeds to the general using in-depth interviews with the participants (Holloway, 2013). The researcher collects data from participants who have experienced the phenomenon and develops a combined description of the core of the lived experience for all of the participants. Other forms of data collection may include observation and another documentary evidence (Moustakas, 1994). The researcher analyses the data by going through the interview transcripts to highlight "significant statements" or quotes that offer an understanding of how the participants experienced the phenomenon, then develop cluster of meaning from these data. These important statements and themes are used to write a description about the participants experiences (Moustakas, 1994).

However, whilst phenomenology acknowledges the researcher's perspective and uses open, in-depth qualitative interviews to collect data, there are also aspects of phenomenology that are not appropriate to this study. For example, phenomenological studies, in general, tend to interview fewer participants compared to other qualitative approaches and it tends to 'divorce' the participant from their social setting (Creswell, 2003). Whilst phenomenology was not chosen as the main method for this research, due to the fact that the study aimed for more contextualised account of risk, the research has adopted semi-structured interviews as the main data collection tool (also associated with phenomenology) because it is interested in what risk means to people, how they perceive it, the way they understand it, and how they use risk information in the decision-making.

4.7.3 Using constructivist grounded theory to analyse data

This section discusses the choice for using a social constructivist grounded theory approach in relation to data analysis. The decision has been based on two primary issues: firstly, the aims of the research question and secondly the researcher's philosophical position. Essential to consideration of the most suitable paradigm was the aim of the research and the knowledge needed to achieve them. The philosophy underpinning constructivist grounded theory can complement other approaches in relation to qualitative data analysis rather than stand in opposition to them (Charmaz, 2006). The subjective approach to the study of social phenomena concentrates on qualitative analysis, in order to construct concepts and theories. Corbin and Strauss (2008, P: 10) state that:

> *"Concepts and theories are constructed by researchers, out of the stories that are constructed by research participants, who are trying to explain and make sense out of their experiences and/or lives, both to the researcher and themselves"*

Corbin and Strauss (2008) argue that it is these various constructs, which permit researchers to construct knowledge. As themes emerge from the research, constructivist design can develop over time to integrate features in a new design. This flexibility and the themes that derived from various construct, let researchers construct knowledge (Corbin and Strauss, 2008). There are several different views of "reality" in terms of what represents "knowledge" (Denzin and Lincoln, 2003). In order to access people with diabetes' and Health Care Professionals' perception of risk an exploratory approach located within the constructivist paradigm was judged to be appropriate:

> *"Constructivism assumes the relativism of multiple social realities, recognises the mutual creation of knowledge by the viewer and the viewed and the aims towards interpretive understanding of subjects meanings" (Charmaz, 2000, P:510).*

The researcher's perception of what establishes "knowledge" (epistemology) impacts on the theoretical perspective, methodology and methods applied to a study (Schwandt, 2001). The researcher's view of the world and the nature of being (Ontology) and the ways in which this may be understood through means of enquiry (epistemology) have influenced the study along with the researcher's decision to use constructivist grounded theory in relation to data analysis

(Charmaz, 2006). Ontologically, the researcher perceives meaning in the social world to be socially constructed, that is to say, there are several realities as opposed to a sole “truth” (Charmaz, 2006). It is the researcher’s argument that the data collected in this current study will not establish “reality” because true knowledge does not exist independently to be discovered but rather is socially constructed.

As part of this approach it is proposed that the researcher’s views and experiences be taken into account (Schwandt, 2001). Therefore, Charmaz’s (2006) version of ground theory is explicitly located within the constructivist paradigm in contrast to other approaches within grounded theory such as Strauss and Corbin’s (1998) approach whose philosophical stance has been subject to much interpretation (Jeon, 2004). The constructivist version of grounded theory therefore takes into account that the researcher is not “neutral” in his approach to the study (Charmaz, 2006). That is to say, the researcher has selected the topic of risk communication, and brought his interest in people with type 2 diabetes. Social process such as risk communications and people interactions are likely to involve a range of subjective experiences including personal emotions and interactions with others. As Health Care Professionals, interact with patients and other Health Care Professionals, the researcher believes that access to personal subjective accounts is vital when exploring the diverse issues surrounding an illness or complications which may in certain cases last for years or even for ever. The researcher’s experiences of people with diabetes in both personal and professional life are as results of observing others. The constructivist grounded theory approach is perfectly positioned to develop areas of enquiry where further exploratory research is necessary. It provides a research framework that goes beyond the means of data collection to include guidelines for how researchers treat the data and the analytical outcomes that stem from the data analysis process. Charmaz (2006, P: 2) conceptualises constructivist grounded theory as providing:

> *“Systematic, yet flexible guidelines for collecting and analysing qualitative data to construct theories ‘grounded’ in the data themselves.” (Charmaz, 2006).*

Thus, researchers study early data and start to divide, sort, and combine these data through qualitative coding. Coding refines data, arranges them, and give us a handle for making comparisons with other parts of data (Charmaz, 2006). Initial codes indicate certain areas to explore further during subsequent data collection (Charmaz, 2006; Newby, 2010). Therefore, the researcher would compare the events and views that participant talks about, and the codes with the next person we talk with, and the next person, and the next. By making and coding numerous comparisons, our analytic understanding of the data starts to take shape. During this stage, the researcher will write initial analytic notes called memos about the codes and comparisons and any other ideas about the data that occur to the researcher. Through studying data, comparing them, and writing memos, which is a particular type of written note that enclose the product of researcher’s analysis (Strauss, 2008), the researcher describes ideas that best fit and interpret the data as ‘tentative’ analytic categories (Charmaz, 2006). Once predictable questions arise and gaps in the categories come into sight, the researcher seeks data that answer these questions and may fill the gaps. Researchers may go back to participants to find out more and to strengthen these analytic categories. As the process progresses, these categories not only combine as the researcher interprets the collected data but also the categories develop into more theoretical categories because the researcher engages in successive levels of analysis. Based on the aims of the study, it was essential that theories regarding risk perception and its effect on risk communication and people’s behaviours emerged from the data, which would add to the existing knowledge.

4.7.4 Sampling strategy

An adequate sampling process and sample size is a key component when seeking to answer any research question. According to (Marshall, 1996), an adequate sample size for qualitative research is the one that sufficiently answers the research question. The total number of participants is determined by the progress of the research and recruitment can stop when no new themes or categories emerge from data; what is termed ‘data saturation’ (Bryman, 2008). In this study a convenient sample was used; that is the selection of the most accessible subjects (Marshall, 1996). Convenient sampling is the least costly to researchers in terms of effort and time, but it may result in poor research quality data and “lack of intellectual credibility” (Marshall, 1996). Therefore, it is imperative to describe how the convenience sample is different from a perfect sample that was randomly chosen. It is also necessary to explain the possible effects of the people who were not selected to the research in order to enable the reader to get good idea of the sample that has participated. This also enables the reader to assess the differences between the research results and the results from the entire population (Explorable.com, 2009). The sampling commenced by interviewing participants that were purposively chosen because they have good knowledge and experience with the phenomenon being explored and who are able to express their experiences. Convenient sample was used in order to access those people with diabetes who have different level of risk and with different grade of diabetic retinopathy who use to attend diabetic screening every year. Furthermore, it was essential to include participants from different gender, age, and ethnic back ground.

4.7.5 Data collection/semi-structured interviews

Qualitative research from within a social constructionist framework commonly employs semi structured interviews to collect data (Charmaz, 2006; Dick, 2005; Glaser, 1992). A semi-structured interview is a flexible way of asking questions that can be shaped by the interviewee’s own understanding and researcher’s interests (Bryman, 2004). Semi-structured interviews allow the researcher to investigate people’s perceptions of risk and risk communication and authentic insights can be gained into people’s experiences using open-ended questions (Dingwall and Miller, 1997). It allows participants time and space to talk freely about their personal thoughts, understandings, and experiences. Semi-structured interviews have the ability to generate in-depth detail about peoples experiences and the meanings of these experiences (Whittaker, 2002), allowing insight into their internal reality.

As the study topic is relatively under-researched, semi-structured interviews appeared the most appropriate method for a number of reasons. First, it allows the researcher to explore how patients think and talk about diabetes and diabetic retinopathy screening. It provides the researcher with the opportunity to create an environment in which patients feel that they are able to talk as freely as possible. Semi-structured interviews (face to face) provide the opportunity for flexibility (Dingwall and Miller, 1997) in order to cover a broad range of issues. Face to face interviews are practical and feasible within the time and cost constraints of the study:

> *“When we talk with someone about the world, we take into account who the other is, what that other person could be presumed to know, where that other is in relation to our self in the world we talk about” (Baker, 1982:109).*

Dingwall and Miller (1997) argue that the research interview constitutes a deliberately created opportunity to talk about something that the researcher is interested in and which may or may not be of interest to the respondent. However, as (Bryman, 2004) has argued, there exist a wide range of issues that are simply not amenable to observation and creating a specific situation in which to ask people about different phenomena can be the only viable method of researching them. Semi-structured interviews employ a set of topics to inform questions in the style of conversation. However, there are a number of fundamental constraints which can affect the quality of an interview. These factors include variation between interviewee and interviewer (Cohen, 1982) such as mutual trust (especially when discussing a sensitive topic such as risk of blindness or diabetes self-care management with a minor ethnic group whose English is not their first language), social distance between interviewer and interviewee, misunderstanding about the use of language, which may be clear to one but not to the other. The interviewee may also well adopt avoidance tactics by not addressing the question or not saying anything (Cohen, 1982). This can be overcome by having follow-up questions or/and probes or by rephrasing the questions (Corbin and Strauss, 2008). Therefore, the researcher considered the broader picture and was aware of the factors that may have influenced the interviews. For example, the researcher considered the place of the interview whether it was conducted at the hospital, GP practice, or at participant’s home. The second issue considered by the researcher was whether the participant was relaxed or anxious during the interview. Another important factor was taken into consideration whether the interview was conducted at the same time of retinal screening or after a week or a month to explore the effect of the results on participants. Such factors were considered in order to minimize researcher's influence on the reliability of the results (Marshall, 1996).

Other data collection methods were considered such as focus groups and structured interviews. Structured interviews mean that participants answer questions that are pre-set. It can be used if the focus of the study is narrow and the researcher wants to establish a particular fact (Silverman (2001). Focus groups usually refer to a group interview with around 10 individuals designed to discuss a specific issue or idea. The group are asked a series of questions by the researcher or moderator to which they can freely contribute and share their opinions and ideas. Kamberelis and Dimitriadis (2013) argue that focus groups provide the diversity of responses as well as have other advantages. Kamberelis and Dimitriadis (2013) also highlight some problematic issues with focus groups, such as protecting individual's "anonymity". Researchers are expected to respect individuals and therefore protect their integrity including their right to be anonymous. This means that focus groups may be beneficial when concentrating on public issues rather than individual's issues, as individuals may not feel comfortable when personal issues are discussed in the presence of others. Writing (2015) argues that focus groups may not be as in-depth as individual interviews as they may not wish to expose how they feel. In addition, participants may not express honest views and feelings as they may hesitate to express their opinions, particularly when their views oppose the thoughts of rest of the group. Other important issues with focus groups (particularly with novice researchers) is that there is heavy reliance and dependence on the researcher's skills in order to ensure that the opinions of each participant is heard (Krueger, 1988). The researcher or moderator (intentionally or unconsciously) may also influence the outcome of the focus group. McKie (1995) used discussion groups to find out about participation and views on screening. Although she states that the use of established groups ensured that women felt comfortable with each other and provided important support mechanisms, she felt that using this approach can have a reverse effect, with women being reluctant to talk about things in front of others that they may have otherwise disclosed. Therefore, in relation to sensitive and upsetting topics such as diabetes and blindness participants may feel intimated by the presence of others and may open up more in a one to one situation. In addition, group discussions of blindness and diabetes especially when participants are not adherent to the recommended treatment may cause unnecessary distress to patients.

4.7.6 Case summary

The principles of constructionist grounded theory, which informed the analysis of the data, suggest that after the interview takes place the researcher should write a case summary (Charmaz, 2006). These have been shown to help the researcher to get some initial thoughts, ideas, and themes regarding the interview. This can start with the essentials of the interview; what made it interesting, what was special or strange about the case, what was frequent and what was different from others. It is essential for the researcher to distinguish between their own ideas by drawing circle around these ideas and ideas that emerged from the interview. This should include a description of what has happened during the interview and not an interpretation of the interview. The researcher also may write a reflection after each interview as how the next one can be improved (Corbin and Strauss, 2008).

4.8. Development of data analysis

4.8.1 Treatment of literature

Engaging in any form of grounded theory research requires the researcher to address a set of common characteristics such as theoretical sensitivity, treatment of the literature, constant comparative analysis, coding, and memo writing. The time at which the literature requires to be reassessed or developed in the research process in grounded theory is deeply disputed between the traditional and evolved forms of grounded theory. Glaser’s suggestion is to hold back reviewing literature in the practical area under study (Glaser, 1992) to overcome any corruption or weakness with the analytical process (Mills, 2006).

This approach also recommends that the data is a separate component from both participants and researcher. On the other side, the evolved form of grounded theory supports the proactive engagement with the literature from the start of the research process (Strauss & Corbin, 1998).

4.8.2 Theoretical sensitivity

Theoretical sensitivity is presenting the views of participants and taking the position of others during data collection process (Corbin and Strauss, 2008). Theoretical sensitivity differs from one researcher to another as it is a skill that develops overtime through work with both data and people (Corbin and Strauss, 2008). Constructivist grounded theory necessitates that the researcher views issues and problems from the perspective of participants. According to Corbin and Strauss (2008), it is important to see the truth as the participants see it rather than the researchers' perception. A lack of theoretical sensitivity will result in a mixture of empirical description with some preconceived conceptual description. For this study, theoretical sensitivity was adopted alongside reflections in the following ways. First, the researcher's professional experience as an ophthalmology nurse practitioner provided precious insight into every stage of the study, such as designing interviews, understanding the background and situations of the participants and the creation of codes and categories. The researcher also had the chance to join a well-established research team and his communication and relation with other members of the team expanded his perspectives on the thought of risk, in particular during the theoretical coding process. Opportunities to publish scientific posters on risk communication and risk tools (Appendix 13) also enhanced his theoretical sensitivity and grip on issues around the concept of risk and communication.

4.8.3 Data coding

Data coding is a way of attaching a name or description to the text. It helps the researcher to handle and organize large amounts of unstructured data and also informs additional data collection (Charmaz, 2006). It is the initial stage of the analysis process, which begins the process of categorizing and organizing data (Charmaz, 2006). Thus, it facilitates the conceptualization of the data, the construction of the theory from the data and in addition establishes the quality of the theory that emerges. It is an essential process that links raw data and emerging theory so as to provide the theory with explanatory power. There are three stages to the coding process (Strauss, 1998). The first stage is “input”; the researcher starts searching for the theory from the first line of first interview that the researcher codes. This process aims to break the data into conceptual elements. It is difficult at this stage to connect the codes together. The second stage is the “drugless trip”; in which the data is in the mind of the researcher. At this stage many ideas emerge about the theory, but without any lucidity. The third stage is “saturation”; the researcher notes down the results from the analysis of the data leading to the development of theory. Strauss (1998) also highlights three sets of coding used during data analysis. These are open, axial, and selective coding. Open coding involves the initial section of data in order to explore all possible features about the phenomenon that is being researched. This leads to the development of descriptive codes or categories from the preliminary data that had been collected. During this aspect of the coding process, the researcher is required to search for a “core category” that is central to other categories, with the aim being able to produce theory that describes changes and dimensions of peoples’ behavioural (Glaser, 2002). The links between the codes can be established throughout the axial coding process. Axial coding involves the development of a coding paradigm, which identifies a central phenomenon, explores causal conditions, specifies actions that result from the phenomenon and identifies the context that influences these actions and the outcomes of the phenomenon. In this level of coding, the descriptive codes are grouped at a more abstract level and linked by relationships that emerge from within the codes. The open coding and axial coding described as substantive coding which allows conceptualization of “the empirical substance of the area of research” (Glaser, 1978: 55). Axial coding consists of a strong analysis about one category at a time that helps understanding about associations and links between categories and sub-categories (Strauss, 1994). This progressively solid conceptualization facilitates the connections to be made between different categories. Analysis at this level involves “inductive and deductive thinking” and making comparisons within data. Selective coding is the third aspect of coding (Charmaz, 2006. This involves the integration of categories from axial coding forming conceptual links that facilitates development of the theory. This level of coding seeks to establish a core category that establishes connections between itself and other categories (Charmaz, 2006). The significant characters at this stage of analysis are the theoretical coding and memo writing. This means that the data is viewed theoretically rather than descriptively. The core category is that results should be solid but complete and should conceptualize the connections between all three coding levels (open, axial, and selective) in order to be able to describe differences in the categories.

4.8.4 Memo writing

Memos are defined as "*a specialised type of written records-those that contain the products of our analyses*" (Corbin and Strauss, 2008: 117). Writing memos assists the investigator to become more analytical and it provides opportunities to reflect on the situation, which in turn assist in construction of theoretical codes. Writing regular memos are a critical element of the formulation and improvement of theory in the research. Glaser (2001) argues that researchers will not be able to produce a strong theory without writing continuous memos from the beginning of the research. Therefore, researchers should have "pacing time", which means that researchers should stop coding in order to allow time for writing memos during the whole stages of generating theory. However, researchers must keep the process on-going; sorting old memos and writing up new memos as it is continuous process that is a fundamental element of constant comparative analysis.

4.8.5 Constant comparative analysis

As mentioned earlier, within constructivist grounded theory, researchers are expected to sustain theoretical sensitivity throughout the research process in order to ensure that the generated theory is grounded in the research data instead of assumptions or hypothesis (Charmaz, 2006). Constant comparison is comparing incident with incident for similarities and differences (Glaser and Strauss, 1967). The constant comparative analysis method assists thinking regarding the data, ideas, categories or themes that come out, thus enhancing theoretical sensitivity (Jeon, 2004).

4.8.6 Patient involvement in the development of this study

The original idea for this research came from the FLURRI study, as the participants seemed highly concerned at the proposal of reducing screening frequency to patients, who are at low risk (Lindenmeyer *et al.*, 2014; Hipwell *et al.*, 2014). The FLURRI team had a Primary Principal Investigator who endorsed the decision to develop research questions around this topic. The protocol was further developed with the collaboration of members of the Warwick Diabetes Research and Education User Group (WDREUG), who reviewed the research questions, the interview schedule questions, and the sampling processes. This group of approximately 10 people with diabetes have been meeting bi-monthly since 2001 to consult with the diabetes research team on the development, execution, analysis, and dissemination of the research projects. They have been involved in 8 previous publications and contribute to INVOLVE activities. A further 10 members were involved via email.

4.8.7 Reflexivity

An important aspect of the research was to ensure reflexivity during data collection and data analysis processes (Corbin and Strauss, 2008. Reflexivity is a self-awareness of researcher’s own influence on research process achieved through critical self-consciousness. Researchers may have different feelings and emotions, such as being happy, angry, or sad when collecting or analysing the data. Such feelings may be conveyed to participants. If this happens during the data collection process it may influence the participants’ responses and how they react or answer questions. In addition, such emotions and feelings may appear during memo writing as a response to certain issue (Corbin and Strauss, 2008). As an experienced ophthalmic nurse with an interest and active role in diabetes care and blindness prevention the researcher may have preconceived ideas about patient education and the role it can play in diabetes self-care management and prevention of diabetes related eye complications. Recognition of any influence that the researcher may have on the research is, therefore, essential. This is crucial to ensure that the research position is separated from clinical position.

4.8.8 Researcher as clinician

As the previous section outlined, researchers have a responsibility to reflect upon their own position in the research and explain how they believe this may influence the study (Creswell, 2003). Therefore, it is important that the researcher sets out their personal biography and then reflects upon on how it may influence the study. It is important to make a distinction between the researcher role and the clinical role. For example, should participants recognise the researcher this can influence the research as people may not be as open as they should be. Furthermore, it can be difficult for Health Care Professional to ignore patients concerns and deny their clinical experience. Therefore, it was appropriate to set out before the interview began that should participants have any diabetes-related eye questions that these would be answered after the interview by Health Care Professionals at the research site. Should participants have had any questions or concerns regarding their health care, the protocol dictated that they would be referred to their GP practice or local Patient Advice Liaison Service (PALS). Interviewing people with diabetes and Health Care Professionals who may know the researcher should always be considered as this may influence the information given. Therefore, participants were reassured that the study was completely separate to their health care. Participants were also informed that their identity would be protected throughout the study and any information they provided would be confidential. Participants were also assured that data protection legislation (Data Protection Act 1998 and subsequent amendments) and University of Warwick Research Governance procedures would be followed.

4.9. Ethical issues

There are fundamental ethical principles that should be considered in health research, such as beneficence, non-maleficence, and respect for autonomy (Beauchamp and Childress, 2001).

4.9.1 Respect for autonomy

Underpinning the concept of informed consent is the belief that those participating in research should not feel forced to do so. Instead, the decision should be made voluntarily, with appropriate knowledge of the potential implications (Green and Thorogood, 2004). Participants should therefore be made aware that they are a crucial element of the research and the researcher should make sure that participants understand the purpose of the research. This information is normally provided through a participant information sheet. Appropriate time should also be considered prior to participation to ensure that participants are fully aware of these issues. Informed consent should be sought from all participants, including those who do not speak English as their first language. Before interviews commence, an opportunity would be provided for potential participants to ask questions prior to deciding whether to take part, to ensure that fully informed consent is given. In the event that a participant was unable to read and write the researcher, through the NHS interpreter, would ensure thorough comprehension and the participant’s mark would be obtained on the consent form.

4.9.2 Non-maleficence

The second ethical principle is known as non-maleficence; i.e. “do no harm” to participants (Craig, 2000). The concept of risk and the risk of visual impairment could be very sensitive and distressing to people with diabetes. Therefore, careful consideration needs to be taken by researchers when such issues are discussed. Therefore, relevant contact numbers were provided via participant information sheet in order to provide an independent advice to those who may potentially be affected. “Do no harm” is also significant to researcher. Previous studies suggest that conducting interviews can have an emotional impact on the researcher (Craig, 2000; Lalor, 2006). Therefore, guidelines have been developed to provide security and maintain safety to researchers (Craig, 2000). Communicating risk information is a sensitive issue, however, the aim of the study was not to provide risk information but to explore the perception of risk and the views that people with diabetes have regarding existing risk communication tools as well as the new developed tool.

4.9.3 Gate keeping

The nature of health research itself can be seen as significant to people with diabetes due to financial reasons and the impact on their time (Lakerveld *et al.* 2008). This has the potential to influence the level of participation that can have a significant impact on the external validity of a study (Lakerveld *et al.*, 2008). A few issues have to be considered in the health research such as recruitment process and involvement of gatekeepers. Health research may use gatekeepers to help recruit participants. A gatekeeper is an individual who controls the research access such as a manager or individual within a group or community who makes the final decision as to whether the researcher gains access to carry out the research (Saunders, 2006). In studies where participants are being accessed via an established health care context, such as in primary care/GP practices or hospital clinics, those who may be invited to participate can be easily influenced by the knowledge, motivation, and authority of the employees/clinicians in that clinic. This may impact on the recruitment process because those people would be making significant decisions regarding the recruitment and therefore may pose risks to the validity of the study (Saunders, 2006). Thus, gate keepers may influence the recruitment process in the following ways: 1) by limiting the circumstances of who is entered into the study, 2) the way they explain the research study to individuals, and 3) restricting access to data and participants. These matters were managed by arranging meetings with practice managers, clinicians, and receptionists to provide consistent information about the study. For example, the literature suggests that participants are more likely to participate if they were asked by a doctor rather than a receptionist (Symonds *et al.*, 2012). Another issue that could raise a potential ethical issue is in cases where participants may have been over persuaded to take part as they may have concerns that their health care will be compromised. However, this issue can be dealt with when confirming informed consent and by gaining assurances that participants are happy to participate in the research prior to their interview.

People with diabetes may face additional barriers in accessing services; e.g. due to their ethnic background, and as such these groups may be less likely to participate in research. This may also be linked to the non-availability of study materials in the appropriate languages. Thus, the researcher may adopt strategies to increase interview participation, such as employing a bilingual interviewer, translators, link-workers, practice staff/professionals support. Where Primary Care staff identified a particular language need for a specific patient, link workers can be contacted by practice staff to facilitate recruitment.

4.9.4 Adverse events

The occurrence of adverse events as a result of participation within this research was not expected. However, it was envisaged that the interviews may have raised issues regarding diabetic screening results, risks, and benefits of diabetic eye screening, which could be a sensitive issue to some participants. In such cases, if a participant raised a concern then the researcher would reiterate the contact numbers of counselling services in the hospital, as well as voluntary organizations such as Diabetes UK. In addition, the researcher would offer to contact a family member or friend when required. Participants would also be reminded in their information letter and before their interview that they are in no way obligated to take part in the research and that they may withdraw at any time without giving any reason. As mentioned earlier, should participants have any questions or concerns regarding their Health Care they would be referred to their GP practice or local Patient Advice Liaison Service (PALS). Furthermore, the researcher would arrange regular power point presentations to Primary and Secondary Care staff ensuring that they are aware of such potential issues and to provide support to the participants.

4.9.5 Risk of recognising the researcher in the clinical setting

The role of researcher as a clinician can influence the quality of the data collected (Creswell, 2003). In such cases, participants may not be as open during the interview and may not provide complete answer assuming that the researcher knows the answer due to their professional background. The concept of power has to be recognised prior to the interviews with Health Care Professionals, whereby, participants, particularly if they are senior staff with existing experience in diabetes and diabetes eye complications, may influence the interview.

4.10. Conclusion

In this chapter, the author sets out the justification for adopting a qualitative research methodology that draws upon social constructivist grounded theory in relation to the data analysis. To summarise, the choice of a qualitative approach placed within social constructivist paradigm has been directed by the explicit aims of the current study. Firstly, from philosophical point of view; the emphasis on interpretation and meaning is appropriate to the current study because it seeks to understand the relationship between the person and society through people’s actions and interactions. Second, constructivist grounded theory helps with the process of data collection and analysis with the aim of developing exploratory work in the field of risk communication. Third, it takes into consideration the significance of the role of the researcher in the development of theory. In the next chapter, the methods that adopted in the study will be presented.

Chapter 5. **Methods**

5.1. Introduction

The aim of this chapter is to describe the methods used in this study. The chapter details the reasons why the study adopted a two-stage approach, followed by the recruitment process, data collection, and the data analysis process.

5.2. Research aims and research methods

The purpose of this research was to explore how diabetes and diabetic retinopathy screening are understood by people with diabetes and Health Care Professionals, and to establish the most appropriate methods by which risk information about diabetic retinopathy can be effectively communicated to help informed choice. Given the research aims, a qualitative approach was identified as the most appropriate way of conducting this research.

5.3. Ethical approval

An application was made through IRAS (Reference 12/WM/0103). The proposed research received National Research Ethics Committee approval and subsequent Research and Development approval from the study site (Appendix 11). Academic and clinical supervision from the University of Warwick as well as clinical supervision from the study site has overseen the conduct of the research. The researcher was also guided by the ethical and professional codes of conduct pertaining to the nursing, studying and research aspect of their work (NMC, 2008). Before starting the recruitment process, a substantial amendment (101879/340465/13/264/13380) to the final protocol was obtained in order to widen the recruitment criteria, adding more recruitment sites and adding more people at higher risk in order to understand risk perception (Appendix 12).

5.4. Research design

A two-stage qualitative research strategy (Figure 5.1) using semi-structured interviews with people who live with type 2 diabetes was conducted.

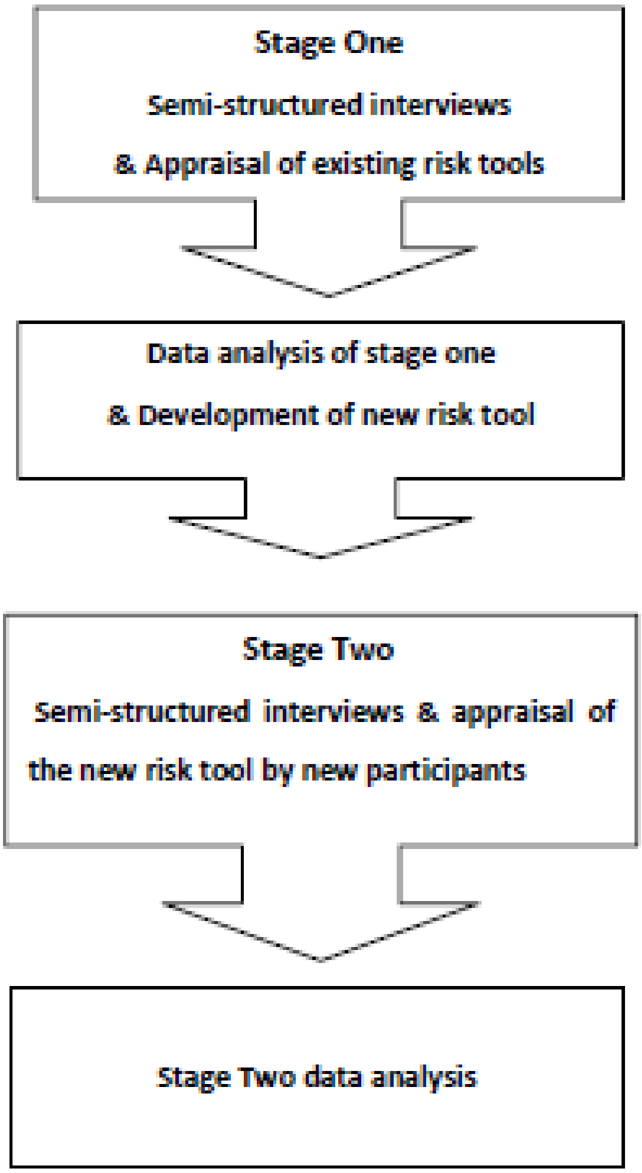


Figure 5.1 Research Design

5.5. Stage One

5.5.1 Study setting and population

Participants were recruited from five GP practices in a Primary Care Trust and a specialist eye clinic in a Secondary Care Trust within a large city in the Midlands. These Trusts were chosen because they represented populations living in different areas of this city, including pockets of deprivation, rural locations, and more prosperous locations. People with type 2 diabetes were targeted because they would be subject to diabetic eye screening extended intervals and because type 2 diabetes accounts for about 85% of all cases of people with diabetes (DiabetesUK, 2013). The extension of diabetic eye screening intervals is raising the need to understand risk perception in the majority population currently accessing screening even though they are at less risk of progression to sight-threatening diabetic retinopathy, due to living with it for less time compared to those with type 1 diabetes. In addition, the study was also informed by significant differences in the prevalence of diabetic retinopathy between White Europeans and South Asians (Raymond *et al.* (2009) and the earlier diagnosis of type 2 diabetes in South Asians meaning that they live with it for longer. Therefore, this research includes people of South Asian origin and White British with Type 2 diabetes to understand how diabetes and diabetic retinopathy screening is perceived and understood by this group. The study also wanted to explore whether people's perceptions of risk impact on their behaviours regarding their diabetes self-care management.

5.5.2 People with diabetes Inclusion/Exclusion Criteria

The English national screening programme for sight-threatening diabetic retinopathy offers a digital photographic screening to all people with diabetes over the age of 12 years (Scanlon, 2008). This study focused on adults with type 2 diabetes. The inclusion criteria are as follows.

5.5.3 People with diabetes Inclusion Criteria

- Aged 18 years or over
- Able to give informed consent
- Has a confirmed diagnosis of type 2 diabetes
- Has attended at least one diabetic retinopathy screening appointment within the last 3 months
- Speaks English or a language that available interpreters are able to interpret at interview and can translate study materials
- White British or South Asian

5.5.4 People with diabetes Exclusion Criteria

- Unable to give informed consent, for example has a learning disability or Alzheimer's Disease
- Unable to be interviewed in a language that can be translated by the researcher or available interpreters
- People with type 1 diabetes

5.5.5 Study site recruitment

The researcher worked with the Lead person for the regional Screening Programme and Primary Care Research Networks to recruit GP practices and patients to this study. The regional screening programme datasets were used to identify practices for purposive recruitment according to high and low levels of health need and low and high uptake of diabetic retinopathy screening services. In addition, the Index of Multiple Deprivation was used to identify practices with the highest and lowest levels of deprivation. The Index of Multiple Deprivation is based on Census data by postcode/ward and provides a score that indicates likely demand for Primary Care services. It considers income, unemployment, health deprivation and disability, education and skills, housing and services, crime, and the local environment. General Practitioners were sampled from across the different levels of the Index of Multiple Deprivation which also identified practices in areas with high and low health need.

This process identified ten GP practices (two practices from each IMD quintile) and one Secondary Care Trust from which potential participants could be recruited to the study. The researcher contacted the GP practices and the Secondary Care Trust and gave an overview of the study and sought their consent to participate. In addition, managers in the potential research sites were sent an information pack by post or/and electronically detailing the aims of the study and explaining why they were being asked to take part. Each site was given at least one week to consider their participation. Of these, five practices refused to participate, and five practices and the Secondary Care Trust showed an interest in the study. Of these, the one Secondary Care Trust and five GP practices were purposively selected as sites of recruitment as these were representative of practices across the full range of deprived and more affluent areas. The Index of Multiple Deprivation scores for these locations ranged between the highest score of 57.46 and the lowest of 9.55, and the screening uptake ranged between the highest score of 96% and the lowest score of 57% as shown in Table 5.1. Consent to participate in the study was obtained from practice managers and the head of the Secondary Care Trust's research and development unit.

Research sites were provided with copies of the participant information pack (invitation letter, consent form and participant information sheet) to be handed or posted to potential participants. Research sites were also informed that each participant would receive a £20 research incentive to encourage them to participate in the study, as well as their travel expenses. Previous studies show that incentives increase representation in research (Olsen *et al.*, 2012; Thomson *et al.*, 2012). The researcher also visited the research site managers to re-assure them that the research protocol would be followed and to provide more details about the study. This included the recruitment process, inclusion and exclusion criteria, and they were encouraged to discuss any questions or concerns they might have, such as interview time, length of the interview, place of interview, patients and staff recruitment. For example, one practice manager was concerned about patient information and confidentiality, whilst another practice manger raised the possibility of rescheduling the interview in cases when the practice was busy or there was a no room available to conduct the interview. The researcher showed flexibility with the practice's and participant's needs such as changing interview date, time, place, and so forth. All research sites were also informed that they would be contacted regarding the recruitment of participants to Stage Two of the study.

Table 5.1 Practice Characteristics

Practice number	IMD score	IMD Quintile	Screening uptake
Practice 1	24.13	Deprived (4th quintile)	68%
Practice 2	44.99	Most deprived (5th quintile)	57%
Practice 3	9.72	Above average (2nd quintile)	96%
Practice 4	9.55	Above average (2nd quintile)	85%
Practice 5	57.46	Most deprived (5th quintile)	72%

IMD: Index of Multiple Deprivations

5.5.6 Recruitment of people with type 2 diabetes

The regional screening teams used their database to purposively identify a number of people with type 2 diabetes from each practice who were stratified according to age, gender, ethnicity, length of diagnosis, grade of diabetic retinopathy and that they had attended at least one diabetic retinopathy screening. Each potential participant also met all aspects of the inclusion criteria. The name of each potential participant was then passed to the nominated gate keeper (Gallo *et al.*, 2012) who ranged from practice receptionists, doctors, nurses, and diabetic screeners and who contacted these individuals. The researcher arranged power point presentations to gatekeepers in order to provide information about the study, which groups the study was asking them to recruit and to answer any questions they may have. The recruitment of potential participants was therefore carried out by gatekeepers who contacted them to give an overview of the study, posted or emailed a participant information pack and explained to the individual that entry into the study was entirely voluntary and that their treatment and care would not be affected by their decision. In this way the researcher did not receive any participant details prior to informed consent being obtained. Potential participants who had a question about the study had the opportunity to ask the practice staff or to call the researcher on the phone number that was provided in the participant information sheet. Prior to interviews taking place, each participant sent their signed consent form to the researcher.

The use of gatekeepers to recruit participants was considered as a potential concern because their decisions about who to recruit may have been influenced by their knowledge, and interests in the study, as well as by their negotiation skills and the daily pressures associated with a busy practice (Gallo *et al.*, 2012; Symonds *et al.*, 2012). In order to ensure that this research is culturally competent (Zeh *et al.*, 2012; Papadopoulos, 2004; Papadopoulos, 2006), every effort was made within time and budgetary constraints, to facilitate access for participants for whom English is not their first language. A detailed translation and interpretation protocol that details these procedures can be found in Appendix 5. The researcher had access to bilingual link workers provided by the researcher's trust. This allowed potential people with diabetes to be contacted in an appropriate language by telephone or directly in person within the clinic to encourage recruitment of non-English speakers. Link workers were given information about the study and the practices by the researcher. Link workers liaised closely with practices to identify the relevant linguistic skills needed during recruitment. However, all people with diabetes were English speaking and chose to be interviewed in the English language. A link worker was available on two occasions as back up but was not required as participants preferred to be interviewed in the English language. Assuming a positive response rate of approximately thirty per cent, up to fifteen people with type 2 diabetes within each practice were invited to participate in the research. Thus, a total of seventy five people with type 2 diabetes were invited to participate over a two month period between September and November 2012. Within the first four weeks, fifteen consent forms were signed and returned to the researcher. Gatekeepers were asked to follow-up those individuals who did not return the consent forms by sending out another pack to all potential participants. This also ensured that gate keepers would not be able to identify those people who eventually participated in the study. A further five consent forms were signed and returned to the researcher eight weeks after the initial pack was sent. A total of twenty consent forms were returned to the researcher and each of these participants were contacted by telephone by the researcher to arrange an interview appointment at a time and the location of the participants' choice. The study aimed to include equal numbers of participants according to their grade of diabetic retinopathy. This decision was made on the basis of receiving more consent forms from certain practices than others that included more people with certain grades of diabetic retinopathy, which could be due to the influence and motivation of gatekeepers during the recruitment process (Symonds *et al.*, 2012).

Twenty participants were recruited to this study. Participants were from different grades of diabetic retinopathy to explore the influence of diabetic retinopathy grade on perception of risk. These groups included twelve males and eight females. Of these, eleven were White British and nine were South Asians. Seven participants were females and thirteen were male. Participants were divided into four groups (Table 5.2) depending on their most recent screening outcome. Group one: seven participants (three White British and four South Asians) with no diabetic retinopathy (R0); Group two: six participants (four White British and two South Asians) who had background diabetic retinopathy (R1); Group three: four participants (one White British and three South Asians) with pre-proliferative diabetic retinopathy (R2); and Group four: three participants (thee White British and none South Asians) who had proliferative diabetic retinopathy (R3). The age of the participants ranged from forty years to eighty six years with a mean age of 62 years.

Table 5.2 Sampling Strategy for Stage One

Group	Grade of diabetic retinopathy	White British	South Asians	Total
Group 1	No diabetic retinopathy (R0)	3	4	7
Group 2	Background retinopathy (R1)	4	2	6
Group 3	Preproliferative diabetic retinopathy (R2)	1	3	4
Group 4	Proliferative diabetic retinopathy (R3)	3	0	3
Total		11	9	20

5.5.7 Health Care Professionals

A range of Health Care Professionals, working with people with type 2 diabetes from White British and South Asian backgrounds, were recruited from the same research sites used to recruit people with diabetes (see Table 5.3). Practices' managers at these sites were asked to identify a list of staff linked with the diabetic screening programme and that each potential Health Care Professional met all aspects of the inclusion criteria. The researcher then contacted potential Health Care Professionals, with their permission, and a participant information pack was sent by post/electronically. Health Care Professionals were given at least one week to consider their participation. Health Care Professionals were also given the opportunity to contact the researcher and to ask questions about the study prior participation using the telephone number provided in the participant information pack. In order to ensure that this research is culturally competent (Zeh *et al.*, 2012; Papadopoulos, 2004; Papadopoulos, 2006), every effort was made to access South Asian Health Care Professionals. All eligible practices staff who agreed to participate in the study and who returned their consent form to the researcher were then contacted by phone and convenient time and place was arranged for them to be interviewed. A total of five Health Care Professionals from the five practices were approached over a two month period between September and November 2012 and of these two agreed to participate in the study. In addition to practice staff, Regional Screening Programme lead identified relevant screening staff and provided the researcher with contact details. Following the same procedure, one diabetic screener, from the Secondary Care Trust, was contacted and agreed to participate. Two ophthalmologists were approached directly by the researcher who provided participant information pack about the study asking them to participate, giving them one week to consider participation. Two ophthalmologists signed and returned their consent form.

Thus, a total of five Health Care Professionals with different roles agreed to participate in the study (Table 5.3); two ophthalmologists, one diabetic screener, and two General Practitioners.

Table 5.3 Health Care Professionals sampling strategy for Stage One

Ophthalmologist	General practitioners	Diabetic screener	Total
2	2	1	5

5.5.8 Data collection

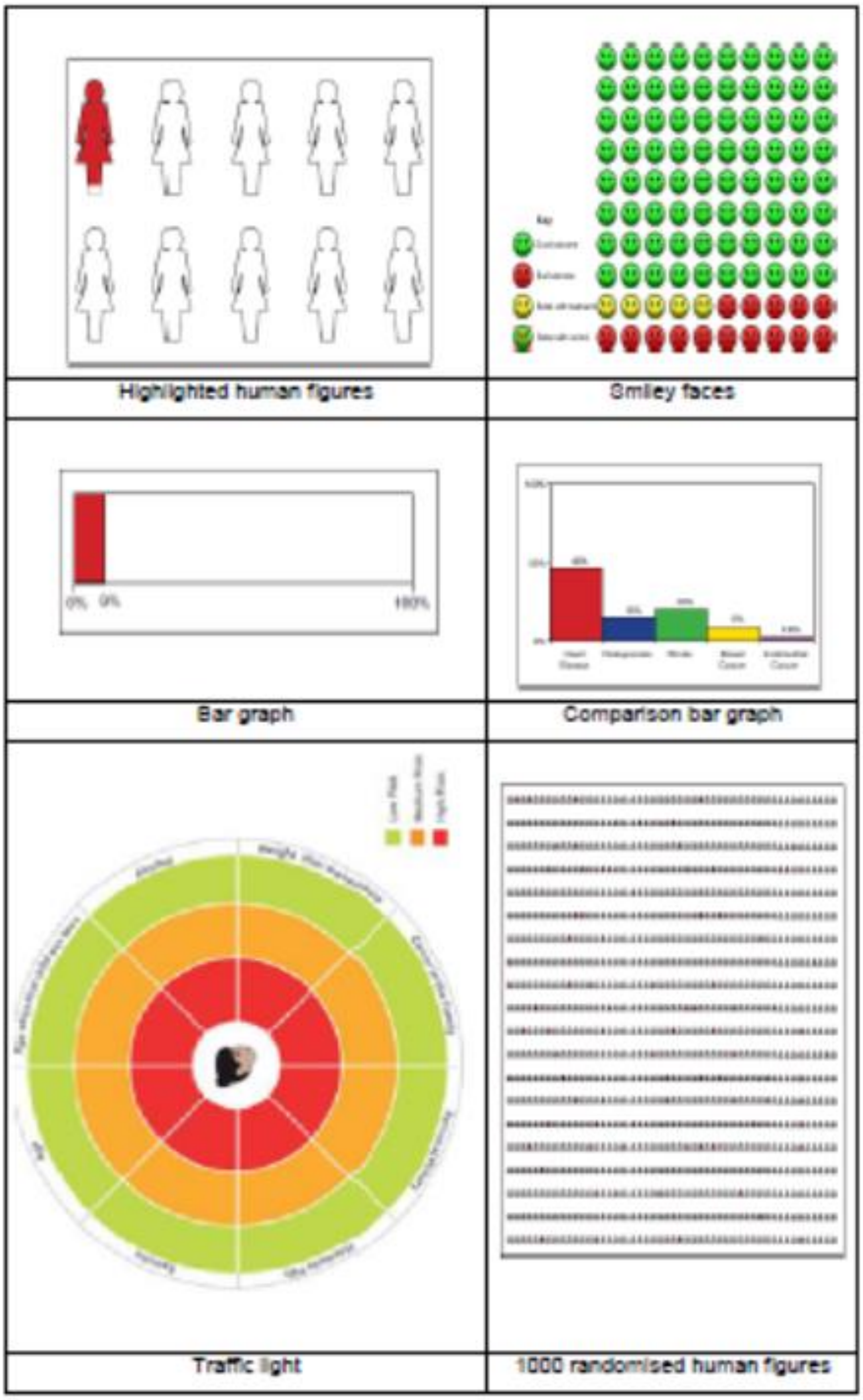
A total of twenty five semi-structured interviews were conducted at Stage One (twenty people with diabetes and five Health Care Professionals). These interviews were conducted by the researcher over a three month period (October, 2012 to December, 2012). As mentioned in Chapter Two, current practice suggests that diabetic eye screening results should be reported to people with diabetes within three weeks of their screening appointment (NSC, 2003). Therefore, interviews with the people with diabetes were conducted within three months of their screening appointments in order to make sure that people with diabetes had received their diabetic retinopathy screening results. Once the consent form was received by the researcher, each participant (twenty people with diabetes and five Health Care Professionals) were contacted to arrange the interview at a time and place of their preference.

