

**A Balancing Act:  
An investigation of people's experiences  
and explanations of recurrent hypoglycaemia  
and help-seeking behaviour**

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## **Abstract**

Diabetes is a rapidly growing health concern in the developed world. Hypoglycaemia is a major risk factor in people with diabetes. Each year, about 7000 calls relating to hypoglycaemia are made to the Scottish Ambulance Service (SAS), including a considerable number of repeat callers. Very little is known about people's experiences and explanations of recurrent hypoglycaemia; in particular, why some individuals manage their recurrent hypoglycaemic episodes independently, while others require more direct healthcare support.

This thesis investigated participants' experiences and individual explanations of recurrent hypoglycaemic episodes, in order to understand their health help-seeking behaviour. To do this, it compared the experiences of people who had called the emergency services within one month prior to recruitment (SAS participants), with those people who had not done so (non-SAS participants). The study employed a multiple methods longitudinal approach to prospectively capture participants' experiences of hypoglycaemic episodes, using qualitative semi-structured interviews, hypoglycaemia and blood glucose diaries and follow-up telephone interviews over a six month period. Thirty participants were involved in the study, recruited through the Scottish Ambulance Service, Diabetes UK (Scotland), and the University of Stirling. All participants resided in the central belt of Scotland. Qualitative data was analysed using the framework method, and quantitative data was analysed using descriptive statistics.

This study found that hypoglycaemic episodes had a wide ranging impact on people's everyday life. It was not only the actual hypoglycaemic episode that affected participants' everyday life, but also fears and worries about future hypoglycaemic episodes, the preparations that participants engaged in, and the process of recovery.

Hypoglycaemia unawareness was found to be a major problem for many people living with diabetes. It appeared to be associated with the likelihood of needing external help. There were differences between participant groups with regard to management of hypoglycaemia unawareness. Non-SAS participants adopted strategies to prepare for future hypoglycaemic episodes, and appeared to be more knowledgeable about their diabetes and its management, resulting in needing less external help. SAS participants experienced more severe hypoglycaemic episodes. Consequently, they relied more on external help.

Findings of this study call for a re-conceptualisation of the previously recognised 'balancing act' of managing diabetes and hypoglycaemic episodes. This study introduces the concept of a hypoglycaemic episode balancing continuum (HEBC) which enables a deeper understanding of the factors involved in this balancing act: it demonstrates that people balance the various risks differently, depending on whether they prioritised their fear of hypoglycaemia over fears of long-term complications. People's position on the continuum directly affected their management strategies for hypoglycaemic episodes.

Most hypoglycaemic episodes were managed by the individual without requiring any external help. However, participants' ability to self-care differed and deficits occurred, resulting in participants being more likely to need involvement of others

(family/friends). When the capacity of others to help broke down, participants' were more likely to need SAS emergency care. In order to explain how hypoglycaemic episodes are managed, this thesis has developed a hypoglycaemic episode help-seeking network (HEHS network), which helps to identify the various agents involved in helping to manage hypoglycaemic episodes.

Findings from this study have implications for clinical practice. For example, looking at hypoglycaemia unawareness, this study has shown that current understanding may fail to take account of participants' real experiences, which show hypoglycaemia unawareness to be a fluid phenomenon that can affect people at various times. If blood glucose levels can fail to predict onset of hypoglycaemic episodes, healthcare professionals may need to broaden the range of blood glucose readings that might indicate a hypoglycaemic episode and tailor specific advice to individual patients.

To reduce the use of emergency services, more attention must be paid to hypoglycaemia unawareness and better advice provided about this condition. Also, more education should be provided for family members/carers, given the crucial role they play in the management of diabetes and hypoglycaemic episodes, and being a link in the process leading to increased use of emergency services.

The HEBC could be developed into a useful 'screening tool' to help healthcare professionals identify those at greater risk of hypoglycaemic episodes and those at greater risk of long-term complications, and to target advice more specifically to these patient groups. Further research could explore family member/carer knowledge in more detail to better understand their role in helping to manage hypoglycaemic episodes.