5.5.9 Conducting semi-structured interviews with people with diabetes

Twenty semi-structured face-to-face interviews with people with diabetes were conducted at a time and place of their choice. Of these, eleven interviews were completed at the hospital (three at diabetic screening and eight at the eye clinic), six interviews at their GP surgery, and three interviews at their homes. Each interview lasted for approximately 45 to 60 minutes. The researcher started each interview by greeting the participant, introducing themselves and summarizing the purpose of the study. The researcher also spent time explaining the details of the study and ensured that each participant understood the information provided in the information sheet. The researcher answered all questions that the people with diabetes had concerning their participation in the study. Although written consent had been obtained at earlier date, informed consent was gained again in relation to the interview and regarding their permission to audio-record it. People with diabetes were then reminded of their right that they could withdraw at any time without giving reason or it is affecting their treatment. Participants were also made aware (Appendix 1: consent form; Appendix 3: participant information sheet) that should they withdraw from the study that the data collected to that point would be erased and not included in the final analysis. However, no individual asked to leave the study. Should one of these participants had lost the capacity to consent during the course of the study, the interview would not have been conducted and any data collected would have been erased.

Various issues were explored in the interviews with people with diabetes (see Appendix 4 for Interview Schedule) including their experiences of diabetes and diabetic retinopathy screening, risk perception, language barriers, and communicating risk information. At the beginning of each interview, people with diabetes were asked general questions about their type of diabetes, medication, diet, duration of diabetes, and how they were managing their diabetes. Then they were asked about their experience with diabetes since diagnosis to explore their knowledge about diabetes and diabetic retinopathy, beliefs, understandings of diabetes, impact of diabetes on their daily life, impact of diabetes on sight, knowledge of risk factors of developing diabetic retinopathy, and personal perception of risk. People with diabetes were also asked to describe their experience regarding the diabetic retinopathy screening programme since diagnosis, how many times they had attended to diabetic eye screening, how many times they did not attend, who send them the invitation, who performed the screening test, how they were notified of the results, their understanding of the results, and the impact of the results on their diabetes management. People with diabetes were then asked to describe the method of communicating the diabetic screening results and possible ways to improve it. The researcher was also keen to explore their reactions and suggestions regarding the best way of delivering the diabetic retinopathy screening results and risk messages about diabetic retinopathy. Data also were collected from people with diabetes regarding the kind of risk information that should be presented during a consultation for people with diabetes and in the diabetic screening results. This was followed by questions about methods of communicating risk information about diabetic retinopathy in general by Health Care Providers. People with diabetes were also asked about their views of providing risk information by using different format such as numbers, words, percentages, and probabilities. Personal perception of risk was further investigated by asking people with diabetes how they perceive own risk and by estimating the probabilities of their risk based on their understanding of such formats and by reflecting on the diabetic retinopathy screening results. This was followed by questions to understand the impact of understanding personal risk on diabetes self-care management and the influence of personal risk on anxiety.

As there is currently no risk communication tool used in relation to diabetic retinopathy, a set of different risk communication tools currently used in other clinical settings (Figure 5.2) were shown to people with diabetes in order that they could appraise them and choose the most appropriate and effective tool and format for communicating risk message about diabetic retinopathy. People with diabetes were asked about their opinions and views regarding the clearest and most helpful tool that could be modified and used to communicate risk information about diabetic retinopathy. In addition, the researcher collected background data about the participants to provide a fuller understanding of their social lives. This information was used to explore connections between diabetes self-care management and their perception of risk.



Highlighted human figures

Smiley faces

Bar graph

Comparison bar graph

Traffic light

1000 randomised human figures

Figure 5.2 Risk communication tools in clinical settings

In addition to the data collected from the semi-structured interviews, field notes were also written during and after the interviews (see Appendix 17). These notes included observations on participants' reactions, facial expressions during the interviews, particularly when the people were discussing their own risk. These also informed new ideas that the researcher needed to consider for subsequent interviews (Charmaz, 2006). In the first three interviews, the researcher found it difficult to write field notes during the interview as he was trying to ensure that the participants were asked all of the questions contained within the interview schedule. However, as the researcher became more confident regarding the interview questions it became easier to write field notes and also to keep the interview informal and conversational (Charmaz, 2006). The latter was achieved by asking well-planned open-ended questions and having a series of probes that increased the researcher's confidence and allowed him to concentrate on what the people with diabetes were saying. At other times, people with diabetes were very accommodative as they stopped talking and provided time for the researcher to write his notes. The researcher used different techniques to encourage the people with diabetes to talk more about their experiences (Charmaz, 2006). This included asking questions such as: "Is this your first time attending a diabetic retinopathy screening?" And using open-ended prompts, such as "Could you tell me a little more about you experience?" And, "Can you explain what you mean?"

The anonymity of the participants and individual practice anonymity were protected in all documentation relating to the study. The regional screening manager knew which practices were eligible to participate but did not know which practice or which individual participated. Practices were given a unique number and participants were given pseudonym.

The first step performed by the researcher after each interview was completed was to write a case summary (Charmaz, 2006). This started with the essentials of the interview; what made it interesting and also identifying what was special or peculiar about the case (what was common and what was different from others?) This early analysis helped the researcher to generate some initial ideas and themes (Charmaz, 2006). The researcher distinguished between what happened during the interview and his own ideas by drawing a circle around his ideas, which was mainly a description of what has happened during the interview and not an interpretation of the interview. The researcher also wrote a reflection after each interview as how the next interview could be improved

(Corbin and Strauss, 2008). The mp3 files were also downloaded to university computer promptly after the interview was finished.

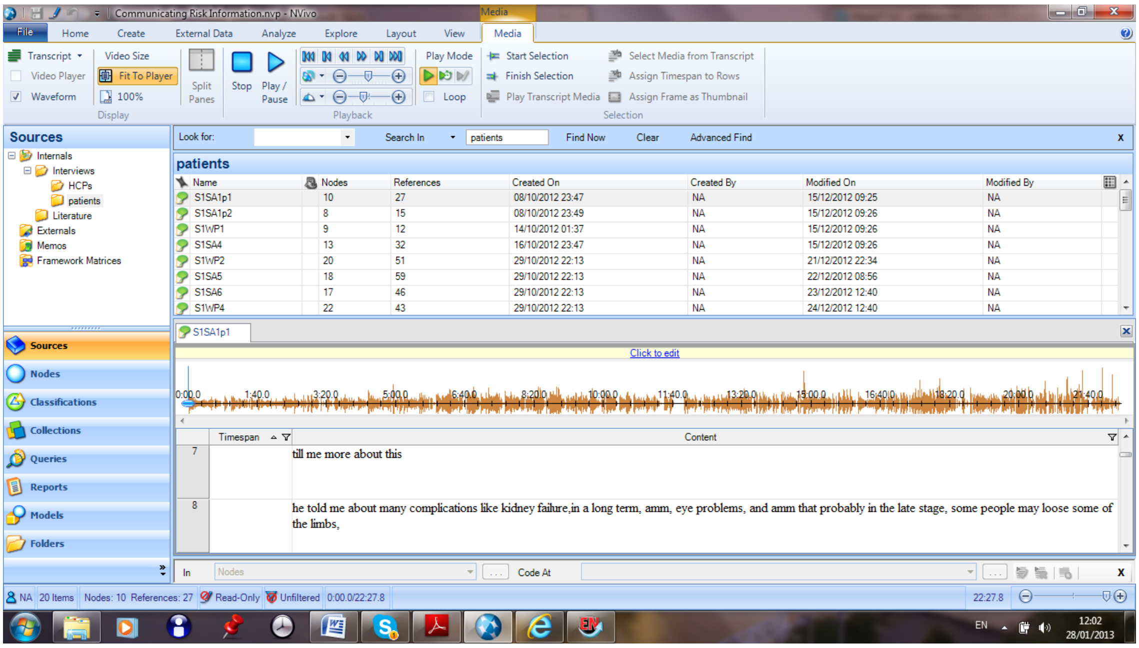
5.5.10 Semi-structured interviews with Health Care Professionals

The interviews with Health Care Professionals were conducted at the participant’s place of work or at their home at their discretion. Each interview was lasted approximately 45 to 60 minutes. The purpose of the Health Care Professionals’ interviews was to explore their views regarding how people with diabetes perceive diabetic retinopathy risk. These interviews also covered issues as how risk message about diabetic retinopathy risk and diabetic screening results should be communicated and what information should be included. The interviews also covered differences in understanding numerical risk information between people with diabetes and Health Care Professionals (see appendix 8: Health Care Professional’s interview schedule). Health Care Professionals were also asked about their views of using visual risk communication tools and to appraise existing risk communication tools that have been used in different clinical settings (Figure 5.2). They were also asked to about their views of the most appropriate tool that could be modified to develop a new diabetic retinopathy tool, which could be used to provide risk information about diabetic retinopathy to people with type 2 diabetes. The Health Care Professional’s anonymity and the individual practice anonymity were protected in all documentation relating to the study. This ensured that participants were not able to identify their practice or individual Health Care Professionals. Practices were given a unique number and participants were given pseudonym.

5.5.11 Data recording and transcription

All 25 interviews (20 interviews with anonymity and 5 interviews with Health Care Professionals) were audio-recorded and transcribed using a digital recording machine. All participants (people with type 2 diabetes and Health Care Professionals) were asked to complete and sign consent form giving their permission to record the interview. Data was recorded as mp3 folders. Should participants have refused to have their interviews recorded the researcher would have taken written notes. The quality of the recording was very clear due to the digital recording system and there was no problem encountered with the transcription process. A recording test was performed before each interview in order to test the machine and minimise data loss. A backup recording machine with extra batteries was also available for emergency use. Recording the interviews enabled the researcher to maintain more regular eye contact with participants and also to concentrate on what they were saying.

Interviews were transcribed verbatim by the researcher and checked by the researcher for any typing errors or missing text. The transcription process helped the researcher to engage more with the data and helped with the analytical process as the transcription progressed (Macaden and Clarke, 2006). NVIVO 10 software (Figure 5.3) was used to manage and organise the data. The software strengthens the analytical rigidity by improving simplicity with the ability to trace back the original data in an easy retrievable technique. The software was downloaded through the university website, and used to facilitate, organise, analyse, and structure information. All interviews were imported into the software for data management and analysis. The Figures below show the special aspect of the software that helped with data management. (Bazeley P., 2007).



patients

Name	Nodes	References	Created On	Created By	Modified On	Modified By
S1SA1p1	10	27	08/10/2012 23:47	NA	15/12/2012 09:25	NA
S1SA1p2	8	15	08/10/2012 23:49	NA	15/12/2012 09:26	NA
S1WP1	9	12	14/10/2012 01:37	NA	15/12/2012 09:26	NA
S1SA4	13	32	16/10/2012 23:47	NA	15/12/2012 09:26	NA
S1WP2	20	51	29/10/2012 22:13	NA	21/12/2012 22:34	NA
S1SA5	18	59	29/10/2012 22:13	NA	22/12/2012 08:56	NA
S1SA6	17	46	29/10/2012 22:13	NA	23/12/2012 12:40	NA
S1WP4	22	43	29/10/2012 22:13	NA	24/12/2012 12:40	NA

	Timespan	Content
7		till me more about this
8		he told me about many complications like kidney failure,in a long term, amm, eye problems, and amm that probably in the late stage, some people may loose some of the limbs,

Figure 5.3: NVIVO software

5.5.12 Stage One data analysis

Qualitative data analysis is an iterative process which started with the commencement of the research, progressed through the development of the research design, and continued through data collection. It was necessary for the researcher to engage with the data for the data analysis to be comprehensive and accurate concerning the social process that being investigated. This engagement involved the collection of data, the transcription and coding of data and also the reflection during these stages (Charmaz, 2006). Data analysis formed part of the research method used and was consistent with the philosophical underpinnings of a constructivist grounded theory approach. The results from the study were linked to the data, so that readers can follow the data through to the evaluation, clearly seeing how the results have emerged. The results in Stage One also led to further research ideas and questions that were explored in Stage Two.

The philosophical assumptions that people construct and interpret their social worlds underpinned decisions relating to both data collection and data analysis within this study. Evidently, the study was interested in the ways in which participants discussed and interpreted their perceptions and experiences in relation to diabetes, the ways in which they managed their diabetes and how they made sense of the potential complications and risks they associated with diabetes. One aspect of this was an interest in the meaning that participants attributed to diabetes, which was often framed in terms of their experiences. For example, one of the participants perceived his diabetes as “the simplest”, which can also be interpreted as the least dangerous signalled by the fact that he only used oral medication as a means of control:

> *“I think I have the simplest one, or I don’t know what you normally type it or write it, but it’s the simplest one, the safe side one, the normal average one. … I take tablets only, Glucophage since 2006.” (Bara, 55, South Asian, R0)*

It was also clear that when participants considered the risks associated with their diabetes that they tended to look outwards and their perceptions and experiences in relation to those around them. The following example illustrates how the same participant constructed his knowledge of associated risk through the experience of others, with the clear association of vision loss with the taking of insulin rather than oral medication:

> *"My mother in law had diabetes, she lost her eyes, and she lost her vision completely because of diabetes, she use to have insulin three to four times a day." (Bara, 55, South Asian, R0)*

5.5.13 Treatment of literature

For this particular study, literature was used from the very beginning of the study. As the study was addressing the methods of risk communication, it was significant for the researcher to be very familiar with the risk communication issues particularly when it involves providing sensitive or depressing information. Therefore, the researcher's knowledge has been expanded about the perception of risk and how to communicate risk information. This was very helpful in designing the interviews in addition to the purposive sampling that was used in the study as discussed earlier. It was important that the researcher ensure that the main aspects of risk communication and perception of risk are covered and not missed out during the interviews. Utilizing the literature all the way through the study process surely enhanced and encouraged the thought processes rather than suppressed or inhibited the researcher. It expanded the perspectives and possibilities for the data that was inspected more closely during the theoretical coding specifically.

5.5.14 Theoretical sensitivity

A key principle of social constructivist grounded theory is that the researcher adopts a reflective approach and considers their role and contribution to the resulting theory (Corbin and Strauss, 2008). Thus, the researcher reflected on their involvement and considered their role in the data collection process in relation to the interview questions, coding, and analysis. Charmaz (2006) notes that researchers are part of the world they study and the data they collect and, therefore, construct their theories through their past and present participations and interactions with people, perspectives, and research practices. This was evident in this study as the researcher’s role was integral to analysis process as the theory that emerged from this study was developed by the researcher. Despite the fact that participants were the main data source, the researcher integrated with the data by creating and developing the questions and identifying the most important areas to be explored. Furthermore, the researcher’s academic background and professional job as a nurse working with people with diabetes and encountering eye problems shaped the study.

5.5.15 Validity and reliability

Validity in data analysis depends on the fair representation of the data, which can be completed by making sure that the results are generated from the data collected. Two academic supervisors undertook coding alongside the researcher in line with good practice (Charmaz, 2006). The widespread experience of the secondary coders highlighted further nuances in participants’ responses and resulted in constant development of the coding structure and the researcher’s understanding. Data was coded consistently from the beginning to the end by three different coders (NA, JS, and AD) to minimise the possibility of the interpretation bias and to maintain consistency testing. The following example shows disagreement between the researcher and the academic supervisor, as the following quote was initially coded by the researcher (NA) as “REALISTIC”:

Symptomless participants appeared to be “REALISTIC” as they have had their screening test for many years and yet the results were always negative:

“I am not going to have any complications with diabetic I don't think, it’s been stable now for a couple of years 3 years now I mean I just have two tablets and I don't have any problem you know so nothing varies with me I can as Megan said like she does my blood sugar for me and it’s no different to what we had 6 months ago so I am not too concerned really at all at the moment” (Nick, 79, R0)

However, it was suggested by the academic supervisor JS that people may not believe themselves to be at risk because they are bio medically trained but more because they are optimistic in light of their experiences. This participant may be in this category. Such coding and interpretative discussions were resolved through discussion.

5.5.16 Position of the researcher

It is essential that the researcher reflects upon his/her position in the research and sets out how their role as a researcher influenced or shaped the study (Creswell, 2003). The researcher in this study has a clinical background as an ophthalmic nurse with over twenty years of experience in a clinical setting. At the point of commencing this research the researcher had worked in the field for nearly two decades. He had conducted forty five qualitative interviews with people living with type 2 diabetes and their Health Care Providers. At the start of the research, the researcher has very limited personal experience as to what it was like to live with long term illness and had never experienced receiving sensitive risk information from his Health Care Provider. However, during the time of conducting this study, he was invited by his general practitioner to attend a general cardiovascular check-up. After the examination, the results were communicated to him using different formats; probabilities and a visual tool. For the first time, he had to consider the methods of communicating risk information from a personal perspective. The time that the Health Care Professionals spent with him during consultation and way in which risk information was presented made him acknowledge his personal experience of communicating risk information. The researcher started by considering a few questions such as: Who needs to know information about risk perception? Why is understanding people's perception of risk important? And what information about risk perception and methods of risk communication is required? The implications of this, from a methodological point view, was that the researcher was not only interviewing people with type 2 diabetes from a research perspective the researcher was also interviewing them with an increasing personal experience of perception of risk having received risk information from a Health Care Provider. Although this personal experience was relatively limited, the researcher believes that this experience guided him to a greater depth of understanding and possibly connection with participants. It was also crucial for the researcher to separate his role as a researcher from his professional role as an ophthalmic nurse. Therefore, those participants who had any questions or concerns regarding their health care were referred to their GP practice or local Patient Advice Liaison Service (PALS) as per the research protocol.

5.5.17 Memo writing

Writing theoretical memos provided a written record of the data analysis process that documents the researcher’s thoughts and ideas on certain issues that have emerged during the interviews. This provides information on thought progression so this could be reviewed and modified through the data analysis process (Corbin and Strauss, 2008). Memo writing was continuous during the data gathering process as recording the flow of thoughts assisted the open coding analysis and facilitated the process of constant comparison. It is helpful at this stage to provide a worked example of memo writing. One participant told his story of being diagnosed with type 2 diabetes and at this point in his narrative he reflected on the impact of diabetes on his sight and his priorities regarding self-care management.

“I think if the diabetes keeps high that could affect the eye could like go blind blindness or something like that. So I’ve got to keep my diet keep controlling my diet, and for myself probably try to do exercise and take the medicine on time.” (Yazan, 40, South Asian, R0)

The following exerts are from the memos written by the researcher:

“Yazan is highlighting the potential impact of diabetes on his sight as it could lead to blindness or sight loss if high level of blood sugar continues. He is establishing a diabetes self-care management plan to keep his diabetes under control by controlling his diet, exercising, and taking (diabetes) medication on time. The importance of diabetes self-care management is emphasised as he uses verbal confirmation such as I, my diet, myself.”

This led the researcher to consider whether the prevention of diabetes complications was the central focus for people with diabetes who don’t have eye complications and, if so, how does prior eye complications influence the perception of risk? The direction of the theoretical sampling was guided by the following question: in other people with diabetes with different grade of diabetic retinopathy or visible eye complications does prevention of complications or further deterioration feature the same? The aim of this was not only to expand understanding of prevention of diabetic retinopathy, but also to look at how diabetes and the absence of eye complications relate to each other.

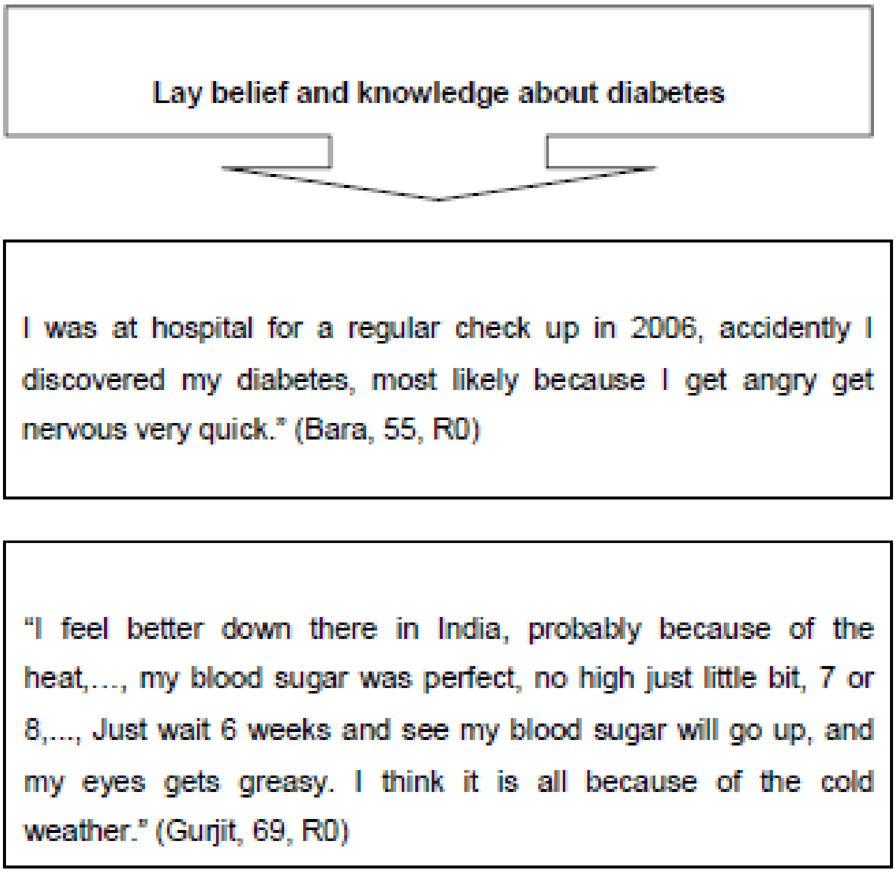
5.5.18 Field notes

In addition, field notes documented important observations and indicated a reflexive approach. These reflect the self-awareness of researcher regarding their own influence on research process achieved throughout critical self-consciousness. Field notes were also important to record participant’s reactions to particular questions and to compare these with the interview response (Charmaz, 2006). Appendix 17 illustrates an example of field note.

5.5.19 Coding

As per the principals of Charmaz’s constructivist grounded theory, the process of data analysis was rigorous and started at the same point of as the data collection process (Charmaz, 2006). Coding has helped the researcher to manage unstructured data and directed him to concentrate on further data collection. Descriptive codes for textual data were taken from the semi-structured interviews. This was performed in two main phases: 1) an initial phase involving naming each word, line, or section of data and followed by 2) a selection of significant frequent codes in order to synthesise and organise the large amount of data. During the initial coding, the researcher was flexible to all possible theoretical directions indicated by the initial reading of the data. The researcher started by making sense of what diabetes meant to people with diabetes and to Health Care Professionals. Careful attention was given to understand acts, accounts, views, scenes, and silences from participants’ view. The researchers then created the codes by defining what he saw in the data.

Data analysis in constructionist grounded theory consists of three sets of codes: open, axial, and selective coding (Charmaz, 2006). Open coding: implicates the primary breaking of data to explore all the possible aspects or information about the phenomenon being studied. This results in the progress of descriptive codes from the initial data collected. In this study, all the transcripts were subjected to open coding by allocating meaningful theme names to each line or paragraph of the transcript, as shown in the following figure (Figure 5.4).



Lay belief and knowledge about diabetes

I was at hospital for a regular check up in 2006, accidently I discovered my diabetes, most likely because I get angry get nervous very quick." (Bara, 55, R0)

"I feel better down there in India, probably because of the heat,..., my blood sugar was perfect, no high just little bit, 7 or 8,..., Just wait 6 weeks and see my blood sugar will go up, and my eyes gets greasy. I think it is all because of the cold weather." (Gurjit, 69, R0)

Figure 5.4: The process of Open Coding

This was followed by axial coding, known as theoretical coding (Strauss *et al.*, 1990), which examined the relationship between categories of the phenomenon in the data. Axial coding: involved the development of a coding paradigm which identified a central phenomenon, explored causal conditions, and identified the context that influenced the actions. In this level of coding, the descriptive codes were grouped at a more abstract level and linked by relationships that emerged from within the codes. According to Jeon (2004), the stage of open coding and axial coding is recognized as substantive coding which enabled conceptualisation of "the empirical substance of the area of research". Axial coding enabled links to be made between categories. Furthermore, comparisons have been made between codes to enabled links that have been made between them and made the emerging analysis solider. The following figure (5.5) shows an example of the outcome of axial coding was linking a number of codes about people's knowledge and understanding of diabetes with codes about the impact of diabetes on risk perception. These codes were linked together as a result of axial coding and the category of personal factors that affects perception of risk emerged.

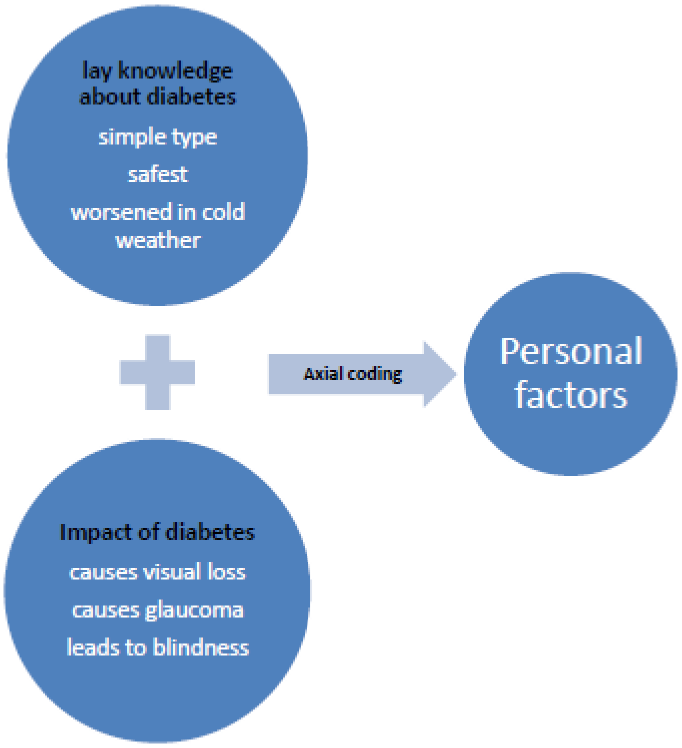


Figure 5.5- The process of Axial Coding

Selective coding: involved the integration of categories from axial coding forming conceptual links that facilitates the interpretation of the data. This level of coding seeks to establish a core category that establishes connections between itself and other categories (Charmaz, 2006). This means that the data was viewed theoretically rather than descriptively. The following Figure (Figure 5.6) illustrates the processes of selective coding:

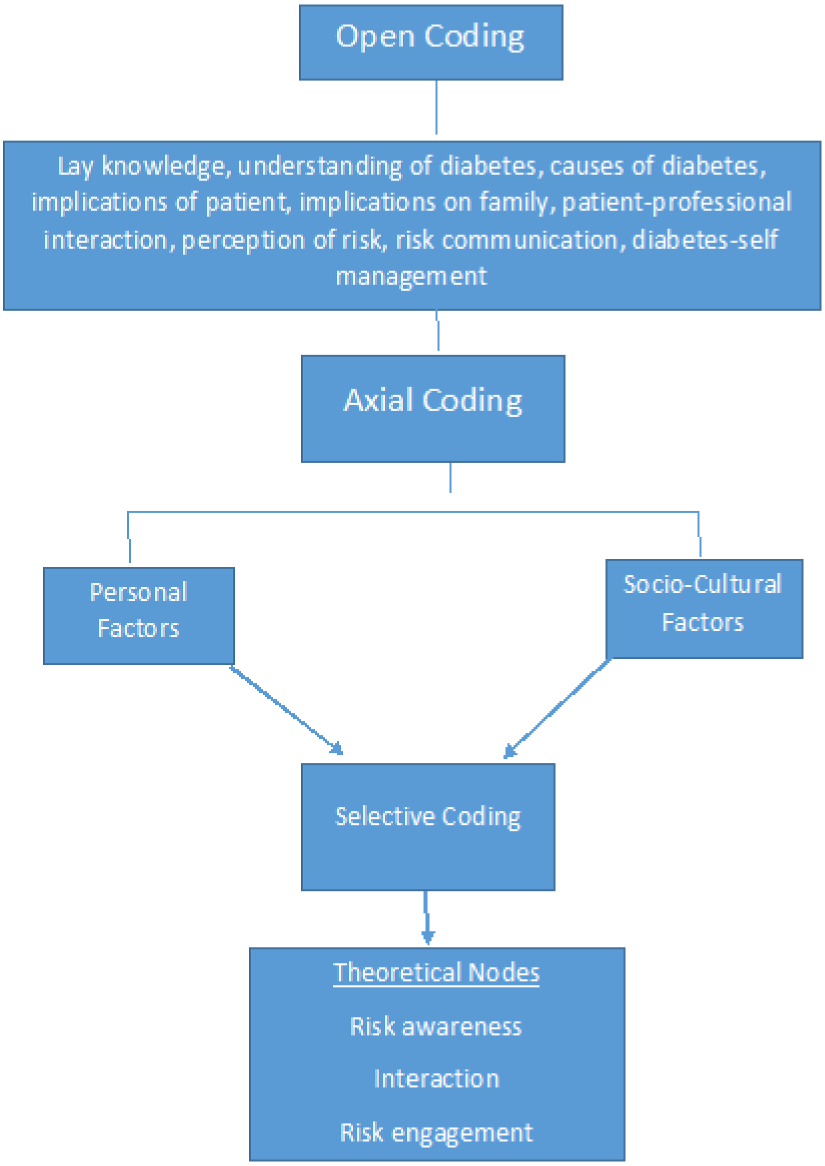


Figure 5.6 The Process of Selective Coding

5.5.20 Constant comparative analysis

Thematic analysis of the data was conducted concurrently and following the fieldwork phase, by constant comparison of the data. The researcher also compared within and between the data from people with diabetes and Health Care Professionals' interviews to gain insight into both sets of participants' views of risk communication and understanding. In addition, constant comparison was performed between different ethnicities, gender, and people with different grade of diabetic retinopathy. These themes helped produce the new risk tool and generate further themes that were explored in the interviews with people with diabetes and Health Care Professionals. A potential problem with thematic analysis is that the researcher subconsciously has pre-conceived ideas regarding themes (Charmaz, 2006), and potentially may failed to spot other themes which may be present in the data. This method of comparing and raising questions is rooted in the entire research process to sharpen the researcher's thoughts and therefore help understand the content of the data. The researcher used the constant comparative method not to describe or verify comparisons, but rather to assist in the conceptualization and categorization of the data and analysis (Charmaz, 2006).

The following quotes highlight the constant comparison of data from people with diabetes and Health Care Professionals in regard to how they make sense of risk messages that are designed to instil anxiety as a means of changing certain behaviours:

"Probably strong messages would be an eye opener, wouldn't it, to say that blindness could actually happen. I think it depends on your consultant as well at the hospital and, yes I just think you can't have a nicely nicely approach, you have got to have that with your consultant yes but they do need to be more, you know put fear into the patient." (Claire, 45, White British, R3)

"I normally say that the diabetes has damaged their retinae with high sugars and that this is non-reversible damage, but then we can stop further progression with good control" (Andy, Ophthalmologist, White British)

5.5.21 Conclusion of Stage One

In Stage One of the research, a qualitative study was conducted using semi-structured interviews with a purposive sample of 25 participants. Of these, 20 participants were diagnosed with type 2 diabetes, two primary care physicians, two ophthalmologists, and one retinal screener. People with diabetes were purposely recruited to fall into four groups of people with diabetes with different grades of diabetic retinopathy. The aim of Stage One was to explore how people with type 2 diabetes perceive diabetic retinopathy risk, explore people with diabetes's understanding and interpretation of risk information and different risk communication format, and to appraise existing risk communication tools that have been used in other clinical settings. Data was analysed and used to develop a risk communication tool to provide risk information about diabetic retinopathy and diabetic screening results to people with type 2 diabetes to be used in Stage Two.

5.7. Stage Two

5.7.1 Introduction

The rest of the chapter provides information on the methods used in Stage Two of the study. The researcher begins by summarizing the aims and objectives of this stage and how these influenced the research methods used.

5.7.2 Aims of Stage Two

1. To appraise a newly developed risk communication tool that was developed to communicate risk information about diabetic retinopathy to people with type 2 diabetes and risk information about diabetic screening results (Appendix 14)
2. To explore the influence of the newly developed risk communication tool on risk perception
3. To explore the influence of the new developed risk communication tool on diabetes self-care management
4. To establish a method(s) by which risk information about diabetic retinopathy can be effectively communicated to people with type 2 diabetes to help informed choice

A qualitative approach enabled the research to engage people with diabetes and to focus on the ways in which they appraised a new risk tool and engaged with it. Furthermore, it allowed the researcher to explore possible ways of communicating risk information about diabetic retinopathy and about diabetic retinopathy screening to people with type 2 diabetes. The newly developed diabetic retinopathy risk communication tool is aimed at people with type 2 diabetes who are at low risk of developing diabetic retinopathy and do not require annual diabetic retinopathy screening. Therefore, only people with type 2 diabetes who identified as White British and South Asian and who have either no diabetic retinopathy (R0) or background diabetic retinopathy (R1) were included at this stage.

5.7.3 Stage Two research setting

Stage Two of the study used the same research sites as in Stage One. This included five General Practitioners (GPs) Practices in a large Primary Care Trust and one Secondary Care Trust. These sites were chosen because they represented populations living in different areas including areas of deprivation and more wealthy locations. Due to the high prevalence of diabetic retinopathy among people of South Asian background in the United Kingdom (Raymond *et al.*, 2009), it was essential to include them at this stage in order to appraise the new risk tool and to explore their understandings of it.

5.7.4 People with diabetes Inclusion/Exclusion Criteria

People with diabetes inclusion criteria

- Aged 18 years or over
- Able to give informed consent
- Has a confirmed diagnosis of type 2 diabetes
- Has background diabetic retinopathy (R1) or no retinopathy (R0)
- Has attended at least one diabetic retinopathy screening appointment within the last 3 months
- Speaks English or a language that available interpreters are able to interpret at interview and can translate study materials

People with diabetes exclusion criteria

- Unable to give informed consent, for example has a learning disability or Alzheimer's Disease
- Unable to be interviewed in a language that can be translated by the researcher or available interpreters

- High risk patients with diabetic retinopathy grade (R2) or (R3)
- People with type 1 diabetes

5.7.5 Stage Two practice recruitment

The same process of research site recruitment used in Stage One was followed in Stage Two to ensure consistency in the study. These sites were chosen to represent a diverse population with pockets of affluence and deprivation. The Index of Multiple Deprivation was used to identify practices with the highest and lowest levels of deprivation. GP practices were chosen from the top and the bottom levels of the index of multiple deprivations and identified practices in areas with high and low deprivation. The Index of Multiple Deprivation score varied between the highest score of 57.46 and the lowest of 9.55, and the screening uptake level varied between 57% and 96% (Table 5.4). Demographic factors such as gender, ethnicity, socio-economic status, and working age, are important factors affecting screening uptake (Scanlon *et al.*, 2008; Millett and Dodhia, 2006). These factors impact on people's attitudes, behaviours, perception of risk, and as a result, may impact on people's risk perception and their diabetes self-care management. The researcher again contacted the research sites and gave an overview of this aspect of the study and again sought their consent to take part in the study. Information about the study was again sent by post or electronically. The same five practices and Secondary Care Trust that participated in Stage One agreed to participate in Stage Two. Consent forms were then obtained from practice managers and Secondary Care Trust research and development head. The researcher booked an appointment with the practice manager and discussed the recruitment process and particularly the differences in the inclusion/exclusion criteria, which are different from Stage One.

Table 5.4 Practice Characteristics

Practice number	IMD score	IMD Quintile	Screening uptake
Practice 1	24.13	Deprived (4th quintile)	68%
Practice 2	44.99	Most deprived (5th quintile)	57%
Practice 3	9.72	Above average (2nd quintile)	96%
Practice 4	9.55	Above average (2nd quintile)	85%
Practice 5	57.46	Most deprived (5th quintile)	72%

IMD: Index of Multiple Deprivations

5.7.6 People with diabetes recruitment

Having identified appropriate GP practices and a Secondary Care Trust, the regional screening team again used their database to purposively identify a list of people with diabetes according to age, gender, ethnicity that have either background diabetic retinopathy (R1) or no diabetic retinopathy (R0) and who had attended at least one diabetic retinopathy screening. A list of potential people with diabetes was then sent to the identified gate keepers in each research site; these included practice staff, GPs, screeners, and nurses. The recruitment criteria were again explained to gate keepers, which was the same as in Stage One with certain differences in the inclusion criteria.

The recruitment of people with diabetes was again carried out by the gate keepers. The influence of gate keepers on recruitment process was again considered and a power point presentation was arranged with gatekeepers to facilitate and recruit people with type 2 diabetes according to the inclusion criteria. Every effort was made, within time and budgetary limitations to facilitate access for people with diabetes for whom English is not their first language (Papadopoulos, 2004; Papadopoulos, 2006; Zeh *et al.*, 2012). A detailed translation and interpretation protocol that details these procedures can be found in Appendix 5. Gate keepers spoke to potential people with diabetes and provided an overview of the study, seeking permission to post out or email a participant information sheet including consent forms. Gate keepers explained to the people with diabetes that entry into the study was entirely voluntary and that their treatment and care would not be affected by their decision. This means the researcher did not receive any details of the people with diabetes's prior to informed consent being obtained. Potential participants were again given the opportunity to ask questions to the practice staff or to call the researcher on the phone number provided in the participant information sheet before considering their participation and before sending their consent form to the researcher. Bilingual link workers were available to allow potential participants to be contacted in an appropriate language by telephone face-to-face at the research site in order to encourage the recruitment of non-English speakers. The link workers received information about the study from the researcher to identify the appropriate linguistic skills required during recruitment.

As in Stage One up to fifteen people with diabetes per practice were invited to participate in the research. A total of sixty nine people with diabetes potential participants were invited to join the study over a three month period between January 2013 and March 2015. A total of twenty people with type 2 diabetes agreed to participate in Stage Two of the research. They sent their signed and dated consent form to the researcher using the prepaid envelop that was supplied along with the patient information pack. These participants were then contacted by the researcher by telephone within a week of receiving their consent form to arrange an interview at a time and location of their choice. The interviews within each practice were completed within two weeks and transcribed in a week. Therefore, the completion of recruitment process and data collection was done within 8-10 weeks. The study intended to include equal numbers of participants in each ethnic group. However, due to the restrictions in time and resources, the first 20 participants to consent to take part were included in Stage Two. Of these, nine were White British and eleven were South Asians. Nine participants were females and eleven were males. Participants were divided into two groups (Table 5.4) based on their grade of diabetic retinopathy. Group one: ten participants (five White British and five South Asians) with no diabetic retinopathy (R0); Group two: ten participants (four White British and six South Asians) who had background diabetic retinopathy (R1). As in Stage One, participants in stage 2 also received a £20 research incentive to encourage them to participate in the study. Previous studies show that incentives improve representation in research (Olsen *et al.*, 2012; Thomson *et al.*, 2012).

Table 5.5 Sampling Strategy for Stage Two

Group	Grade of diabetic retinopathy	White British	South Asians	Total
Group 1	No diabetic retinopathy (R0)	5	5	10
Group 2	Background diabetic retinopathy (R1)	4	6	10
Total		9	11	20

5.7.7 Data collection

A total of 20 semi-structured interviews were conducted during Stage Two. The data for Stage Two was collected by the researcher (NA) over a three month period from February, 2013 to April, 2013. As mentioned in relation to Stage One, current practice suggests that diabetic eye screening results should be reported to people with diabetes within three weeks of their screening appointment (NSC, 2003). Therefore, interviews in Stage Two were also conducted within three months of participants screening appointments in order to make sure that they had received their diabetic retinopathy screening results. As soon as a consent form was received by the researcher, each participant was contacted to arrange the interview at a time and place of their preference.

5.7.8 Stage Two Semi-Structured Interviews

Twenty semi-structured interviews with people with type 2 diabetes were conducted in Stage Two. Each interview lasted for approximately 45 to 60 minutes. All interviews were conducted at a time and place of the participants' choosing (see Appendix 4 for interview schedule). Thirteen interviews were conducted at a hospital, 4 interviews at their GP surgery, and 3 interviews were conducted at a screening centre. All people with diabetes were English speaking and were able to be interviewed in English language as per their preference. A participant information pack which included an invitation letter, consent form and participant information sheet were provided by the gatekeepers, either at participants'' regular visit to their GPs, screening centre or sent out by post or email. Consent forms were signed and dated by participants before they entered the study. Consent forms were then sent to the researcher in a prepaid envelops. One copy of this was be kept by the participant and second copy was kept by the researcher.

The researcher started each interview by greeting the participant and summarizing the purpose of Stage Two. The researcher also spent time addressing participants' questions to ensure that they understood the information in the participant information sheet and their involvement in the study. Although written consent had been obtained at an earlier date and participants had appropriate time to consider participation, informed consent was gained again to conduct the interview and to audio-record it. Participants were reminded of their right to leave the study at any time without giving reason or it is affecting their treatment. Interviews in Stage Two of the study asked participants to appraise the new risk communication tool. The aim of this stage was to appraise the risk tool (Figure 5.7) and provide risk information about modifiable risk factors associated diabetic retinopathy. Details about the development process of the risk communication tool is discussed in section 7.2.

Various subjects were explored during Stage Two interviews (see Appendix 4). These included their views of the new risk communication tool, perception of risk, the influence of the new tool on diabetes self-care management, and its impact on anxiety level. However, in order to avoid inducing anxiety to people with diabetes, perception of risk was explored using hypothetical blood sugar readings. For example, participants were asked how they perceived the risk of diabetic retinopathy if someone's HbA1c was in the green zone (HbA1c below 7%), in the amber zone (HbA1c between 7% and 9%), or in the red zone (HbA1c 9% or above) as shown in the Figure 5.6. This information also was used to explore the relationship between perception of risk and its impact on diabetes self-care management and on anxiety level. However, a few of the people with diabetes had performed the self-risk assessment by using their actual HbA1c results. This self-risk assessment was followed by questions about diabetes self-care management. People with diabetes were asked how they would respond to a different HbA1c results in order to explore the potential impact of the risk tool on diabetes self-care management and on anxiety level or distress. Background data about people with diabetes, their families and their settings was also collected during the interview to provide a fuller understanding of their lives and to facilitate the discussion about the new tool. Data was also collected from participants to identify what kind of risk information should be presented when communicating risk information about diabetic retinopathy to people with diabetes.

Figure 5.7 Diabetic Eye Risk Communication Tool

In Stage Two of the study, the researcher also had the opportunity to ask questions that arose after the data analysis of Stage One, particularly about risk perception, anxiety, and risk communication, which enabled the researcher to fill certain gaps in understanding and to strengthen the analytic categories. Along with the predefined interview questions, the researcher was also keen for people with diabetes to suggest areas that they regarded as pertinent and significant to the research subject. The researcher was open to the idea of including these within subsequent interviews. In addition to the semi-structured interviews, field notes were again collected relating to patient’s reactions and facial expressions during the interviews particularly when they performed self-risk assessment and when the idea of extending the diabetic retinopathy screening intervals was discussed. In addition to the semi-structured interviews, field notes (Glaser, 2001) were again collected such as patient’s reactions to the new risk tool, understanding of different level of risk, facial expressions during the interviews particularly when the people were discussing their own risk. At this stage, the researcher found it easier to write field notes during the interview than was the case during Stage One. The researcher became more confident asking the interview questions, writing field notes at the same time, and keeping the interview informal and conversational (Charmaz, 2006).

The researcher was constantly focused and aware of the research questions by asking questions to appraise the new risk tool. The researcher used different techniques to encourage the participants to talk more about the new risk tool (Charmaz, 2006) starting with simple questions, such as have you used a risk communication tool before? And then asking for details using open-ended such as, Tell me about your experience with the risk communication tool? The people with diabetes were also asked to explain how the tool can impact on their diabetes self-care management.

Writing a case summary as soon as possible after each interview was completed was also a feature of Stage Two (Charmaz, 2006). As with the interviews in Stage One, this started with the fundamentals of the interview; what made it interesting, and also spotting what was unusual or strange about the case (what was frequent and what was different from others?) This helped the researcher to get some initial ideas and thoughts (Charmaz, 2006).

5.7.9 Data analysis

In Stage Two, twenty interviews with people with diabetes were audio-recorded using a digital recording machine. Data was recorded as mp3 folders. The recording, transcription process, and data analysis process were identical as in Stage One.

5.8. Ethical issues

There were a few issues in the study. People with diabetes received a £20 research incentive in order to encourage them to participate in the study, as well as their travel expenses. Research incentives were used because the evidence says it improves participation (Thomson *et al.*, 2012; Olsen *et al.*, 2012).

5.8.1 The role of gatekeepers

This study used gatekeepers in Stage One and Stage Two to facilitate the recruitment process. People with diabetes were accessed via established Primary and Secondary Care Trusts, who were invited to participate in the study. Gatekeepers used their knowledge and authority and were making significant decisions regarding the recruitment. The researcher conducted several meetings and carried out power point presentations to the research gate keepers to minimise their influence on the recruitment process in the following ways: 1) by explaining the importance of the recruitment process, 2) explaining the way they explain the research study to individuals, and 3) by providing information sheets to ensure that the people with diabetes had appropriate time to consider participation. However, this was a potential ethical issue as people with diabetes may have been over persuaded to participate or feared that their care would have been compromised. The researcher dealt with this issue by confirming informed consent at point of interview and confirming that people with diabetes had appropriate time to consider participation and they were happy to participate in the research prior to the interview. The researcher adopted strategies to increase interview participation by employing translators and link-workers.

5.8.2 Informed consent

Participation in this study was voluntary. Informed consent was sought from all participants, including those who do not speak English as their first language (Appendix 1 for Patients Informed Consent form, and Appendix 9 for Health Care Professional Informed Consent form). Participants were sent an information form detailing the aims of the study and explaining why they were being asked to take part, giving them at least one week to consider participation. Translation into other languages was considered, in accordance with Bhopal *et al.*'s (2004) and Birbili's (2000) translation guidance (see Appendix 5). This seeks to ensure that conceptual equivalence is achieved, rather than mere literal translation, and that an understandable level of language is used (i.e. not overly formal or 'high'). However, all interviews were conducted in English language as per participant's choice. Before interviews commenced, an opportunity was provided for all participants to ask questions prior to deciding whether to take part, to ensure that fully informed consent was given.

5.8.3 Risk of recognizing the researcher in the clinical setting

Some people with diabetes who took part in the study (Stage One and Stage Two) knew the identity and professional background of the researcher. In the main this occurred when the interview was conducted in the hospital, which was the researcher's place of work. Those who recognized the researcher (Dickson-Swift, 2007) may have answered differently and may did not provide completed answers to the research questions or enough information during the interview assuming that the researcher knew such information and has access to it due to the professional capacity. In such occasions, the researcher adopted a strategy and separated his role as a researcher from his profession. Research questions were said differently and asked again at different time during the interview. However, as an experienced ophthalmic nurse working with people with diabetes and known to some participants, it was difficult to deny professional understanding. Therefore, the researcher was able to negotiate with people with diabetes that if they had questions related to the research or clinical setting that these could be asked at the end of the interview. In addition, the researcher considered referring them to their practice or diabetes nurse to provide answers. One participant requested more information about the possibility of having diabetes related eye complications during the interview at the GP practice. The participant was offered a referral to the practice nurse to discuss the issue in more details. However, the participant preferred to discuss the issue with the ophthalmologist during their next visit as the participant felt that the ophthalmologist was the right person to provide such information.

The researcher sought to conduct interviews during his study days rather than working days to minimise risk of interference with patients and staff. Another significant issue was the concept of power and authority (Dickson-Swift, 2007) which was recognised prior to the interviews, whereby participants particularly the Health Care Professionals had the possibility to influence the proceedings (Dickson-Swift, 2007). Some of the Health Care Professionals were senior staff with existing experience in diabetes and diabetes eye complications. However, the researcher took charge of the interviews and maintained a sense of professionalism and kept focused during the interview to address research questions and control the timing and length of the interview.

5.8.4 Adverse events

The occurrence of adverse events as a result of participation within this study was not expected. Although people with diabetes appeared calm and relaxed during and after the interview, the interviews did raise issues regarding diabetic screening, such as risks and benefits of diabetic eye screening, which was sensitive to some people with diabetes. This issue was raised mainly during Stage Two after using the new risk tool when the participants began to discuss their own risk in relation to the factors presented in the risk communication tool. However, this issue did not appear to be significant to participants as the tool confirmed that they were low risk participants. The other issue that was raised by people with diabetes was regarding the possible change of diabetic retinopathy screening intervals. In such cases, where the people with diabetes raised a concern or were not very pleased with potential changes that they had heard about from their Health Care Providers the researcher made a point of reiterating the contact numbers of counselling services in the hospital, as well as voluntary organizations such as Diabetes UK. In addition, the researcher did offer to contact a family member or friend, when required. People with diabetes were reminded in their information letter as well as before conducting the interview that they are in no way obligated to take part and could withdraw at any time without giving any reason. Where people with diabetes had any questions or concerns regarding their health care, they were referred to their GP practice or local Patient Advice Liaison Service (PALS) as appropriate.

5.8.5 Identity protection for participants

Whilst the regional screening teams knew which practices were eligible to participate they were not informed as to which practices or patients/professionals consented to participate. When the data is presented here and in other environments practice and participant's identities is disguised (for example, by number or pseudonym) to protect the identities of all participants and the practices.

5.8.6 Confidentiality

In order to ensure that confidentiality was maintained during the research process, the following points were taken into consideration:

1. Raw data (e.g. audio tape recordings and field notes) were stored in a locked filing cabinet in a private office.
2. All transcribed data were stored on password protected computer files.
3. Anonymity was assured by (a) the use of pseudonyms for all participants and (b) potentially identifiable information being deleted from transcripts.
4. No personal data were stored on the same document as the transcripts.
5. The data was stored in a secure area of the medical school at University of Warwick and will be kept for 7 years according to university policy.

5.8.7 Researcher safety

The interviews with people with diabetes and Health Care Professionals were mainly conducted in NHS premises, where no risks to the researcher were anticipated. The researcher had accessed these establishments with permission of the individuals responsible for managing them. However, some of the interviews with people with diabetes took place in participants' homes, which raised the issue of ensuring researcher safety. Although it was unlikely that there was any threat to the researcher's safety, the following steps were observed to minimize the risk:

- The researcher advised a member of the supervisory team of any interview that is scheduled to take place in a participant's home;
- The participants' name, address and telephone number were given to a member of the supervisory team for the purpose of ensuring researcher safety and were destroyed when that interview had finished;
- The researcher provided an estimated time of interview completion, allowing between approximately 1 hour and 2 hours;
- The researcher telephoned the supervisor when the interview was completed, to confirm his safety;
- Should the supervisor have not received the confirmatory phone call within the maximum time then they would first telephone the researcher's mobile number and if there was no response, take appropriate action.

5.9. Conclusion of Stage Two

In Stage Two of this research, a total of twenty people with type 2 diabetes were recruited. Participants were divided into two groups based on their grade of diabetic retinopathy. Group one: ten participants (five White British and five South Asians) with no diabetic retinopathy (R0); Group two: ten participants (four White British and six South Asians) who had background diabetic retinopathy (R1). The aims of Stage Two were to appraise a newly developed risk communication tool that was developed to communicate risk information about diabetic retinopathy to people with type 2 diabetes, to explore the influence of the new developed risk tool on risk perception and on diabetes self-care management, and to establish a method(s) by which risk information about diabetic retinopathy can be effectively communicated to people with type 2 diabetes. Semi-structured interviews were conducted between February 2013 and April 2013 and lasted between 45 to 60 minutes. All twenty interviews were audio-recorded and transcribed using a digital recording machine. Data was analysed using constructivist grounded theory approach.

Chapter 6. **Stage One results**

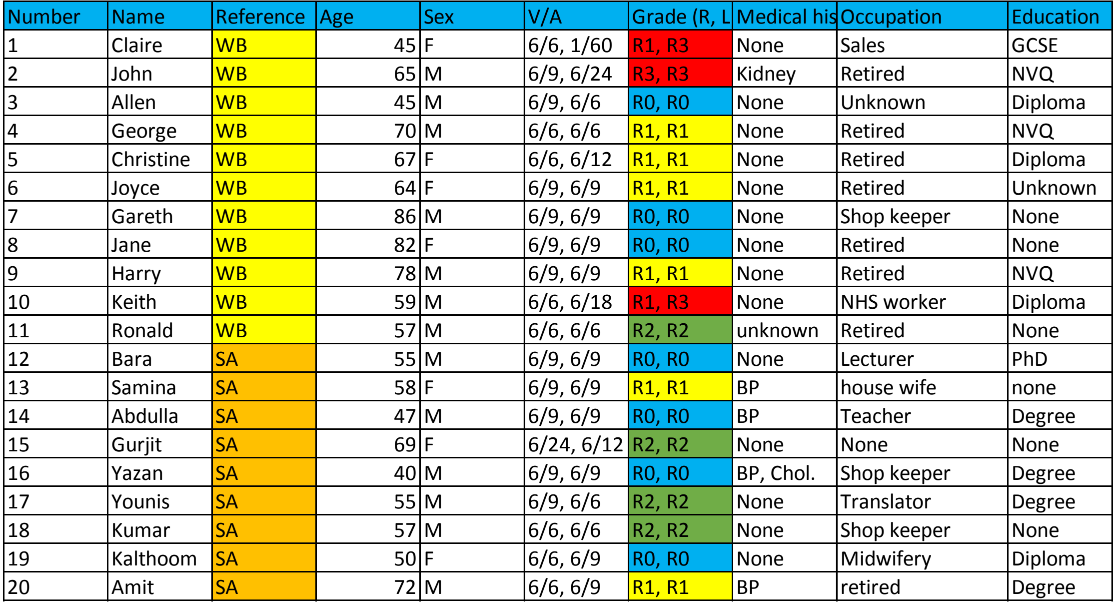
6.1. Introduction

This chapter presents an analysis of the stage one interviews that were designed to explore how the risks and benefits of diabetic retinopathy screening are understood by people with diabetes and Health Care Professionals. The interviews also investigated how people with type 2 diabetes and Health Care Professionals perceive risk information about diabetic retinopathy using numerical and textual format. In addition, they sought to explore the influence of risk information on risk perception and to appraise existing risk communication tools. Finally, the interviews were used to develop a new diabetic retinopathy risk communication tool that can be used to communicate risk information about diabetic retinopathy. The chapter begins by presenting people with diabetes' knowledge and beliefs about diabetes and diabetic retinopathy. The chapter then explores the views of people with diabetes regarding the influence of knowledge and beliefs on risk perceptions of people living with diabetes. And finally, it provides views of the different risk communication tools that have been used in other clinical settings in order to modify one tool to facilitate communicating risk information about diabetic retinopathy to people with diabetes. The chapter will demonstrate that the participants understandings and the perceptions of risk was highly subjective, premised upon their personal circumstances, constructed in relation to those around them and influenced by cultural differences and beliefs. Twenty people with type 2 diabetes and five Health Care Professionals participated in stage one of the study. Their socio-demographic characteristics are shown in Table 6.1 and table 6.2.

Table 6.1 Stage One socio-demographic characteristics

Interview participant	Number 20 People with diabetes
Range age	40-86 years
Mean age	62yrs
Gender	
Male	13
Female	7
Ethnicity	
White British	11
South Asian	9
Grade of Diabetic Retinopathy	
No diabetic retinopathy (R0)	7
Background diabetic retinopathy (R1)	6
Pre-proliferative Diabetic Retinopathy (R2)	4
Proliferative Diabetic Retinopathy (R3)	3
Health Care Professionals	
Ophthalmologist (White British)	2
General practitioner (South Asian)	2
Diabetic screener (White British)	1
Level of education	
Further education (diploma) or Higher education (Masters or PhD)	9
Compulsory education (O level or GCSE) or no qualification	11

Table 6.2 Stage One Participants Characteristics



Number	Name	Reference	Age	Sex	V/A	Grade (R, L	Medical his	Occupation	Education
1	Claire	WB	45	F	6/6, 1/60	R1, R3	None	Sales	GCSE
2	John	WB	65	M	6/9, 6/24	R3, R3	Kidney	Retired	NVQ
3	Allen	WB	45	M	6/9, 6/6	R0, R0	None	Unknown	Diploma
4	George	WB	70	M	6/6, 6/6	R1, R1	None	Retired	NVQ
5	Christine	WB	67	F	6/6, 6/12	R1, R1	None	Retired	Diploma
6	Joyce	WB	64	F	6/9, 6/9	R1, R1	None	Retired	Unknown
7	Gareth	WB	86	M	6/9, 6/9	R0, R0	None	Shop keeper	None
8	Jane	WB	82	F	6/9, 6/9	R0, R0	None	Retired	None
9	Harry	WB	78	M	6/9, 6/9	R1, R1	None	Retired	NVQ
10	Keith	WB	59	M	6/6, 6/18	R1, R3	None	NHS worker	Diploma
11	Ronald	WB	57	M	6/6, 6/6	R2, R2	unknown	Retired	None
12	Bara	SA	55	M	6/9, 6/9	R0, R0	None	Lecturer	PhD
13	Samina	SA	58	F	6/9, 6/9	R1, R1	BP	house wife	none
14	Abdulla	SA	47	M	6/9, 6/9	R0, R0	BP	Teacher	Degree
15	Gurjit	SA	69	F	6/24, 6/12	R2, R2	None	None	None
16	Yazan	SA	40	M	6/9, 6/9	R0, R0	BP, Chol.	Shop keeper	Degree
17	Younis	SA	55	M	6/9, 6/6	R2, R2	None	Translator	Degree
18	Kumar	SA	57	M	6/6, 6/6	R2, R2	None	Shop keeper	None
19	Kalthoom	SA	50	F	6/6, 6/9	R0, R0	None	Midwifery	Diploma
20	Amit	SA	72	M	6/6, 6/9	R1, R1	BP	retired	Degree

WB: White British, SA: south Asian, V/A: Visual Acuity

6.2. Individual’s knowledge and beliefs about diabetes and diabetic retinopathy

6.2.1 Understanding diabetes and diabetic retinopathy

The start of the interviews with participants was designed to gain an understanding of the ways in which they made sense of their diabetes and their knowledge and understanding about the condition and the associated risks. It was clear that many of the people with diabetes in this study lacked certain knowledge regarding their diabetes, including the complications associated with it and regarding diabetes self-management. For example, whilst they all knew that they were diagnosed with diabetes, many were unable to specify the type of diabetes they had. Participants variously described their diabetes in many different ways, such as “type b”, “class b”, “second type”, “simplest”, “safest”, and the “safe side one”:

“I suffer from type b diabetes since two years. I take tablets normally.” (Younis, 55, South Asian, R2)

“I think I have the simplest one, or I don’t know what you normally type it or write it, but it’s the simplest one, the safe side one, the normal average one. … I take tablets only, Glucophage since 2006.” (Bara, 55, South Asian, R0)

When discussing the perceived cause of their diabetes people with diabetes put forward a wide range of various possible causes. For example, many of them attributed the cause of their diabetes to stress and certain aspects of negative emotions:

“I was at hospital for a regular check-up in 2006. Accidentally I discovered my diabetes, most likely because I get angry, get nervous very quick.” (Bara, 55, South Asian, R0)

A number of the people with diabetes also believed that their diabetes was inherited as they had a number of family members with diabetes:

“I was only 45 when I first had it. …I thought I was too young to have diabetes, but my doctor explained it to me as we all have diabetes, the whole family, we got it from our father side, me, my sister and young brother although he is younger than me he had diabetes longer than me.” (Kalthoom, 50, South Asian, R0)

Moving on, their knowledge and understanding in relation to the potential risk factors that might lead to them developing diabetic retinopathy was also wide-ranging. Although most of them recognized high levels of blood glucose as a risk factor, the participants in this study put forward a range of risk factors associated with developing diabetic retinopathy:

“Well, blood pressure will be one, cholesterol will be another one, may be the eye condition, glaucoma could be another one, emm, emm, anything that could complicate the case.” (Younis, 55, South Asian, R2)

Despite the fact that they acknowledged that Health Care Professionals had discussed the risk factors of diabetic retinopathy to them, it also appeared that they lacked understanding, which was linked to the lack of specific focus on the potential problems associated with cholesterol, hypertension, and sugar levels:

"My doctor did not mention anything about cholesterol level. No, but he did ask me if I take any cholesterol tablets and I said yes. He did ask me if I have any blood pressure, and I said yes, and he asked me about the tablets and I gave him the name and the name of the diabetic tablets as well. And he said to me, that you have to control yourself properly to avoid any problems any health problems in the future." (Yazan, 40, South Asian, R0)

"Well from last year it was like if you have too much sugar in your blood and it goes up in your eyes and the blood starts problems. It could give me a lot of problems with my eyes. I have also heard not that I have experienced it but I also." (Kumar, 57, South Asian, R2)

As previously mentioned, type 2 diabetes was generally perceived as the "safest type" of diabetes compared to type 1. Across their accounts, people with diabetes perceived that those who have type 1 were at higher risk of having complications such as vision loss, which was associated with the taking of insulin rather than non-adherence with blood glucose control:

"My mother in law had diabetes, she lost her eyes, and she lost her vision completely because of diabetes, she use to have insulin three to four times a day" (Bara, 55, South Asian, R0)

The level of understanding and interpretation of certain medical terms associated with diabetes and vision problems, such as "macula" and "retinopathy", varied between the people with diabetes. Although it was clear that people had heard these terms before, either from their General Practitioner (GP), optician, or ophthalmologist, others appeared to be unfamiliar with them.

A number of the people with diabetes stated that they had not heard them before and talked more in terms of diabetes as a complication to people's eyes or diabetic eye in more lay terms:

"I never heard of the term you just mentioned. My doctor did mention diabetes complications to eyes, but not what you just said." (Ronald, 57, White British, R2)

Whilst people with diabetes appeared to understand certain medical terms, the majority appeared to have limited understanding of medical abbreviations that have experience of being used by health providers:

"HAB1c and all that I didn't understand. But blood glucose levels and things like that I could understand." (Gareth, 86, White British, R0)

The lack of knowledge and understanding among people with type 2 diabetes was also recognized by Health Care Professionals who suggested that more attention and consideration should be given by other Health Care Professionals to explain and provide more details to patients:

"My experience has been very different in different hospitals that I have worked in with different patient populations. I think there is a lot of confusion about eye disease and people hear words like glaucoma and cataracts and they get it all kind of mixed in together. I still think there is a lot of confusion about in what way it affects the eyes and you know what can be done about it and how they can try and prevent it. I think that eye disease needs to be brought up by the general practitioner and the practice nurse and they need to be aware that the retinae and diabetes is controlled but I think a lot of patients don't appreciate that there is that relationship between the systemic disease and their eye condition." (Andy, Ophthalmologist, White British)

It appeared that Health Care Professionals were aware that some people with diabetes have different levels of understanding and, therefore, some tended not to use medical terms such as “diabetic retinopathy”:

“I don’t tend to use the word retinopathy because I think it is a bit of a difficult word that people probably don’t understand.” (Andy, Ophthalmologist, White British)

However, it was also clear that some used medical terms such as “macula” that may have not been understood by people with diabetes:

“I would say to him. You have changes in the eye and if you control your diabetes, the diabetes will not lead to blindness. If we don’t control it, it will be progressive to the degree it involves the macula and once the macula is affected you are in trouble.” (Fawzi, GP, South Asian)

“Some of them don’t know the terms. I think the ones who have been diabetic for longer do because obviously they get told when they come to screening. Well, they do by me anyway. I think if they are coming to clinic the doctor will tell them, but I think if they are quite a new diabetic then don’t understand the terms. Again, I feel comfortable telling the patients, describing retinopathy and maculopathy, but not all of them know the term.” (Kate, Screener, White British)

However, it also appeared that Health Care Professionals sought to provide comprehensive information about diabetes and its complications including long term complications and its impact on people with diabetes. For example, in the following extract, Abdulla is talking about his General Practitioner:

“I have type 2 diabetes that I have been diagnosed with since 2005. I was diagnosed by my local GP, after having some tests, blood tests, and if not mistaken, glucose test. After I was diagnosed with diabetes, emm, my GP made an appointment for me to see him, and he explained to me in great

details about diabetes and what are the things that could happen to me if I don't look after my diabetes. He told me about many complications like kidney failure, in a long term, emm, eye problems, and emm, that probably in the late stage, some people may lose some of the limbs." (Abdulla, 47, South Asian, R0)

6.2.2 Implication of diabetes

All people with diabetes perceived that their diabetes has or would have some sort of effect on their sight. For example, some people with diabetes believed that their diabetes may lead to vision loss while others were not sure what would be the implications of diabetes on their sight:

"I think if the diabetes keeps high that could affect the eye could like go blind, blindness or something like that. So, I've got to keep my diet keep controlling my diet, and for myself probably try to do exercise and take the medicine on time." (Yazan, 40, South Asian, R0)

"I went for a routine blood test. Just really at normal testing with the doctor. It must be 5 years plus now. The doctor said you have the type 2 version. He prescribed tablets and advised me to look after what I am eating otherwise it could cause blindness and other parts of your body can get into trouble with it such as gangrene and things like this. So far it is controlled with tablets." (George, 70, White British, R1)

Others, such as Samina, believed that diabetes could lead to different complications other than in relation to their eyes, such as stroke, hypertension, and heart problems, which she believes may result in vision loss:

"Yes he (Doctor) said to keep controlling blood sugar, you got to look after yourself. He mentioned things like you just got to make sure that you got to look after yourself right, otherwise you could have problems with things like if people don't look after themselves they could have high blood pressure, could have stroke, could have heart trouble, there could be other

complications. It could make you go blind and stuff like that. The blood pressure could make you blind so can your diabetes can make you blind so it's like important that you look after yourself." (Samina, 58, South Asian, R1)

Some people with diabetes were unclear about diabetes complications. They believed that diabetes could lead to glaucoma and blindness:

"Probably diabetes can affect my sight I would've thought, gives you glaucoma, isn't it, can send people blind. I know you have to look at your feet very well." (Ronald, 57, White British, R2)

In comparison, Health Care Professionals seemed divided regarding patient's knowledge of diabetes complications. General Practitioners believed that patients are aware of diabetes complications and that individuals were aware that diabetes causes blindness when they present with complications:

"Everyone with diabetes knows that it causes blindness, all of them know." (Fawzi, GP, South Asian)

However, the ophthalmologists argued that symptomless patients may not be aware of the full impact of diabetes, particularly those who have good visual acuity:

"I think the majority understand, particularly those that have had some early changes and some visual changes. They then fully understand what the implications are. But for those that have perfectly normal vision I am not sure some of them understands the impact of the changes are likely to permanent once they get them." (Andy, Ophthalmologist, White British)

Although it was clear that many people with diabetes were aware that diabetes can lead to changes in their eyes, some of them were unaware that these changes could lead to permanent vision loss. Furthermore, they tended to believe that their doctor or ophthalmologist would treat any potential eye problems and effectively cure them of the problem:

“Well, I don’t have problems so far. Should things changed, the doctors would sort it out for me.” (Younis, 55, South Asian, R2)

“Perhaps because everything was normal to me even when I had changes it was improved after some time. So, there is always a way to get thing right for us. You guys are doing a great job in the hospital.” (Joyce, 64, White British, R1)

Despite the varied understanding apparent in the people with diabetes who took part in this study, among the Health Care Professionals there was consensus that all people with diabetic retinopathy would be informed that this may lead to non-reversible damage in the retinae due to high levels of blood glucose. Thus, the Health Care Professionals in this study were eager to point out that all people with diabetes were told how they may avoid the progression to sight-threatening diabetic retinopathy by adhering to good diabetes self-management:

“I normally say that the diabetes has damaged their retinae with high sugars and that this is non-reversible damage, but then we can stop further progression with good control. I think they understand that there is something going on related to their diabetes I think most of them understand that quite clearly, but I am not sure what they understand or that they understand what we mean by retinopathy. I think the majority of them don’t understand the meaning of it.” (Kate, Screener, White British)

However, it was also clear that health professionals generally perceived “educated people” and those who had regular attendance at their appointments at Hospital Eye Services to have better understanding of their own condition. As a result, these patients were far more likely to be aware that diabetes affects the eye:

"I think the more educated people or people that have been coming to clinic more often have an understanding that diabetes affects the eyes. I think that a lot of them would appreciate that it is kind of at the back of the eye rather than at the front of the eye, particularly if they get the hang of what dilating diabetic retinopathy drops are for and you know what we do when we examined them but I think they have very limited knowledge about what actually goes on at the back of the eye." (Andy, Ophthalmologist, White British)

However, an individual's level of education was not necessarily linked to good knowledge or understanding of diabetes among the people with diabetes in this study. For example, people with diabetes who had a higher degree (masters or PhD), or further education (Diploma), provided a range of understanding which could be perceived as less knowledgeable that those with compulsory education (O Level/GCSE) or no qualifications (see participants characteristics in Table 6.2). For example, as mentioned in a previous quote, type 2 diabetes was described by Bara, who is a senior lecturer at a university, as the "simplest type, safe side one, and normal average one". Rather than their educational background, it appeared that individuals who had existing symptoms or eye complications provided explanations that were closer to those provided by a range of Health Care Professionals than those who did not have symptoms or eye complications:

"He mentioned complications especially when I had the bleed. I mean that was a bit of a shock and with the diabetes that is what usually happens if you're under control. It is the diabetes out of control, too many high blood sugars, what happened I was told the blood vessel behind the eye starts swelling up and suddenly pops." (Keith, 59, White British, R3)

Health Care Professionals also perceived people with diabetes who have visible eye complications or changes in their vision as having better understanding of their own eye health status and the risks of disease progression, which was in contrast to symptomless patients:

> *"I think the majority understand, particularly those that have had some early changes and some visual changes they then fully understand what the implications are." (Andy, Ophthalmologist, White British)*

It was also the case that people with diabetes who had existing eye complications or advanced levels of retinopathy believed that everyone with diabetes to be at risk. Therefore, perhaps unsurprisingly, they believed that the diabetic eye screening programme is beneficial for all people with diabetes regardless of their level of risk. This view was inevitably influenced by their past experience:

> *"I think anyone with diabetes should have eye screening definitely every year. I think they are at risk if they have got diabetes anyway, aren't they, everyone with diabetes should be screened." (Claire, 45, White British, R3)*

In contrast, symptomless individuals perceived diabetic eye screening to be more effective to those who are high risk because they would be more closely monitored:

> *"I think the most benefits will be for patients who are at high risk as they would be monitored more closely, it would prevent any problem with the eye." (Abdulla, 47, South Asian, R0)*

6.2.3 Causes of diabetes complications

The role of beliefs about diabetes appeared to influence the knowledge and understanding among people with type 2 diabetes, particularly amongst those participants of South Asian background, as demonstrated in the quotes below. For example, a number of people with diabetes believed that complications may happen due to external forces such as God's will, cold weather, fate, and body function, which are all outside of their control. For example, one participant, Bara, believed that complications may happen due to external forces such as God's will. In other words, he believed that if something is meant to happen, such as deterioration in his vision or blindness, he can do nothing about it and no one can stop it:

> *"It is alright, it did not bother me, I mean, there is nothing you can do if something is coming from Allah (God), you have to accept it, whatever you do would not stop the will of Allah. There is nothing you can do, you may try to do something, but it is something not in your hand, but I tried to do my best." (Bara, 55, South Asian, R0)*

In addition to the previous example, Amit believed that blood glucose may become uncontrollable due changes in body function which is believed to be outside their control, despite people adhering to medication to the same level as they use to do:

> *"Sometimes you can't keep your blood sugar always stable and under control. Sometimes it become uncontrollable, you can't control it all the time, your body function changes, may be you are taking your medication to the same level and everything is fine, but your body is not the same to function like, you know, five years ago. Five years ago I was completely different person. I could get up and walk, do exercise, does not matter at all, but my health slowly decline. I can walk but with difficulties because my knees are painful." (Amit, 72, South Asian, R1)*

People with diabetes had a range of different beliefs regarding their complications and what causes deterioration to their visual acuity. For example, Gurjit attributed the deterioration in her sight to cold weather:

> *"I feel better down there in India, probably because of the heat. My blood sugar was perfect, no high just little bit, 7 or 8. Just wait 6 weeks and see my blood sugar will go up, and my eyes get greasy. I think it is all because of the cold weather." (Gurjit, 69, South Asian, R2)*

In addition, some of these participants attributed the deterioration in their vision to their age rather than their diabetes:

“My eyes are deteriorating now, it is because of my age I suppose, you know what I mean, whether diabetes is causing it, I don’t know. ...I think I am at low risk, I have not thought much about my eyes in relation to diabetes, it is just my age, it is nothing to do with diabetes.” (Harry, 78, White British, R1)

Similar to Harry, Abdulla attributed the deterioration in his sight to age rather than diabetes even though he is relatively young:

“I am 47 this year old, or nearly 47, I don’t think I have any problem in relation to diabetes, but I do believe that my sight is getting weaker, every year I feel that compare to the previous year, so it seems it is not my diabetes is affecting my sight I assume it could be something else, it could be age as some people get problems due to their age.” (Abdulla, 47, South Asian, R0)

In addition to cold weather, Gurjit believed that bad luck contributed to her diabetes:

“Why me having diabetes and all these problems, what did I do in my life. I think it’s my bad luck having diabetes and these problems.” (Gurjit, 69, South Asian, R2)

These external forces appeared to influence their beliefs to a stage where many felt diabetes complications could not be stopped or controlled:

“I don’t really know my chances of developing complications in my eyes. I hope nothing will happen in the next five years, but you know what can I do, if it comes it comes, we can’t stop it can we? I think it’s away from our control.” (Yazan, 40, South Asian, R0)

6.2.4 Severity of risk

The perceived severity of risk varied between people with type 2 diabetes. For example, some of these participants appeared to believe that they were at low risk. Others believed that they were at higher risk, while a few perceived that all people with diabetes, regardless of their level of risk, have the same chance of developing diabetes complications. It appeared that people's perceived severity of risk was influenced by many factors, such as knowledge, experience and visible symptoms. For example, Yazan was one of the respondents who perceived the risk to be roughly the same for everyone with diabetes:

"I am not sure, I don't think so I think it's the same chance, diabetes is diabetes, and eye pressure is the eye pressure, it is the same chance with everybody, it is more how we deal with it." (Yazan, 40, South Asian, R0)

It was also apparent that perception of risk appeared to be understood within a wider context of experience and their social interactions with others. People with diabetes were influenced by the past experience of seeing or looking after people with diabetes. For example, Kalthoom described the case of her mother who she defined as careful in terms of controlling her diabetes and who, therefore, experienced no problems with her eyesight:

"You see my mother was a diabetic, but she was on tablets.... She was on a very strict diet, and never had problems." (Kalthoom, 50, South Asian, R0)

In contrast, other people with diabetes were more aware of risk as they appeared to have been influenced by caring for or seeing people with uncontrolled diabetes and who experienced problems with their vision:

"It can send people blind. I know you have to look at your feet very well. A friend of mine, couple of years ago he had a nasty infection in his toe, he ignored it and lost his toe." (Ronald, 57, White British, R2)

Personal experience and their interactions with others could therefore influence people's perceived risk and inform people's understanding of personal risk. However, the potential downplaying of risk can result in vision loss in the future. For example, John who has proliferative diabetic retinopathy (R3) and who received laser treatment several times in the past appeared aware of the perceived severity of his condition. However, it was also clear that he gave emphasis to treatment as the most effective way of preventing vision loss:

"I think it takes 12 months to lose vision if you are at high risk, isn't it. But if your blood vessel could burst you could be blind straight away. It should be yeah anytime yeah then you could be blind, that was what I was told. But it would be a few years before you go blind if you are low risk, yeah few years. Not necessarily if you get the right treatment." (John, 65, White British, R3)

It was also apparent that those people with diabetes but without existing visible symptoms or eye complications were unsure of the time frame in relation to them potentially developing sight-threatening diabetic retinopathy. Their sense of uncertainty is clearly apparent in the following extract:

"One thing that diabetes may cause is blindness … how long does it take for someone to become completely blind or partially blind, that is what I don't know" (Abdulla, 47, South Asian, R0)

The notion of uncertainty regarding the progression of diabetic retinopathy was also apparent amongst Health Care Professionals accounts. They believed that the classification of the patient as low risk or high risk depended not only the on grade of retinopathy, but also on the impact of the disease and possible effectiveness of treatment and effect on visual acuity, which illustrated their lack of uncertainty regarding its progression:

"Not necessarily the figures of getting it but the impact of that disease giving the actual treatment that you can deliver to it. So something that is relatively small percentage but has a severe visual impairment and is

untreatable to me it terms a much higher risk overall as opposed to somebody that maybe has higher risk of developing but can be treated relatively easily and reversed I think I may put at a lower risk." (Hayley, Ophthalmologist, White British)

However, perhaps not surprisingly, the Health Care Professionals in this study often tended to towards more medical notions of associated risk and the progression of diabetes. For example, one of the General Practitioners, who reflected on his personal experience caring for people with diabetes predominantly from Asian background, believed that all people with diabetes are at high risk due to the nature of diabetes as "a progressive condition":

I don't believe that there is much at low risk because diabetes is such a progressive condition. If they don't have high blood pressure this year and you consider them as low risk, next year they might have high blood pressure. That's why I am dodgy about clarification more risk and high risk. I consider all diabetic patients at high risk, all of them." (Fawzi, GP, South Asian)

In was also the case that most of the participants with diabetes perceived that Asian populations are at higher risk of eye complications associated with diabetes compared with white population, due to hereditary factors and variations in life style:

"Well I would probably say Asians are at higher risk, but only from things I have read in the paper or when I first had diabetes. These people are more at risk of getting diabetes it does mention the black population Asians and that sort of people may be due to their lifestyle or perhaps hereditary." (Christine, 67, White British, R1)

In addition, it also appeared that those people with diabetes who also had co-morbidities were unable to allocate the symptoms they experienced to the specific condition:

"I do a lot of reading, if I was having trouble reading, it was getting blurred I would be really worried then … I have got so many things wrong with me. I have got coronary heart disease, arthritis and diabetes and eye problems, so I don't know which symptoms apply to which illness." (Gareth, 86, White British, R0)

According to most Health Care Professionals, people with diabetes who have been seen in an eye clinic perceived themselves at higher risk. This was particularly the case for those who have significant eye disease, those who have undergone laser treatment, or those who have had invasive treatment or eye injections. A few people with diabetes perceived that any damage caused by diabetes in the retinae as to be treatable by doctors, but it was clear that damage may not be reversible:

"I think people we see tend to have more significant eye disease particularly if they start needing laser treatment or surgery or injections or whatever, then I think they have obviously appreciated that can be quite serious. Once they have got that damage, it's permanent and established and not reversible." (Andy, Ophthalmologist, White British)

Importantly, there was a notable variation in perceived severity of risk between people with diabetes and Health Care Professionals when risk information was communicated to people with diabetes. Health Care Professionals perceived that a risk score of five per cent or more as high risk due to the nature of the non-reversible damage that could happen to the eye as a result of diabetic retinopathy:

"I would put that down as a high risk. I think anything higher than 5% I would probably quote as high risk particularly I would put into a package where most of these are non-reversible." (Hayley, Ophthalmologist, White British)

In contrast, people with diabetes perceived themselves to be at low risk of developing diabetic retinopathy if their risk score was fifteen per cent or less. They only perceived themselves to be at high risk if their risk score increased to fifty percent or seventy-five per cent:

> *"For me fifteen per cent is low risk, I think the high risk is about fifty per cent or seventy-five per cent." (Samina, 58, South Asian, R1)*

In addition to the significant variation in risk perception between people with diabetes and Health Care Professionals, a number of the people with diabetes also appeared to have difficulty understanding statistical and mathematical information when risk information was communicated to them in this form and asked for clearer information to be given:

> *"I don't know, maybe none of them, none of them, because we are not understanding in the community. My ethnic group does not understand percentages and numbers. We do not understand writing, you can tell us this thing is not good, this thing is good, say it direct." (Gurjit, 69, South Asian, R2)*

Health Care Professionals who specialized in diabetes related eye complications appeared to perceive low risk patients as those who keep their blood glucose under good control and do not have diabetic changes in their eye or insignificant changes due to having diabetes:

> *"I think low risk is mainly somebody is well controlled, and my definition is it would have to be somebody with no diabetic changes and I hope that is the category that it comes under. I mean you could have low risk in somebody who has had diabetes for a long time so the duration is longer so it will have some diabetic changes at the back of the eyes." (Kate, screener)*

As previously mentioned, people with diabetes generally perceived those who were treated by oral hypoglycaemic medications to be at a lower risk compared to those who were treated by insulin injections. For example, in the following quote, Allen defines himself as currently at low risk for developing sight-threatening diabetic retinopathy, but he is also evaluating his risk of developing such problems. Currently, he is taking metformin and his disease appears to be well controlled and, therefore, he thinks he is at low risk. Whilst he may progress to taking insulin, until that occurred he would continue to perceive himself to be low risk:

"Emm, because I am on metformin, I am assuming I am at low risk, otherwise I'll be on injections if I was high risk." (Allen, 45, White British, R0)

Other people with diabetes perceived themselves as low risk for different reasons, such as reassurances from their Health Care Provider. For example, Kumar experienced some changes in his retinae (R2), but his visual acuity remained (6/6) and he considered himself at low risk of developing eye complications. Despite the evidence of some change, he appeared to be reassured by the message communicated to him by his GP. Kumar described how he was told that there was improvement in his results (diabetic screening image) which impacted on his perception of risk:

"Well because of my last result (diabetic retinopathy screening) which was like improvement, I now don't class myself as high risk." (Kumar, 57, South Asian, R2)

The risk information that was given to people with diabetes such as "slight sugar" in the back of the eye without proper explanation appeared to have resulted in a misinterpretation of the facts and therefore a misunderstanding of the risk message which may lead them to underestimate their risk:

"He just said that there was slight sugar in the back of the one eye. I didn't really, I didn't feel that it was so severe, as it was to be quite honest with

you and then when I came to see the consultant it was still ok but then it seemed to deteriorate over the next three or four years." (Claire, 45, White British, R3)

Similarly, risk information that was communicated in such terms as "not big changes" also appeared to make people with diabetes feel that they were at low risk:

"You mean the changes in the back of my eyes, oh yes, it's not a big changes as I can't describe, you know, if it is big changes then I would have worried, but sometime you got back in your mind, is it something going to spread or blind you, you know thing like that but after seeing screening results myself, it appears to me that there are not any concern to me unless next time I come if it shows that the patches larger than what it is appear this time then I will be probably worried." (Amit, 72, South Asian, R1)

In addition, many of the people with diabetes stated that because they followed their doctor's advice they perceived themselves to be at low risk:

"I am not worried too much about it because I manage my diabetes with the help of the doctor. If there is problem, my doctor calls me and explains. I am happy with my diabetes care I think I am at low risk because I do everything as instructed by my doctor, if I did not manage my diabetes I would be at higher risk." (Kalthoom, 50, South Asian, R0)

"I feel I am at low risk because I do consciously follow doctor's advice and take my medications when I am supposed to take them, and I do on the whole avoid the food that I should be avoiding you know high sugar and fat content foods etc." (Abdulla, 47, South Asian, R0)

In summary, this section about Individual's knowledge and beliefs about diabetes and diabetic retinopathy indicates that many of the people with diabetes in this study appeared to lack knowledge about their diabetes, and risk factors for developing diabetic retinopathy. People with diabetes appeared to perceive type 2 diabetes as safer than type 1. They also believed that people with type 2 diabetes and who are treated with oral medications are at a lower risk than those who treated with insulin. Many participants attributed the cause of their diabetes various reasons such as to hereditary factors, stress, and certain aspects of negative emotions. Health Care Professionals suggested that GPs should provide detailed diabetes education to people with diabetes. However, it was evident that GPs provided a wide-ranging information and diabetes education. Despite the fact that medical terms, such as retinopathy appeared difficult to understand by people with diabetes, it also appeared that Health Care Professionals regularly used these terms when risk information about diabetic retinopathy or screening's results were provided.