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## Declaration

I hereby declare that this thesis embodies the results of my own research and that I am the full author of this thesis, except where otherwise stated.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## **Chapter 1 - Introduction**

This thesis is an applied piece of health research which has been informed by sociological thinking. Applied health research has been defined as “research that has potential to improve health or quality of life” (Fathalla 2004:27). The sociological lens was selected because diabetes is not just an illness affecting the physical body, but also a condition that is managed within the context of people’s social life. The sociological approach underlines prevention, health promotion and the social construction of health and illness, rather than focussing on medical treatment alone (Freund et al. 2003).

### **1.1 Personal interest**

The main motivation for this study is personal. My younger brother was diagnosed with diabetes when he was just four years old. So throughout my childhood, I have experienced what it meant for a close family member to live with diabetes and manage hypoglycaemic episodes. I saw how many aspects of everyday life had to be adjusted to accommodate his diabetes, both by him and the family.

Diabetes and its complications are ever present in the lives of people living with the condition. For example, several times my brother was shaky and needed to eat something, no matter what time of day it was. From this experience, I have always wanted to learn more about diabetes. In this sense, I could relate to the subject matter.

Beyond personal reasons, the research area also captured my interest, particularly looking at how people cope with long-term conditions. I wanted to hear from people,

to understand how they make sense of their condition. This is in part because my research interests are in the dynamics of sociology, illness experience and health. But also, I saw there was a lack of studies looking at people's experiences and individual explanations for hypoglycaemia; despite hypoglycaemia being a reality for people living with diabetes.

## **1.2 Rationale for thesis**

Diabetes is a rapidly growing health concern in the developed world with an alarming global incidence rate (WHO 2009; International Diabetes Federation 2012). Hypoglycaemia is a major risk factor in people with diabetes (Briscoe and Davis 2006; Frier 2008). Many people who experience hypoglycaemic episodes self-manage these events; others do not (The Scottish Government 2010). Very little is known about people's experiences and explanations of recurrent hypoglycaemia. In particular, very little is known about why some individuals manage their recurrent hypoglycaemic episodes independently, while others require more direct healthcare support.

To date, diabetes research has paid little attention to people's experiences of hypoglycaemia. Although hypoglycaemia has been mentioned in the literature in the context of diabetes complications, there are few studies that focus on people's experiences of hypoglycaemia in particular. Much of the research about hypoglycaemia has used a quantitative approach, and clusters around 'fear of hypoglycaemia' and its impact on diabetes self-management (e.g. Shiu and Wong 2000; Leiter et al. 2005; Currie et al. 2006; Belendez and Hernandez-Mijares 2009; Anderbro et al. 2010), see section 3.3.4.1.

Most people manage hypoglycaemic episodes independently, though some need external support from family members, their wider support network or emergency services. A proportion of this support is delivered by the Scottish Ambulance Service (SAS). Each year, about 7000 calls relating to diabetes are made to the SAS, which includes a considerable number of repeat callers (The Scottish Government 2010).

The recurrence of hypoglycaemic episodes, especially severe hypoglycaemic episodes, is a major interest of the Scottish Ambulance Service (SAS), who are partly funding this study. The SAS aims to find out more about underlying reasons for repeat call-out of emergency services. This appears to be a novel and important area of research, since the structured review did not find any studies looking at recurrent hypoglycaemic episodes in the context of people's experiences of hypoglycaemia (see section 3.3).

The Scottish Government (2010) Diabetes Action Plan aims to reduce diabetes emergencies. The Diabetes Action Plan also indicates that the SAS wants to reduce episodes of recurrent severe hypoglycaemia. Understanding the underlying reasons and people's experiences of hypoglycaemic episodes could help to address the problem of recurrent hypoglycaemia, as well as designing appropriate policy responses. Therefore, it is important to investigate why some people repeatedly rely on emergency services in response to hypoglycaemia and others appeared to self-manage or engage the help and support of others (see section 2.10.1). This may help offer insights into how the management of hypoglycaemic episodes or their impact can be better supported (by healthcare professionals or others) to enable better self-care practices.

Given the findings of the literature review (see chapter 3) and the quality of existing research, there is a need for good quality research to investigate people's experiences of hypoglycaemia more specifically within their overall experience of diabetes. This study explored the perspectives of people living with diabetes to address: participants' experiences of hypoglycaemic episodes; including the experience of hypoglycaemic emergencies (i.e. when an ambulance is called to attend a person experiencing a hypoglycaemic emergency). It investigated participants' perspectives regarding why hypoglycaemic episodes occur, how they are avoided and how they are managed. This study adopted a sample that allowed for comparison of two groups of people with diabetes: those who had recently used emergency services to manage a hypoglycaemic episode (Scottish Ambulance Service (SAS) participants), and a group of people primarily recruited via Diabetes UK who self-identified as not having recently used emergency services (non-SAS participants).