These data have illustrated also that the majority of people with diabetes in this study appeared to believe that diabetes would have some impact on their sight. However, the perceived effects of diabetes were viewed in a diversity of ways. Although some people with diabetes appeared to link diabetes with sight loss, others were uncertain as to what extent diabetes would impact on their sight. Health Care Professionals appeared divided regarding people with diabetes's knowledge about the impact of their diabetes. People with diabetes's knowledge appeared to be influenced by many factors, such as beliefs, past experience, and visible eye complications or changes in visual acuity. Health Care Professionals perceived "educated people" and those who were seen at hospital eye services to have better knowledge of their diabetes condition. However, it was evident that level of education was not linked to good understanding or better knowledge of diabetes and its complications. People with type 2 diabetes used specific ideas about diabetes causation and diabetes control and regulation to make sense of their predicament. A number of people with diabetes, particularly South Asians, believed that complications may happen due to external forces such as God's will, changes in body function, cold weather, age, bad luck and fate. It was perceived by a number of people with diabetes that these external forces are outside their control.

This section has illustrated also that perceived differences in the severity of diabetes was a key theme when people with diabetes discussed the risk associated with diabetes. For example, most people with diabetes viewed people of South Asian background to be more vulnerable to diabetic retinopathy and diabetes complications compared with White British. It seems that people with diabetes perceived themselves at high risk if treated with insulin, had a past medical history, and were treated in a hospital. Those who perceived themselves at low risk tended not to have existing eye complications or visible symptoms, were treated with oral medications, were often reassured by Health Professionals, and tended to adhere to Health Professional's advice. Health Care Professionals stressed that categorizing peoples' risk as "high risk" or "low risk" should be based on their grade of diabetic retinopathy, the potential impact on sight, and the effectiveness of treatment. It was evident that there was massive variation in perceived severity of risk between people with diabetes and Health Care Professionals and that there were differences between the two groups in understanding when numeracy scales, such as percentages or probabilities were used. The data did not show any differences in risk perception between the different genders or between different participants with different grades of diabetic retinopathy. This could be due to the small number of participants in each of these different groups.

6.3. Factors influencing self-reported behaviour

6.3.1 Doctor-Patient interaction

This study also found that the relationships between people with diabetes and their Health Care Professionals appeared to influence the ways in which people with diabetes made sense of their diabetes and the associated risk. For example, was aspect of this was the ways in which they received the information given to them and how they digested the information:

"We have had a lot of different consultants at the hospital. Obviously you get on with some and you don't get on with others. I personally think it

depends on how it is put across to me and whether I actually like the person, not a good thing but you know. I think you need that relationship definitely with either your diabetes nurse or whoever it is." (Claire, 45, White British, R3)

Older participants appeared to be more concerned regarding their signs and symptoms and appeared to count more on their GPs to explain it for them:

"I would take the advice of the doctors. They know more than I do about it. I have got so many things wrong with me. I have got coronary heart disease, arthritis and diabetes so I don't know which symptoms apply to which illness." (Gareth, 86, White British, R0)

It was also the case that those people with diabetes who reported having good relationships with their GPs suggested that this facilitated access to those services involved in their diabetes management:

"I do think that we have been spoiled really because we have got a good relationship with our doctor and the nurse and we have never had any problems and if I was worried that my sugar was very high I would ring them up and just have a chat with them and they will talk to me and yes I think we are very lucky." (Jane, 82, White British, R0)

6.3.2 Diabetes education

People with diabetes who had attended diabetes education courses appeared to have changed their attitudes towards their diabetes and had become more aware of the risks associated with diabetic complications:

"Well it's still there but it is not as bad as it was it somehow seems to have retracted naturally because I was going to have laser treatment and it was all about the control of my diabetes. My diabetes was running too high. I

went on a diabetes course and they helped me to control my sugar levels a lot better." (Kumar, 57, South Asian, R2)

Diabetes education appeared to have encouraged people with diabetes to think more about their diabetes management and encouraged people with diabetes to control their blood glucose:

"He told me straight really, he told me to alter my diet, life style, he said if you want to drink, you can have a drink, if you want fish and chips or curry, have them but in moderation, if you want chocolate have one but in moderation and it seems it did the trick, yea he is really very good GP." (Allen, 45, White British, R0)

It was also apparent that such health education sessions and receiving educational materials appeared to influence people's understanding of diabetes and could lead to improvements in their diabetes self-management:

"Complications can happen over that one year. Yes we were always told that there are complications obviously with the kidneys, with the eyes, we were always told that, yes. I think that comes when you read any leaflet about diabetes, you know that just comes with diabetes and you have to do something about it." (Claire, 45, White British, R3)

"I do know a little bit about it. I have read a little bit. It causes blindness, I would sort of do anything that I was told to do." (George, 70, White British, R1)

6.3.3 Existence of visible symptoms or eye complications

There was also evidence that people with diabetes's experience of diabetes complications appeared to influence reported behavioural change:

"I mean personally I keep a very stringent eye on my diabetes anyway especially having so many bleeds at the back of my eye where I have

> *ended up having laser treatment on it, so I am doing blood tests quite a few times during the day just to make sure everything is stable." (Keith, 59, White British, R3)*

This was in comparison to some of the symptomless people with diabetes who demonstrated less self-motivation regarding making changes to their diabetes self-management:

> *"If I was diagnosed with it, probably would've changed. We are human beings, you know, once I have not been diagnosed with it, probably none of us may go and read about it until we have been diagnosed with it." (Abdulla, 47, South Asian, R0)*

These data indicate that there were several factors that appeared to influence the perception of risk among people with type 2 diabetes. These included good Health Care Professional-patient relationship, diabetes education, and the presence of existing visible eye symptoms or eye complications or loss in visual acuity. The perceived relationship between people with diabetes and their Health Care Professionals appeared to influence the ways in which people with diabetes received the information given to them and facilitated the ways in which they understand the information. Good relationships with their GPs facilitated access to those services involved in their diabetes management. Older participants appeared to be more worried regarding their signs and symptoms and appeared to depend on their GPs to explain it for them. People with diabetes who had attended diabetes education courses appeared to have changed their attitudes towards their diabetes and had become more aware of the risks associated with diabetic complications. Furthermore, diabetes education appeared to encourage people with diabetes to think more about their diabetes management and encouraged people with diabetes to control their blood glucose. Health education sessions and receiving educational materials appeared to influence people's understanding of diabetes and could lead to improvements in their diabetes self-management. There was also evidence that diabetes complications appeared to influence reported behavioural change.

This was in comparison to some of the symptomless participants who demonstrated less self-motivation regarding making changes to their diabetes self-management.

6.4. The use of fear messages during risk communication

6.4.1 People with diabetes's perception of fear messages

People with diabetes appeared to understand the need for and therefore accept the use of explicit language in relation to sight-threatening diabetic retinopathy as this was believed to make people more aware of the risk. This was particularly the case for those people who are non-adherent with health professional's advice and at higher risk of developing sight-threatening diabetic retinopathy:

> *"Probably strong messages would be an eye opener, wouldn't it, to say that blindness could actually happen. I think it depends on your consultant as well at the hospital and, yes I just think you can't have a nicely nicely approach, you have got to have that with your consultant yes but they do need to be more, you know put fear into the patient." (Claire, 45, White British, R3)*

Although most people with diabetes supported the use of explicit messages a few found some words difficult, particularly the word "blindness". They preferred using more "friendly" words, such as eye complications. Keith, for example, who has proliferative diabetic retinopathy with reduced vision, was sensitive to the word blindness probably because he feels that it's going to affect him:

> *"Well I think blindness is a bit drastic and could frighten people. The best thing is to tell them that they could have complications. I think if you turn around and say to somebody you could go blind with diabetes that is going*

to frighten them if you say complications could occur then I should imagine they would start looking after themselves" (Keith, 59, White British, R3)

One person with diabetes believed that people with diabetes may not accept risk messages regardless of how they were presented. However, rather contentiously, she also suggested that treatment should be stopped for those individuals who are non-adherent:

"Probably some will take it (fear messages) and some wouldn't. They would probably give you a load abuse, telling you to mind your own business but I do think if you don't listen to what they tell you, you should not be able to have treatment." (Jane, 82, White British, R0)

6.4.2 Health Care Professional's perception of fear messages

Some of the Health Care Professionals appeared to use detailed and sometimes explicit information when talking to people with diabetes. Health Care Professionals suggested that they used such information in order to get patients to fully understand the seriousness of their condition and to improve their adherence regarding diabetes self-care management:

"I normally say that the diabetes has damaged their retinae with high sugars and that this is non-reversible damage, but then we can stop further progression with good control" (Andy, Ophthalmologist, White British)

However, Health Care Professionals also stressed that they should also draw upon their expertise when delivering such messages to those who are non-adherent:

"At the same time you don't want to really scare your patients because the vast majority is not going to develop diabetic retinopathy or not significant diabetic retinopathy so, yes it is difficult. I think certainly for those that are not controlled and that are not looking after themselves, not looking after their diabetes I think that is certainly good thing to talk about and stress

that you know blindness can result if they don't sort themselves out." (Andy, Ophthalmologist, White British)

Thus, whilst using the word "blindness" may appear shocking, some health professionals justified its use in terms of stimulating people with diabetes to become more responsible regarding their diabetes management. However, it was also felt that such messages may not be effective with everyone:

"The word blindness is often quite a shocking word so I think if you really want to emphasize something, if you really feel that a patient needs to take control themselves then use the word blindness. I think that would make them take responsibility. I have used that word before because I felt I had got to say it because they are not listening, they are not looking after themselves so I have used the word blindness and you know stop you working and driving and some people still don't care." (Hayley, Ophthalmologist, White British)

6.4.3 The use of fear messages in risk communication to prompt behaviour change

Some people with diabetes reported that they would be more likely to change their behaviours if fear messages were used by their Health Care Professionals when communicating risk information about diabetic retinopathy or diabetic retinopathy's results. For example, some participants used their personal experience to illustrate how they had reacted to such messages by improving their diabetes self-care management and life style:

"People are more likely to change their attitudes once they have been threatened. I had my diabetes for many years, I tell you, for years, I abuse the situation for a lot of years, I was going away with all sort of things and certain ideas, then my doctor told me if you don't alter your life style you will be in load of trouble. So, I have altered my life style, and had lots of tablets a day, and he is happy with everything now. I use to be a publican; I use to drink quite a lot, but never smoked in my life never smoked never." (Ronald, 57, White British, R2)

Thus, it was felt that more explicit messages were more likely to result in behavioural changes. Therefore, strong messages were perceived to act as an "incentive" in order to save the vision of certain individuals:

"I think blindness is obviously quite emotive thing, yes so I think if people knew that then that might be quite an incentive to look after their diabetes than say kidney problem or heart problems or whatever." (Andy, Ophthalmologist, White British)

It was also apparent that some people with diabetes appeared not to be initially too concerned when diabetic retinopathy screening results indicated that they had changes in their diabetic retinopathy grade. However, the use of explicit language by their Health Care Professionals had appeared to impact on their diabetes self-care management and resulted in changes in their lifestyle:

"I am a shamed to say it that the screening results have not really impacted on me but then I was told that if I was not careful I would become blind. Perhaps after few weeks I was more careful with what I eat." (Joyce, 64, White British, R1)

One of the people with diabetes, George, described the use of such language as a "shock treatment" and a potential way to get patients' attention regarding the severity of their risk:

"You have got to tell how is it? Haven't you. I think I would rather be told. I think it would, if somebody perhaps drinks a lot and to be told, look if you don't stop drinking then you will go blind, it's really up to you. I think the shock treatment is probably the best" (George, 70, White British, R1)

The Health Care Professionals interviewed for this study appeared to believe that people with diabetes respond better to strong risk messages. There was evidence that they had used such messages when they felt that patients were not listening to them. However, it was also clear that they preferred not to use strong language as they did not want to upset their patients:

> *"I think strong message is more effective because they will have a good idea about what is going on. Mild message they will say ok I am alright I have no problem at the moment but you have to emphasize on them" (Suresh, GP, South Asian)*

In summation, it appeared that most people with diabetes accept the use of plain language as this was perceived to make people more aware of the consequences of their behaviour. However, a few people with diabetes felt some words such as "blindness" were too strong and may scare people. Therefore, they preferred the use of more friendly words. Some of the Health Care Professionals seemed to advocate the use of fear messages in order to get patients to fully understand the seriousness of their condition and to improve their adherence regarding diabetes self-care management. In addition, Health Care Professionals stressed that they must use their skills and knowledge when delivering such messages taking into consideration the seriousness of diabetic retinopathy, people with diabetes's behaviour, and the probabilities of developing sight-threatening diabetic retinopathy. It appeared that a number of people with diabetes more likely to change their behaviours when fear messages were used. They reported responding to such messages by improving their diabetes self-care management.

6.5. Responses to being at risk

Perhaps unsurprisingly, those people with diabetes who had experienced retinal changes tended to interpret their risk in relation to their past experiences. For some, their experiences had led them to appear more 'optimistic' about their diabetes and their chances of developing sight-threatening diabetic retinopathy. In contrast, others were more 'realistic' about the possibility of developing sight-threatening diabetic retinopathy in the future. It was also apparent that perceiving themselves to be more at risk of developing sight-threatening diabetic retinopathy could also invoke other emotions and responses, such as low mood or depression, underestimation of risk, denial, and sarcasm.

6.5.1 Optimism

A number of people with retinal changes appeared more optimistic regarding their chances of developing further complications. For example, some people with diabetes perceived that they were doing better than others and, as such, they are less likely to experience complications:

"I don't think I will be that one in the next five years. No, because I always think positive. You know what I mean, I always think of the good things you see, I don't think of the bad. Terrible isn't it." (Harry, 78, White British, R1)

It was also the case that people with diabetes often perceived their chance of developing diabetic retinopathy to be less than others of the same age group and who had diabetes for the same duration. Though they often could not explain why this was the case:

"Well my chances of developing diabetic retinopathy are probably less may be I don't know why, I think that but probably less." (Joyce, 64, White British, R1)

Those people with diabetes who had attended eye screening for some time and whose screening results were negative also believed that they were less likely to develop eye complications:

"I have been twice now and had it done and there has been nothing wrong you see so personally I think it will probably be the same next time you know." (Samina, 58, South Asian, R1)

It was also the case that people with diabetes who perceived that they had good control of their diabetes appeared more optimistic regarding their chances of developing complications:

“No No, I would like to think no, I don’t think there will be chance for me to be 1 out of 10 (patient laugh) probably this is optimistic no, ah, as far as now today at this moment, my diabetes is very well controlled.” (Bara, 55, South Asian, R0)

It was also clear that certain individuals did not believe themselves to be at risk because they keep their diabetes under control:

“I am not going to have any complications with diabetic I don't think. It’s been stable now for a couple of years, three years now I mean I just have two tablets and I don't have any problem you know so nothing varies with me I can as Megan said like she does my blood sugar for me and it’s no different to what we had 6 months ago so I am not too concerned really at all at the moment.” (Harry, 78, White British, R1)

People with diabetes who had previously experienced eye problems or who had previously experienced episodes of bleeding tended to deem themselves as “realistic” regarding their risk of developing future problems. Hence, they were less optimistic regarding the future:

“Well when you say I mean I don’t wish it upon myself to have problems, I do try to take care, but I know from the past it was getting bad, it is possible that something could happen within like the next 5 years.” (Kaur, 59, South Asian, R1)

Similarly, Christine, who has background diabetic retinopathy, appeared less optimistic about her chances of not developing sight-threatening diabetic retinopathy. However, she also attributed the possibility of future complications due to her getting older rather than her lifestyle:

> *"Yes, I may develop eye complications in the next five years, I would think so, it's possible, not because of my lifestyle, but as I say the ageing process." (Christine, 67, White British, R1)*

6.5.2 Underestimation of diabetic retinopathy risk

This study also found that some people with diabetes appeared to underestimate their risk even though they were having difficulties with their diabetes self-management. This appeared to be due to either a lack of understanding of the actual risk or due to insufficient information having been communicated to them about the condition:

> *"I didn't expect it to be as serious because I did feel that I did keep my blood sugars under control, maybe not 100% but as good as anybody else would. I didn't really understand it until I came to the hospital appointment and then the consultant just said. I didn't feel anxious at that time because it wasn't, when I got to the hospital the consultant just said that she was going to just keep an eye on me. It wasn't as bad then and then it deteriorated over the next few years." (Claire, 45, White British, R3)*

For example, Amit appeared to underestimate his risk despite the fact that he had background diabetic retinopathy (R1). Amit did not appear concerned during the interview because he perceived the changes to be small. However, he did acknowledge that he would become concerned if he was to be informed that his condition was deteriorating:

> *"Last time he has done picture as well last year and he said there is some sort of abnormalities in the back of my eyes so that is why I came in here, but the patches seem to be not that big. It is like aaa it is there very fainted way you know, so I am coming back again in 6 months' time to have my eyes pictured again to see whether it's going to spread or whether it is going to stay as is it is. But it's not affecting me at all you know, at the moment I have got eye drops and I can see little bit blurred and I can't read much, otherwise I can read papers with my glasses and I have got long distance glasses." (Amit, 72, South Asian, R1)*

6.5.3 Emotional responses

A number of people with diabetes described how their risk of eye problems resulted in them feeling a range of emotions such as guilt, low mood or depression, and food restriction. For example, some people with diabetes expressed feelings of guilt which they related to them having underestimated their risk and not taking certain precautions, only to then develop eye complications as a result:

> *"I did not give any attention at the beginning, I do not feel anxious, I feel naughty, yes, I do feel guilty, because emm, you know, I am aware of it is my fault, it is not somebody else fault. I feel it is my fault because I am not controlling my blood sugar, I've been type 2 diabetic for long time, over ten years." (Joyce, 64, R1)*

Other people with diabetes who had underestimated their risk and as a result felt guilty also appeared motivated to improve their diabetic self-management:

> *"I have started you know putting more effort to keep things under control, I start watch what I eat, I joined the gym, started to do exercise, I did lose some weight, then I put it back on. I was so angry I thought it is my fault that I did not control my diabetes, and that start affecting my eyes." (Kalthoom, 50, South Asian, R0)*

It was also evident that some people with diabetes experienced adjustment problem with their diabetes. For example, Kalthoom described how she denied her diabetes when first diagnosed as she could not believe that it was possible for her to get diabetes because she was young, healthy, and fit. As a result, she now believes that she put herself at higher risk by not complying with health professional advice and by not taking her medication:

> *"I also could not accept my diabetes because I was only 45 when I first had it, and I thought I was too young to have diabetes, because I am the first female in my generation in our family to have diabetes, it was very difficult to accept it, I did accept it but after one year, I did not take*

> *medication during that year. I was always very healthy with my diet and my exercise, which is why I could not accept it, it very hard to accept it." (Kalthoom, 50, South Asian, R0)*

A number of the people with diabetes appeared to have low mood that they associated with being at risk. It was also the case that needle phobia and pain due to daily needle breaks contributed to their low mood and led to poor self-care management as individuals did not keep their blood glucose under control. For example, Samina felt that her low mood was impacting on her management of diabetes, which put her at risk of worsening sight-threatening diabetic retinopathy:

> *"I don't even check my blood sugar (laugh), no chance to break my finger to check sugar level. I am scare to death, no way, I don't check it. If I am at home and I feel that my blood sugar dropped down I would have taken it, but I don't have sticks to check it. I just know that it is my diabetes, I just know it. I feel down, I am sometimes depressed, I could not go out of bed so I eat if I want to eat and if I don't have anything up there, then I make sure that I have biscuits, crackers and any pop and water. I just check my blood sugar when I go to the hospital. If I have to test it I just test the urine I go to the toilet and test it there but I don't test the blood. I am scared of needles." (Samina, 58, South Asian, R1)*

In a similar vein, Kaur, who has background diabetic retinopathy (R1), reported being scared of having complications. She was particularly down when she talked about her mother's experience as she also had diabetes and experienced sight-threatening diabetic retinopathy:

> *"I feel very depressed sometimes. My mom also got diabetes, she can't see much now, and things got worse, she is really struggling, but I don't know much about my mom because I live here, and she lives in India, I ring my mom every day and ask her if everything is alright, or no, sometimes she is ok sometime she is miserable, sometimes she is crying sometime they don't want to live anymore, they want to die, they turn*

heating off and everything, everything turned off and they were sitting like that my mom, she is not happy at all. She is old lady, she is 86 my mom." (Kaur, 59, South Asian, R1)

In addition, people with diabetes also described how not being able to eat the food of their choice could also contribute to their reported depression. For example, a number of people with diabetes reported feeling depressed because they had stopped eating what they like and had started eating what they had been instructed to eat, regardless whether they like it or not. It also appeared that the South Asian participants in this study were more affected by this because of the limited range of appropriate food in the UK:

"I have spoken to my GP several times and I know exactly what to do, he does to me, I have to eat brown stuff no added sugar, not sugary things, I have to eat no cheese, low calorie milk, I eat healthy food all the time, and you know, I am not allowed sugary drinks not allowed orange juice, you are not allowed these and that." (Kaur, 59, South Asian, R1)

It was also apparent that Health Care Professionals recognized that the complexity of the disease and fear of complications could result in patient's being depressed:

"That's why they are frightened, what is the cause of depression in their diabetes? Fear, they do feel that they might get blind or their kidney fail or they have heart attack. They are frightened of the complications because when we diagnose diabetes they have no complications except the erectile dysfunction." (Fawzi, GP, South Asian)

Symptomatic people with diabetes who had advanced diabetic retinopathy (R2 and R3) and those with low visual acuity tended to believe that they were at higher risk of further vision loss and therefore often appeared anxious about the future:

"I think it (diabetes) would yeah affect my eye in the next few years, I am really devastated." (John, 65, White British, R3)

Individuals with existing complications could also be distressed by sudden changes in their condition:

“It suddenly went blurred, the first time it happened I was outside and it was quite a strange sensation and when I looked up I could see what I know now was the blood just floating around and it was like a big cobweb. It frightened me because I wasn’t sure what was happening.” (Keith, 59, White British, R3)

Certain participants with eye complications not only appeared more anxious they also wanted more risk information to enable them to maintain their vision:

"For me, really anything is high risk even one in million. Yea because diabetes is there, I would like to know what is happening to my eyes. I have different problems in my eyes and would like to know and they usually complicate, different conditions complicate each other, so in my case, I have glaucoma, so I need to know, anything just to stay safe." (Younis, 55, South Asian, R2)

These accounts demonstrate how people with diabetes responded in different ways to their risk of developing diabetic retinopathy. Some of them placed emphasis on positive thinking as a means of coping with the unknown risks whilst others were more pessimistic about the possibility of developing the condition. Alongside and linked to this were a range of emotional responses that included guilt, low mood, fear of developing diabetes complication, anxiety, and self-reported depression. These responses were influenced by the age of individuals, presence of existing visible symptoms or eye complications, past experience, lack of understanding of the actual risk, insufficient information having been communicated to them about their condition, family history, diabetes self-management, and reduction in visual acuity.

6.6. Responses to visual risk tools

The use of visual risk communication tools (Figure 6.1) appeared to be favoured by Health Care Professionals and people with diabetes compared to using verbal risk communication as a means of providing risk information about diabetic retinopathy to people with diabetes.

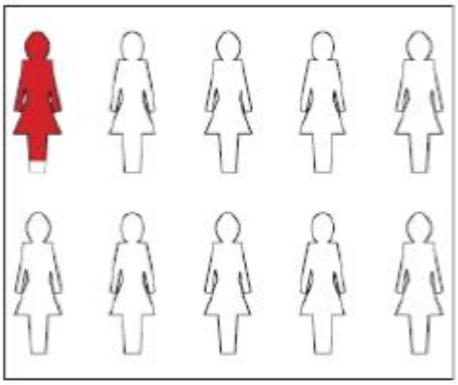
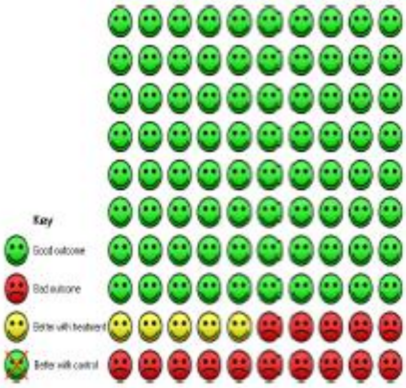
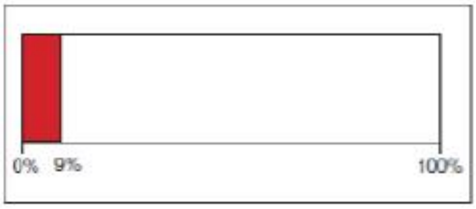
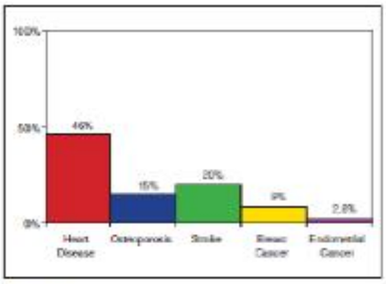
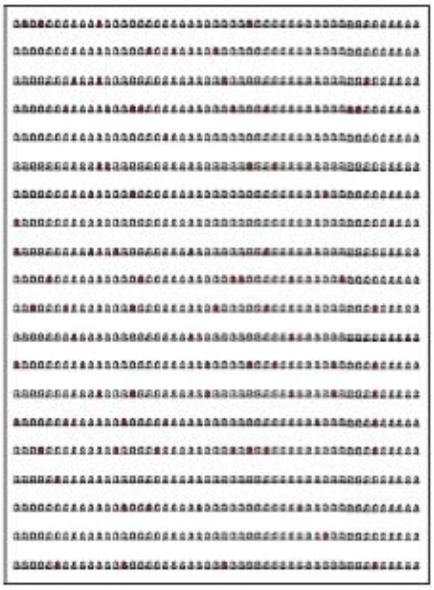
	
Tool One: Highlighted human figures	Tool Two: Smiley faces
 	
Tool Three: Bar graph	Tool Four: Comparison bar graph
 	
Tool Five: Traffic light	Tool Six:1000 randomised human figures

Figure 6.1 Risk communication tools in clinical settings

The responses of people with diabetes and health professionals varied in relation to the different risk communication tools and format presented. Of these, some risk communication formats were deemed to be more acceptable while others were not found to be useful by people with diabetes for a number of different reasons. For example, particular risk communication tools appeared to present an understandable risk message, were easy to see, and provided risk information about the level of risk without the need for further explanation:

“Yes I suppose so I mean if you say high risk I think that might jolt them into thinking I have got to keep an eye on it. Yes putting it down on paper like that it really puts the message over.” (Keith, 59, White British, R3)

Visual risk communication tools were perceived to provide clearer message and it was felt that people with diabetes would be more likely to take notice of the risk message communicated through a picture rather than just simply hearing the message from their Health Care Professionals:

“Well I would think it could possibly give you a clearer message to see it like that because if somebody said you are sort of fifty per cent, if you saw it on there you would think that would be better more explained I think. I think so because if you said whatever on there you would take more notice of it on a picture; I think that would be better yes.” (Jane, 82, White British, R0)

Health Care Professionals advocated the use of visual tools such as the patient’s own retinal image as this was perceived to improve patients understanding:

“There are two types of optometrists some of them are clever they put the photograph so I can let the patient have you know and look that will fix in their brain some of them just words because the picture will make better impression.” (Suresh, GP, South Asian)

Health Care Professionals generally supported visual tools for those from ethnic minority groups or those who struggle with the main language used:

"Yes and I think if you have got something visual because obviously a lot of wording in diabetes can get quite complicated. I think if you have got something visual because obviously not everybody can understand languages the same as everybody else because obviously we see a mixed race of ethnicities so if you have got something that is quite visual so green is good, red is poor then I think it does give a good understanding of how their control is." (Kate, screener, White British)

A number of the visual risk communication tools were viewed as less appropriate by the majority of the people with diabetes and Health Care Professional due to different reasons. For example, the highlighted human figures (Figures 6.2) was not supported as people with diabetes felt that it could give wrong impression that they are at low risk or low probability of developing eye complications:

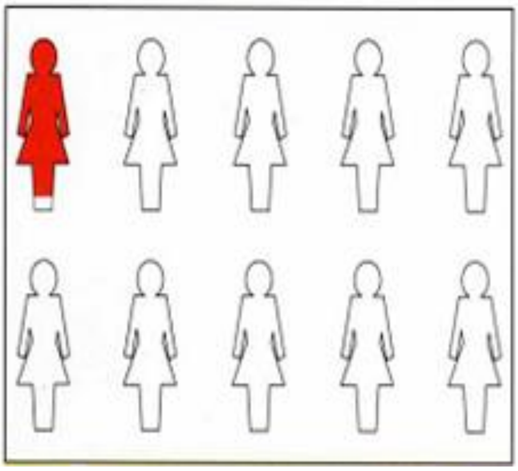


Figure 6.2 represents highlighted human figures

"See, that one (highlighted human figures), like, it says 1 in 10 people, would probably think I am not going to get it yet. So I would probably block

that one out, that one probably, yes that is really low as well." (Claire, 45, White British, R3)

Other people with diabetes responded to the highlighted human figures (Figure 6.2) in other ways:

"I'd always believe that I am not in that bracket." (Samina, 58, South Asian, R1)

A number of risk communication tools were not favoured by people with diabetes due to their inability to understand scientific materials. Such tools were even of concern to a few of them. For example, the bar graph (Figure 6.3) was not favoured and described by people with diabetes as "boring" and "too technical":

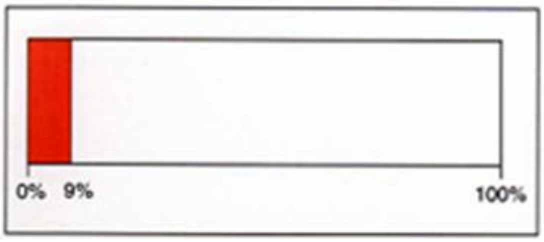


Figure 6.3 represents bar graph format

"The rectangle with one end highlighted looks boring and too technical." (Abdulla, 47, South Asian, R0)

While Health Care Professionals show their concern as they state that bar graph gives wrong risk message particularly to non-educated individuals. Their main concern was that people with diabetes, who are at high risk, may not understand these risk tools and perceive their risk as low risk. The main concern was that the lack of perceived severity of risk may lead to people underestimate their risk, and therefore not prioritise their diabetes care:

"My personal view is that this actually makes quite a high risk look quite low. Yes I think bar graphs sometimes would throw people and I think people who are not particularly educated would struggle with a bar graph and because you have some people that are professors and some people that haven't finished school so I think you would probably have to gauge it according to your patient as you talk to them." (Hayley, Ophthalmologist, White British)

Similar to single bar graph, the graphic that displays the use of multiple bar graphs appeared also not supported by people with diabetes. For example, risk tool number four (Figure 6.4), represents a vertical bar graphs format that was used to communicate comparative lifetime risks for a 50 year old woman including the risk of heart disease, osteoporosis, stroke, breast cancer, and endometrial cancer was not supported either by Health Care Professionals or by people with diabetes. Claire described it as not attractive tool that stimulate people to understand their level of risk:

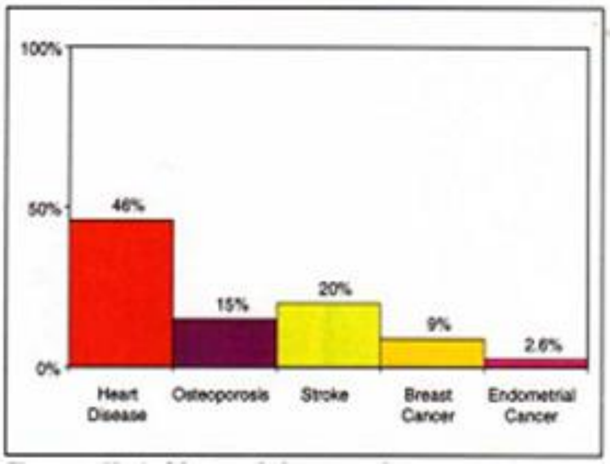


Figure 6.4 represents vertical bar graph format represents lifetime risks of heart disease, osteoporosis, stroke, breast cancer, and endometrial cancer

“I don’t think that figure (Figure 6.4) comparing different condition is a good one, I don’t think that would wake people up”. (Claire, 45, White British, R3)

People with diabetes who had an advanced level of diabetic retinopathy were facing a significant challenge in not being able to see the contents of some risk communication tools. This was clear in the case of Claire and George who both struggled to see the thousand-consecutive highlighted human figures (figure 6.5):

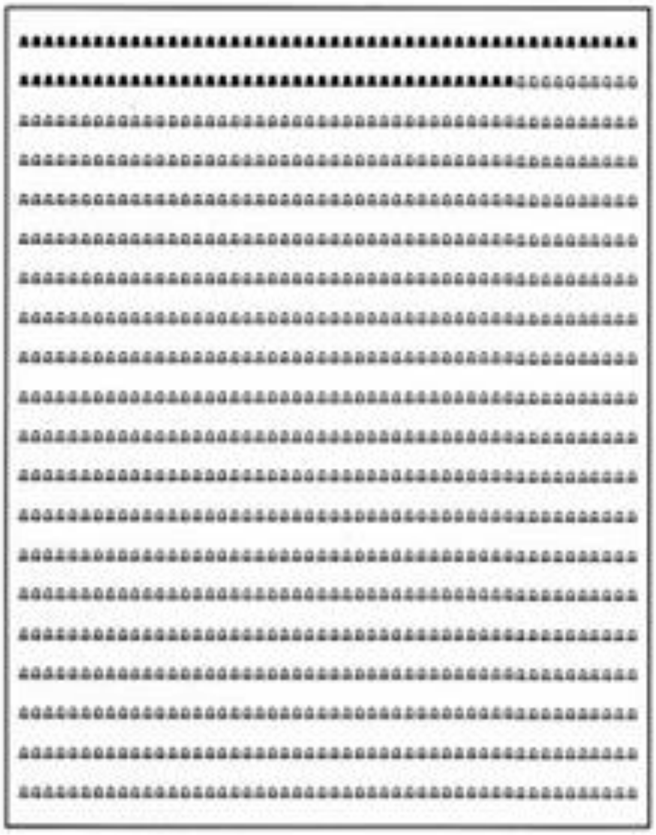


Figure 6.5 represents a thousand-consecutive highlighted human figure formats

“This one (A thousand figures) made my eyes go funny. It‘s not nice. I think the other tools are much better. It looks like a pixellated PC screen.” (Claire, 45, White British, R3)

“Again I would find that more complicated, it is not easy to see the black bits for a start, I would not go for that one either.” (George, 70, White British, R1)

The poor quality of risk communication tools in terms of its visual presentation appeared to influence people with diabetes’ decision as not a tool of preference, even though they had normal diabetic retinopathy screening photo (R0). For example, in the following extracts, Jane and Abdulla are talking about their difficulty seeing the human figures (Figure 6.6) and therefore the tool was not supported:

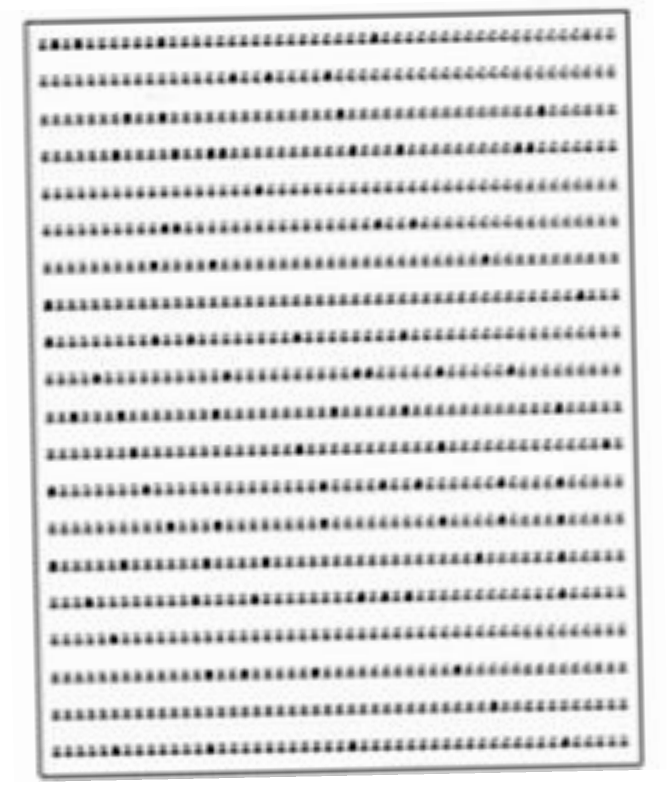


Figure 6.6 represents a thousand-randomly highlighted human figure formats

“You can't be serious, that's a joke I can’t even see it.” (Jane, 82, White British, R0)

"This one didn't make sense. It is very difficult to see and to be honest with you it did not make sense to me. Personally, I don't like it." (Abdulla, 47, South Asian, R0)

Although George had good visual acuity, he did not like the consecutive highlighted human figures or the bar graph. The human figures, in particular the thousand consecutive and randomised figures, were deemed to be difficult for those who have low visual acuity:

"The thousand-random highlighted human figures are not good, I don't like that one. I would find that more complicated, it is not easy to see the black bits for a start, I would not go for bar one either." (George, 70, White British, R1)

Some people with diabetes supported the use of smiley and sad faces (Figure 6.7):

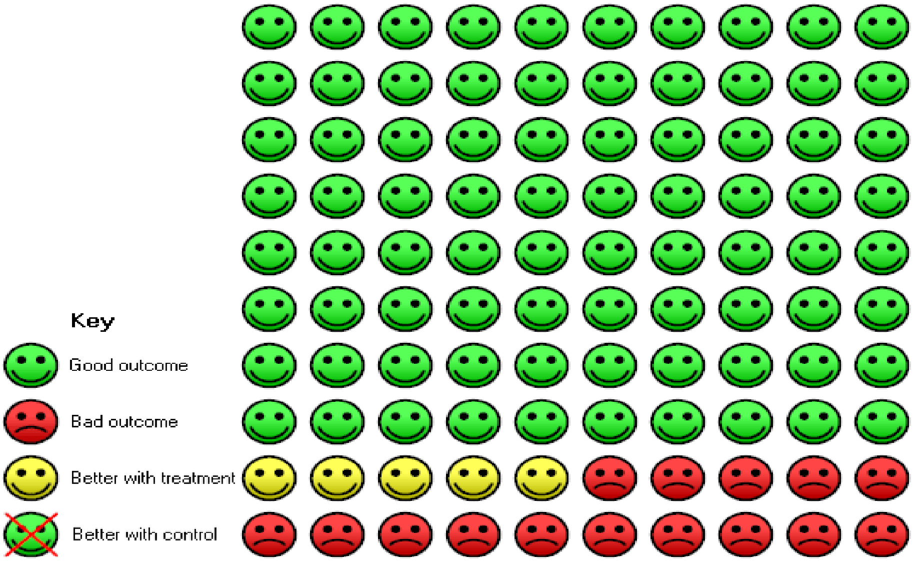


Figure 6.7 represents the advantages of taking statin tablet for 10 years, five patients would be saved and would not have cardiovascular event (yellow faces)

"I think that graph is better (smiley and sad faces). Yes that is the one" (Jane, 82, White British, R0)

However, the smiley faces were also considered to give the wrong impression regarding personal risk as they potentially left individuals with the impression that they are at low risk:

"Looking at this (smiley and sad faces), I'd assume I am a green low risk." (Abdulla, 47, South Asian, R0)

Many of people with diabetes and the Health Care Professionals appeared to favour the traffic light approach, which was perceived to personalize risk. In particular, it was believed to better capture people's attention because it allowed individuals to perform a risk self-assessment:

"This is also good tool because you have got the three (colours), rather you have got more in the middle in the risk factor than around the edge, yes definitely. I think if each patient had to fill that in honestly, yes, but they need to be explained to as well because they don't always get explained to, it depends obviously on their consultant. I mean if like you just said, you have got more in the middle then obviously you need to sort yourself out." (Claire, 45, White British, R3)

A number of the people with diabetes favoured the traffic light system (Figure 6.8) that has been used to communicate risk information in cervical cancer screening (Chiu, 2009). This was because it included the risk factors associated with developing the condition. Abdulla suggested that the cervical cancer risk factors should be replaced by diabetic retinopathy risk factors:

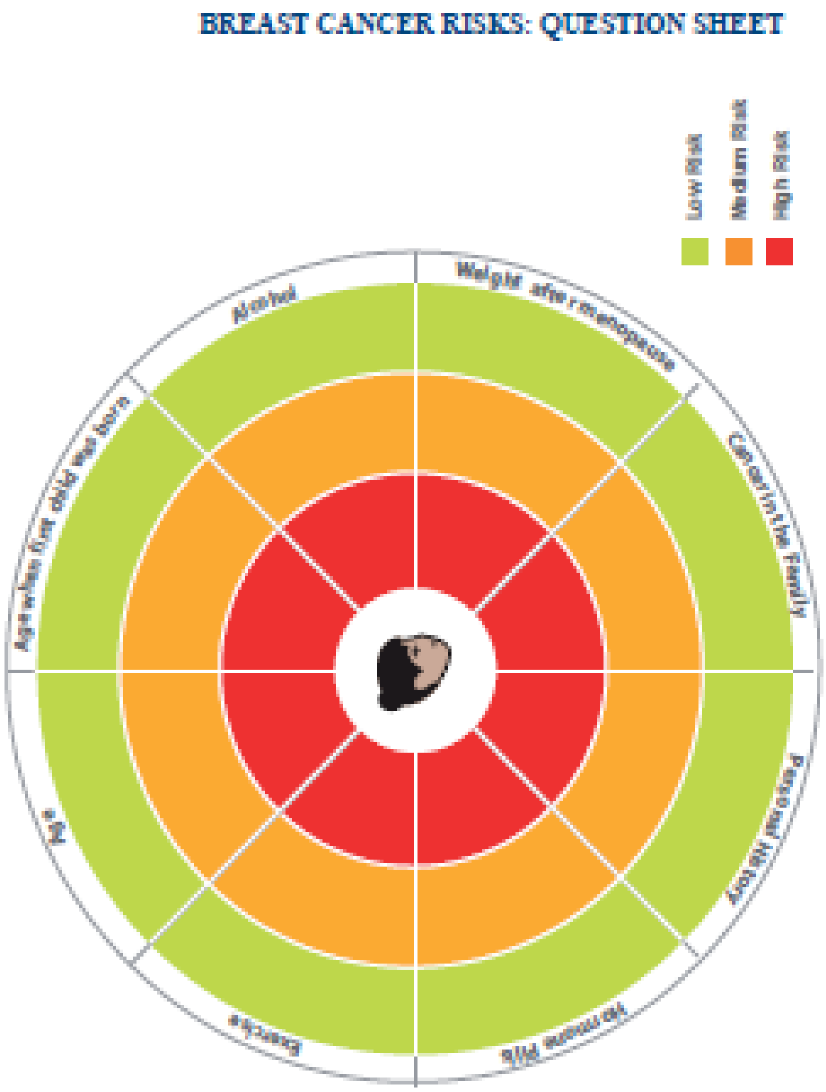


Figure 6.8 represents a breast cancer self-assessment risk tool

“I think if you change these risk factors, if you replace them with the risk factors of diabetic retinopathy, you know like you say family history and the type of diabetes the duration and the blood sugar control and the blood pressure. It would be amazing” (Abdulla, 47, South Asian, R0)

This particular tool was also supported by health professionals, as it could be modified and include risk factors of developing diabetic retinopathy:

“I think this is good it kind of if you include all the factors of diabetes. I think most patient would find it helpful to know where they were on the chart.” (Kate, screener, White British)

It was perceived to allow individuals to evaluate their diabetes management in a clear and easy style, which was not necessarily the case with written information. It was felt that this tool was useful because it drew all of diabetic retinopathy risk factors together that could guide health professionals during consultation and utilize their time more efficiently:

“I think if they can justify what they put down then that would give a nice clear representation. It would immediately give you a clearer impact that you don’t see necessarily in the written what’s down in the written notes. If you can quickly surmise looking at all the 6 or 7 factors that these are all well controlled, then it is the evidence that they are then that would put patients into the appropriate category to consider longer or shorter duration of screening.” (Andy, Ophthalmologist, White British)

Health Care Professionals felt that the use of a colour coding system facilitated risk interpretation. They perceived that people with diabetes would absorb and understand the risk information in more appropriate ways and attach different colour coding to different level of risk:

“A green or red traffic light system I think would make people understand very easily and they can understand that if everything is looking green things are looking good and if things are into red then they have a got something that they should be worried about even if they don’t necessarily understand why they need to be worried or what the reason for it is. If you have got a colour representation it is very effective.” (Andy, Ophthalmologist, White British)

To summarise, risk communication tools appeared to be favoured by both people with diabetes and their Health Care Professionals. It was perceived as good way to provide a clear message and communicate risk information about diabetic retinopathy. Risk communication tools were perceived to be particularly helpful to ethnic minority groups and those with literacy issues. However, people with diabetes and their Health Care Professionals also raised their concerns about the presented risk communication tools for different reasons. One concern raised by Health Care Professionals and people with diabetes is that some risk communication tools may give the wrong impression in that high risk could be viewed as low risk. The majority of people with diabetes, particularly those who have existing vision loss symptoms or eye complications, along with Health Care Professionals, favoured a tool that personalised risk information. These allowed individuals to evaluate their diabetes management in a clear and easy style unlike written information. It was favoured by Health Care Professionals as it could gather all risk factors in one tool that could guide them during consultation and utilize their time more efficiently.

6.7. Conclusion

This chapter highlights a few issues in regard to people perception of risk by people with diabetes. These included knowledge and beliefs, factors influencing self-reported behaviours, the use of fear messages, responses to being at risk, and their responses to various risk communication tools. The data has shown that the participants understandings and the perceptions of risk was subjective, premised upon their personal circumstances, constructed in relation to those around them and influenced by cultural differences, beliefs, the individual’s knowledge, type of diabetes, presence of visible eye complications, and the individual’s past experience. The perceived risk varied between people with diabetes. There was difference also in risk perception between people with type 2 diabetes and Health Care Professionals. Few factors appeared to improve behavioural changes such as good relationship between people with diabetes and their Health Care Providers and the use of fear messages. People with diabetes responded to being at risk in different ways, such as being optimistic, underestimating diabetic retinopathy risk, or having emotional responses such as denial, low mood and self-reported depression. The lack of knowledge about diabetes and its complication points out the importance of designing educational material that address people with diabetes's educational needs, how to frame the risk messages, and takes into consideration the differences in perception of risk between people with diabetes and their health professionals. Several factors influenced perception of risk such as individual's knowledge and health education, ethnicity, Professional-patient interaction, methods of risk communication, and presence of visible symptoms. These factors should be considered by Health Care Professionals before providing risk information about diabetic retinopathy in addition to grade of diabetic retinopathy, the potential impact on sight, and the effectiveness of treatment. People with diabetes and Health Care Professionals highlighted their preference in relation to framing risk message and the use of fear messages to improve their adherence regarding diabetes self-care management. In addition, Health Care Professionals stressed that they must use their skills and knowledge when delivering such messages taking into consideration the seriousness of diabetic retinopathy, people with diabetes's behaviour, and the probabilities of developing sight-threatening diabetic retinopathy. It appeared that a number of people with diabetes more likely to change their behaviours when fear messages were used. People with diabetes responded to being at risk of developing diabetic retinopathy in various ways. Some of them appeared optimistic and others appeared more realistic about the possibility of having the condition. Other responses were noticed such as underestimation of risk and emotional responses that includes guilt feeling, low mood, fear of developing diabetes complication, anxiety, and self-reported depression. These responses were influenced by the age of individuals, presence of existing visible symptoms. Health Care Professional and people with diabetes support the use of visual risk communication tools to facilitate inform decision. Most of them favour a tool that personalised risk information and allows individuals to evaluate own risk in a clear and easy style.

Chapter 7. **Stage Two Results**

7.1. Introduction

This chapter presents the findings of the stage two interviews that were designed to explore the views of people with diabetes regarding a newly developed diabetic retinopathy risk communication tool together with its perceived influence on knowledge, risk perception, beliefs, and levels of anxiety. Finally, the chapter explores people's preference of the most appropriate methods of communicating risk information about diabetic retinopathy and diabetic retinopathy screening results to people with type 2 diabetes.

7.2. Development of the new diabetic eye risk communication tool

Existing risk communication tools that have been used in other clinical settings have been discussed in Chapter Four. Stage One of the study explored the preferences of people with diabetes in relation to risk communication tools that personalize risk information (Chiu *et al.*, 2009). From this, a tool was developed to provide risk information about diabetic retinopathy to people with type 2 diabetes. Initially, the new risk communication tool was modified and included all the risk factors that contributes to diabetic retinopathy including type of diabetes, duration of diabetes, previous retinopathy, blood glucose level, blood pressure, lipid level, smoking, and family history (Figure 7.1).

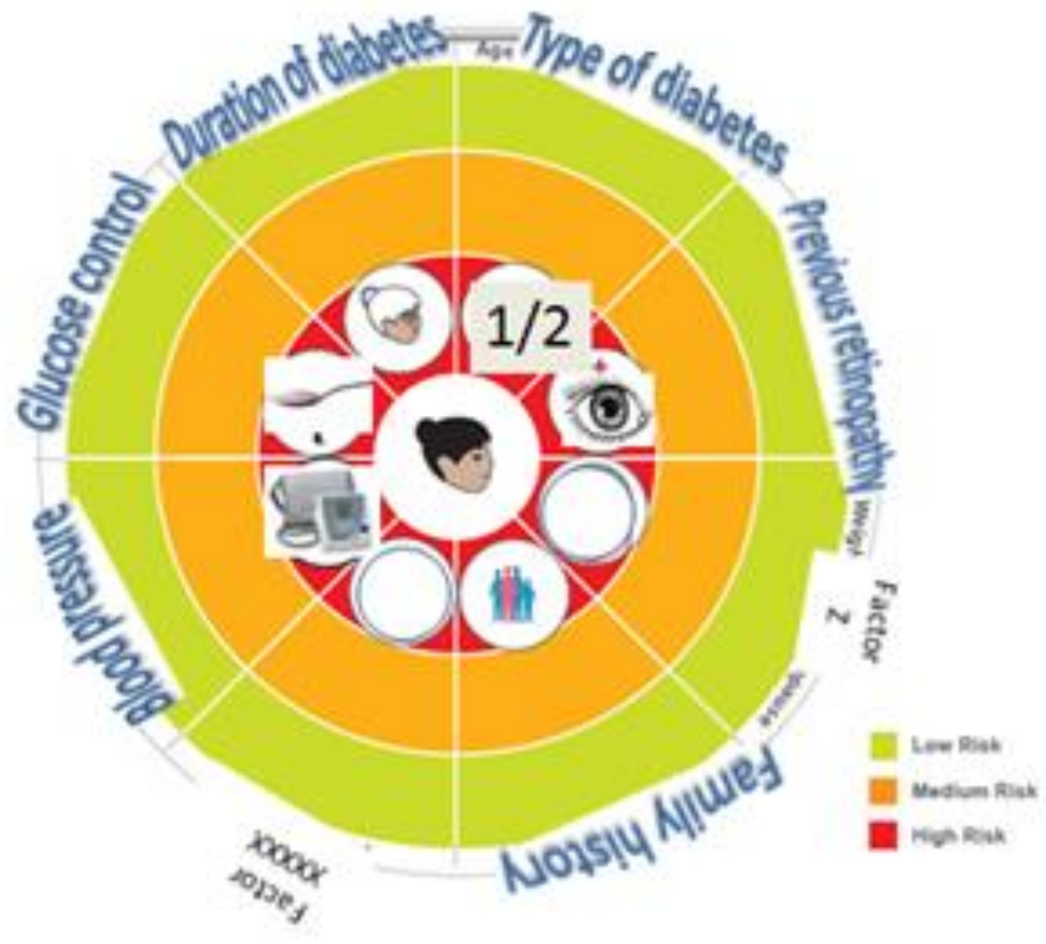


Figure 7.1 Diabetic Eye Risk Communication Tool including all risk factors

The tool was presented to Warwick Diabetes Research and Education User Group and to the research team. Warwick Diabetes Research and Education User Group members felt that the tool was too complicated, when all the risk factors are included, and hence requested fewer risk factors be presented and include the most significant risk factors only. Based on the available evidence as mentioned in chapter two (section 2.11.1), the researcher then decided to keep only four risk factors in the final version of the new risk tool (Figure 7.2), including blood glucose level as the most significant modifiable risk factor, in regards to the progression of diabetic retinopathy (Yau *et al.*, 2012), that potentially can motivate people with diabetes to control their blood glucose level to remain at low risk of developing diabetic retinopathy. The new risk communication tool is divided into four quarters (see figure 7.1). Each quarter represents one of the most significant risk factors for developing sight-threatening diabetic retinopathy; type of diabetes (Stratton *et al.*, 2001); duration of diabetes (Stratton *et al.*, 2001); the most recent HbA1c (UKPDS, 1998) and changes in the retina found in the last screening result. These risk factors were prioritized in the new diabetic eye risk communication tool based on the available evidence to make it "comprehensive", easy, friendly, and less complicated for individual's to use (Weinstein and Sandman, 1993). Each quarter was divided into three parts, and each part was given specific colour. The outer part is a green colour that means low risk, the middle part is amber indicating medium risk, and the inner part is red indicating high risk.

Figure 7.2 Diabetic Eye Risk Communication Tool

The new diabetic eye risk communication tool was appraised by twenty people with type 2 diabetes (R0 and R1). The socio-demographic characteristics of this group are shown below in Table 7.1 and Table 7.2

Table 7.1 Stage Two socio-demographic characteristics

Interview participant	Number=20
Range age	40-78 years
Mean age	61.5
Gender	
Male	13
Female	7
Ethnicity	
White British	9
South Asian	11
Level of retinopathy	
R0	10
R1	10

R0: No diabetic retinopathy, R1: background diabetic retinopathy

Table 7.2 Stage Two Participants Characteristics

Number	Name	Reference	Age	Sex	V/A	Grade (R, L	Medical his	Occupation	Education
1	Nick	WB	79	M	6/6, 6/6	R0		Retired	None
2	Jack	WB	62	M	6/6, 6/6	R0		Mechanic	Diploma
3	Doug	WB	66	M	6/9, 6/6	R1		Teacher	Degree
4	Petty	WB	55	F	6/6, 6/6	R0	CABG,BP	Shopkeeper	None
5	Joy	WB	64	F	6/6, 6/9	R1		None	Unknown
6	Geralrd	WB	53	M	6/9, 6/9	R1		Unknown	Unknown
7	George	WB	70	M	6/6, 6/9	R1		Retired	NVQ
8	Gareth	WB	86	M	6/6, 6/6	R0		Retired	Unknown
9	Jean	WB	75	F	6/9, 6/9	R0		Pensioner	GCSE
10	Lily	SA	72	F	6/9, 6/6	R1		Retired	Diploma
11	Amy	SA	54	F	6/6, 6/6	R1	BP	Nurse	Degree
12	Salma	SA	50	F	6/6, 6/6	R0		Bank	Degree
13	Amjad	SA	76	M	6/9, 6/9	R0		Retired	NVQ
14	Bashar	SA	72	M	6/5, 6/6	R0	BP	Retired	None
15	Amin	SA	72	M	6/9, 6/12	R1		Shopkeeper	GCSE
16	Hassan	SA	62	M	6/6, 1/60	R1	Optic Neur	Taxi driver	None
17	Ali	SA	73	M	6/6, 6/9	R1		Retired	Degree
18	Rehana	SA	68	F	6/6, 6/6	R0		Unknown	Unknown
19	Sam	SA	57	F	6/6, 6/6	R0		Secretary	Degree
20	Kaur	SA	59	F	6/12, 6/18	R1	Obesity	None	Diploma

WB: White British, SA: south Asian, V/A: Visual Acuity

7.3. Responses to the new diabetic eye risk tool

The new tool was generally reported to be helpful and easy to use by people with diabetes. It was described as a good visual representation that may improve the understanding of risk for some people:

"I think this tool is very helpful. A visual representation for some people is the only way they can understand it." (Nick, 79, R0)

One positive aspect of the tool was that it enabled people to see how they could balance non-modifiable factors (e.g. years with diabetes) with modifiable ones (e.g. Blood Glucose levels):

"This diagram or traffic light system, I think I am in the safe side. Three green (quarters) is very good, and this one in the amber shows that I had diabetes for longer than five years, but my diabetes sugar level is in the green side, because it is well controlled. It is less than seven always and I haven't got any changes in my both eyes, so probably my understanding is that I am in the safe side. This is really good way of explaining it to me, I can see that I am at low risk." (Mubarak, 47, South Asian, R0)

A number of people with diabetes, particularly those who scored four greens in the risk tool, appeared to be reassured by using the new risk tool. It provided them with information about their level of risk, as well as highlighting areas of concern in order to help them keep their diabetes under control:

"Having four in the green side, I must be at low risk then isn't it, still I should be careful so I don't go beyond, I have to stay like this and keep myself in the green side." (Jack, 62, R0)

The new risk communication tool was also perceived as something that could be used by a range of Health Care Professionals, such as GPs, practice nurses, opticians, or diabetic retinopathy screeners:

I guess the best person who should go through it should be health professional, I think the doctor himself or practice nurse, or I think the optician who does diabetic screening would be good to explain it to people." (Mubarak, 47, South Asian, R0)

7.4. The influence of the new risk communication tools on risk perception

People with diabetes' appeared to find the new risk tool useful for making sense of their future risk, as most people with diabetes appeared to be aware of the different risk categories (high, medium, and low). In short, they could link the different risk categories contained within the tool to the probability of them developing complications:

"Low risk means that there is low possibility of me getting complication with my eyes, and high risk means there is higher possibility of me getting complications with my eyes, if my blood sugar is high that means I am at higher risk, and if I had my diabetes for long time that also means that I am at high risk which may create problems. I may be at old age probably I will classify that I would be at high risk, or when I attend the eye screening if I had changes in my eyes or my vision deteriorated, then probably I would be at high risk. But now I think I am at low risk." (Mubarak, 47, South Asian, R0)

A number of people with diabetes also appeared to make a connection between their perception of risk and their blood glucose results after using the tool. However, it was felt that some people with diabetes, particularly those who lacked knowledge, may require more information about the differences in blood glucose level at certain times; for example, the ways in which blood glucose levels may vary before and after taking medication. The following quote highlights the confusion that people with diabetes may have regarding the differences between HbA1c and blood glucose level:

“I think I am at high risk because of my blood sugar, isn’t it? My blood sugar is between seven-to-nine which is amber. But you know sometimes when I eat something in the night time and I don’t take medication and I eat, then in the morning my blood sugar come to eleven and twelve, before medication it is six and seven in the morning but if I eat any food, it goes up and up and up, I have to eat, you know, I am diabetic, so yes I am at high risk, because when I when I eat, I got sugar in my blood then I am at higher risk, because I got no energy, I can’t walk much so I got no energy and I can’t do nothing, but if I got low sugar, I have to put sugar in my tea, and swallow it and drink it, and I got more energy to walk and thing like that so I can do things but then I got sugar high, I don’t know what to do, I really don’t know what to do, because if I got no eating sugar, then my energy is gone, I can’t walk much.” (Kaur, 59, South Asian, R1)

The use of the new risk tool was also tied in with the ways in which people with diabetes made sense of their diabetes and diabetic retinopathy. For example, Lily scored one red, one green, and two ambers when she used the tool. However, whilst she then perceived her risk as high, she attributed her high risk to noticeable symptoms such as watery eyes or not wearing sunglasses, as opposed to her blood glucose level or other risk factors:

“I think I am at higher risk, because I am naughty, I keep forgotten my glasses, and my eyes keep running water, in the summer it is always watery, and people say why are you always crying?” (Lily, 72, R1)

7.4.1 Knowledge of diabetic retinopathy risk factors

The new risk communication tool appeared to help individuals understand the risk factors associated with developing diabetic retinopathy:

“This traffic light system is really good way of explaining the risk factors of diabetic eye, I was a bit worried but now I can see clearly that I am at low risk.” (Hamza, 40, South Asian, R0)

Thus, providing risk information in a clear and attractive style was perceived to improve patients' understanding of their own risk and there was also some evidence to suggest that people with diabetes may change their diabetes self-care management as a result:

> *"Doing this test, made me think a lot deeper than I did before ... because I have 2 reds and 2 greens, I should give more attention to my diabetes to keep my eyes safe." (Alan, 45, R0)*

It was also apparent that the new tool could re-assure those who were at low risk. This group described how they felt positive about their diabetes and the ways in which they managed it and also noted the potential benefits of continuing with their regime:

> *"Having scored 4 greens means that I am doing the right thing, so I should continue the good work and keep my blood sugar under control and look after my diet" (Hamza, 40, South Asian, R0)*

The use of certain colours appeared to help in understanding risk, particularly the colour red that is generally associated with danger which in this case was associated with high risk of blindness and complications. In addition, the universal association of red with danger was found to facilitate the presentation of risk for those who could not read or whose their first language was not English:

> *"Yes, I can understand this, green is safe, red is more risk of complications and blindness may be, yes, red is danger." (Amy, 54, South Asian, R1)*

There was also some evidence to suggest that using the tool could help people with diabetes to become more aware of the fact that diabetic retinopathy is associated with the duration of diabetes:

"Green means less danger and red means more danger. The fact is because I had it for long time that means I am at more risk, because the longer you have it there are more risks associated with it you know." (Doug, 66, R1)

The design of the risk tool, which incorporated the traffic light system, also appeared to encourage people with diabetes to interpret their own risk by comparing their position in relation to conventional use of such colours. In other words, they could interpret their own risk easily, because the colour coding where green means safe and red means danger is internationally accepted and widely used. Therefore, individuals could easily confirm that their risk is low and that they were managing their diabetes effectively:

"This tells me that what I understand is obviously it is traffic light system, isn't it? So green is go. So I am assuming green is giving the perception that is I know what I am doing and how to manage my diabetes effectively, red is danger I would be worried if I had more in the red zone." (Alan, 45, R0)

7.4.2 Diabetes Self-Care Management

The use of the risk communication tool was also perceived as being able to help people with diabetes to remember risk factors and to incorporate this knowledge into their self-management, particularly in terms of it being something that might encourage people to keep their blood glucose levels under control. The following quote from Mubarak demonstrates that he perceived the tool would help him to retain the information that he was given by his Health Care Provider. He scored one red (duration of diabetes) and three greens, which he interpreted as not being at risk:

"This tool tells me, my understanding, having 3 greens, there is high possibility of not having diabetes complication in my eyes, obviously, I got red one because I have had diabetes for long time, this tells me that I may have some complication with my eyes but I think having 3 in the green side, so far no changes in the eyes, good glucose control always less than

> *seven, and having type 2 diabetes, so I assume I am in the safe side, I understand that I have no control on duration of diabetes or type of diabetes, but I can keep my blood sugar under control to keep my eyes free of any future changes … well, my doctor did explain thing to me and did explain that diabetes could cause blindness, but to be honest, this tool helped me a lot to remember such information." (Mubarak, 47, South Asian, R0)*

Many of the people with diabetes viewed diabetic eye screening as a re-assurance regardless of their level of risk (as discussed in the previous chapter):

> *"I believe everybody should attend eye screening regularly as told by doctor, because you never know, things may happen quickly and suddenly. I feel confident now after using this tool, I feel that I am at low risk, and that is what the doctor says as well, that I have to keep my blood sugar under seven." (Salma, 50, South Asian, R0)*

The design of the risk tool as traffic light system appeared to improve awareness of the importance of diabetes self-care management and could lead people with diabetes to re-evaluate their personal care. For example, Salma suggested that she would change certain behaviours in relation to her diabetes:

> *"The red colour means either I am not looking after myself then I need to do something about it, but if it happened not because I am not looking after myself then I need to take steps to make sure that does not get worse, or whatever the medical outcome will be. If I had something in the amber or the red, obviously I need to change my plan, but, if I carry on looking after myself I should, emm, I might still be just here (amber), I might not progress further." (Salma, 50, South Asian, R0)*

People with diabetes viewed the risk communication tool as a good means of self-assessment and could help people with diabetes control their blood glucose level. For example, it appeared that the risk tool helped Mubarak to understand that his risk would remain low by keeping his blood glucose level within recommended parameters. Moreover, this could then protect him from developing sight-threatening complications:

"I think it is clear and good tool, for people with diabetes to identify themselves, if they are in the green or red side, if there is a greater possibility for them having complications with their eyes, obviously, again, probably this is not hundred per cent perfect, but it helps a lot. I think I should maintain my diabetes well controlled below 6.5, so no changes to my eyes would happen probably. I should be wise and look after my diabetes, watch what I eat and try to keep things under control." (Mubarak, 47, South Asian, R0)

Thus, it appeared that the new risk tool could help individuals to focus on their diabetes care in order to prevent further deterioration:

"Obviously, if you have things scored in the amber, this means that things are not quite right, and things could deteriorate and become more in the danger zone." (Amjad, 76, South Asian, R0)

Using the risk tool appeared to encourage people with diabetes to think critically about their diabetes and the risk factors that could have an effect on their eyes. For example, Mubarak became aware that having diabetes for a long time may not be a problem as long as he did not experience changes or damage in the retina:

"I think will not be wise of me to think too much about what is going to happen in the future because I am in the safe side and all my screening tests show that photographs were clear that there is no problem at the moment anyway. The number of years I have had diabetes is not many years, if I have had changes in one of my eye probably I would be concerned about it, and probably I will think that I started to be at risk." (Mubarak, 47, South Asian, R0)

7.4.3 The impact of the risk tool on behaviour

Those people with diabetes who scored four greens with the new tool appeared to be reassured and saw this as a sign of ‘reward’ for trying to control their blood glucose level:

> *“What I found is, by doing this test with what you call it risk tool, this made me think to be honest a lot deeper than I did before, I do feel happy now, you made me by just doing this exercise alone, think really deeply about it more than I have done before, it made me feel happy that I am actually at low risk and I need to keep the hard work I am doing. This is really good it is fantastic, thank you.” (Petty, 55, R0)*

It was also apparent that using the tool could motivate low risk people with diabetes, particularly those with no risk factors, to report that they would continue to control their diabetes:

> *“Having four greens means to me that I am coping ok with my diabetes, I think, because I am controlling it very well. I understand that I need to keep my blood sugar down to stay at low risk. I am concentrating on my diet as well as my tablets really. Sometimes I go out for a pop meal, and I have a pint which has sugar in it. But only I have one pint of drink don’t get me wrong I am not a drinker. Sometimes the meal I have can have gamon steak, which is a bit high in fat, but I don’t take a lot of it any way. So I think although I do it occasionally, this tool tells me that I am still doing well with my blood sugar.” (Nick, 79, R0)*

As is apparent in the example below, it was also evident that such emotions may change, particularly if his blood glucose level improved. Thus, the traffic light system appeared to offer people with diabetes insight into the benefit of behavioural changes. For example, the modifiable risk factor (HbA1c) could alter from one colour to another based on people’s diabetes self-management. Thus, if a person with diabetes scores amber this could change to red colour if their diabetes self-care management deteriorated or could change to green colour if their diabetes self-care management improved:

“Obviously I am in a sort of warning phase where I am not quite ready yet which is like you got to take direct and immediate action but you heading towards it as I see it from this traffic light system, I have amber and could move to red you know, emm, I feel a bit anxious, you know because I thought I was doing ok actually but with this traffic light system, you are not doing too bad but you could be doing a lot better, but at the same time you could be doing a lot worse, but if you don’t pay attention it could be costly. Yes that makes very good sense, as I say I can see very well now, I do realize that there is direct correlation between diabetes and eye complication which I understood anyway, because as I said anyway my understanding is that my diabetes is not bad at all really, you know, I understand the complications and stuff.” (Alan, 45, R0)

People with diabetes reported that if they were able to see improvements or deteriorations in their risk score when using the tool then that could also encourage them to improve their diabetes self-management:

“It is good now (blood sugar level), better than before, this morning it was seven and a half only, I should keep it always low, you know before, my blood sugar was really high, always thirty-five or forty, now it is seven or ten sometimes goes up to fifteen but this is very rare. I always try to keep it low as much as I can.” (Bashar, 72, South Asian, R0)

The traffic light system also highlighted the importance of the amber zone between high risk and low risk as this prompted people with diabetes to recognise the importance of moving towards the green zone:

“Well still I think I am in the middle, don’t I, I think I need to keep my blood sugars level down, yes, I think that is the way to save my vision. I think I am at moderate risk now, emm, looking at this, I can’t go back now, and I had my diabetes for many years and couldn't be changed. I presume if I take my self to the green rather than midway between amber and green, which is going to be my hope to secure my sight.” (Joy, 64, R1)

However, it was also apparent that the risk tool could increase people's levels of anxiety, particularly if they did not control their blood glucose and were in danger of future complications. In contrast, if they were able to control their blood glucose they could reduce the risk to their sight:

"Well, with this traffic light system you know it could be really two ways, although it could increase peoples anxiety level, it tells you that you need to do a bit more, well actually if I do a bit more to sort of limit sugar intake I will be going back to green and if I increase my sugar intake, I will be heading towards red, if I don't pay attention to it I am going to red, and towards complications, so I mean it is always going to be anxious because you start think, ok, am I doing the right thing am I having too much now, or too little because it worries me sometime because I might have low blood sugar level you know and I am not sure is that to do with the mood because I was diagnosed few years back with clinical depression and I was wondering, emm, ok how much is this sort of health based and how much is due to psychologically base you know, I agree with you, I should keep my sugar intake low, keep it under control." (Alan, 45, R0)

7.4.4 The impact of the new risk tool on health beliefs

This section demonstrates how people with diabetes integrated their score on the risk tool with their own health beliefs around diabetes. For example, some people with diabetes did not perceive themselves to be at risk despite the fact they had diabetes for long time, their blood glucose was uncontrolled, and they had changes in the back of their eyes. For example, in the case of Amin, the risk tool made him more conscious of his risk though he also sought to remain optimistic:

"For me, the red colour means danger signs (laugh), the yellow is medium and green is low risk. …I have one in the green, two in the amber and one in the red side, at the moment I am at low risk for me personally, but it depends on how people maintain to look after themselves, how they control their blood sugar, I am not getting young I am getting old now, I think my risk is balanced between the two (high risk and low risk), I would

say I am in between, I could not tell you exactly, I think it is in between" (Amin, 72, South Asian, R1)

Chapter six showed the differences in understanding risk. For example, a five per cent risk appeared high to one person with diabetes and low to another person. The majority of people with diabetes classified themselves as low risk or high risk before they used the tool. This tool appeared to get people with diabetes to think about the facts and appraising themselves according to their own way of life and own values. Similar to Amin, Hassan avoided using the word "high risk" despite the fact that he might be at higher risk, preferring to categorize himself as medium risk:

"I think I am at medium risk, having one item in the red side, one item in the amber and two in the green." (Hassan, 62, South Asian, R1)

In contrast, Amy, who scored one red, one amber and two greens and, as such, may not be perceived to be at high risk, believed that she is at high risk because she also had hypertension. Thus, her distress during the interview appeared to be related to her more general concerns regarding wider health issues:

"I think I am high risk now, it is in between actually, but I said it is high risk for me because I have other health problems. I have high blood pressure also, and I think its related to each other, the blood sugar and blood pressure are connected with each other, I know diabetic retinopathy is one of the most serious complications of diabetes I know, but the problem is because of the high blood pressure, it might cause some other problems not only eyes, this is why I said I am at high risk." (Amy, 54, South Asian, R1)

To summarise, the data in this chapter indicates that the new risk tool was reported as helpful and easy to use by people with diabetes. It was described as good visual representation that may improve the understanding of risk of diabetic retinopathy. It also enabled people to see how they could balance non-modifiable factors with more modifiable risk factors. A significant number of people with diabetes appeared to be reassured by using the new risk tool, which could be due to the fact that the recruited people with diabetes were at low risk. The lack of negative comments about the tool may be due to the fact that the participants in stage two were at low risk. Most people with diabetes appeared to be aware of the different risk categories (high, medium, and low), and therefore, they appeared to incorporate their perception into the new risk tool. However, a number of people with diabetes also appeared to link their perception of risk and their blood glucose results rather than HbA1c results after using the tool. Providing risk information in a clear method appeared to provide people with a new way of understanding of their own risk and was often linked to them discussing how they may change their diabetes self-care management as a result of this new way of thinking about and framing the risks associated with diabetes. in particular, the new risk tool was found to facilitate the presentation of risk for people with poor literacy or whose first language was not English. The design of the new risk tool as traffic light system also seemed to make people with diabetes understand their own risk by comparing it with the usual use of such colours. The risk tool appeared to help people with diabetes to remember certain risk factors. Furthermore, people with diabetes were critically thinking about the risk factors and its effect on their eyes. It appeared that people with diabetes who have scored four greens were pleased as they believed that they had been rewarded by controlling their blood glucose. The tool appeared to motivate low risk people with diabetes, particularly those with no risk factors to keep on controlling their diabetes. In contrast, the tool may induce distress in those who believed that they were at high risk. Therefore, people with diabetes were able to see improvements or deteriorations in their risk score based on their blood glucose results which could also encourage them to improve their diabetes management. People with diabetes have used their data and incorporated it with their own health belief system. Although the majority of the people with diabetes classified themselves as low risk or high risk before the tool, this tool appeared to get people with diabetes to think about the facts and appraising themselves according to their own way of life and own values. The traffic light system highlighted the importance of the amber zone between high risk and low risk and people with diabetes could recognize the need to move closer to the green zone (low risk). It may encourage behavioural change and save people with diabetes's sight.

7.5. Communicating diabetic retinopathy screening results

The chapter now moves on to present the findings from participants in stage one and stage two of the study in relation to communicating the results of diabetic retinopathy screening. Data is incorporated from the forty people with diabetes and the five Health Care Providers to answer the question that explores people's preference of the most appropriate way of communicating risk information about diabetic retinopathy and diabetic eye screening results to people with type 2 diabetes. Stage 1 and 2 data were combined in order to develop a broadly appraised model of communicating risk information about diabetic retinopathy disease and communicating diabetic eye screening results. As mentioned in chapter two, after diabetic eye screening is performed, the photograph of the retinae (the back of the eye) is sent to a trained and accredited regional NHS retinal grading teams, who carry out a two- or three-stage image grading method. This recognizes any changes that could point out sight-threatening diabetic retinopathy that necessitates monitoring or treatment. The grading teams communicate the results to the people with diabetes and their Health Care Providers. Screeners are not expected to give diabetic eye screening results at the time of screening for clinical and quality assurance reasons. However, despite this, it does appear that there is variability in terms of some screeners providing patients with their results.

7.5.1 Time and place

Interviews with people with diabetes identified that, despite the English National Screening Programme, the communication of the results of diabetic retinopathy screening did not appear to be a standardised process across all health professionals. For example, diabetic retinopathy screening results appeared to be communicated to people with diabetes at different times, places, and by different people based on who did the eye screening and where it was done.

Although eye screening tests for this sample were mainly carried out either by the opticians or by diabetic retinopathy screeners in the hospital, communicating the screening results appeared to vary between different practices and different professionals. For example, some people with diabetes reported that they had received the result at the same time as eye screening:

> *"The optician when he does the eye screening, he tells me everything is fine." (Abdulla, 47, South Asian, R0)*

However, it was also clear that diabetic retinopathy screening results may not always be communicated to people with diabetes at the time of diabetic retinopathy screening:

> *"No results were given at the time of eye screening, he said he is going to send it to the hospital and they will contact me." (Ali, 73, South Asian, R1)*

The preferences of the people with diabetes in this study regarding these practices were mixed. A number of the people with diabetes did not object to receiving the results some period after the eye screening, but most preferred that the diabetic eye screening results to be provided at the same time or within twenty-four hours. Their main concern was that there could be a chance for the results to go unreported or for the results not to reach the patients at their home address, which was a clear cause for anxiety:

> *"Well if they can't do the results straight away, if technology is not there to give them the results you know if they have to be analysed by another doctor then I think within the twenty-four hours you should be notified if something is wrong, if you don't hear from people you assume that everything is ok." (Gerald, 53, R1)*

For example, Salma had not received her diabetic retinopathy screening results. Therefore, she believed that her results were normal as a consequence of them not being reported to her and did not question whether the results had simply been misplaced:

> *"The results were fine, otherwise the doctor would have said something to me, and I assume no news is good news." (Salma, South Asian, 50, R0)*

Perhaps not surprisingly, those people with diabetes who perceived themselves as at higher risk tended to be more anxious and preferred the results to be communicated to them at the time of the examination, particularly if there are was evidence of changes in their eyes. This is apparent in the following quote from Younis, who has diabetic retinopathy (R2):

> *"I think it should be the optician, there and then, I would like to know. I think they should have it yes, they do the tests, and they do know if there is anything, I think they should also relate that information to my GP." (Younis, 55, South Asian, R2)*

However, some of the Health Care Professionals interviewed pointed out that diabetic eye screeners may not provide such information to avoid providing patients with the wrong results. Instead, they described how the results should go for grading first:

> *"I think it is different with the opticians because they are purely screeners so they are only taking pictures so I think they prefer not to tell the patient because if the screening grading protocol goes through is that somebody may agree with somebody and disagree with somebody else. So what the optician tells the patient may change further along the line because it has been graded by other people. So I think that it is better that they don't." (Kate, White British, Screener)*

(N.B. Kate is referring to the fact that when opticians undertake screening they are not part of the quality assurance/grading process unlike the retinal screeners who both screen and grade).

It was also clear that delays in the communication of diabetic retinopathy results could lead to anxiety. For example, Jack, who is fifty five years old and who has background diabetic retinopathy (R1), reported being anxious and dissatisfied because the screener did not offer him any results, which simply prolonged his anxiety. He was clearly frustrated about not having been given any results from the procedure:

"Well, I got a letter saying they are going to keep me under supervision and they will keep looking at my eyes but no reason why I can't have results, I have diabetes for many years. The lady who did the picture says I can't tell you anything because I am not qualified, I can't give any results, and if there is anything the doctor will talk to you about it." (Jack, 60, R0)

7.5.2 Face-to-face communication

Not all people with diabetes preferred face-to-face to receive diabetic retinopathy screening results. Their views were wide-ranging regarding the most appropriate method of communicating diabetic retinopathy screening results. However, most of the people with diabetes preferred face-to-face communication rather than receiving the results via a letter:

"I suppose I would be happy with word of mouth, somebody (Doctor or optician) explaining it to me rather than getting letters. I think it would come better." (George, 70, R1)

This appeared to be related to the perceived delay in people with diabetes receiving their screening results. For example, a number of the people with diabetes were unhappy with the current process of reporting the diabetic retinopathy screening results because they associated this with what they thought was an unnecessary delay, which could also cause anxiety among people with diabetes:

"The hospital sends the results to my GP then my GP tells me the results and it could take long time and makes me anxious." (Rehana, 68, South Asian, R0)

In addition, some people with diabetes appeared to prefer receiving diabetic retinopathy screening results face-to-face due to the fact that they have experienced problems with reading letters because of to the condition in their eyes or because they had literacy problems or language barriers:

"Well earlier I wasn't very good at reading, now I am ok, but I would have preferred like to talk rather than to have email or letter." (Kumar, 57, South Asian, R2)

The Health Care Professionals in this study also preferred that screening results was communicated face-to-face using risk communication tools or the patient's actual retinal image in order to facilitate patients understanding. As with the people with diabetes, the Health Care Professionals also perceived that face-to-face screening results communication overcame problems people may have with not being able to read letters, understand English, or understand the medical terminology:

"I do not think that sending the results to the patient means anything to them. I think face to face chat is much better, because they don't understand the medical terminology in the letters and there maybe jargon and I think it is better discussed verbally face to face with the picture in front of them then they will have a clue. If they want copy of the picture we ask them to make an album, so we can compare one year by year and then they will be happy by doing that." (Suresh, GP, South Asian)

In addition to the visual risk tools, Health Care Professional also preferred that the level of diabetic retinopathy risk was calculated using risk calculators to educate the people with diabetes and to improve the understanding of their personal risk:

> *"My first response was that this risk calculator could generate great data to educate our patients after their diabetic retinopathy screening or their regular consultation about the seriousness of their condition, but also calculate the benefits of improving their health."* (Hayley, Ophthalmologist)

It was also the case that a number of people with diabetes preferred that their GP provided them with the results of their screening tests as they had a good relationship with their GP, and so felt more relaxed. It was also apparent that people found it easier to access appointments with their GPs:

> *"I would feel more comfortable if my doctor was informed about it first and then I would go, or my doctor would call me for an appointment, and I think I will be informed, emm, face to face by my doctor, probably I would feel more comfortable by my doctor, but I would not like to be informed by letter."* (Abdulla, 47, South Asian, R0)

In contrast, other people with diabetes wanted such screening results information to come directly from their optician or their ophthalmologist as they believed that they were the experts more so than GPs:

> *"The optician I would think or here at the clinic. I know the information gets passed on to the GP as he can tell you when he sees you, can't he? I've got to admit the last time the diabetic consultant was informed of the results of my eye test and he sent me a copy of the report, which I think was quite a good idea."* (Gareth, 86, R0)

It was clear that a number of the people with diabetes were aware that GPs are not eye specialists, which underpinned their preference for their diabetic retinopathy screening results to be provided by an ophthalmologist or optician. It was these professionals who had the specialist knowledge and, therefore, could better answer any concerns that they may have:

"I think the eye clinic or optician because they explain more, but the GP is not specialized in that area, he is just general doctor, but eye clinic or optician can explain it much better." (Sam, 57, South Asian, R0)

It was also the case that a number of people with diabetes were satisfied with having received a copy of their report or of their retinal screening image as these provided a record of the problem and they could discuss issues with their family:

"I think probably if he puts it down in writing, you know the doctor tells you what the problems are if they put it down in black and white as well you see if you are having these problems I mean you know you have got it in black and white and you are able or the family knows what's going on as well. You know just like a report on when a patient comes in just give them like a bit of a report a written report just what the problems are if any then that's a double check then." (Harry, 78, R1)

7.5.3 The use of numerical information and descriptive words

Individual level of risk is a key component in the communication of health risk messages. Therefore, when receiving risk information or diabetic retinopathy results, people with diabetes need to know if they are at high risk or low risk of developing sight-threatening diabetic retinopathy. In chapter six (section 6.3.4) the author discussed the perceived severity of risk and the variation in severity of risk between people with diabetes and Health Care Professional particularly when numerical data is used. This section discusses the preferences of people with diabetes and Health Care Professionals with regards to the use of numerical information and descriptive words in order to provide risk information about the diabetic retinopathy screening results.

In this study, people with diabetes were divided in their views as to what was the most effective information regarding their level of risk following their diabetic eye screening. Some suggested using percentages, such as people having a two per cent, five per cent, ten per cent, or twenty-five per cent chance of developing diabetic eye complications in the next five years:

“It depends on the doctor. They know how to communicate really. Personally I think the percentage is the right way to do it.” (Gareth, 86, R0)

Some people with diabetes suggested that risk information and diabetic eye screening results should be communicated using plain words, such as high risk or low risk because some patients may not understand probabilities and percentages:

“Not everybody understands what ten per cent means. If you’ve got an older person they might not understand the term you are talking about. So you know should be put into something that is plain English and say look you know you are at a very high risk, you give the patient, you should tell them what is going on.” (Gerald, 53, R1)

Others preferred using both probabilities and words as it helped them understand their risk better as well as their diabetic retinopathy screening result:

“Sometimes it’s good idea to use numbers sometimes use words, when the doctor saw me before to discuss an operation, he told me there is risk one in one hundred to lose vision or bleeding, I think it’s better to explain it, and to tell you are at high risk so I will be able to know what is my risk and what is the end result.” (Sam, 57, South Asian, R0)

People with diabetes appeared to prefer a simple and clear approach when risk information is communicated. In other words, they wanted their Health Care Professionals to avoid using medical or unusual terms:

“You should be told straight, you shouldn’t dress it up in medical terms. If you say to somebody your eyes are getting worse if you don’t change whatever you are doing if you don’t change your eating habits or your diet then obviously you are going to make yourself worse, so possibility we can’t help you anymore.” (Gerald, 53, R1)

Some people with diabetes, such as Rehana, did not have a preference in terms of whether numerical information or descriptive words were used to convey her degree of risk. She wanted to be told in clear terms of her risks though she was also aware that not all patients would want to be told in such terms and as such was concerned about others, particularly those who may become anxious and more worried if risk was communicated in such a way to all patients:

"I don't mind what way they use to tell me about diabetes or my risk of having complications as long as it's accurate. For me I think the truth is the best, whether it is low or high or if it is damaged, the truth is the best. If the patient can take it, if they think they are strong it is best to tell them the truth but if the patient is weak they might take it to heart and think a lot about it." (Rehana, 68, South Asian, R0)

Jean suggested that a family member or carer should escort those who are at risk to make sure that the message is understood by people with diabetes:

"I think they should tell you exactly what the risk is ... because I mean there is no point in them telling them for their own good that they have got to take care or whatever has got to be done if they I know it sounds silly but people have got to listen and if they are not able to do that they have got to have an escort with them or something so long as they know the family knows what's going on, it is important." (Jean, 75, R0)

Some of the Health Care Professionals felt that involving family members in the process of risk communication could benefit people with diabetes as some did not appear to understand the message or they experienced language barriers. It was also apparent that Health Care Professionals believed that some patients found it difficult to retain the information they were given and/or believe that they are not at risk and so may not implement the information they are given:

"We are kidding ourselves once they reach home the wife asks what did the doctor say he said well I am alright I am on the borderline I am diet I

am this and that, they don't relay the same message we sent. They take the message seriously but they forget." (Fawzi, GP, South Asian)

Health professionals could sometimes be frustrated when an interpreter was needed to translate risk information to people with diabetes. Kate, for example, questioned the credibility of translators, particularly if a translator is a family member. The frustration appeared to increase when the same information rephrased in different ways several times, but did not appear to register because either the translator was not translating well or was translating the information in a way designed to reassure the patient rather than communicating risk information:

"Well obviously one of the things is whether they can actually really understand what you are saying, so simple language barrier is obviously critical. If you are having to go through an interpreter that can make a difference because you don't know if they are translating exactly what you say to the patient. If it is a relative and they sometimes particularly when a patient is asking the same question repeatedly and throughout the discussion, you do get a feeling then that actually this is not going in or thinking it all. Sometimes you know that reinforcing just to check, I need to do this, or I don't need to do this. When you get the third or fourth occasion or so, should I do this or not do this, you know that you are probably not communicating well." (Kate, Screener)

One of the Health Care Professionals reported that they used plain words with "non-educated" people and use scientific language and numbers such as percentages and probabilities to more "educated" people. However, it was not clear how this Health Care Professional determined or assessed individuals' level of education:

"I don't like to use numbers; they will forget it when they reach my door. If I said eighty per cent, seventy per cent, forty per cent, thirty per cent then once they leave the surgery they forget it does not mean anything to them. It has to be words emphasizing, Ok. So either I will put mild or moderate

or severe or sometimes I say right it is getting worse but I think percentage is for the educated people it is excellent but not for the non-educated people. When you do that when you ask them next visit what did I say the probability they forget. If you want a probability you have to type it and enforce your words with the written message if you want to get proper message." (Fawzi, GP, South Asian)

It also appeared that not all Health Care Professionals support the use of percentages when communicating screening results. In the case of Kate, for example, she appeared to use probabilities for high risk information and to use words if the risk to the individual was low:

"Some patients I don't think they understand percentages at all. So I usually reinforce it if I am using a percentage. If it is 50% I then say that means there is one in two chance that you could develop it but when we are talking about very small risk factors I tend to use low risk medium risk or high risk, that tends to be something they understand or is more relevant to them." (Andy, Ophthalmologist)

Health Care Professionals used descriptive words in order to provide detailed information about signs and symptoms, complications, treatment and management when consulting people with diabetes as many of their patients don't understand numerical information.