This study used a longitudinal approach to explore participants' perspectives and experiences of recurrent hypoglycaemia over time. This approach also enabled prospective data collection, allowing access to actual hypoglycaemic episodes (Polit and Beck 2003). The study employed a multiple methods approach, with qualitative semi-structured interviews forming the basis of the investigation, and quantitative data being collected on participants' daily blood glucose readings and recording of hypoglycaemic episodes. This design allowed capturing actual hypoglycaemic episodes and understanding how participants' responses to (low) blood glucose levels may vary. It also helped to explore participants' experiences of living with diabetes and hypoglycaemia, thus giving an insight into people's everyday life ('life worlds')

managing a chronic condition (Hawkes et al. 2009). It also helped understand people's individual explanations for hypoglycaemic episodes as they happened, and their coping strategies, as well as how hypoglycaemic episodes affected their everyday life.

### **1.3 Structure of thesis**

The following chapter of this thesis (chapter 2) provides background information about diabetes and hypoglycaemia; the clinical conditions of interest to this study. It discusses complications and health-related risks of diabetes, including risks relating to hyperglycaemia and hypoglycaemia. This study focussed on hypoglycaemia. The challenges of defining hypoglycaemia were also considered. The final sections of chapter 2 describe the symptoms, management of hypoglycaemia, use of emergency services, risk factors and the differences between type 1 and type 2 diabetes relating to hypoglycaemia.

Chapter 3 presents the findings of the literature review investigating people's experiences and perspectives of living with diabetes and hypoglycaemia. The chapter is in two parts, covering both the experience of living with diabetes, as well as hypoglycaemia. It highlights that hypoglycaemia can have a considerable impact on the well-being of people living with diabetes, potentially affecting them in two ways: one, directly through the effects of a hypoglycaemic episode, and two, indirectly through fears and worries about recurrent hypoglycaemic episodes happening (Lundkvist et al. 2005). Chapter 3 also includes a detailed rationale for this study.

Chapter 4 then introduces theoretical perspectives concerning illness experience. This includes a discussion of potentially relevant theories from the fields of chronic illness

experience and help-seeking behaviour. The chapter also considers the usefulness of theories to this study.

Chapter 5 describes in detail the methods used to conduct this study, including study aims, research questions, study design, sampling strategy and recruitment issues. It also highlights ethical implications and provides an overview of the schedule for data collection. The chapter finally considers how the data were analysed.

In chapter 6, characteristics of the study population as well as results from the hypoglycaemia and blood glucose diary are presented. Chapters 7 and 8 present study findings and describe the hypoglycaemic episode balancing continuum (HEBC) and the hypoglycaemic episode help-seeking network (HEHS network), which were both developed from the analysis of study data.

Chapter 9 discusses the findings with reference to the wider literature. The chapter also discusses the strengths and limitations of this study. In particular, it emphasises that the longitudinal design combining qualitative semi-structured interviews with blood glucose and hypoglycaemia diaries helped to obtain a rich and in-depth understanding of participants' experiences of recurrent hypoglycaemic episodes. Finally, chapter 9 considers the implications of study findings for clinical practice and future research.

## **Chapter 2 - Background**

### **2.1 Introduction**

Diabetes has become one of the major health threats of the 21st century. Despite the condition having an age long history, recent prevalence figures show that numbers have increased exponentially. The World Health Organization (WHO) estimated that in 2009, about 220 million people had diabetes globally, predicting that these numbers would rise to about 366 million by 2030 (WHO 2009). However, a more recent figure from the International Diabetes Federation (2012) has shown that there were already about 371 million people living with diabetes worldwide.

In the United Kingdom, four key factors have been highlighted to be responsible for this increase in prevalence, namely: the ageing population, which has resulted from increases in life expectancy due to advances in medical treatment, and the ageing of the 'baby boom' generation; increases in diabetes incidence driven primarily by increases in obesity; decreases in mortality in those with diabetes; and immigration from countries with higher diabetes prevalence rates (Wild et al. 2004).