"Well, it depends because many of the patients we see in the practice don't understand probabilities and percentages and we have to explain their condition to them. We have to tell them your diabetes is progressive and it might affect the blood pressure. We have to control your diabetes. Why my eyes are getting worse because your diabetes is not controlled. How can I control it I am on insulin we have to review the insulin. I am on tablet we have to review the tablets. So that's as much as you can do. If it is extensive of course it has to be the ophthalmologist who deals with the results." (Fawzi, GP, South Asian)

To summarise, communicating the results of diabetic retinopathy screening did not appear to be standardized among health professionals. It appeared to be communicated to people with diabetes in different times, places, and by different people based on who did the eye screening and where it was done. Most people with diabetes preferred that the diabetic eye screening results to be communicated face-to-face and at the same time or within twenty-four hours after performing the diabetic retinopathy screening. A number of the people with diabetes were unhappy with the current process of reporting the diabetic retinopathy screening results. For example, delay in the communication diabetic retinopathy results could lead to unnecessary anxiety. The Health Care Professionals also preferred face-to-face screening results communication in which they could use a range of methods such as risk communication tools, risk calculators, and individuals' retinal images in order to facilitate and improve their understanding. Health Care Professionals also felt that involving family members in the process could benefit people with diabetes. Some people with diabetes preferred that their GP provided them with such screening results information as they have had good relationship and found it easy to access appointments, while others favoured their optician or ophthalmologist as they believed that they were the experts in the field. The data also indicated that people with diabetes were divided regarding the most effective risk communication format. Some suggested using numerical information percentages and some suggested using descriptive words. Others preferred using all of them jointly. Health Care Professionals argue that providing numbers such as probabilities may benefit the people with diabetes when it's provided with written copy of the results.

7.6. Conclusion

The new risk communication tool was reported as useful, easy to use by people with diabetes, and described as a good visual representation that may improve the understanding of risk. After using the tool, people with diabetes appeared to be re-assured, become more aware of risk categories. The use of the new risk tool was also tied in with the ways in which people with diabetes made sense of their diabetes and diabetic retinopathy. Furthermore, providing risk information in a clear method appeared to encourage behavioural change.

It was found to facilitate the presentation of risk for those with low literacy, or whose their first language was not English. The design of the risk tool as a traffic light system also seemed to make people with diabetes interpret their own risk by comparing it with the conventional use of such colours where green means safe and red means danger. It made them realize that controlling blood glucose is in their hand and not their Health Care Professionals.

The data also showed that communicating the results of diabetic retinopathy screening did not appear to be standardized. Most people with diabetes preferred that the diabetic eye screening results to be provided face-to-face, at the same time or within twenty-four hours to avoid unnecessary anxiety. The Health Care Professionals also preferred face-to-face using risk communication tools. Health Care Professionals also believed that involving family members could benefit people with diabetes. Improving professional-patient relationship can improve risk communication. Risk information should be communicated by using simple approach and to avoid using medical or unknown terms. Such subjective measures are difficult to predict but such professionals need to use a standard means of communication.

Chapter 8. Discussion

8.1. Introduction

This chapter discusses the findings of this study which focuses on the ways in which people with diabetes along with Health Care Professionals perceive and experience the risks associated with diabetes and the ways in which both groups make sense of risk communication as its central focus. The study highlights several principle findings regarding people with diabetes's perception of risk such as:

- This study has shown that peoples' knowledge of their diabetes and diabetic retinopathy is varied.
- It also shown a range of beliefs about the cause of diabetes and its complications, this was evident even though most participants had diabetes for longer than five years and were seen regularly by their Health Care Professionals.
- Another aspect of this study is the substantial variation in perception of risk between people with diabetes and Health Care Professionals.
- Diabetes self-care management is influenced by individuals' lay beliefs and knowledge about blood glucose, which also influences people's diabetes self-care management.
- The authority of peer advice influenced individual's behaviour even though this may go against professional advice.
- Perceived high risk was linked to being older, having type 1 diabetes, being treated with insulin injections, being of South Asian origin, having visible symptoms or other eye problems, and having co-morbidities, which were all put forward for why people were at a higher risk of developing sight-threatening diabetic retinopathy. In contrast, low risk was linked with type 2 diabetes, treatment with oral hypoglycaemic drugs, reassurance by their Health Care Providers, and following Health Care Professionals' advice.
- The study identified a number of emotional responses to being at risk such as optimism and pessimism.

- Another issue that was highlighted by this study was the ways in which of people with diabetes often struggled to remember the risk information that was provided during their consultations with their Health Care Providers. It was also apparent that individuals often interpreted risk information in a variety of ways which appeared to be linked to their wider understanding about their health literacy as well as there being language barriers.
- This study found that communicating risk information using visual tools appeared to be received positively by people with diabetes, with people appearing to understand the information in relation to diabetes and their risk of diabetic retinopathy and potentially could lead to better diabetes self-care management.
- Ophthalmologists and opticians were seen as knowledgeable about eye conditions more so than general practitioners.

The risk of developing diabetic retinopathy and risk communication tools were investigated in this qualitative study among people with type 2 diabetes. In order to understand how people with type 2 diabetes perceived the risk of developing diabetic retinopathy, it was necessary to explore their level of understanding of diabetes itself and from there develop a model for communicating risk information about diabetic retinopathy and diabetic retinopathy screening results.

The effectiveness of risk communication depends on people’s understanding of the risk information given to them; the form in which the risk information is communicated may influence the decision-making process. In this study risk communication appeared to have an impact on people’s perception of risk and understandings, and therefore, could influence the ways in which they deal with their diabetes. The next section discusses the main factors that influenced risk perception.

8.2. Knowledge about diabetes and diabetic retinopathy

This study revealed a range of understanding in relation to people's diabetes and risk of diabetic retinopathy. It also revealed a range of beliefs about the cause of diabetes and its complications, which was the case even though most participants had diabetes for longer than five years and were seen regularly by their Health Care Professionals. The participants in this study reported a range of knowledge about diabetes, diabetic retinopathy, the causes of the condition, medical terms, abbreviations, and the implication of diabetes and diabetic retinopathy on their sight. For example, individuals put forward a range of names to specify the type of diabetes they have as well as perceived cause of their diabetes. This finding was supported by many previous studies in which knowledge of diabetes has been found to be varied among people with type 2 diabetes (Iqbal *et al.*, 2008). For example, Shrestha *et al.* (2007) found that people with diabetes were not aware of common ocular conditions. Alongside the fact that many of the people with diabetes had varied knowledge about medical terms, this study also found that health professionals often used medical terms that were not fully understood by people with type 2 diabetes. This appeared to be because health professionals sometimes overestimated or underestimated their patients' recognition of medical terms (Aufseesser *et al.*, 1995; LeBlanc *et al.*, 2014; Yoshida and Yoshida, 2014). However, this made it difficult for these people to take on board risk information they were given, which they found difficult to understand and confusing. The use of abbreviations was also found confusing by some patients. This study, therefore, highlights that Health Care Professionals should pay greater attention during consultations to the ways in which they communicate diabetes information generally to their patients and specifically risk information about diabetic retinopathy.

In this study, providing individuals with knowledge about blood glucose appeared to result in self-reported change in their diabetes self-care management. For example, once people with diabetes recognized that their HbA1c level had fallen between 7%-9% (in the amber zone) they appeared to be encouraged to improve their daily glucose observation. This echoes the findings of highlighted by Pace *et al.* (2006) regarding individuals' knowledge of normal values for blood glucose level. A recent study found that people with diabetes who hold negative perceptions about their diabetes (individual’s knowledge and experiences of their diabetes) were more likely to attend diabetes clinics than those participants who had positive perceptions about their diabetes (Thongsai, 2015).

It appeared in this study that a number of people with diabetes did not like risk information when it was communicated using percentages or probabilities. Similar findings were reported by previous studies (Gigerenzer and Edwards, 2003; Saver *et al*., 2014). Saver *et al.* (2014), for example, argue that providing quantitative risk information is unlikely to assist individual patients to understand their diabetes related risks.

Another important issue highlighted by this study is the perception among Health Care Professionals that “educated” people have better understandings of their medical condition. One significant outcome of this was that they did not provide more detailed risk information to patients perceived as “educated” such during their consultations. However, this study found that people with diabetes who have a degree or higher (e.g. Masters or PhD) or had been in further education (e.g. Diploma) did not demonstrate any better understanding than those who only had compulsory education (e.g. O level/GCSE) or who had no qualifications. Across these education groups, the people with diabetes did not always appear to understand the full extent of the complications related to diabetes or the implications of diabetes on their vision. Whilst the majority of people with diabetes had a general perception that diabetes causes eye complications, their knowledge about diabetic retinopathy was often limited, for example, the fact that some participants had a perception that any risk or damage to the eye can be easily cured by an ophthalmologist or their Health Care Provider. Similar findings were reported by Saver and colleagues (2014). Another study in South India found that people with type 2 diabetes had adequate knowledge regarding the symptoms of hypoglycaemia, but the range of complications were only known by one third of the participants (Shriraam *et al.*, 2015).

This study revealed that diabetic eye screeners may not provide patients with relevant information regarding their diabetic screening results because of concerns about providing inaccurate information. As such they were following procedure in not providing patients with information and sending the results for grading first. Therefore, one way forward is to improve patients' and professionals' education via educational programmes, which was advocated by previous studies (Ockleford *et* al., 2008; Carey *et al.*, 2014). However, there are two potential sets of problems with this approach. Firstly, individuals who are symptomless may not seek medical advice until they have noticeable symptoms or eye complications. This particular group may, therefore, not see such educational programmes as relevant to them. A similar finding was reported by Pace *et al*. (2006). Another study also concluded that individuals are more likely to take part in structured self-care management education programmes when they feel at risk of complications, that they believe diabetes complications are serious, and/or they believe that the programme may help them to avoid such risks (Ashtarian *et al.*, 2012). Furthermore, other issues that may influence participation in education programmes include a lack of personal motivation among both patients and Health Care Providers and certain access difficulties that were also highlighted by Pace *et al*. (2006). In addition, a recent study (Winkley *et al.*, 2015), conducted to determine why people with type 2 diabetes do not attend structured education sessions, highlighted three main reasons for non-attendance. These were 1) a lack of information regarding the perceived benefits of such education programmes; 2) personal preferences, such as the timings of the appointment; and 3) the shame and stigma associated with diabetes, which may preclude people from informing others of their diagnosis.

The second set of problems associated with education programmes are related to the variation in risk perception and understanding between patients and Health Care Professionals. Interestingly, this study revealed considerable variation in the level of risk perception between people with diabetes and Health Care Professionals. For example, the people with diabetes in this study perceived a ten-to-fifteen percent risk as low or very low because ten is closer to zero rather than hundred. Thus, according to people with diabetes, risk was only perceived as high if it was fifty per cent or higher. In contrast, Health Care Professionals perceived that a ten-to-fifteen per cent risk of developing diabetic retinopathy was serious and a very high risk and would, therefore, be worried if they were the patient due to the seriousness of the complication and the possibility of visual impairment. This considerable variation in risk perception may also help to explain why patents may not conform with health professional's advice because they assume they are at low risk and thus do not need to change their behaviour. Therefore, as has been suggested by Vlaar *et al.* (2015), increasing risk perception alone is unlikely to increase attendance at diabetes prevention programme. In addition, Edwards and colleagues (1998) suggested the standardization of language regarding risk across Health Care Professionals would be useful for patients and would help Health Care Professionals to become more consistent in their perceptions and definitions of risk when communicating with each other and their patients. However, they found that the standardization of risk messages between health professionals may not be appropriate due to the difference of interpretation of risk messages among patients. Edwards *et al*. (2013) found strong evidence that personalized risk information included within risk communication interventions improve understanding. This supports the design of the diabetic retinopathy risk tool in this study that enables people with diabetes to understand their diabetic retinopathy risk when risk information is communicated to them by their Health Care Professionals.

8.3. Lay beliefs about diabetes

The beliefs of people with diabetes and their knowledge of causes of diabetes appeared to impact on risk perception. People with diabetes in this study appeared to use certain ideas to make sense of their condition. For example, a number of the people with diabetes attributed their diabetes as the consequence of external forces, such as God's will, changes in body function, cold weather, bad luck and fate. They believed that these external forces were beyond their control, and therefore, they felt that they could do nothing about it. In other words, there was a sense of not having control of their diabetes. Similar findings were reported by Macaden and Clarke (2010) who investigated the influence of locus of control on risk perception among South Asian people with type 2 diabetes in the United Kingdom. Locus of control refers to individual's belief about whether the results of our actions depend on what we do or on actions of those (other people/other forces) outside our personal control (Wallston *et al*., 1976). Macaden and Clarke (2010) found that individuals attributed their cause of diabetes to external forces such as bad luck and divine planning or familial disposition. According to Macaden and Clarke (2010), many of these individuals also tended to depend on their Health Care Provider to intervene with their diabetes due to low sense of ‘self-autonomy’ and were not actively engaged with decision-making regarding their diabetes. A recent qualitative study conducted in the UK by Greenhalgh *et al.* (2015) to investigate the influences on the risk behaviour of South Asian women and how these influences interact and build over time. The study recruited 45 women of Bangladeshi, Indian, Sri Lankan, or Pakistani origin aged between 21 and 45 years with a history of diabetes in pregnancy. Participants were recruited from diabetes and antenatal services in London, UK. Data collections used group discussion and individual narrative interviews. The study found that the authority of peer advice influenced women’s behaviour even though this may go against professional advice. This was found to be due to the fact that peer advice, particularly when offered through a storytelling set-up, was perceived to be more familiar and meaningful to women. Therefore, Greenhalgh *et al.* (2015) argued that behaviour change interventions aimed at preventing and controlling diabetes are more likely to be successful if they address explicit behaviours by specific individuals in a particular cultural context. In other words, in order to be more successful, diabetes education should concentrate on explanations and interventions that are more meaningful to individuals and groups. Lindenmeyer *et al.* (2010) reported that people with type 2 diabetes engage in behaviour change interventions in different ways based on a close communication and openness in the direction of collaborative approaches to improve their skills and confidence for diabetes self-management. Therefore, engaging people with type 2 diabetes with the diabetic retinopathy risk tool would benefit them to understand their risk and may then lead to improvement in their diabetes self-care management.

8.4. Perceived severity of risk

This study found that the perceived severity of risk varied between people with diabetes. Whilst most people with diabetes perceived themselves to be either at high or low risk, few believed that everyone with diabetes is at the same risk of developing diabetic related eye complications. In terms of developing sight-threatening diabetic retinopathy, people with diabetes considered those people with diabetes who were older, had type 1 diabetes, were treated with insulin injections, were South Asian, had other eye problems, and had co-morbidities to be at a higher risk of developing sight-threatening diabetic retinopathy. In contrast, people with diabetes considered those who had type 2 diabetes, were treated with oral hypoglycaemic drugs, believed that their blood glucose level was under control, were reassured by their Health Care Providers, and those who were following their Health Care Professionals' advice all perceived themselves to be at low risk. Kesavamoorthy *et al.* (2015) found that people with diabetes perceived their risk of developing diabetic retinopathy to be significantly higher if they had co-morbidity factors compared to those without co-morbidity factors. Females consider themselves at higher risk more than males. Men generally view themselves as less vulnerable to health problems compared to women (Dolan, 2014). In relation to diabetes, similar findings were reported by previous studies (Homko *et al*., 2010; Reyes-Velazquez and Sealey-Potts, 2015). Homko *et al.* (2010) found that women with type 2 diabetes perceived their risk of developing complications to be significantly higher than men although they had the same level of knowledge of diabetes complications. More recent study conducted by Reyes-Velazquez and Sealey-Potts (2015) also found that women had a higher risk perception than men for diabetes onset. Therefore, future research needs to take onboard these findings and explore the differences in risk perception between men and women.

8.5. Factors influence risk perception

This study revealed that perceived risk was influenced by several factors such as knowledge, the presence of existing symptoms or eye complications, family history, co-morbidity factors, treatment, type of diabetes, age, and personal experience. Interestingly, the study found that years of education and grade of diabetic retinopathy were not linked to better understanding. In particular, the study highlighted significant differences between people with diabetes' perceptions of risk and the perceptions of Health Care Professionals. The wider evidence also suggests that, low levels of literacy can limit how people access information regarding risk, due to difficulties in reading and writing, or problems with communication (Pace *et al.*, 2006). This issue can also affect whether individual's access appropriate learning materials and can minimise the opportunities they have for engaging in meaningful risk communication.

8.5.1 Presence of visible symptoms or eye complications

This study highlights the importance of educating people about their diabetes, particularly those who are asymptomatic. The study found that those people with diabetes with existing symptoms or eye complications could talk about this in more depth and with more knowledge than symptomless people with diabetes. Similar findings have been found in relation to people with diabetic foot ulcers who were found to report better control of diabetes and were more likely to follow professional advice than those people with diabetic retinopathy; i.e. the latter may not have been so apparent to the individual (Searle *et al.*, 2008). However, not experiencing symptoms could eventually lead to a sight loss, particularly if these same individuals believed that they would eventually receive some "warning shots" which would allow them time to change their behaviour and improve their diabetes (Saver *et al.*, 2014). Another study found a positive correlation between the knowledge demonstrated by individuals regarding their diabetic retinopathy and laser treatment, which normally happened at advanced retinopathy (Aufseesser *et al*., 1995; Fenwick *et al*., 2013). Another recent study also found that patients had a reasonable understanding of the risk factors associated with diabetic retinopathy. However, their levels of understanding were potentially attributed to their past history as fifty per cent of participants in this study had proliferative diabetic retinopathy (R3) and most participants had undergone laser treatment, which may have influenced their understanding (Fenwick *et al.*, 2013).

Asymptomatic people with diabetes in this study did not appear to value risk prevention measures and tended to delay seeking medical care. Not only did this have a potential impact on their sight, it may also affect their quality of life. Other studies have found that patients with visible complications, such as foot ulcers, placed a greater emphasis on the personal control of diabetes (Searle *et al.*, 2008). In such cases, it appears that people would benefit from understanding the symptomless nature of diabetic retinopathy, at least in the early stages of the condition, as a means of encouraging people to control the progression of the disease and, as a result, prevent acute complication or sight-threatening diabetic retinopathy.

This study also highlighted that the early progression and risk factors of developing diabetic retinopathy should be sufficiently well understood by people with diabetes to identify disease progression measurement limits. Although individuals can control some of the modifiable risk factors such as blood glucose level, blood pressure, lipids, and attendance at diabetic screening, the non-modifiable risk factors such as age, duration of diabetes, type of diabetes, and diabetic changes to the eye, should be taken into account (Genuth *et al.*, 2003). Identifying risk factors and what form preventive care should take is an important part of managing diabetes and thus, preventing the progression of retinopathy (Boren *et al.*, 2007).

8.5.2 Personal experience

This study found that participants' perceived severity of risk was best understood within the wider context of their personal experience as it was these experiences that were seen to increase or decrease the perceived severity of risk. For example, individuals were influenced by the experience of seeing people with diabetes, such as a family member or friend, who did not manage their diabetes and who had complications as a result. This could be contrasted with individuals' experience of seeing people with diabetes who managed their diabetes and who experienced no health problems. Thus, the emotional impact of witnessing complications with a family member or friend, particularly if these complications were severe, appeared to influence their perception of risk. Similar findings have been evident in previous studies. For example, Saver *et* *al.* (2014) found that nearly sixty per cent of participants reported that such experiences had influenced their perception of risk. Walter *et al.* (2004) reported that a member of a family with chronic illness history such as cancer, coronary heart disease, or diabetes develop a personal sense of vulnerability. The impact of witnessing a family member develop complications has also been found to be influenced by the nature and severity of the complication as well as the relationship and/or closeness of the participant to the affected person (Walter and Emery, 2005). Therefore, engaging asymptomatic people with symptomatic ones may influence their risk understanding regarding the development of diabetic retinopathy, and consequently may lead to behavioural changes.

8.6. Psychological response to being at risk

8.6.1 Optimism vs Pessimism

The people with diabetes in this study were divided regarding their probability of developing diabetic retinopathy. Some of them contextualised their increased vulnerability of developing complications in terms of being from a South Asian ethnic background or due to their age. In contrast, other participants appeared to connect their reduced future likelihood of developing complications with their previous experiences, particularly those who attended eye screening and whose results were always negative. Therefore, from that, they believed that they were unlikely to develop diabetic retinopathy in the future. Such individuals appeared to be optimistic about the future and that they would not have complications. They generally believed that they were doing well and better than others, so were less likely to suffer from complications. This may be explained by the Health Belief Model, a psychological model developed by Rosenstock in the 1950s (Rosenstock, Strecher, & Becker, 1988). The Health Belief Model seeks to understand patient behaviours in relation to self-care and treatment concordance and suggests that the willingness of a person to commit to a change in behaviour depends on how severe they view their health problem to be. As such an an optimistic stance may reduce anxiety that would ordinarily be generated when an individual acknowledges personal susceptibility and increased risk in relation to a disease that is considered serious (Janz and Becker, 1984). Optimism may happen when people with diabetes feel confident about their chances of having a positive outcome or avoiding negative outcome. Self-esteem is also threatened when an individual fails to avoid a potential danger, especially if it is perceived that it is possible for an individual to have avoided the problem (Shepperd *et al.*, 2002). Thus, individuals who judge their own vulnerability as lower compared to others therefore maintain or even increase their levels of self-esteem (Branstrom *et al.*, 2006).

8.6.2 Understanding of diabetic retinopathy risk

People with diabetes who perceived themselves at low risk appeared to diminish their potential risk of experiencing complications for a variety of reasons. This included their knowledge about their condition and the ways in which they made sense of risk messages they received, being younger, their ethnic background, and being treated with oral medications rather than insulin injection. Those individuals who tended to perceive themselves to be at lower risk of developing sight-threatening diabetic retinopathy were less likely to take preventative measure to avoid that outcome. This finding concurs with previous studies (Janz and Becker, 1984). According to the Health Belief Model (HBM), individuals who perceive themselves to be at lower risk of experiencing a negative health outcome will be less likely to take preventative measures (Janz and Becker, 1984). Similar beliefs were reported by Saver *et al.* (2014) where people with diabetes tended to downplay or underestimate the associated mortality risk. Similarly, Branstrom *et al.* (2006) reported that people tend to underestimate the fact that exposure to sun is a significant risk factor for them developing skin cancer, despite the fact that they appeared to be aware of the consequences of sun exposure.

8.6.3 Emotional response to being at risk

This study found that, in hindsight, a lack of diabetes self-care management could subsequently lead to feelings of guilt. The ways in which people with diabetes constructed these feelings was clearly influenced by how they now made sense of their condition. For example, those who had tended to perceive themselves as relatively at low risk were less likely to express guilt that they had failed to self-manage their condition. In contrast, those who deemed themselves to have been aware that they were at increased risk but who did not take action to improve their self-care management were more likely to express some feelings of guilt at not having acted sooner. The main point being is that many individuals felt they could have managed their diabetes in a better way and possibly have prevented complications from occurring.

People with diabetes who perceived themselves at higher risk also appeared to report lower mood or more depression than those who did not perceive themselves in such terms. Those who were symptomatic, who had low visual acuity, who had personal experience of someone who developed complications were more concerned than others about the possibility of developing complications, which was particularly apparent among the South Asian participants in this study. Previous studies (Holt *et al.*, 2014b; Williams *et al.*, 2015; Holt *et al.*, 2014a) also reported a higher prevalence of depressive symptoms among South Asian and Black Caribbean groups compared to White Europeans. Individuals tended to attribute their low mood or depression to past experience of seeing a friend or relative developing complications, food deprivation, vulnerability to complications, complexity of disease, and lack of communication skills. This low mood was also implicated when they described why they did not want to experience the physical discomfort associated with checking blood glucose level (finger prick testing), particularly as they were symptomless. This may help to explain some of the higher rates of depression among South Asians people in previous studies (Holt *et al.*, 2014b; Williams *et al.*, 2015; Holt *et al*., 2014a).

8.7. Risk communication and informed choice

Counselling people with type 2 diabetes about diabetic retinopathy and presenting them with recommendations about diabetic retinopathy screening involves the presentation of risk and benefit information. However, there is a lack of evidence as how to guide health professionals about the most effective approach when sharing clinical evidence with people with type 2 diabetes

(Edwards, 2001; Elwyn, 2012; Fagerlin, 2011; Lipkus, 2007; Schapira, 2006). This study found that people with diabetes repeatedly reported that they had not received adequate information from their Health Care Providers to help them understand their personal risk of developing diabetic eye disease. Michie *et al.* (2004) found that only half of the participants in their study in relation to cervical cancer understood that a normal result entailed a residual risk, that is the amount of risk left over after natural risk have been reduced by risk controls, if results were communicated without an additional explanation regarding this risk. However, the understanding of residual risk improved when participants were informed that their result indicates a low risk of developing cervical cancer in the next five years (Marteau *et al.*, 2001b).

Another issue found by this study to influence risk communication was the ability of people with diabetes to remember the risk information that was provided during their consultations with their Health Care Providers. Individuals may also experience limitations in relation to their ability to understand risk information due to health literacy and language barriers. Previous studies reported that South Asian people considered language to be the main and most frequent barrier to receiving health education (Brar *et al.*, 2009; Syed *et al.*, 2008). It is clear that individuals are more likely to convert risk information from their Health Care Providers into appropriate behavioural change when they understand their health condition and engage in treatment decisions (Anderson *et al.*, 1995). For example, Schillinger *et al.* (2002) found that poor health literacy was associated with worse glycaemic control and higher rates of diabetic retinopathy. Therefore, methods that facilitate risk communication and improve patients' understanding of diabetic retinopathy risk, regardless of their literacy condition, are required.

This evidence was the motivation to create a diabetic retinopathy risk communication tool that personalises risk and increases Health Care Providers' abilities to communicate risk information in busy clinical settings. The creation of this tool was informed by the shift to a model of shared decision-making within the consultation process (Edwards, 2006). The shared decision-making model is when the preferences of individual patients and the knowledge of their Health Care Provider are integrated within the chosen self-care management process.

A systematic review conducted by Edwards *et al.* (2013) found strong evidence that personalized forms of risk estimate that are integrated within consultations and screening programmes; e.g.in relation to colorectal cancer, lead to more informed choices being reported.

8.8. The influence of visual tools on risk perception

This study found that communicating risk information using visual tools is beneficial for people with diabetes. People with diabetes and Health Care Providers advocated the use of visual tools as it was viewed as facilitating risk communication, believed to improve people's knowledge, influenced risk perception, and as a result could lead to behavioural change. However, people with diabetes had various opinions regarding different visual tools due to the nature of the tool and their condition. For example, presenting risk information using highlighted human figures (one in ten), bar graph, and smiley faces made people underestimate their risk. Other studies have reported similar results (Lee and Mehta, 2003; Schapira *et al.*, 2006; Lipkus and Hollands, 1999). Lee and Mehta (2003) found that communicating risk information about blood transfusions using a written or visual format was effective in improving people's knowledge as well as reducing the perception of risk. Schapira *et al.* (2006) reported that risk was perceived to be lower when risk information was delivered using bar graph compared with pictorial display. Furthermore, Schapira and colleagues found that presenting risk information with random highlighted human figures was more accurate compared to consecutive figures. However, the people with diabetes in this study, particularly those with low visual acuity, often struggled to see the highlighted human figures (thousand figures), whether these were the consecutive highlighted figures or the randomized highlighted figures.

A recent study conducted by Saver *et al.* (2014) among people with type 2 diabetes showed that some participants could not understand risk information, despite the fact that the risk information was presented via methods recommended by previous research (Edwards *et al.*, 2002; Edwards *et al.*, 2006a; Lipkus, 2007). The current study reports empiric data showing that participants were able to interact with this tool and were able to make sense of the information it provided about their own risk. The lack of knowledge of an individual's own risk might explain why, in previous studies, symptomless people with diabetes were non-complaint with diabetic eye screening and diabetes self-management(Boren *et al.*, 2007; Hipwell *et al.*, 2014; Lindenmeyer *et al.*, 2014).

8.9. Responses to risk communication tools in different clinical settings

This study highlighted the responses of people with diabetes and Health Care Providers to different risk communication tools that have been used in other clinical settings. In general, most people with diabetes and Health Care Professionals advocated the use of risk communication tools when communicating risk information about diabetic retinopathy or about diabetic screening results. It was perceived that risk communication tools provide clear messages and that people with diabetes would take notice of the message through a visual tool or a picture rather than simply hearing the message from Health Care Professionals. Previous studies (Tait *et al.*, 2010; Lipkus and Hollands, 1999; Lipkus, 2007; Ancker *et al.*, 2006; Schapira *et al.*, 2001) reported that the use of a visual format was effective when communicating risk information to patients. However, many considerations have to be taken into account when considering which format is more effective. In this study, Health Care Professionals supported the use of visual risk tools for those from an ethnic minority group or those who have difficulty with languages. Similar findings have been reported by McWhirter and Hoffman-Goetz (2012). However, the responses of people with diabetes were diverse regarding each risk tool. For example, the use of human highlighted figure (10 figures) was not supported because people believed that it would give them the wrong impression that they were at low risk of developing diabetic retinopathy. People with diabetes described the bar graph as "boring" and "too technical" and therefore it was not favoured by them. Health Care Professionals believed that the bar graph would give the wrong message for people with diabetes. The human highlighted figure (a thousand figures) was rejected by people with diabetes due to the fact that it was difficult to see it, particularly for those with low visual acuity or with sight problems. It was described by people with diabetes as looking like a pixelated PC screen. The use of smiley faces was supported by a few people with diabetes. However, it was also believed to provide the wrong impression regarding personal risk as a number of people with diabetes thought it would lead them to see themselves as low risk. Lipkus and Hollands (1999) reported that people were least accurate when extracting information from a bar graph format. The bar graph was perceived as too analytical, because it was difficult to understand and hence had less impact (Schapira *et al.*, 2001). Hawley *et al.* (2008) found that pictographs (using human figures) to be more effective than bar graphs at communicating general knowledge. Therefore, according to a range of different themes that have been identified in the literature and based on the findings in this study it was essential to modify/design a new risk communication tool in order to provide risk information about diabetic retinopathy to people with diabetes.

Counselling people about diabetic retinopathy and diabetic retinopathy screening involves the presentation of risk and benefit information. In addition, the patients' charter states that patients have a right to be given a clear explanation of any treatment proposed, including any risks and alternatives, before they decide whether to agree to the treatment. Making an informed decision depends on a patient's level of understanding of the relevant risks that are given to them. Informed patients are more likely to make wiser decisions and adhere to their treatment (Epstein *et al.*, 2004). Therefore, it is essential that risk information is provided in a clear and concise way.

As has been made clear, no risk communication tool was available in relation to diabetic retinopathy. Therefore, the decision was made to talk to people with diabetes with regards to existing risk communication tool in other clinical setting. This enabled the timely development of a new diabetic retinopathy risk communication tool that facilitates the presentation of diabetic retinopathy risk to people with diabetes. This appears to be fit for purpose and is timely given a recent change in policy regarding the extended screening intervals (NSC, 2016). The next section considers the advantages and disadvantages of the new diabetic retinopathy has risk communication tool.

8.10. Advantages and disadvantages of the new diabetic retinopathy risk communication tool

The findings in this study indicate that the new diabetic retinopathy risk communication tool was reported as good visual representation that may advance the understanding of risk of diabetic retinopathy among people with type 2 diabetes. A significant number of participants appeared to be reassured by using the new risk tool, which could be due to the fact that the recruited people with type 2 diabetes were at low risk. The findings also highlighted that most participants appeared to be aware of the different risk categories such as high risk and low risk, and therefore, they appeared to integrate their perception into the new risk tool. It provided them with risk information in a clear method that appeared to improve peoples' understanding of their own risk and therefore may improve diabetes self-care management. The new risk tool was found to smooth the progress of the presentation of risk information for those who are considered illiterates, or whose first language was not English. The design of the new risk tool as a traffic light system too appeared to make people with diabetes understand their own risk by comparing it with the conventional use of such colours where green means safe and red means danger is internationally accepted and widely used. The traffic light system highlighted the importance of the amber zone between high risk and low risk and people with diabetes could recognize the need to move closer to the low risk zone.

In contrast, the tool may induce distress to those who believed that they were at high risk. Despite the fact that the tool did not include all the risk factors of developing diabetic retinopathy, as discussed in chapter 7 (sections 7.2), it appeared that it was fit for purpose as people with diabetes were able to see improvements or deteriorations in their risk score based on their blood glucose results which could also encourage and motivate them to improve their diabetes management. Furthermore, the tool may require further modification in order to communicate risk information about diabetic retinopathy to people with type 1 diabetes. Previous studies that have been conducted with people with cancer have found that visual risk tools, were effective at providing risk information (Hollands and Spence, 1992; Lee *et al.*, 2003) and were favoured by patients (Edwards *et al.*, 2002).

8.11. The elements of diabetic retinopathy risk communication

This study found that whilst Health Care Professionals preferred to provide detailed information about diabetic retinopathy and the results of diabetic retinopathy screening, people with diabetes wanted a simple, clear approach. They also wanted their condition to be explained to them face-to-face rather than receiving the results later or through a letter sent by post. This was favoured by people with diabetes for many reasons, including avoiding unnecessary anxiety due to the delay in receiving the results, which can take up to three weeks. Health Care Professionals also advocated face-to-face explanations as they that enabled them to explain the risk of developing diabetic retinopathy using either individualized retinal image or/and a risk communication tool. Furthermore, people with diabetes appeared more comfortable when risk information about diabetic retinopathy was provided by an ophthalmologist or optician who they believed have more knowledge about eyes rather than their general practitioner.

This study found that there was no one model that was found to be adequate to communicate the risk of diabetic retinopathy to people with diabetes. Therefore, the researcher devised a model based upon previous studies (Roach and Marrero, 2005; Epstein *et al.*, 2004). This model may work best for people with type 2 diabetes. The researcher used the most relevant aspects of previous models and developed this new model in order to provide effective individualized risk communication about diabetic retinopathy. This can be communicated in five common steps as shown below. Table 8.1 summarises these five steps that can provide useful guidance to Health Care Professionals to enable them to communicate risk information about diabetic retinopathy to people with diabetes.

Table 8.1: Elements of diabetic retinopathy risk communication

Step1	Understand the individuals' and carers' knowledge, experience, and expectations
Step 2	Construct partnerships
Step 3	What is diabetic retinopathy? Simple graphic illustration of the eye using plain and simple language Retinal image Patients testimonials
Step 4	What is my risk of having diabetic retinopathy? Compare HbA1c with recommended targets Calculation of individual risk using risk calculator (www.risk.is) Visual diabetic retinopathy risk communication tool Assign risk severity (high, medium, low) Compare individual risk with average risk
Step 5	How can I reduce my risk? Assess motivation for achieving/ maintain normal HbA1c values Develop a care plan by shared decision-making

Step1: Understand the individual's knowledge, experience, and expectations

This study has clearly demonstrated that Health Care Professionals need to take account of patient's knowledge, experience and expectations. Good evaluation of individual's knowledge, experience, and expectation, plus their ability to read information and ability to absorb and understand risk information can help and guide health professionals and facilitate risk communication. According to Shrek *et al.*, (2014) assessing and understanding perceived risk can provide a framework for individuals to improve their self-care behaviours and glycaemic control. Another important issue that was highlighted by Saver *et al.*, (2014) is assessing individual's knowledge of risk factors, which may contribute to a treatment plan.

Step 2: Construct partnerships

This study highlighted the significance of relationship between people with diabetes and Health Care Professionals. This relationship appeared to influence individuals' perception of risk and improved adherence with health professional's advice. As a result, participants appeared re-assured and received risk information with confidence. Flexibility of health professionals when offering appointments also enhanced individual's confidence. Epstein *et al.* (2004) suggests building a partnerships between patients and Health Care Professionals to build trust and facilitate the transfer of information by expression of empathy, acknowledgment of the complexity or difficulty of the issue, an expression of mutual understanding (e.g., *"I think I understand*,…"), increasing patient/ family involvement (e.g., "*I would like to help you understand*"), and fostering partnership (e.g., "*We need to make this decision together*")

Step 3: What is diabetic retinopathy?

With consideration to diabetic retinopathy risk, most people with diabetes in this study wanted to know 1) what is diabetic retinopathy? 2) Was he/she at risk of developing diabetic retinopathy? 3) What can they do to lower or avoid the risk or slow disease progression?

Because the term "diabetic retinopathy" was not fully understood among people with diabetes in this study, it seems appropriate to structure the discussion about diabetic eye disease. In order to fully understand diabetic retinopathy and its implications on sight, relevant information must be provided about what might happen? And how might diabetic retinopathy or diabetic eye disease develop?

This study also revealed that individuals' risk perception was affected by their beliefs in relation to the causes of diabetic retinopathy, whether it is preventable, and the consequences of the problem on their sight. To illustrate the causes of increased diabetic retinopathy risk, the link between diabetic retinopathy and individual's specific behaviours should be explained in clear and easy plain non-medical terms (Yoshida and Yoshida, 2014; LeBlanc *et al.*, 2014; Fagerlin *et* *al.*, 2011). This method was found to be successful in providing patients with more precise information regarding their cardiovascular disease risk as a means of dampening down excessively optimistic perceptions of individual risk(Rothman and Kiviniemi, 1999). For example, if an individual smokes cigarette, has uncontrolled blood pressure, uncontrolled blood glucose, a simple and clear statement such as “smoking, high blood pressure, and high blood glucose all act together to cause damage to blood vessels in the back of your eye and this can cause problems to your sight”. This approach appeared successful in communicating the increased risk of cardiovascular disease to people with diabetes (Roach and Marrero, 2005). However, many individuals may have received such information, but did not understand the message, and therefore, people with diabetes and Health Care Professionals in this study advocate the use of visual risk communication tool to make diabetic retinopathy easy to understand, regardless of an individual’s literacy level. This study clearly demonstrated that using an individualized retinal image when communicating risk information was advocated by health professionals, as it reinforced the risk message about the cause of diabetic retinopathy.

In order to point out the consequences of diabetic retinopathy on an individual’s sight, this can be done by using two approaches based on the research findings: 1) highlight the similarities between the individual and others who have experienced similar condition; and 2) graphically show the severity of the consequences linked with the event by presenting a similar retinal image. These two approaches were found to be effective also in communicating risk information about cardiovascular disease among people with diabetes (Rothman and Kiviniemi, 1999). Furthumore, people with diabetes and Heath Care Professionals in this study pointed out that engaging the individual with other people with diabetes who have experienced sight-threatening diabetic retinopathy may influence their understanding of risk and therefore, enhanced their adherence with diabetes self-care management. Rothman and Kiviniemi (1999) suggest providing patients with a brief videotape testimonial from a designated individual with diabetes from similar ethnic and age group. The significance of diabetic retinopathy and potential sight-threatening nature of diabetic retinopathy must be clearly communicated to make sure the individuals are adequately aware of the consequences and to motivate them towards behavioural change.

Step 4: What is my risk of having sight-threatening diabetic retinopathy?

People with diabetes and Health Care Professionals appeared divided about the most intuitive approach of risk communication and whether to use plain word such as “high, medium, and low risk”; or statistical information such as “a ten per cent risk of developing sight-threatening diabetic retinopathy in the next five years”; or to use probabilities such as “one in ten chance of developing sight-threatening diabetic retinopathy in the next five years”. However, Health Care Professionals in this study appeared to use different approaches with patients based on their level of understanding, education, and ethnic background. Therefore, according to Roach and Marrero (2005) an effective risk communication approach is to start the risk discussion by describing the individual’s statistical risk for their condition. However, due to the massive variation in risk perception between patients and Health Care Professionals as mentioned earlier, the level of risk must be attached to the risk statement. For example, “you have twenty per cent risk of developing sight-threatening diabetic retinopathy or a diabetic eye complication in the next five years, and this is high risk or very serious risk”, based on the impact of the retinopathy on an individual’s sight. Paling (2003) suggests avoiding using descriptive words such as “low risk” or “high risk”, as well as advocating the use of a consistent denominator to avoid misinterpretation of risk information. However, when communicating a normal diabetic retinopathy result or eye examination results to people with diabetes, there are always chances for false negative results, therefore, Petticrew *et al.* (2001) suggests that, when results are communicated, individuals should be informed that they have a low risk but negligible, and that the risk of developing diabetic retinopathy remains.

Health Care Professionals in this study advocated the use risk calculators to provide individualised risk information. Risk can be calculated by Health Care Professionals using a risk calculation tool, which is available online (www.risk.is). Experimental testing for safety and efficacy of the risk calculator was done using patient records relating to diabetic retinopathy at Aarhus University Hospital, Denmark (Aspelund *et al.*, 2011). For example, Mr. X is forty years old, who had type 2 diabetes mellitus for the last five years, he has no previous retinopathy (R0), his blood pressure is well controlled (120/80 mmHg), and with a HbA1c seven per cent he would have a diabetic retinopathy screening interval of sixty months. The diabetic retinopathy screening interval would be twenty-five months if blood pressure rose to 150/90 mmHg, with HbA1c seven per cent. However, Mr. X would require diabetic retinopathy screening after twelve months with blood pressure of 150/90 mmHg, and HbA1c nine per cent. Mr. X would require screening after six months with blood pressure of 160/90 mmHg, and HbA1c twelve per cent. Table 3.2 shows the proposed diabetic retinopathy screening interval for Mr. X, based on individual risk factors.

In order to optimize the risk message, Roach and Marrero (2005) recommended comparing an individual's personal risk to an average risk. This can be done by using the risk calculator as shown in Table 8.2. Health professionals can compare individual's parameters such as the readings of the third, fourth, and fifth row, with the normal "average" values such as in the second row. Such comparison was found to be effective in communicating risk information about cardiovascular disease among people with diabetes (Rothman and Kiviniemi, 1999).

Table 8.2 Diabetic retinopathy screening interval based on patient individualised risk factors

Name	Age	Type of diabetes	Duration of diabetes	HbA1c	Blood pressure	Previous diabetic retinopathy	Calculated risk of developing STDR every year	Risk	Screening intervals
Mr X	40	T2DM	5 years	7%	120/80	No	0.4%	Low risk	60 months
				7%	150/90	No	1.5%	Medium risk	25 months
				9%	150/90	No	3.2%	High risk	12 months
				12%	160/90	No	14.5%	High risk	6 months

T2DM: Type 2 Diabetes Mellitus, STDR: Sight-threatening Diabetic Retinopathy

The risk calculator can provide the Health Care Professional with individualized statistical data that can facilitate communicating the risk information. However, as the Health Care Professionals in this study made clear, such information may be helpful to guide them about the most effective screening interval, but it may not lead to better understanding of risk or to behavioural changes because it provides typical risk information only to people with diabetes and it does not engage them to improve their diabetes self-care management. Therefore, another way of engaging patients and providing risk information is by using risk communication tools that facilitate the reception of risk information, improve individual's understanding, and lead to behavioural changes. The new diabetic eye risk communication tool was reported as easy to use by participants. For example, it enabled them to see how they could balance non-modifiable factors (e.g. years with diabetes) with more modifiable ones (e.g. blood glucose levels). Therefore, individuals may prioritize improving their diabetes self-care management in order to prevent further deterioration. Individuals can interpret their risk by comparing it with the colour code. Individuals understood their own risk easily, because the colour coding where green means safe and red means danger is internationally accepted and widely used (Gil and Le Bigot, 2014). In addition, individuals' perception of future risk also appeared to be incorporated into the new risk tool, as most participants appeared to be more aware of risk category (high, medium, and low). They appeared to attach the different risk categories to probability of them developing complications. Personalized risk tools found to increase individuals knowledge, and increase accuracy of risk perception (Edwards *et al.*, 2013).

This study has shown how Health Care Professionals have to decide what sort of risk communication language is effective. Based on their initial assessment, they have to choose whether gentle language is acceptable particularly for low risk patients or whether fear and threatening language is more appropriate, particularly for those who appeared non-adherent with medical advice. The strength of the fear message should reflect the nature of the condition, severity, and impact of the disease. Previous studies suggested using strong language as it helps promote people's behaviours (Stephenson and Witte, 1998). The higher level of threat necessities a stronger risk message. According to French *et al.* (2006) individuals request more details when risk information is more threatening. Honey *et al.* (2014) argues that peoples' responses to risk messages are due to individual's personal characteristics although it may be influenced by the communication style between the individuals and their health providers. In contrast, Peters *et al.* (2013) argue that threatening messages rarely result in behaviour change, and the frequent use of fear and threatening messages may lead to defensive reactions(Good and Abraham, 2007).

In diabetic retinopathy screening where the evidence about benefits and harm is clear, Health Care Professionals may have recommendation for how to best meet patients' goals. The Health Care Professionals should inform the people with diabetes, guided by the diabetic retinopathy risk communication tool and risk calculator, why diabetic retinopathy screening is recommended based on the clinical evidence, and how that recommendation is generated clearly from the patient's goals and the evidence.

Step 5: How can I reduce my risk?

Risk reduction recommendations are the last important aspect of risk communication. This study has demonstrated that health professionals should provide their patient with information that can help them to reduce their risk. Understanding the risk without adopting risk reduction strategies would not reduce the risk. This can be challenging to Health Care Professionals as it involves behavioural change. Health professional must discuss all the risk factors associated with developing sight-threatening diabetic retinopathy. However, they must also give consideration to the most significant modifiable risk factor of developing sight-threatening diabetic retinopathy which is HbA1c, and make it clear to individuals that by controlling HbA1c, risk of developing sight-threatening diabetic retinopathy will remain low.

At this stage, the diabetic eye risk communication tool can be used and explain to the individual that his/her HbA1c value should remain in the green colour and not move to amber or red. Getting patients engaged with the risk tool would establish that they are part of decision-making process that will increase their chances to adhere to health professional's recommendations (Roach and

Marrero, 2005). The diabetic eye risk communication tool can guide health professionals to recommend an appropriate screening interval for people with type 2 diabetes, not only for those who have four greens, but also others who have had diabetes for a long time but their HbA1c remain under control.

Furthermore, health professionals expressed the importance of providing written information to patients. This could be a personal copy of an individual's retinal image, a copy of the diabetic eye risk tool, and information about medications despite the problem of medication non-adherence (Haynes *et al.*, 2002). Furthermore, the introduction of "passport for care", where patients records their medications and appointment, was found to be useful in a clinical setting as it improves adherence to medication (Barber *et al.*, 2014; Jubraj andBlair, 2015), improves follow-up (Poplack *et al.*, 2014), assists Health Care Professionals in decision-making (Newell *et al.*, 2014), and enhances healthy life-style choices (Vaczy *et al.*, 2011).

Another important aspect is Involving a family member as it was favoured by health professionals and some participants such as the elderly and those who have language barriers, as they may not fully understand the risk message, or forgotten it at the next visit. A randomised controlled trial among people with diabetes found that more accurate risk perception is noticed two weeks after communicating risk information and the information about risk perception had been forgotten and disappeared by twelve weeks (Welschen *et al.*, 2012). The frame of the risk message influenced an individuals' decision. For example the word "loss" was found to influence screening uptake more than the word "gain" (Edwards *et al.*, 2002). Therefore, health professionals can use it when recommending diabetic retinopathy screening by saying:

"The potential loss from not having diabetic eye screening is...."

Such "framing bias" is considered justifiable according to Edwards and colleagues (2002).At the end of the consultation, it's recommended that health professionals check that an individual understands the risk information by asking them to summarise what they understand, although this is not routinely done (Campion *et al.*, 2002).

To summarise, risk information about diabetic retinopathy can be communicated to people with type 2 diabetes in five common steps as shown above in table 8.1. The findings clearly demonstrated that Health Care Professionals should first understand patients' knowledge, experience, expectations, and their ability to understand risk information. Second, the findings also highlighted the importance of constructing good relationship with patients as this appeared to influence individuals' perception of risk and improved adherence with health professional's advice. Third, most people with diabetes wanted to know what diabetic retinopathy is. It seems appropriate to structure the discussion about diabetic eye disease because the term "diabetic retinopathy" was not fully understood among people with diabetes in this study. The forth step is to provide an individualised level of risk using probabilities and attaching the level of risk to the risk statement. This can be achieved by using risk calculators and engaging them using the diabetic retinopathy risk communication tool to help them understand own risk. The last step is to provide people with diabetes with information that can help them to reduce their risk. Health Care Professional must explain all the risk factors associated with developing sight-threatening diabetic retinopathy. However, they must also give consideration to the most significant modifiable risk factor of developing sight-threatening diabetic retinopathy which is HbA1c, and make it clear to individuals that by controlling HbA1c, risk of developing sight-threatening diabetic retinopathy will remain low.

8.12. Study strengths and limitations

The strength of this study is that it provides primary research that explored participants' experience of risk communication as well as the perception of diabetic retinopathy risk among people with type 2 diabetes and Health Care Professionals.

8.12.1 Insider researcher

The insider position of the researcher was a particular strength of this research. As a long-established and senior ophthalmic nurse, the researcher had credibility with the participants and this helped to enhance dedication to the study. Wide-ranging experience of ophthalmology improved the understanding of the research issues. Employment of reflective and reflexive practice assisted critical engagement and challenging of obstacles. The researcher had a good relationship and power within the ophthalmology department and this helped to work against the potentially negative impact of the study association with achievement of a higher degree and gained support for the study from the senior ophthalmic management team.

8.12.2 Patient and public involvement

The involvement of service users was an essential part of this research and central to its success. The protocol was further developed with the collaboration of members of the Warwick Diabetes Research and Education User Group, who reviewed the research questions, the interview schedule questions, and the sampling processes.

8.12.3 Limitation of the literature review

This section reflects on the process of conducting this study and the most important lessons learned, that is to say study limitations. These include: limitations of the literature review, the clinician-researcher role, and ethical issues arising in the study such as the role of gatekeepers and the researcher/clinician role. The purpose of conducting a literature review was: 1) to provide a review of the literature on diabetes, and the main complications associated with diabetes. The author considers diabetic retinopathy in more detail as the main diabetes related eye complication and 2) to examine the literature about perception of risk and risk communication among people with type 2 diabetes.

Advocates of systematic reviews argue that they are more liable to produce a wide-ranging and fair presentation of the literature (Bryman, 2008). However, qualitative research methodology does not fit with usual systematic review criteria (Bryman, 2008). In order to understand how and why phenomena of interest are important, qualitative research has a great deal to contribute. This is particularly evident in complex intervention studies. Sturt et al (2006) argues there is a need to incorporate complex intervention research into systematic review. One would argue why some parts of the study are designed as a literature review and not a systematic review such as in section 2.14.5, interventions to increase attendance to diabetic screening. There is already a systematic review on this topic and therefore there was no need to repeat one. Systematic reviews focus on a single question whilst a literature review is more comprehensive to various degrees and does not necessarily focus on a single question (Bettany-Saltikov, 2010). Conducting a systematic review of risk communication tools would have been a legitimate exercise and would have highlighted the different risk communication tools. Though this is not really a true limitation, as the aim was not to examine the effectiveness of the risk tools but rather to modify a risk tool in order to facilitate the presentation of diabetic retinopathy risk. In terms of usefulness, it would have produced limited results and possibly cause more confusion to participants. In contrast, the wide-ranging search strategy guiding the literature review established the existing knowledge and highlighted gaps in data. The literature review ensured the research investigated a gap in our knowledge base.

Furthermore, the literature review offered the benefit of being an on-going component of this study. Corbin and Strauss (2008) support the proactive engagement with the literature from the start of the research process. Although the study investigated the impact of risk communication and risk tools on risk perception, the author was not very familiar with the risk communication literature, particularly when it involves providing sensitive or potentially upsetting information. Therefore, he had to expand his knowledge about the perception of risk and how to communicate risk information. This was very helpful in designing the interviews and the decision to employ purposive sampling that was used in the study. The author ensured that the main aspects of risk communication and perception of risk were covered and not missed out during the interviews. Utilizing the literature all the way through the study enhanced and encouraged the thought processes. It also expanded the possibilities for the data to be inspected more closely during theoretical coding. Regular updating of the literature review highlighted new risk communication studies related research that continued to inform the development of the study.

8.12.4 The role of gate keepers

Gate keepers role have a significant impact on the external validity of a study (Lakerveld *et al.*, 2008). In this study where participants have been accessed via an established health care context, such as GP practices and hospital clinics, those who have been invited to participate have been influenced by the knowledge, motivation and authority of the employees and clinicians in that clinic. This may impact on the recruitment process because those people would be making significant decisions regarding the recruitment and therefore may cause risks to the validity of the study. These issues have been managed by arranging meetings with practice managers, clinicians, and receptionists providing them with information about the study and involving doctors and nurses in the recruitment process. As the literature suggests, participants are more likely to participate if they were asked by a doctor rather than a receptionist (Symonds *et al.*, 2012). Another issue that was taken into consideration was in those cases where participants may have been over persuaded to take part because they were concerns that their health care will be compromised. However, this matter was dealt with when confirming informed consent and by gaining assurances that participants were happy to participate in the research prior to their interview. It was also recognised that a number of people with diabetes have faced additional barriers in accessing services due to their ethnic background and language barriers. Thus, the researcher adopted strategies to increase interview participation, such as employing a bilingual interviewer and translators.

8.12.5 The clinician-researcher role

A number of people with diabetes who took part in the study knew the identity and professional background of the researcher when the interview was conducted in the hospital, which was the researcher’s place of work. Those who recognize the researcher may have answered differently during the interview assuming that the researcher knew such information and has access to it due to the professional capacity. Therefore, the researcher adopted strategies to encourage the participants to expand on his/her answer by having follow-up questions or/and probes or by rephrasing the questions.

8.13. PhD journey and interruption of studies

My PhD journey started in 2008 at the University of Nottingham. In my first year, I attended courses such as quantitative methods and analysis, qualitative research methods, and philosophy of health science module. In addition, I attended courses to improve my research skills such as being an effective researcher and research methods during 2008 and 2009 as well as attended relevant conferences. I then developed my literature review and methodology chapter to answer the following research question: "why people with diabetes do not attend diabetic retinopathy screening?"

At the time when I applied for ethical approval at the end of 2010, I was informed by a member of the research ethics committee that ethical approval had been granted for similar research and I should get in touch with the FLURRI research team at the University of Warwick. I was very frustrated at that point as I had spent two years at the University of Nottingham conducting the literature review and applying for ethical approval. A few days later I had several meetings with my supervisors and then there was few email exchanges between the researcher and the FLURRI team at the University of Warwick. This ended with the researcher transferring his PhD to the University of Warwick in July 2011 and joining the FLURRI team. As a result, the researcher had to address a different research question regarding communicating risk information about diabetic retinopathy to people with diabetes. Joining a well-established research team (FLURRI) was very beneficial to me as my previous supervisors at the University of Nottingham did not have a good connection with the diabetic retinopathy screening programme. Therefore, they strongly recommend that I join the FLURRI team because of their strong connections with the English diabetic retinopathy screening programme. Since then I have then undertaken more courses to improve my research skills and knowledge as well as attending national and international conferences, which have impacted positively on my PhD journey. Furthermore, I have presented three posters and one oral presentation at international conferences.

However, transferring to the University of Warwick caused further delays as a result of changing the research question. This meant that the researcher had to conduct a second literature review and reapply to another research ethics committee. It would have been ideal to complete the PhD study without further interruptions. However, being a part time clinician, a partially funded PhD student, and a father of four boys in the school, whom some were undertaking University, GCSE and A level examination, also proved to be considerable challenges. Following completion of the data collection, in order to provide financial resource to be able to continue supporting my family as well as complete my PhD study, I had a break from the University to work abroad between 2013-2015. The duration of PhD registration has meant that over the period supervisors have moved to other posts and institutions and I have had a succession of supervisors, which have impacted positively and negatively on the personal and professional development as a researcher. For example, I have gained a wide-ranged experience from my supervisors in terms of knowledge, research methodologies, and personal and professional development. In contrast, changing supervisors caused delays as I had to re-shape my research questions several times to reflect on the research focus. Joining a well-established research team had positive impact significantly on the researcher’s knowledge and experience. This helped the researcher in many ways such as designing the study, data collection, data, analysis, and improved his skills in applying for research ethical approval. Despite the severe delay in my PhD study, I do not regret transferring my study to the University of Warwick and joining the FLURRI team.

Chapter 9. **Thesis conclusion**

In conclusion, this qualitative study has explored how diabetes and the risk of diabetic retinopathy is understood by people with type 2 diabetes and Health Care Professionals. The original idea for this research (communicating risk information about diabetic retinopathy to people with type 2 diabetes) came whilst undertaking the FLURRI study. The team were aware of an ongoing discussion in the national screening programme about possible extended screening intervals for people at low risk of developing diabetic retinopathy. During FLURRI fieldwork, when participants were asked about the views on extended screening intervals, many participants seemed concerned at the proposal. Additionally, the FLURRI study highlighted issues such as lack of communication as reasons for non-concordance with diabetic eye screening (Lindenmeyer *et al.*, 2014; Hipwell *et al.*, 2014).

This study adds to the field of research in several ways:

1. It provides insight into people with type 2 diabetes' knowledge and beliefs relating to diabetes and diabetic retinopathy;
2. It explores the impact of risk communication on perception of risk;
3. It explores the impact of risk communication tools on peoples' understanding of risk;
4. A model is proposed for communicating risk information about diabetic retinopathy to people with type 2 diabetes.

9.1. Implication for practice

- Education programmes in relation to diabetes should include more information about the risk of diabetic retinopathy. Education programmes should concentrate on explanations and interventions that are more meaningful to individuals and groups and the ways in which diabetes is constructed and interpreted in everyday life.

- Health Care Professionals should assess individual's knowledge and beliefs about their condition before communicating risk information and then check the level of understanding after providing risk information.

- Risk information should be personalised and provided in a clear and attractive style based on level of understanding, particularly to the symptomless participants.

- Health Care Professionals must be aware that individual's will interpret the evidence in different ways when providing risk information using numerical data. Furthermore, Health Care Professionals should not assume that individuals understand the information with their patients without checking for themselves regardless of other markers such as social class, ethnicity, or gender.

- Engaging people with type 2 diabetes with a peer group may benefit them in making sense of their risk and may then lead to changes in their diabetes self-care management. Engaging family members may also help individuals change their diabetes self-care management particularly those non-English speaking or with language barriers.

- A number of factors such as type of diabetes, individual's age, ethnicity, type of medical treatment, co-morbidity factors, and the presence of visible symptoms or eye complication must be considered when risk information about diabetic retinopathy is provided.

- Health Care Professionals must give more attention when risk information about diabetic retinopathy is communicated to make sure that those who may underestimate their risk have understood the message. In contrast, those who may be more pessimistic about their probability of developing diabetic retinopathy must be re-assured and provided with information that can help them to stop disease progression.

- Those individuals who underestimated their risk of developing sight-threatening diabetic retinopathy were less likely to take preventative measure to avoid complications. Therefore, one way forward is to engage those individuals by asking them to perform self-risk assessment using the diabetic retinopathy risk communication tool. Good explanation about individual risk and the probability of future complication may help them balancing unseen risk with their personal discomfort such as pricking their figure when checking blood glucose.

- Providing people with diabetes with a copy of diabetic retinopathy screening photo, a copy of the diabetic retinopathy risk tool, and written risk information may help individuals remember their risk once they go home.

- Diabetes related eye complications risk information is better communicated using personalised visual risk communication tool as it helps individuals to interact with the tool, it provides them with risk information in a clear method and makes people with diabetes more aware of the different risk categories such as high risk and low risk.

- The study also suggests that risk information about diabetic retinopathy should be provided in a simple way, clear approach and face-to-face rather than receiving the results later or through a letter sent by post. This approach reduces anxiety.

- People with type 2 diabetes and Health Care Professionals reported that risk information about diabetic retinopathy is better communicated using the five steps as detailed in section 8.10

9.2. Implication for policy

The study took a qualitative approach to explore the perceptions and experiences diabetes and diabetic retinopathy risk among people with type 2 diabetes alongside Health Care Professionals. This enabled the production of diabetic retinopathy risk communication tool. Following a review of the evidence, the UK National Screening Committee recommended that the diabetic retinopathy screening intervals should be changed for people with type

2 at low risk of sight-threatening diabetic retinopathy from one year to two years (NSC, 2016). This recommendation to change the screening intervals from one year to two-year screening intervals is based on the evidence from a large observational study, which showed that it was safe to extend the screening intervals in low risk people with type 2 diabetes. In contrast, people at high risk of developing sight-threatening diabetic retinopathy will remain annually. The development of the diabetic retinopathy risk communication tool is timely with regard to the policy change. Using the risk communication tool may help people with type 2 diabetes to feel more comfortable with extended intervals, due to low risk status, when they have been used to annual screening. The findings appear to indicate that low risk people felt reassured by the new risk tool so that indicates that it is fit for purpose in supporting people with diabetes' adjustment to extended intervals.

9.3. Implication for research

- Future quantitative studies should examine how a range of service users interpret specific risk tools associated with different conditions

- Future research is needed to evaluate the new diabetic retinopathy risk communication tool for improving patient treatment satisfaction with extended screening intervals and improving self-management behaviours to ensure maintenance of low risk.

- More research is needed to evaluate the tool for reductions in modifiable risk factors in people with type 1 and type 2 with different stages of diabetic eye disease.

- Future research is needed to evaluate the newly developed risk tool for use by different Health Care Professionals related to diabetes (e.g. ophthalmologists, practice nurses, eye screeners, optometrists, pharmacists, GPs, and other members of the diabetes team).

- More research is needed to explore the perceptions and experiences of risk among people with type 1 diabetes.

- Future research is needed to modify the risk tool in order to facilitate communicating risk information about diabetic retinopathy to people with type 1 diabetes.

- More qualitative studies are needed to explore risk perception differences between symptomatic and asymptomatic people with diabetes

9.4. Implementation of the newly developed risk tool

It is anticipated that 2 papers will be submitted for publication on 1) patient's perception of risk of diabetic eye disease and 2) the development of the risk communication tool. The Director of the English National Diabetic Retinopathy Screening programme is one of the supervisors which will facilitate access to implementation of the risk communication tool into clinical practice. Discussion are underway to assess the validity and reliability of the tool across broader populations prior to implementation. These further studies will incorporate evaluation of the processes for successful implementation alongside validity and reliability evaluations. This will enable the identification of training and support needs for health professionals using the risk communication tool in routine clinical practice.

Word Count: 82259

(excluding Tables and Appendices)

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Appendices

University Hospitals Birmingham NHS
NHS Foundation Trust

THE UNIVERSITY OF
WARWICK

APPENDIX 1: Declaration of Informed Consent

(Patients; v1)

Participant ID number……………

Please tick

1. I have read and understand the 'Patient Information Sheet (v1)'. ☐
2. I understand that taking part in this study will involve me being interviewed, providing some personal information, and two short surveys. ☐
3. I understand that the discussion will be recorded and that the recording will be destroyed at the end of the study. ☐
4. I understand that there are no known expected discomforts or risks involved in my participation in this study. ☐
5. I understand that I am free to withdraw from the study at any time prior to the end of the study, without giving a reason, by contacting the e-mail address or telephone number below. This will not affect my care. ☐
6. I give my permission for my GP practice to provide access to my diabetes records and that this will be used for the purposes of this research only. ☐

If you would prefer to be interviewed in a language other than English, this can be arranged. Please state the language you wish to use in an interview:…………………………………………..

I give my informed consent to take part in this study. I understand that although a record will be kept of my participation in the study, my data will be identified by a number or an alternative name (pseudonym) only.

Signed ………………………………………… Dated ………………………………

Name (please print in full) ....

Phone number(s) ....

Email address: ....

Address:...

....Post code:

.... *(We will only use this information to contact you about the study)*

In case of any query, please contact the lead researcher: Nidal Al-Athamneh 07426883070 or n.al-athamneh@warwick.ac.uk In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 2: Patients Demographic Data Collection

(Patients; v1)

IN CONFIDENCE

Participant ID number……………

This sheet will be stored separately from all other information, to protect your identity

Date of birth (please write in): Date .... Month……………..……… Year….………..

1. **Sex** (please circle one): Male/Female

2. **What type of diabetes do you have?** (Please tick one):

   Type 1 Diabetes ☐ Type 2 Diabetes ☐

3. **Do you have any other long term conditions?** (Please tick one): Yes/No
   If yes, please state what these are: ....
   ....

4. **Which of the following groups do you consider that you belong to?**
   (Pease tick one)

White British	☐	White Irish	☐	White other	☐
Black African	☐	Black Caribbean	☐	Black other	☐
Indian	☐	Pakistani	☐	Bangladeshi	☐
Chinese	☐	Other	☐	Please state.............................	

5. **What type of work do/did you do?**
   ....
   ....
   ....

6. **What is the highest level of qualification you have?** ....
   ....

Thank you for your help!

In case of any query, please contact the lead researcher Nidal Al-Athamneh 07426883070 or n.al-athamneh@warwick.ac.uk; In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 3: Patients Information Sheet

(v1)

Study Title: Communicating risk information about diabetic retinopathy to people with diabetes

Invitation:

You are invited to take part in a research study that is being conducted as part of educational study at the University of Warwick. Before you decide whether to take part or not, you should understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask us if anything is unclear or if you would like more details. Our contact details are at the bottom of every page and in sections 12 and 13. Thank you for reading this information sheet.

What is the purpose of this study?

People with diabetes sometimes develop problems with their eyes that can lead to vision loss and blindness. This damage to the eye is known as Diabetic Retinopathy and can be detected early through screening, which involves patients having digital photographs taken of their eyes. These photographs can identify early signs of damage caused by diabetes, before the patient becomes aware of any symptoms. Research has shown that people who attend the Diabetic Retinopathy Screening Programme are less likely to suffer loss of vision or blindness, compared with people who don't attend, because they receive their treatment sooner when less damage has occurred. For more information, please see the enclosed leaflet. This research aims to find out how the risks and benefits of diabetic retinopathy screening programme are understood, and to establish the methods by which risk information can be effectively communicated.

The results will be given to the Diabetic Retinopathy Screening Programme managers and General Practitioners, so that they are aware of the issues that have been raised. You will not be identifiable as we will keep your personal details confidential and protect your identity.

Why have I been chosen?

You may have offered to take part after hearing about the study in the local media, or at your GP practice. You are eligible to take part because you have been diagnosed with diabetes, and have previously been asked to have photographs taken of the back of your eyes. Your experiences of this process may help us to understand what influences people's decisions whether or not to go to the screening, or whether they understand the result once it has been communicated to them by their GP, optometrist, or diabetic screening staff. We are asking for the views of people with diabetes who have previously attended their diabetic eye screening, and will also be asking the views of health professionals involved in the screening programme.

Do I have to take part?

It is entirely up to you to decide if you want to take part or not. If you do decide to take part, you will be given this information sheet to keep and asked to sign a form, enclosed, saying that you agree to take part (consent form). You will be free to withdraw from the study at any time before the end of the study (estimated at August 2013), without giving a reason – this will not make any difference to the treatment that you receive. A decision to withdraw or not to take part will not be passed on to your medical team. If we have already collected information from you and you choose to withdraw, we will destroy all the information we hold for you and not use it in the study.

What will I have to do?

You are being asked to take part in a research interview, which will last approximately 45 minutes to an hour. This will probably take place at your GP practice, or other venue of your choice (to be confirmed), or by telephone. We will be able to pay your travelling expenses and you will receive a £20 gift voucher. You will be asked about your experiences of living with diabetes, your perception and view of risks and benefits of diabetic retinopathy screening, and how risk information about diabetic retinopathy should be communicated to people with diabetes.

Before you start talking to the researcher, you will be given a form to fill in with your personal details; the researcher can help you with this if necessary. You will also be asked to fill in two short surveys, which will ask you a few questions about diabetes self-care management, and aspects of living with diabetes that you find difficult; the researcher can help you with this if necessary. These forms take no more than 15 minutes to complete. Patients come from lots of different backgrounds, so have very different experiences that can affect their diabetes and lead to different views about diabetic eye screening, which we are interested in. We will also ask your GP practice to send us the result of you most recent blood glucose test.

You will be asked to agree to the discussion being audio recorded (the recording will be destroyed at the end of the study). The recording will then be put into writing and your views will be carefully considered, along with the other participants' views. Any paperwork that is produced as a result of this research study (for example, for the Diabetic Retinopathy Screening Programme management) will refer to you by an ID number only (e.g. 'participant number 10'), or an alternative name (pseudonym).

What are the possible disadvantages of taking part

The only disadvantage is likely to be the time that it takes for you to participate in the interview. No other disadvantages are expected.

What are the possible advantages of taking part?

The views of everyone who talks to us will be considered carefully. These views will be used to suggest improvements to the Diabetic Retinopathy Screening Programme organisers (we will refer to you by an ID number or an alternative name only). The information we get from this study may help other people in future. You may learn more about your diabetes and eyes and this may help your health. We will give you a £20 voucher at the end of the research interview.

Will anyone else know I have done this?

Only the lead researcher/interviewer and the member of staff at your GP surgery who sent you this information pack will know exactly who has been invited to take part. Your name or details will not be given to anyone else – you will only be referred to by participant ID number or an alternative name (pseudonym) in any paperwork. So the Diabetic Retinopathy Screening Programme management, hospital specialist etc. will not know that you have done this. No-one else will be told exactly who has taken part. All information will be treated confidentially. Only the research team will have access to your personal details, the audio recording and the written copy of our conversation, which will be kept in locked filing cabinets. The recordings will be password protected and erased at the end of the study (estimated at December 2013). The Data Protection Act (1998) will be followed at all times. The only circumstance, in which we might have to pass your details to another person, is if you disclose illegal behaviour. In this case, we will be obliged to inform the authorities, to deal with the matter appropriately. However, such a disclosure will not be shared with anyone else if this not necessary.

Who is organising and funding the research?

This research is being organised by Queen Elizabeth Hospital Birmingham and Warwick Medical School at the University of Warwick. It is self-funded study.

What happens to the results of the study?

A summary of the results of the research will be sent to all participants later in the project. The research findings will be passed to the team who organise the English National Diabetic Retinopathy Screening Programme, so that they can see what needs to be done to help more people with diabetes to understand risks and benefits of their eye photography. The results will also be distributed at relevant professional conferences, so other people can benefit from your views (you will be identified by an ID number or pseudonym only).

I have some questions. Whom can I ask?

If you have any questions, now or at any point in the research, please contact the principal researcher,
Nidal Al-Athamneh 07426883070 or n.al-athamneh@warwick.ac.uk

What if something goes wrong?

If you are unhappy about any aspect of this study, you may complain to the University of Warwick. The University has comprehensive public liability insurance. Any complaint should be addressed to In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

What do I do now?

If you want to take part in this research, please sign both copies of the Declaration of Informed Consent. Keep one for your records ***and return the other in the envelope provided*** (it does not need a stamp).

Thank you for reading this!

If you want to take part in the research, please sign the enclosed Consent Form, and return it in the envelope provided

In case of any query, please contact the lead researcher: Nidal Al-Athamneh 07426883070 or n.al-athamneh@warwick.ac.uk In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 4: Patients Provisional Interview Schedule

(v1)

Questions for patients
Stage 1

1. What do you know about DRS, how often needs to be done?
2. How do you feel about changing the screening intervals from once a year to once every 2 or 3 years for people with diabetes who are at low risk? Does it concern you? Or relieve you as no need to come every year? (any benefits or risks)
3. What is the most effective interval of DRS? Every year, 2 years 3 years 5 years etc.
4. Should the policy changed, how would you cope/adapt yourself? What are your alternatives? More visits to optician, eye clinic, GP, etc.
5. What kind of message will the patients receive when their doctor advice them to attend once every 2 years as they are at low risk of developing DR? Will that affect their personal diabetic control, as they may think that they are doing well, and no need to take medicine, or change their diet control?
6. How do you think is the best way to inform patients about their risk of developing DR? (by GP, DRS, eye clinic, diabetic clinic, etc and why?
7. What it is the best method of presenting risk information to patients? (using umbers, percentages, probability, words, figure, combinations or all (present the tools), which is more valuable: individual risk or average, fear messages or positive messages).
8. When a GP, DRS staff, etc presents to someone the risk of developing DR as 10-15% in the next 5 years, how do you interpret this? Low risk, high risk?
9. Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
10. How serious would it be to get DR in the next 5 years?
11. Is there anything you'd like to add that we haven't covered in the interview?
12. If I tell you that there is chance 1 in 1000 for someone to develop DR in the next 5 years, what is your chance to be that person?
13. How likely do you think you will develop DR in the next 5 years?
14. How likely you think you will develop DR in the next 5 years compare to others (gender, ethnicity, age group) are you more likely, less likely, to get DR and why?

Stage 2

Questions for patients

1. Can you tell me about diabetic retinopathy and screening programme?

(how did you hear about it, why it is being done, how often do you need to go for screening, when do you stop going for screening, why important to attend, what are the benefits and risks of DRS)

2. Can you tell me about your most recent retinal screening experience?
   When, where, what they found, who told them what, what do they understand about the implication of what they were told, how will you cope, what would you do to keep your diabetes under control
3. After receiving the risk information (result that you have received from DRS, GP, eye clinic, etc) how likely would it be to develop DR in the next 5 years?
4. How did the results impact on your diabetes management?

For patients with no retinopathy (R0)

5. My understanding from your GP is that you have no signs or retinopathy at present. How does that fit with your understanding?
   For patients with background retinopathy (R1)

6. My understanding from your GP is that you have early signs of retinopathy (background). How does that fit with your understanding?

APPENDIX 5: Translation and Interpreting Protocol

(v1)

A5.1 Study Materials Translation

The language(s) that study materials will need to be translated into is not yet confirmed. As the cost of having all materials professionally translated is prohibitive, the following has been adapted from Bhopal et al. (2004) principles for adapting written research materials into different languages and Birbili's (2000) translating guidance:

- A bilingual person who understands the target language and culture will translate the study's materials into the target language, ensuring conceptual equivalence (not simple literal translation) is achieved;
- As the bilingual person may not be representative of the target population because of education, age, sex etc., if possible, a representative of the target population will assess meaning and acceptability of the translated materials and modifications will be suggested;
- The bilingual person will amend materials as appropriate, comparing translations with the original English-language materials, to ensure conceptual equivalence is maintained;
- A second bilingual person who understands the target language and culture will validate the materials using the target language and English materials;
- The two bilingual people and the principal researcher will meet (if possible) to discuss the back-translations, negotiating a "best fit" to ensure conceptual equivalence is maintained;

  The resultant materials will be piloted with at least two monolingual members of the target population (if possible) to check face and content validity, with further changes suggested if necessary;

- The bilingual people and the principal researcher will again discuss the suggested modifications and amend materials as appropriate, comparing translations with the original English-language materials, to ensure conceptual equivalence is maintained.

A5.2 Non-English-language data-collection

It is anticipated that some potential participants will want to be interviewed in a language other than English, and they are asked to indicate their language of choice on the consent form, before returning it. Funding exists to cover the cost of interpreters for interviews. A three-way interview with NA (interviewer), the participant and an interpreter will allow detailed data-collection to be undertaken in accordance with ethical guidelines.

A5.3 Data validation process

Full back translation will be too time and resource inefficient for the current study, therefore an acceptable method of validating the interpreter's work, used by Hipwell (2009), will be used. Following verbatim transcription of the English-language sections of the interviews, a research-trained, fluent speaker of the target language(s) will be employed to validate the accuracy of the translated transcripts, using the audio files and the English transcripts. The ‘track changes’ function of Microsoft Word will be used by the validator to highlight any areas where discrepancies may have occurred, to alert the researchers conducting the analysis. The interpreter and validator will both be paid the appropriate hourly professional rate for this work.

APPENDIX 6: Health Professionals Demographic Data Collection

(V1)

IN CONFIDENCE
Participant ID number……………

1. **Date of birth**: Month…………..……….. Year………..…

2. **Sex** (please circle one): Male/Female

3. **What is your role with the English National Diabetic Retinopathy Screening Programme?**

   Screening only ☐
   Trainer ☐
   GP ☐
   Health Care Asst ☐
   Grading only ☐
   Programme manager ☐
   Specialist nurse ☐
   Other (please state) ☐
   Screening & grading ☐
   Optometrist ☐
   Practice manager ☐
   ……..……..……………………

4. **How long have you been working with diabetic retinopathy patients in this role?** (Please tick one):

   Less than one year ☐ One to three years ☐ More than three years ☐

Thank you for your help!

This sheet will be stored separately from all other information, to protect your identity

In case of any query, please contact the lead researcher: Nidal Al-Athamneh 07426883070 or n.al-athamneh@warwick.ac.uk
In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 7: Health Professionals Information Sheet

(Health professionals v1)

1. Study Title:

Communicating risk information about diabetic retinopathy to people with diabetes

2. Invitation:

You are invited to take part in a research study that is being conducted as part of educational study at the University of Warwick. Ask us if anything is unclear or if you would like more details. Our contact details are at the bottom of every page and in sections 12 and 13. Thank you for reading this information sheet.

3. What is the purpose of this study?

As you will be aware, people with diabetes can develop sight-threatening diabetic retinopathy (DR). Retinopathy screening can identify early signs of damage whilst patients are asymptomatic of DR. Research has shown that people who attend the Diabetic Retinopathy Screening Programme are less likely to suffer loss of vision or blindness, compared with people who don't attend (Gray, 2009). However, DR screening uptake varies across different GP and optometry practices across the country. This research aims to explore how the risks and benefits of diabetic retinopathy screening programme are understood by people with diabetes and health care professionals, and to establish the methods by which risk information can be effectively communicated to help informed choice.

The results will be given to the DR Screening Programme managers, so that they are aware of the issues that have been raised.

4. Why have I been chosen?

You have been chosen because you have been identified as a health professional who works with patients diagnosed with diabetes and the DR screening programme. Your experiences of this process may help us to understand how risk information is been communicated to people who attended for screening. We are also asking for the views of people with diabetes who always attend their diabetic eye screening, and other health professionals involved in the screening programme.

5. Do I have to take part?

Participation in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. You will be free to withdraw from the study at any time prior to the end of the study without giving a reason. If you do not wish to participate, or if you choose to withdraw from the study at a later date, it will have no detrimental effect on your employment. If we have already collected information from you and you choose to withdraw, we will destroy all the information we hold for you and not use it in the study.

6. What will I have to do?

You are being asked to take part in a research interview, which will last around half an hour. This will probably take place at your workplace, or other venue of your choice (to be confirmed). You will be asked about your experiences of dealing with patients who have diabetes, how risk information about diabetic retinopathy is communicated, and how risks and benefits of screening programme is presented.

Before you start talking to the researcher, you will be given a form to fill in with your personal details. Health professionals have many different experiences and might have different views about diabetic eye screening. You will be asked to agree to the discussion being recorded. The recording will then be put into writing and carefully considered, along with the other participants' views. Any paperwork that is produced as a result of this research study (for example, for the Diabetic Retinopathy Screening Programme management) will refer to you by an ID number only (e.g. 'participant number 10'), or an alternative name (pseudonym).

7. What are the possible disadvantages of taking part

The only disadvantage is likely to be the time that it takes for you to participate in the interview. No other disadvantages are expected.

8. What are the possible advantages of taking part?

The views of everyone who talks to us will be considered carefully. These views will be used to suggest improvements to Diabetic Retinopathy Screening Programme organisers, and methods of risk communication (we will refer to you by an ID number or pseudonym only). The information we get from this study may help other people in future.

9. Will anyone else know I have done this?

Only the principal researcher/interviewer will know exactly who has taken part. Your name or details will not be given to anyone else. So neither the Diabetic Retinopathy Screening Programme organisers, nor your PCT management or Commissioners, will know who has participated in this. No-one else will be told who has taken part. All information will be treated confidentially. Only the principal researcher will have access to your personal details and the recording, and only the principal researcher, study director and the data analyst will have access to the anonymised written copy of our conversation, which will be kept in a locked filing cabinet. The digital recordings will be password protected and erased at the end of the study (estimated at December 2012). The Data Protection Act (1998) will be followed at all times.

The only circumstances, in which we might have to pass your details to another person, are if you disclose either unprofessional or illegal behaviour. In these cases, we will be obliged to inform your employing organisation, to be dealt with be dealt with appropriately. However, such a disclosure will not be shared with your peers or managers if this not necessary.

10. What happens to the results of the study?

A summary of the results of this phase of the research will be sent to all participants later in the project. The research findings will be passed to the team who organise the English National Diabetic Retinopathy Screening Programme, so that they can see what needs to be done to help more people with diabetes to attend their eye photography, and improves methods of risk communication. The results will also be distributed at relevant professional conferences, so other people can benefit from your views (you will be identified by an ID number or pseudonym only).

11. I have some questions. Whom can I ask?

In case of any query, please contact the lead researcher: Nidal Al-Athamneh 07426883070 or
n.al-athamneh@warwick.ac.uk; In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

12. Who is organising and funding the research?

This research is being organised by Queen Elizabeth Hospital Birmingham and Warwick Medical School at the University of Warwick. It is self-funded study.

13. What if something goes wrong?

If you are unhappy about any aspect of this study, you may complain to the University of Warwick. The University has comprehensive public liability insurance. Any complaint should be addressed to the study director, Dr Jackie Sturt by telephone 024 765 73753 or email jackie.sturt@warwick.ac.uk.

14. What do I do now?

If you want to take part in this research, please sign both copies of the Declaration of Informed Consent. Please keep one for your records ***and return the other in the envelope provided*** (it does not need a stamp).

Thank you for reading this!

If you want to take part in the research, please sign the enclosed Consent Form, and return it in the envelope provided

APPENDIX 8: Health Professionals Provisional Interview Schedule

(v1)

1. How do you feel about changing the screening intervals from once a year to once every 2 or 3 years for people with diabetes who are at low risk? Does it concern you? Or relieve you as no need for patients at low risk to have DRS every year? (any benefits or risks)
2. What is the most effective interval of DRS? Every year, 2 years 3 years 5 years etc.
3. Should the policy changed, how would it impact on your service? What are your alternatives? More visits to optician, eye clinic, GP, etc.
4. What kind of message should the patients receive when their doctor advises them to attend once every 2 years as they are at low risk of developing DR? Will that affect their personal diabetic control, as they may think that they are doing well, and no need to take medicine, or change their diet control?
5. How do you think is the best way to inform patients about their risk of developing DR? (by GP, DRS, eye clinic, diabetic clinic, etc and why?
6. What it is the best method of presenting risk information to patients? (using umbers, percentages, probability, words, figure, combinations or all (present the tools), which is more valuable: individual risk or average, fear messages or positive messages).
7. When a GP, DRS staff, etc presents to someone the risk of developing DR as 10-15% in the next 5 years, how do you interpret this? Low risk, high risk?
8. Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
9. Is there anything you'd like to add that we haven't covered in the interview?

APPENDIX 9: Declaration of Informed Consent

(Professionals; v1)
Participant ID number……………

Please tick

1. I have read and understand the 'Professionals Information Sheet (v1)'. ☐
2. I understand that taking part in this study will involve me being interviewed and providing some personal demographic information. ☐
3. I understand that the discussion will be recorded and that the recording will be destroyed at the end of the study. ☐
4. I understand that there are no known expected discomforts or risks involved in my participation in this study. ☐
5. I understand that I am free to withdraw from the study at any time prior to the study's end, without giving a reason, by contacting the e-mail address or telephone number below. ☐

I give my informed consent to take part in this study. I understand that although a record will be kept of my participation in the study, my data will be identified by a number or an alternative name (pseudonym) only.

Signed ………………………………………… Dated ……………………………

Name (please print in full) ....

Phone number(s) ....

Email address: ....

Address:...

....Post code: .... *(We will only use this information to contact you about the study)*

Please sign this form & return it in the envelope provided

In case of any query, please contact the lead researcher: Nidal Al-Athamneh 07426883070 or n.al-athamneh@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 10: Letter to GP

Date

GP name

Surgery name

Street name

Town

County

Post code

Dear GP name,

Re: Patient name, Risk Communication Study

I wish to inform you that your patient, above, has participated in the FLURRI study (Communicating risk Information about Diabetic Retinopathy to people with diabetes).

Please see the enclosed information for further details.

Yours sincerely,

Nidal Al-Athamneh

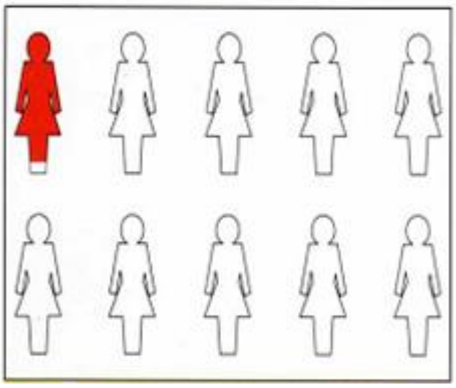
PhD Student,

Warwick Medical School

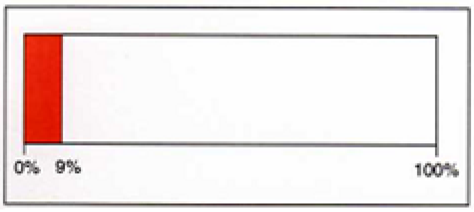
(Encs: Patient Information Sheet, Demographic data-collection, PAID & DSCAQ, Informed consent).