This chapter briefly explains what diabetes is, how it is diagnosed, as well as potential complications of the condition. It also provides information relating to incidence and prevalence of diabetes worldwide. The second part of the chapter (starting from section 2.6.2) focusses on hypoglycaemia (definition, symptoms, risk factors, etc.), thus providing relevant background information for this study.

## 2.2 What is diabetes?

Diabetes is a chronic condition characterised by high blood glucose levels. It is caused by a lack of insulin or a resistance to its action. The clinical term 'diabetes mellitus' derives from two words: 'Diabetes' comes from the Greek word 'siphon' which refers to disorders removing liquids from the body, while 'mellitus' has its origin from the Latin word 'sweet, honeyed'. Hence, 'diabetes mellitus' describes a condition that causes 'sweet urine' (Banks 2005). Diabetes mellitus has been known for thousands of years, however, over time, more and more has been discovered about diabetes mellitus, and the way it is diagnosed has been refined.

There are two forms of diabetes, diabetes insipidus and diabetes mellitus, of which diabetes mellitus is the much more prevalent. Diabetes insipidus is a rare condition caused by the deficiency of a hormone required to concentrate urine (Banks 2005). Diabetes insipidus shares the name 'diabetes' as it also results in the production of large quantities of urine, but it has no relationship to how the body manages glucose (Banks 2005). This study is concerned with diabetes mellitus. The term diabetes will therefore be used to refer to diabetes mellitus.

There are two main types of diabetes, commonly referred to as type 1 and type 2 diabetes. Type 1 diabetes results from the pancreatic beta cells not producing any insulin, while type 2 is consequential to either insulin not being used effectively by the body or its amount not being sufficient to regulate blood glucose levels (Williams and Pickup 2004; Polonsky 2012). Type 1 diabetes is more common in younger individuals, while type 2 is more likely to develop in older populations (Watkins et al. 2003). The two types of diabetes are explained in more detail in section 2.4.1 and 2.4.2.

## 2.3 Diagnosis

In 1965, the World Health Organization (WHO) began publishing guidelines for the diagnosis and classification of diabetes, which has resulted in better and more accurate diagnostic information becoming available (WHO 1999). Following on, in 2003, the WHO Expert Committee on the Diagnosis and Classification of Diabetes Mellitus reviewed its diagnostic criteria, thus paving the way for future recommendations.

WHO (2006) recommends the following diagnostic criteria for diabetes: either a fasting plasma glucose level of 7.0 mmol/l (or higher) or a plasma glucose value of 11.1 mmol/l (or higher) two hours after ingesting 75g oral glucose, and the presence of diabetes symptoms. The main symptoms of diabetes include increased thirst and appetite, the frequent need to pass urine, fatigue and blurred vision (Watkins 2003). If diabetes symptoms are absent, the individual should be tested at least twice on different days.

Following a WHO expert consultation in 2009, the WHO published a report which concluded that people's HbA1c (glycated haemoglobin) value can be used to diagnose diabetes. The HbA1c value provides an index of average blood glucose values for the previous eight to twelve weeks, (WHO 2011). The cut off point for diagnosing diabetes is an HbA1c of 6.5%. However, an HbA1c below 6.5% does not necessarily exclude diabetes, if it has been diagnosed using glucose tests (as described above; WHO 2011).

Clinically diagnosed diabetes needs to be distinguished from impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG). IGT is a term used to describe

higher blood glucose levels than those of a healthy individual, but below the level of a person with diabetes. This could be a result of impaired insulin secretion and/or insulin resistance (IDF 2009). This phenomenon is also known as 'pre-diabetes' (American Diabetes Association 2012). IGT is identified by conducting an oral glucose tolerance test (OGTT), while IFG diagnosis follows a fasting plasma glucose test (FPG). These tests are also used to diagnose diabetes. Both IGT and IFG would be classed as pre-diabetic conditions (NIH 2008).

## **2.4 Types of diabetes**

There are two main types of diabetes: type 1 and type 2 diabetes. A third form of diabetes, called gestational diabetes will be explained briefly at the end of this section.