APPENDIX 11: Risk Communication Tools

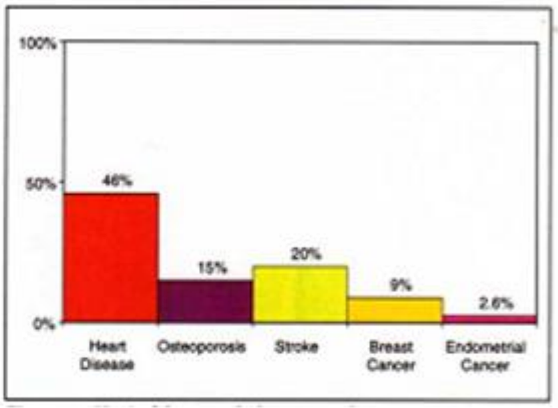
1. Figure 1 represents highlighted human figures used to present a lifetime risk of breast cancer for a 50 year old woman, the lifetime risk of 9% is portrayed in a frequency format with a denominator of 10 (Schapira *et al.*, 2006):



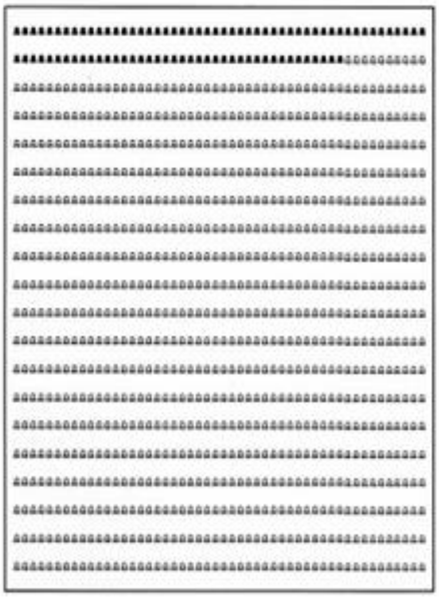
2. Figure 2 represents bar graph format used to communicate lifetime risk of breast cancer for a 50 year old woman (Schapira *et al.*, 2006):



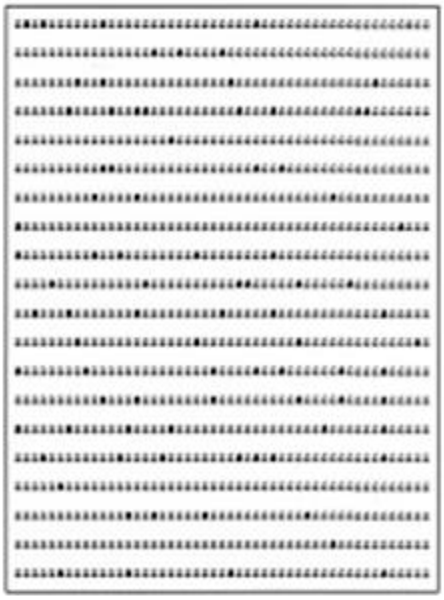
3. Figure 3 represents vertical bar graph format used to communicate comparative lifetime risks for a 50 year old woman including the risk of heart disease, osteoporosis, stroke, breast cancer, and endometrial cancer (Schapira *et al.*, 2006):



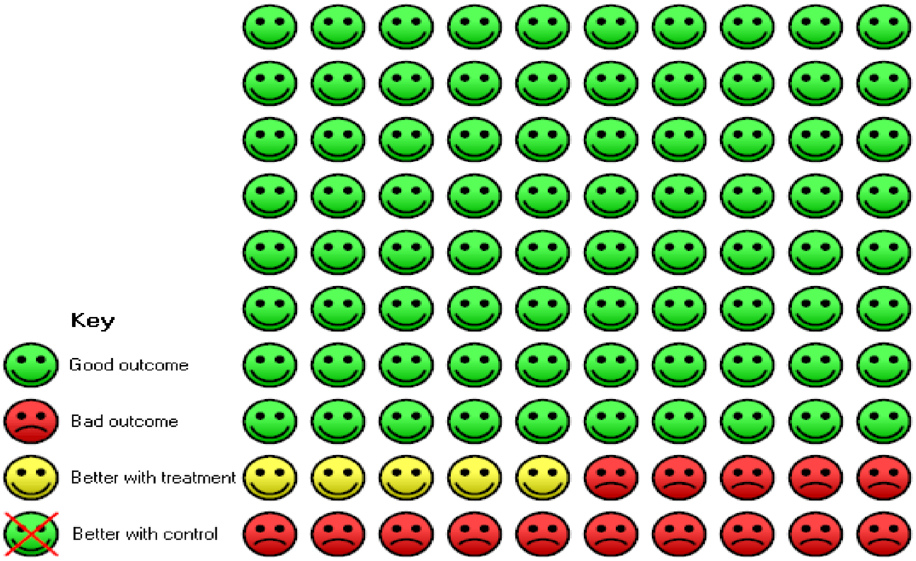
4. Figure 4 represents a highlighted human figure format used to communicate lifetime risk of breast cancer for a 50 year old woman using a denominator of 1000 and consecutive highlighting of figures (Schapira *et al.*, 2006):



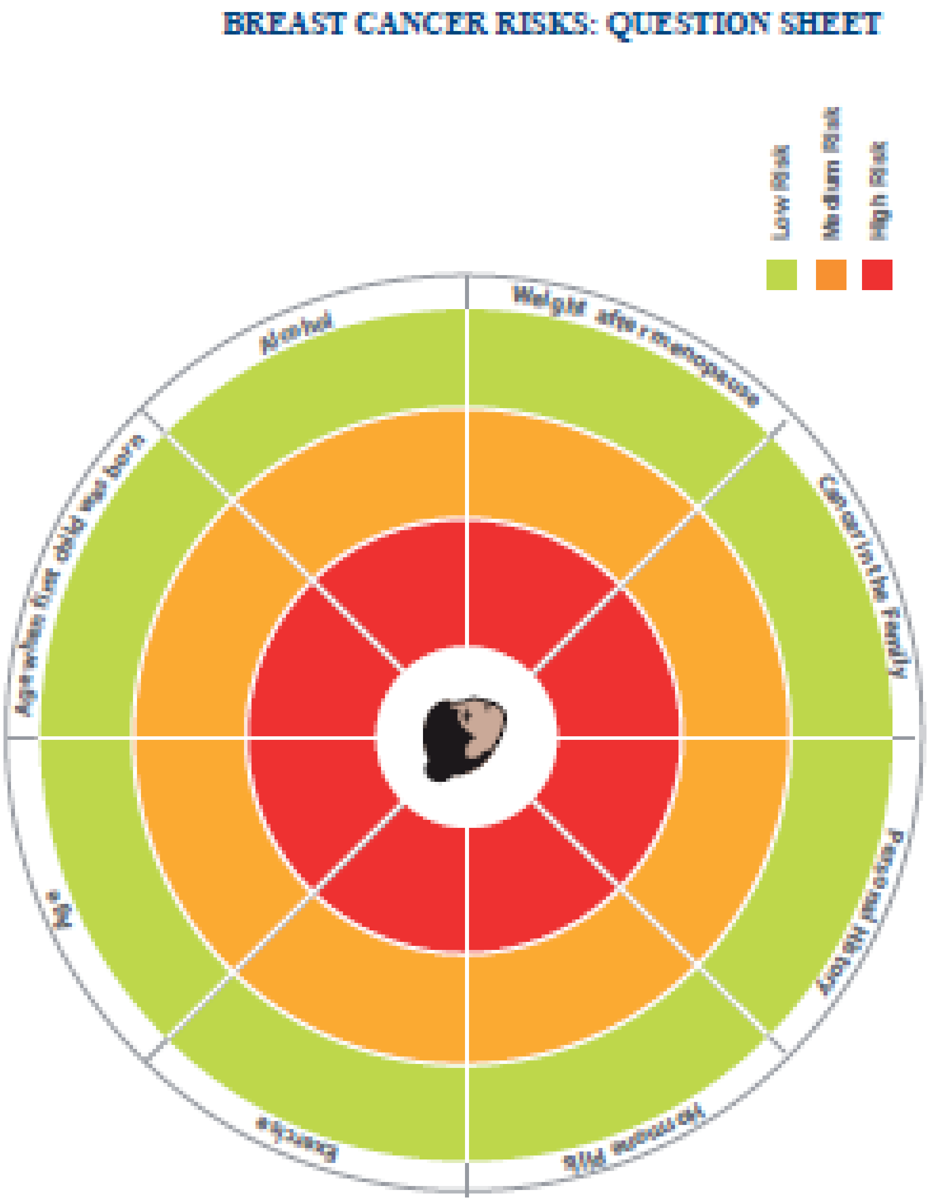
5. Figure 5 represents human figures to communicate lifetime risks of breast cancer for a 50 year old woman using a denominator of 1000 and randomly highlighting of figures (Schapira *et al.*, 2006):



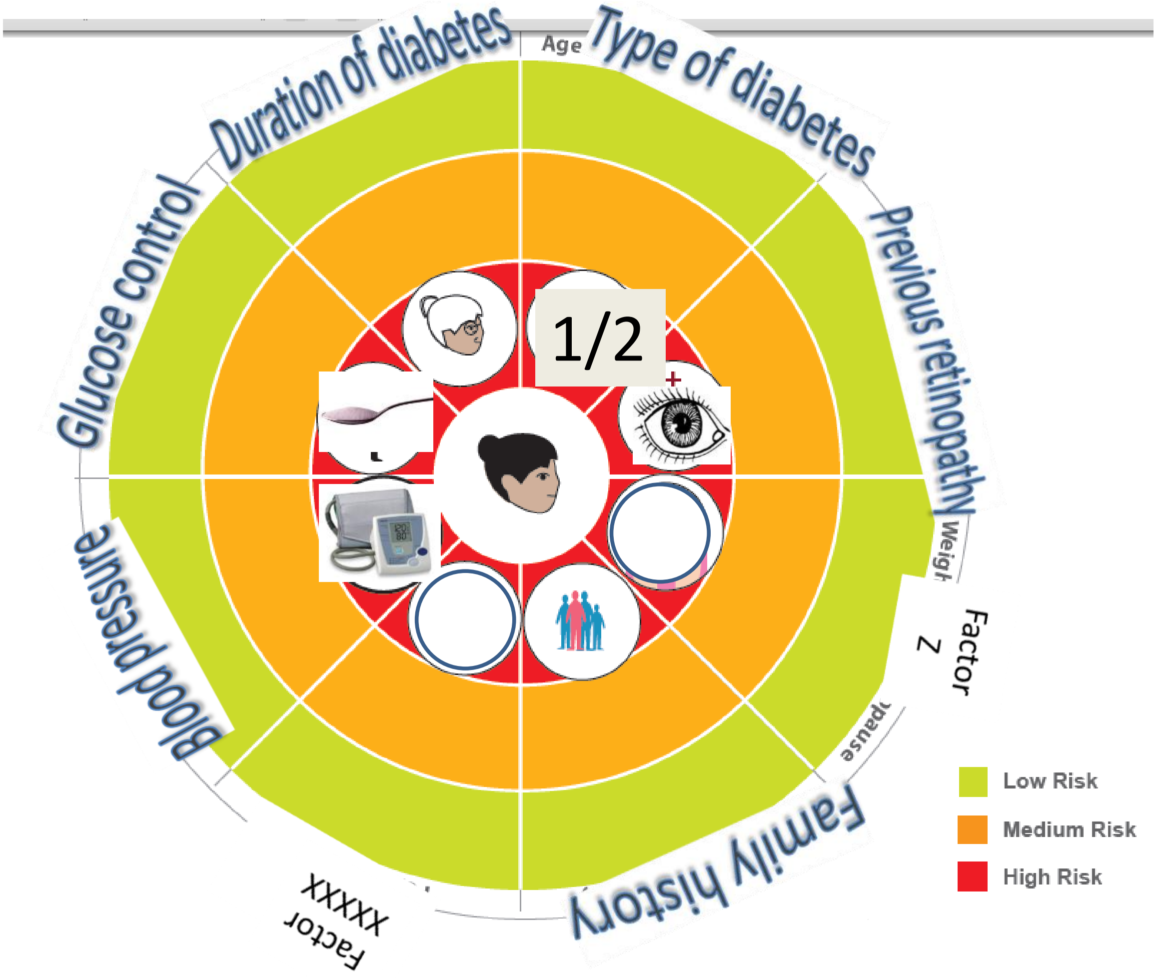
6. Figure 6 represents 80 out of 100 patients (green faces) treated with statin who would not have suffered a vascular event anyway and 15 red faces still suffer an event in spite of the statin, but 5 yellow faces are saved from having a vascular event (Cates, 2009):



7. Figure 7 represents a breast cancer self-assessment risk tool (Chiu, 2009). This tool includes breast cancer risk factors and personalizes the risk:

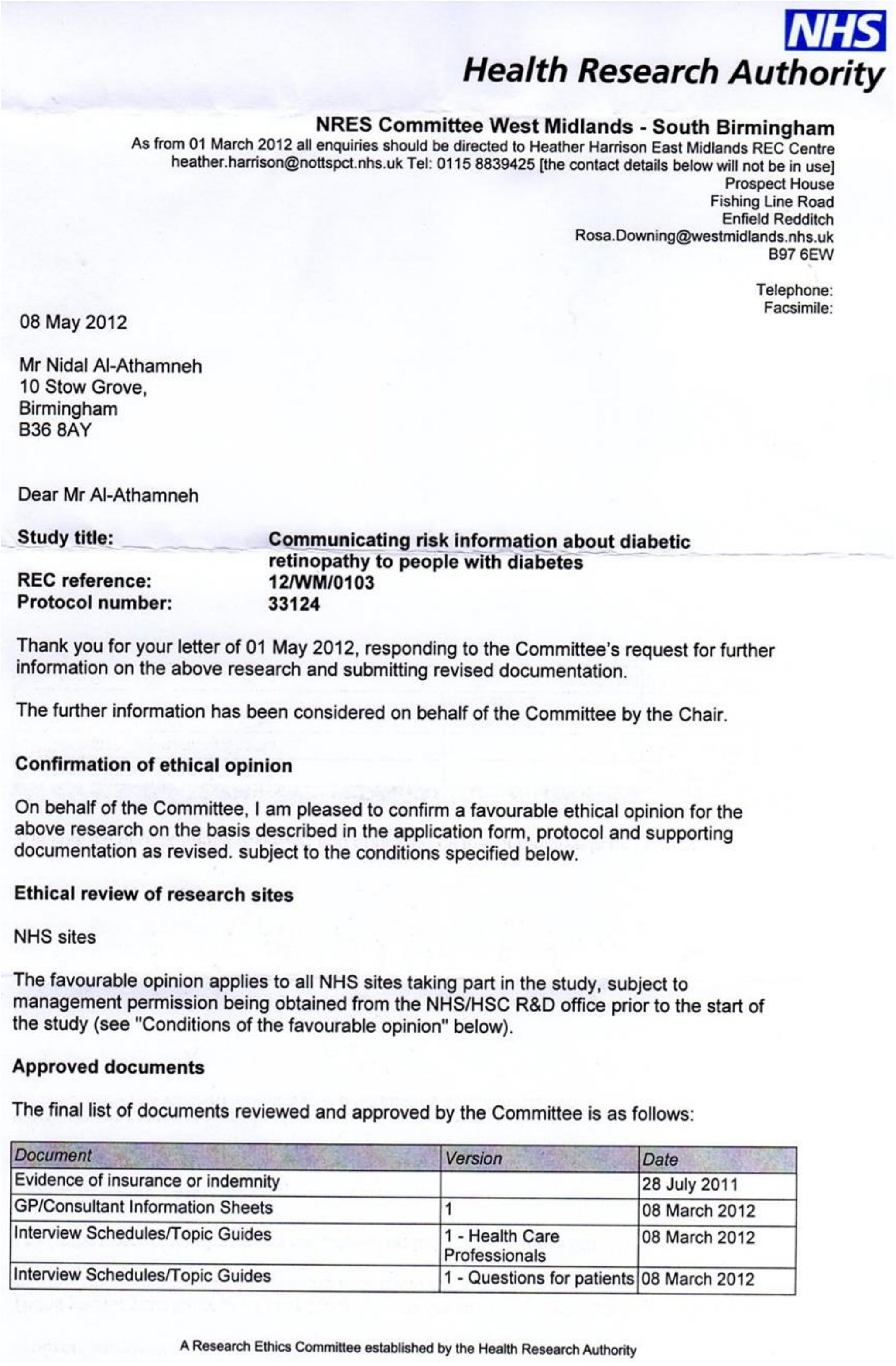


8. Figure 8 represents an example of risk tool during modification process



9. Figure 9 represents the final version of the risk tool after modification process

APPENDIX 12: Research Committee ethical approval



NHS
Health Research Authority

NRES Committee West Midlands - South Birmingham
As from 01 March 2012 all enquiries should be directed to Heather Harrison East Midlands REC Centre
heather.harrison@nottspct.nhs.uk Tel: 0115 8839425 [the contact details below will not be in use]
Prospect House
Fishing Line Road
Enfield Redditch
Rosa.Downing@westmidlands.nhs.uk
B97 6EW

Telephone:
Facsimile:

08 May 2012

Mr Nidal Al-Athamneh
10 Stow Grove,
Birmingham
B36 8AY

Dear Mr Al-Athamneh

Study title: **Communicating risk information about diabetic retinopathy to people with diabetes**
REC reference: **12/WM/0103**
Protocol number: **33124**

Thank you for your letter of 01 May 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

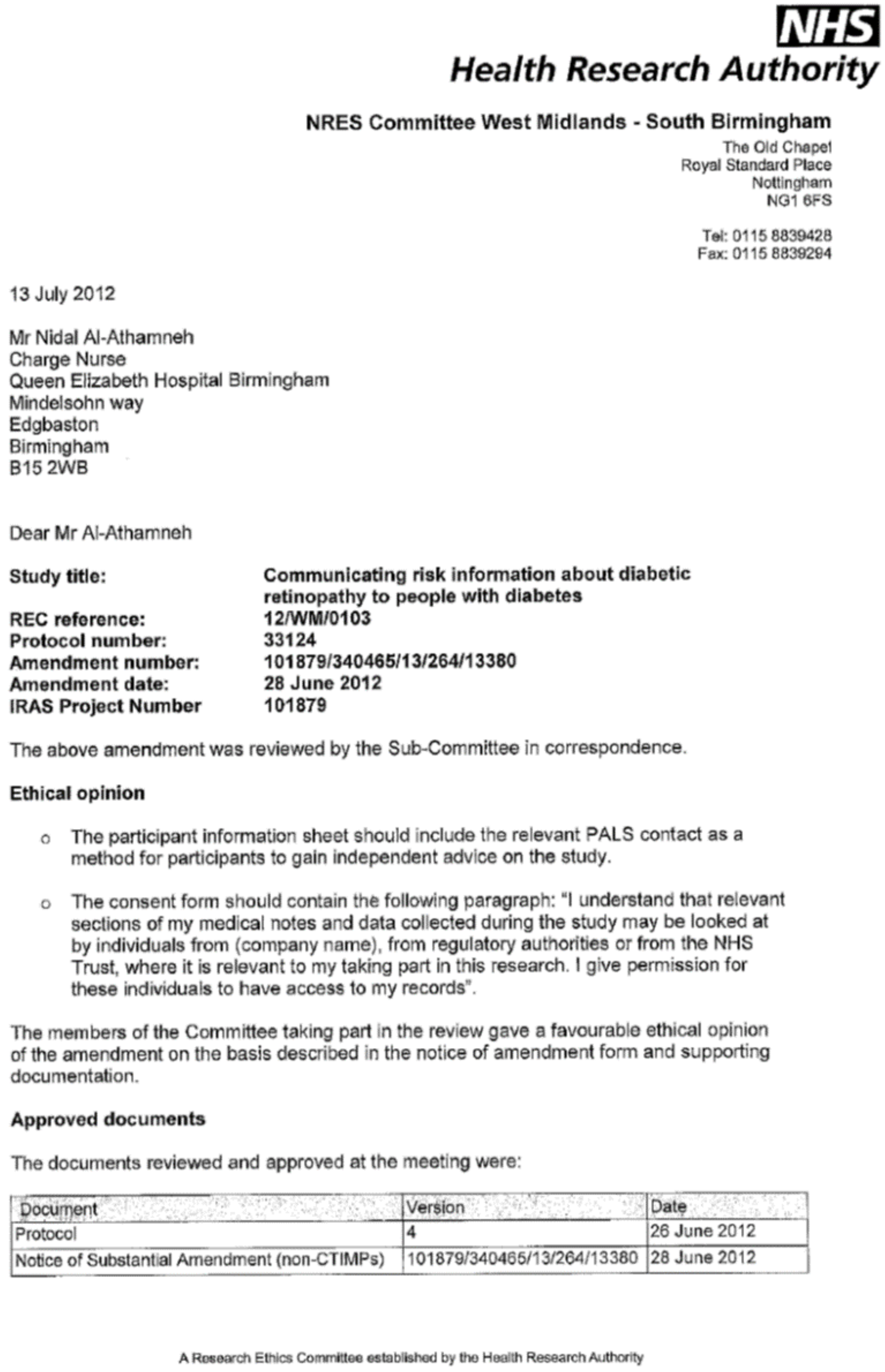
Approved documents

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

Document	*Version*	*Date*
Evidence of insurance or indemnity		28 July 2011
GP/Consultant Information Sheets	1	08 March 2012
Interview Schedules/Topic Guides	1 - Health Care Professionals	08 March 2012
Interview Schedules/Topic Guides	1 - Questions for patients	08 March 2012

A Research Ethics Committee established by the Health Research Authority

APPENDIX 13: Substantial Amendment



NHS
Health Research Authority

NRES Committee West Midlands - South Birmingham
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 8839428
Fax: 0115 8839294

13 July 2012

Mr Nidal Al-Athamneh
Charge Nurse
Queen Elizabeth Hospital Birmingham
Mindelsohn way
Edgbaston
Birmingham
B15 2WB

Dear Mr Al-Athamneh

Study title:	**Communicating risk information about diabetic retinopathy to people with diabetes**
REC reference:	**12/WM/0103**
Protocol number:	**33124**
Amendment number:	**101879/340465/13/264/13380**
Amendment date:	**28 June 2012**
IRAS Project Number	**101879**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

- The participant information sheet should include the relevant PALS contact as a method for participants to gain independent advice on the study.

- The consent form should contain the following paragraph: "I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from (company name), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records".

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	4	26 June 2012
Notice of Substantial Amendment (non-CTIMPs)	101879/340465/13/264/13380	28 June 2012

APPENDIX 14: Diabetes UK poster Manchester 2013

Communicating Risk Information About Diabetic Retinopathy To People With Diabetes

Al-Athamneh N, Sturt J, Stratton IM, Lindenmeyer A, Scanlon PH.
Warwick medical school

Introduction

Diabetes is a global problem affecting over 170 million worldwide, and causing about 5% of all deaths globally each year[1]

There are over 2.53 million people with diabetes live in the UK, and one in 20 adults have the condition[2].Of those, a total of 2,32 million people with diabetes were offered screening, and 1,86 million were screened - increase by more than 130,000 compared to the previous year. Therefore, annual screening may not be affordable for everyone with diabetes.

Diabetes-Related Eye Complications (DRECs) are common and confers a significant burden on the patient's quality of life. If DRECs are left untreated, they lead to the deterioration of vision and, ultimately, blindness. Diabetic retinopathy is the leading cause of visual impairment in the working age group[3].

Counselling patients about their diabetes and gaining complete compliance with treatment, annual screening, and diabetes self-management involve the presentation of risk and benefit information. The patients' charter states that patients have a right to be given a clear explanation of any treatment proposed, including any risks and alternatives, before they decide whether to agree to the treatment or not. Making choice of an informed decision depends on patients level of understanding of the relevant risks that given to them [4] as informed patients are more likely to make wiser decision and adhere actively in their treatment [5]. However, informed decision making occurs only in 9% of outpatients' visits [6].

Aim of study

The main aims are

1) To establish the evidence surrounding the effectiveness of risk communication tools about diabetic retinopathy (DR) to people with diabetes.
2) To identify tools used in other clinical contexts that may have efficacy in Diabetic Retinopathy Screening (DRS).
3) To adapt or develop new risk communication tool(s) for use in routine DR screening for people with diabetes.

Methods

We searched the following database between 1992 and August 2012; MEDLINE, Blackwell Publishing of Synergy, EBSCO EJS, Science Direct (Elsevier Journals), Wiley, BNI, CINAHL, COCHRANE and EMBASE bibliographic database

The following publications were hand searched; Risk Analysis, Risk and Society, Diabetic Medicine, Practice Diabetes International, Diabetologia, Diabetes Care, BMJ and The Diabetes Educator. An electronic table of content was set up for all the relevant journals in order to stay up to date with the latest relevant articles.

The following set of search terms and key words for the review were searched; risk, risk communication, risk perception, risk tool, communication tool, diabetes, diabetic retinopathy & screening.

Results

No risk communication tool was identified for diabetic retinopathy (DR). One individual risk calculator [7] demonstrated effectiveness for DR screening. The risk can be calculated in seconds through the following website, www.risk.is, the algorithm receives clinical data such as patient's age, duration of diabetes, type of diabetes, and HbA1c or blood glucose. Table 1 show an example of the individualised risk and possible intervals for Mr X as shown down in table 1.

Effective tools were identified for communicating risk information in cancer and chronic heart disease as shown in figures 1-6 [8,9,10]. The use of visual aids using graphical formats of risk such as a bar graph or graphics of highlighted human figures was found to facilitate the presentation of risk for those who cannot read or in whom English is not their first language. Communicating the risk to patients using written or visual formats was found to be effective and increase the knowledge of patients as well as reducing the anxiety level about the associated risk.

Table 1: Possible diabetic retinopathy screening intervals based on individualised risk factors [7]

Name	Age	Type of diabetes	Duration of diabetes	HbA1c	Systolic blood pressure	Diastolic blood pressure	Previous diabetic retinopathy	Calculated risk of developing STDR every year	Risk	Screening intervals
Mr X	40	Type 2	5 years	7%	120	80	No	0.4%	Low risk	60 months
				7%	150	90	No	1.5%	Medium risk	25 months
				9%	150	90	No	3.2%	High risk	12 months
				12%	160	90	No	14.5%	High risk	6 months

Patients self assessment, The chart was in the shape of three concentric circles, with the innermost circle (red) indicating high risk, the middle circle (amber) indicating medium risk and the outer circle (green) indicating low risk [10]

This graphic displays highlighted human figure used to present a lifetime risk of breast cancer for a 50-year old woman. The lifetime risk of 0.9 is portrayed in a frequency format with a denominator of 10 [8]

This graphic displays a bar graph format and represents the lifetime risk of a 50-year-old woman developing breast cancer.

This graphic displays the use of multiple bar graphs to represent the lifetime risk of a 50-year-old woman developing breast cancer as well as the lifetime risk of a 50-year-old woman developing heart disease, stroke, and osteoporosis [8]

20 people out of 100 had a heart attack, stroke or bypass surgery over 10 years, compared to 15 out of 100 for the active treatment group [9]

This graphic displays a matrix format with 100 symbols shaped as people in the background and 9 consecutively highlighted symbols in the foreground. This graphic represents the lifetime risk of a 50-year-old woman developing breast cancer [8]

Conclusions

Identified tools may be useful in communicating DR risk to people with diabetes. Continuing work will now pilot these tools to assess it's effectiveness for communicating risk and understanding the relationship of this risk to diabetes self-management.

References

1. WHO (2010) *Diabetes Programme* [online] available via http://www.who.int/diabetes/facts/world_figures/en/index4.html [accessed 01/11/2010].
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4. Michie, S., et al., *Communicating risk information in genetic counseling: an observational study.* Health Educ Behav, 2005. **32**(5): p. 589-98.
5. Epstein, R.M., B.S. Alper, and T.E. Quill, *Communicating evidence for participatory decision making.* Jama, 2004. **291**(19): p. 2359-66.
6. Braddock, C.H., 3rd, et al., *How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting.* J Gen Intern Med, 1997. **12**(6): p. 339-45.
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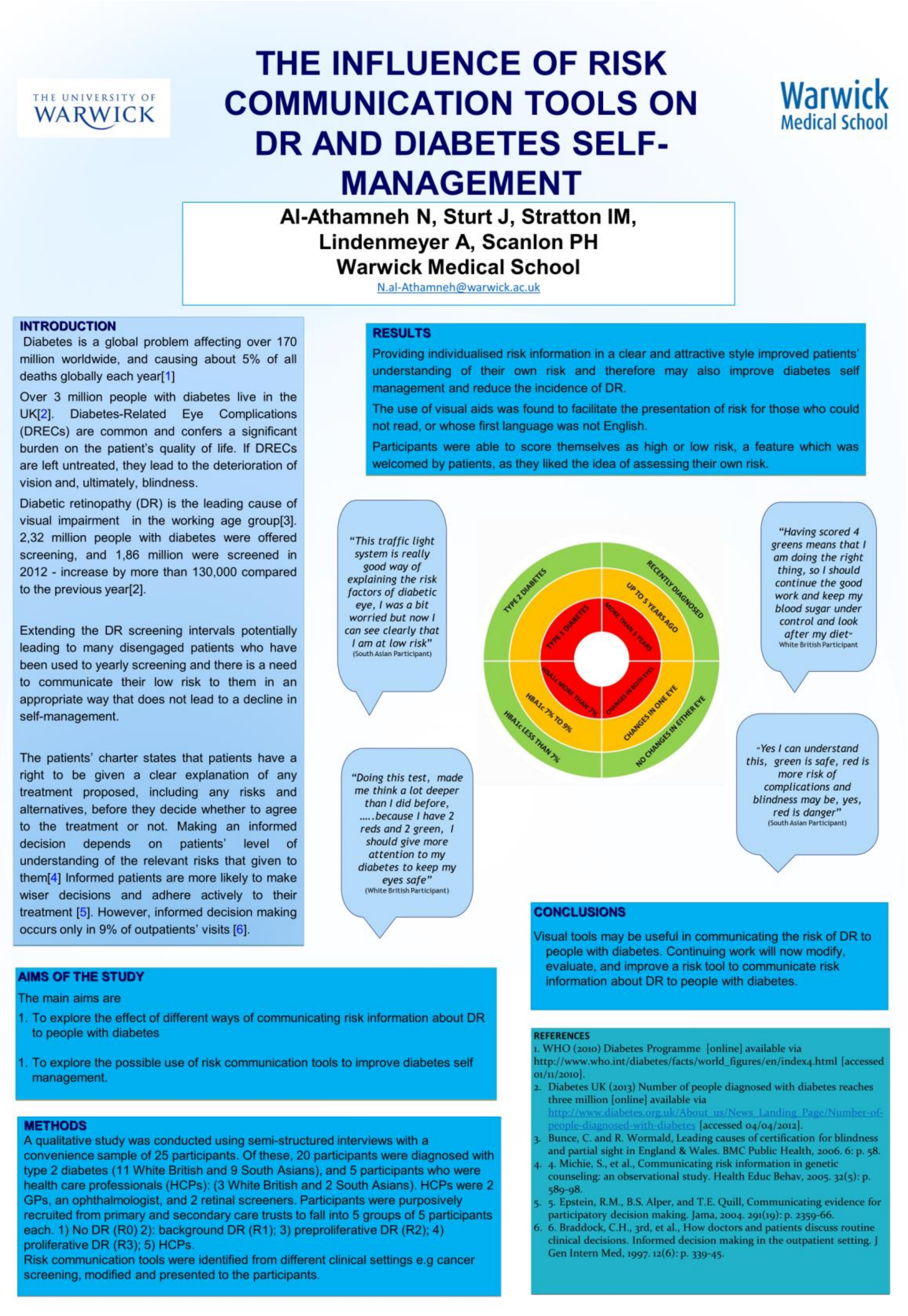
8. Schapira, M.M., A.B. Nattinger, and T.L. McAuliffe, *The influence of graphic format on breast cancer risk communication.* J Health Commun, 2006. **11**(6): p. 569-82.
9. Cates, C (2009) Statin Calculator [online] available via http://www.nntonline.net/visualrx/examples/statins/ [accessed on 10/09/2009].
10. Chiu, C., et al., (2009) Communicating risk information about breast and cervical cancer and cancer screening to women from minority ethnic and low income groups. Sheffield: NHS cancer screening programme.

APPENDIX 15: EASDec 2013 Poster Barcelona Spain



THE INFLUENCE OF RISK COMMUNICATION TOOLS ON DR AND DIABETES SELF-MANAGEMENT

Al-Athamneh N, Sturt J, Stratton IM,
Lindenmeyer A, Scanlon PH
Warwick Medical School
N.al-Athamneh@warwick.ac.uk

INTRODUCTION

Diabetes is a global problem affecting over 170 million worldwide, and causing about 5% of all deaths globally each year[1]

Over 3 million people with diabetes live in the UK[2]. Diabetes-Related Eye Complications (DRECs) are common and confers a significant burden on the patient's quality of life. If DRECs are left untreated, they lead to the deterioration of vision and, ultimately, blindness.

Diabetic retinopathy (DR) is the leading cause of visual impairment in the working age group[3]. 2,32 million people with diabetes were offered screening, and 1,86 million were screened in 2012 - increase by more than 130,000 compared to the previous year[2].

Extending the DR screening intervals potentially leading to many disengaged patients who have been used to yearly screening and there is a need to communicate their low risk to them in an appropriate way that does not lead to a decline in self-management.

The patients' charter states that patients have a right to be given a clear explanation of any treatment proposed, including any risks and alternatives, before they decide whether to agree to the treatment or not. Making an informed decision depends on patients' level of understanding of the relevant risks that given to them[4] Informed patients are more likely to make wiser decisions and adhere actively to their treatment [5]. However, informed decision making occurs only in 9% of outpatients' visits [6].

RESULTS

Providing individualised risk information in a clear and attractive style improved patients' understanding of their own risk and therefore may also improve diabetes self management and reduce the incidence of DR.

The use of visual aids was found to facilitate the presentation of risk for those who could not read, or whose first language was not English.

Participants were able to score themselves as high or low risk, a feature which was welcomed by patients, as they liked the idea of assessing their own risk.

"This traffic light system is really good way of explaining the risk factors of diabetic eye, I was a bit worried but now I can see clearly that I am at low risk"
(South Asian Participant)

"Having scored 4 greens means that I am doing the right thing, so I should continue the good work and keep my blood sugar under control and look after my diet"
White British Participant

"Doing this test, made me think a lot deeper than I did before, …..because I have 2 reds and 2 green, I should give more attention to my diabetes to keep my eyes safe"
(White British Participant)

"Yes I can understand this, green is safe, red is more risk of complications and blindness may be, yes, red is danger"
(South Asian Participant)

AIMS OF THE STUDY

The main aims are

1. To explore the effect of different ways of communicating risk information about DR to people with diabetes

1. To explore the possible use of risk communication tools to improve diabetes self management.

METHODS

A qualitative study was conducted using semi-structured interviews with a convenience sample of 25 participants. Of these, 20 participants were diagnosed with type 2 diabetes (11 White British and 9 South Asians), and 5 participants who were health care professionals (HCPs): (3 White British and 2 South Asians). HCPs were 2 GPs, an ophthalmologist, and 2 retinal screeners. Participants were purposively recruited from primary and secondary care trusts to fall into 5 groups of 5 participants each. 1) No DR (R0) 2): background DR (R1); 3) preproliferative DR (R2); 4) proliferative DR (R3); 5) HCPs.
Risk communication tools were identified from different clinical settings e.g cancer screening, modified and presented to the participants.

CONCLUSIONS

Visual tools may be useful in communicating the risk of DR to people with diabetes. Continuing work will now modify, evaluate, and improve a risk tool to communicate risk information about DR to people with diabetes.

REFERENCES

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3. Bunce, C. and R. Wormald, Leading causes of certification for blindness and partial sight in England & Wales. BMC Public Health, 2006. 6: p. 58.
4. 4. Michie, S., et al., Communicating risk information in genetic counseling: an observational study. Health Educ Behav, 2005. 32(5): p. 589-98.
5. 5. Epstein, R.M., B.S. Alper, and T.E. Quill, Communicating evidence for participatory decision making. Jama, 2004. 291(19): p. 2359-66.
6. 6. Braddock, C.H., 3rd, et al., How doctors and patients discuss routine clinical decisions. Informed decision making in the outpatient setting. J Gen Intern Med, 1997. 12(6): p. 339-45.

APPENDIX 16: EASDec 2014 Oral presentation abstract, Padova Italy

Title: Risk perception of diabetic retinopathy among people with type 2 diabetes

Authors

Al-Athamneh, N.; Sturt, J.; Dolan, A.; Lindenmeyer, A.; Stratton, I.M.; Scanlon, P.H.

Aim

To explore how the risk of Diabetic Retinopathy (DR) is understood by people with diabetes and Health Care Professionals (HCPs).

Methods

A qualitative study was conducted using semi-structured interviews with a convenience sample of 25 participants. Of these, 20 participants were diagnosed with type 2 diabetes (11 White British and 9 South Asians), and 2 primary care physicians, 2 ophthalmologists, and 1 retinal screener. Participants were purposely recruited to fall into 5 groups of 5 participants each. 1) No DR; 2): background DR; 3) preproliferative DR; 4) proliferative DR; 5) HCPs. Risk information about DR was routinely provided to participants by HCPs after annual diabetic screening.

Results

Participants with diabetes were unfamiliar with the term retinopathy, however they were aware that diabetes could lead to changes in their sight or to Sight Threatening Diabetic Retinopathy (STDR). They were unaware that these changes could lead to permanent vision loss. Participants were optimistic about their chance of developing STDR. They perceived the seriousness of risk based on noticeable symptoms and scores of visual acuity rather than grade of retinopathy. Knowledge of risk was even less with the symptomless participants.

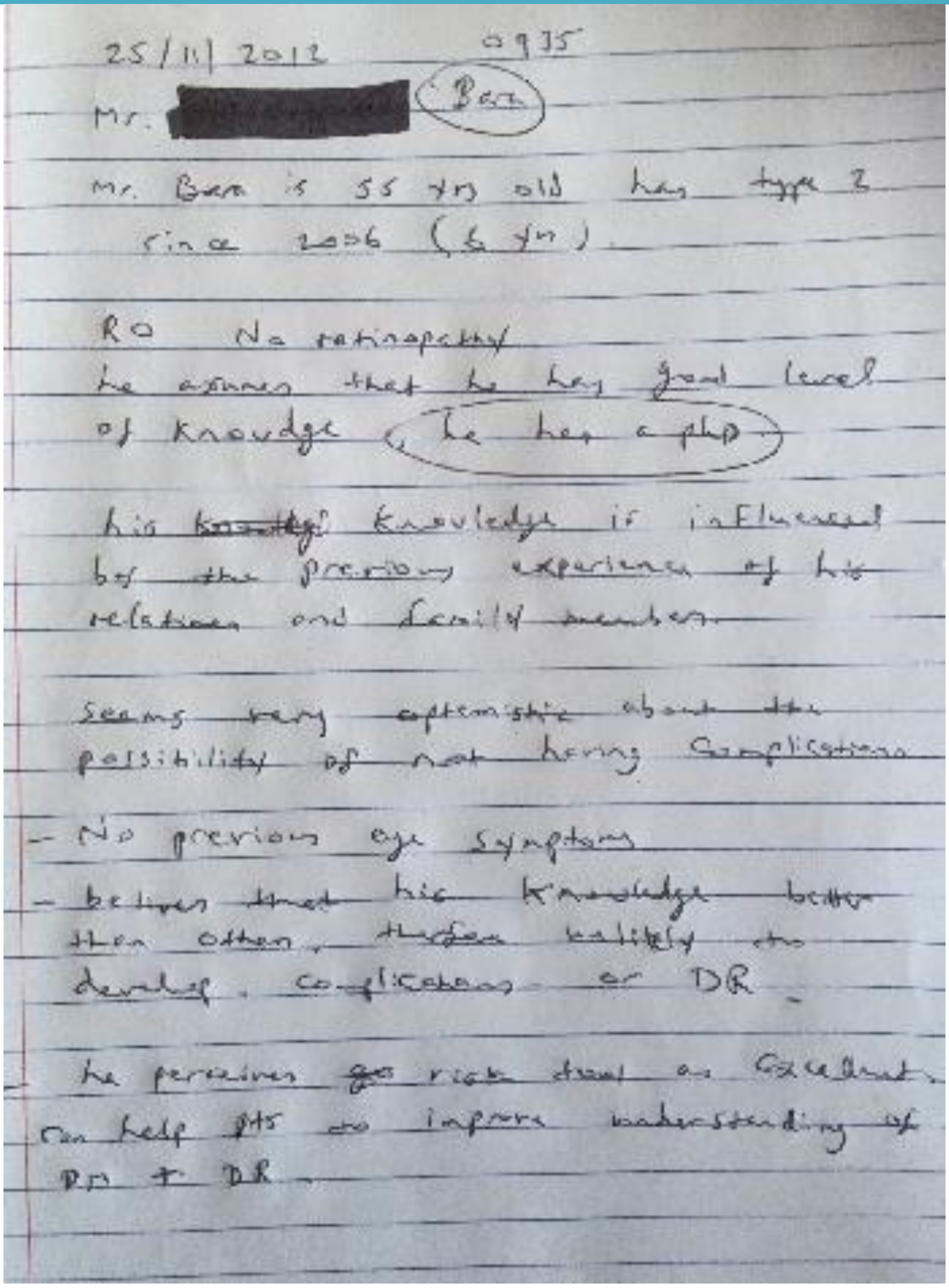
There was a huge difference in the risk perception between participants and HCPs; when HCPs communicated risk message as high risk of developing STDR (such as: the chance of developing STDR is 10 in 100 or 10%), participants perceived it as low or very low risk.

Conclusion

Risk information should be personalised, and provided in a clear and attractive style based on level of understanding, particularly to the symptomless participants. HCPs should assess patients’ knowledge and understanding of risk when risk message is given.

Risk communication tools could benefit participants to understand their own risk of developing DR, and reduces anxiety level. More quantitative study should target the effectiveness of risk tools.

APPENDIX 17: An example of field note



25/11/2012 0935

Mr. [redacted] (Ben)

Mr. Ben is 55 yrs old has type 2 since 2006 (6 yrs).

RO No retinopathy
he assumes that he has good level of knowdge (he has a phD).

his ~~knowlg~~ knowledge is influenced by the previous experience of his relatives and family members.

Seems very optimistic about the possibility of not having complications

- No previous eye symptoms
- believes that his knowledge better than others, therefore unlikely to develop complications or DR.

he perceives ~~go~~ [illegible] [illegible] as excellent. can help pts to improve understanding of DM + DR.