### **2.4.1 Type 1 diabetes**

Type 1 diabetes, which is also referred to as insulin dependent diabetes is more commonly first diagnosed in children and younger adults, though not limited to these age groups. Insulin is vital for human survival as it helps to keep blood glucose levels within a healthy range. However, in people with type 1 diabetes, their body cannot produce insulin, due to destruction of pancreatic beta cells (Daneman 2006).

It is not entirely known what causes type 1 diabetes, but genetic factors seem to play some part; and in many cases an autoimmune reaction, which can be triggered by environmental factors, is responsible for the destruction of beta cells (Daneman 2006).

Weight loss, the frequent need to pass urine, and excessive thirst are some of the symptoms of type 1 diabetes (Watkins et al. 2003). An additional indicator for type 1

diabetes is rapid development of symptoms, as opposed to a gradual development of symptoms in type 2 diabetes (Watkins et al. 2003; Banks 2005).

### **2.4.2 Type 2 diabetes**

Type 2 diabetes is caused by a combination of insulin resistance and insulin deficiency. After the onset of type 2 diabetes, there is usually still some amount of insulin present in the body, but this might either be insufficient and/or the body cells are resistant to its action (insulin resistance). Type 2 diabetes tends to be further exacerbated by obesity and physical inactivity (Stumvoll et al. 2005).

Additionally, type 2 diabetes is a progressive condition, getting worse over time. As a result, initial treatment could be comprised of diet-controlled intervention, weight management and physical exercise, but as the condition progresses, oral hypoglycaemic agents and later on insulin injections may become necessary (Watkins et al. 2003).

Since the condition develops gradually and people have few symptoms initially, it can go unnoticed for years before a diagnosis is established. Treatment of type 2 diabetes can be multifaceted, and needs to take into account other underlying medical conditions, which patients, particularly older patients, might have, e.g. obesity, dementia, high blood pressure, etc. (Watkins et al. 2003; Murata et al. 2004). Barnett et al. (2012) have investigated the distribution of multimorbidity in a large sample in Scotland (N=1,751,841) and found that 23.2% of the sample had two or more morbidities. They recommended that the presence of multimorbidities should be taken into account when designing healthcare/treatment strategies.

### **2.4.3 Gestational diabetes**

A third form of diabetes, gestational diabetes, first occurs in women during pregnancy. In most cases, this type of diabetes resolves after the baby has been born. However, women who have experienced gestational diabetes have an increased risk of developing type 2 diabetes later in life (NIH 2008).

## **2.5 Incidence and prevalence of diabetes worldwide**

Diabetes continues to pose a significant public health risk globally, impacting on the health and well-being of the world population. International estimates have continued to rise. For example, the WHO estimated that in 2009, over 220 million people were living with diabetes worldwide, and that these numbers were expected to rise to about 366 million by 2030 (WHO 2009). One decade later, figures had increased to about 285 million (Diabetes UK 2010). However, a more recent estimate from the International Diabetes Federation (2012) has shown that there were about 371 million people living with diabetes worldwide.

In tandem with the burden of diabetes on the health of the population (prevalence), the numbers of newly diagnosed cases of diabetes (incidence) remain high, as more and more people have been diagnosed with the condition since 2000. For example, the incidence for type 1 and type 2 diabetes in Scotland was 52 cases/100,000/year (Scottish Diabetes Survey 2010). According to Banks (2005), 90% of people diagnosed with diabetes globally are diagnosed with type 2, with approximately 10% being diagnosed with type 1.

Although global figures have continued to rise, considerable variations exist in terms of national prevalence. For example, 2012 figures by the International Diabetes Federation (IDF) show that the three countries with the largest number of people with diabetes were China, India and the United States. China in particular, accounts for over 92 million of the global population of people living with diabetes, with a prevalence rate of 8.82%. In India, 43 million people live with diabetes, with a prevalence rate of 9.01%. Figures for the USA were 24 million, with a prevalence rate of 9.35% (IDF 2012).

In terms of the UK, approximately 2.9 million people were diagnosed with diabetes, of which 237,468 were in Scotland (Scottish Diabetes Survey 2010). A more recent figure has put the UK in the region of 3.3 million (IDF 2012). Explanations for these variations usually range from environmental influences to ethnic and genetic predispositions (Dorman and Bunker 2000; Agency for Healthcare Research and Quality 2001; Feltbower et al. 2002).

A recent study by Ujcic-Voortman et al. (2009) in Amsterdam found that the prevalence of diabetes among Turkish and Moroccan migrants was significantly higher compared to that of the indigenous population, which would support ethnic and genetic predisposition. Williams and Pickup (2004) also compared the incidence of type 1 diabetes in various European countries and found that Finland had the highest incidence level with 48.5 cases/100,000/year, while the lowest was in the Ukraine with only 1.3 cases/100,000/year (Williams and Pickup 2004). Looking at Scotland, recent figures show an incidence rate of 18 cases/100,000/year (Scottish Diabetes Survey 2010). The Scottish figures are the highest in the UK (Watkins et al. 2003).

## **2.6 Complications and health-related risks**

The main complications of diabetes relate to glycaemic instability, namely hyperglycaemia (where blood glucose levels stay too high) and hypoglycaemia (where blood glucose levels drop too low; Williams and Pickup 2004). The following sections explain risks and complications relating to hyperglycaemia and hypoglycaemia.

### **2.6.1 Hyperglycaemia**

Hyperglycaemia is indicated when a person's blood glucose level exceeds 11 mmol/l (Lowth 2012). Risks relating to hyperglycaemia fall into one of two categories:

- Acute risk of ketoacidosis, and
- Risk of developing long-term complications

Ketoacidosis (also known as diabetic ketoacidosis/DKA) happens as a result of lack of insulin in the body, which is much more common in type 1 diabetes. Due to insulin deficiency, glucose cannot enter cells to provide energy. Therefore, the blood glucose level increases (hyperglycaemia) and as it gets higher, glucose is passed out of the body with urine (Watkins et al. 2003). Consequently, the cells do not receive the energy they need and the body starts breaking down fat and protein to provide energy. A by-product of this response is the production of ketones, an acid, which remains when the body breaks down fatty acids in the liver. This process can lead to ketoacidosis, a severe condition characterised by hyperglycaemia, hyperketonaemia and metabolic acidosis (low blood pH; Williams and Pickup 2004). If DKA is not treated appropriately, it can cause the person to go into a diabetic coma which can be fatal.

Treatment for ketoacidosis usually consists of a combination of fluid replacement and insulin injection (Watkins et al. 2003).

The most common long-term complication of hyperglycaemia relates to damage to the blood vessels, which can cause cardiovascular disease, eventually leading to stroke or heart attack. Further long-term complications are eye problems (diabetic retinopathy), foot problems due to restricted circulation, erectile dysfunction in men, kidney and nerve damage (nephropathy and neuropathy respectively; American Diabetes Association 2012). These complications are particularly common if diabetes is left undiagnosed for a number of years (mainly in type 2 diabetes; Watkins 2003).

### **2.6.2 Hypoglycaemia**

This study focussed on hypoglycaemia, which will be discussed in subsequent sections. Hypoglycaemia occurs when blood glucose levels drop below normal values (see 'definition' in section 2.7 below). In people with diabetes, hypoglycaemia arises as a side-effect of treatment with insulin and some sulphonylurea oral medications (Barnett et al. 2010). These are usually required to keep blood glucose levels within a healthy range. However, inappropriately high insulin levels (hyperinsulinaemia) lead to very low blood glucose levels (Williams and Pickup 2004). Elevated insulin levels are a result of either administering too much medication or a reduced need for insulin which can be due to physical exercise, delayed or missed meals or snacks, diminishing insulin requirements following impaired renal function or alcohol consumption (Alwan 1994).

Hypoglycaemia is the most common adverse reaction in insulin-treated type 1 and type 2 diabetes (Wild et al. 2007). In type 1 diabetes, the annual incidence of severe hypoglycaemia is between 1 and 2 cases per individual, which can further increase when other risk factors are present (Frier 2008; see section 2.11). Mild and usually self-treated hypoglycaemia is even more common, occurring on average about twice a week (Frier 2008). In people with type 2 diabetes, severe hypoglycaemia is less common than in type 1 diabetes (UKPDS 1998). However, people with insulin-treated type 2 diabetes experience similar rates of severe hypoglycaemia compared to those with type 1 diabetes, particularly when the duration of insulin treatment is 5 years or more (Heller 2008).

The Diabetes Control and Complications trial (DCCT 1993; focussed on type 1 diabetes) and the UK Prospective Diabetes Study (UKPDS 1998; focussed on type 2 diabetes) have both shown evidence of a reduced risk for long-term complications if blood glucose levels are strictly monitored and near normal. This has brought with it recommendations for tighter glycaemic control, which in turn increases the occurrence of hypoglycaemia (Heller 2008).

Given that hypoglycaemia does not only pose a serious health risk, but it is also accompanied with unpleasant symptoms and often negative experiences, some people develop an associated fear of hypoglycaemia (Wild et al. 2007; see section 3.3.4.1).

## **2.7 Definition of hypoglycaemia**

It is important to define hypoglycaemia, in order to be able to identify and measure its frequency and to give guidelines for treatment. However, there has been some difficulty in agreeing on a commonly accepted blood glucose value to define hypoglycaemia. First, there are two different unit descriptors currently in use; millimol per litre (mmol/l) and milligram per decilitre (mg/dl; see Briscoe and Davis 2006; Diabetes UK 2008).

In the United Kingdom, a commonly accepted threshold for hypoglycaemia is defined as blood glucose values below 4.0 mmol/l (JRCALC 2006; Diabetes UK 2008). But this varies across different authors and has changed over time. Watkins et al. (2003) for example set the threshold for hypoglycaemia at 3.5 mmol/l of plasma glucose concentration (as opposed to blood glucose), while Williams and Pickup (2004) argue for a limit of 3.6 to 3.8 mmol/l. Part of these differences may be due to the fact that plasma glucose is assessed in laboratory testing and gives a slightly different measurement compared to whole blood glucose (Briscoe and Davis 2006).

Another important factor in the definition of hypoglycaemia is the occurrence of symptoms (see section 2.8). There are individual differences regarding the level of blood glucose at which symptoms of hypoglycaemia begin to show. Additionally, people can have different symptoms when they experience a hypoglycaemic episode (Deary 2007). Therefore, the presence of symptoms is significant as is the measurement of blood glucose concentration to clearly establish whether a person with diabetes is experiencing a hypoglycaemic episode. This would help to avoid

unwanted hyperglycaemia (by ingesting more glucose than necessary) as well as treating hypoglycaemia in a timely and appropriate manner.

Strachan (2007) suggests that hypoglycaemia can be defined as “an episode in which typical symptoms occur and the symptoms are reversed by appropriate treatment to raise blood glucose” (p.50). Even though this definition covers the existence of symptoms and action to increase blood glucose levels, it does not feature the measurement and classification of a blood glucose value. Also, the phenomenon of hypoglycaemia unawareness is not included in Strachan’s definition (see section 2.9).

The Diabetes Control and Complications Trial Research Group (DCCT) introduced a definition for severe hypoglycaemia, which has achieved widespread acceptance. It states that severe hypoglycaemia is indicated when assistance from another person is needed to effect treatment and blood glucose concentration is below 50 mg/dl (~2.8 mmol/l; DCCT 1997). Graveling and Frier (2009) concur with this definition, adding that mild hypoglycaemia would be indicated when an individual is able to self-treat.

For the purpose of this study, the definition of hypoglycaemia as blood glucose values below 4.0 mmol/l was used, since this threshold is commonly accepted in clinical practice, and participants would be familiar with this value (see for example JRCALC 2006; Craigie and Lamb 2008; Diabetes UK 2008). Furthermore, the presence (or absence) of symptoms was taken into consideration.

## **2.8 Symptoms of hypoglycaemia**

Symptoms of hypoglycaemia usually start with mild signs like sweating and headache and get progressively worse as blood glucose levels continue to drop (Watkins et al.

2003). According to Williams and Pickup (2004), the brain requires a continuous glucose supply, and if this is not provided, it can lead to central nervous system dysfunction, impaired cognition and in severe cases coma. It is important to recognise that symptoms can differ between individuals (Williams and Pickup 2004).

Symptoms of hypoglycaemia are classed into autonomic and neuroglycopenic symptoms. When blood glucose levels fall below 4 mmol/l, autonomic (mild) symptoms begin to occur. These include sweating, palpitation, shaking, hunger, tingling of lips/tongue and anxiousness. As the hypoglycaemic episode worsens, neuroglycopenic symptoms like difficulty in concentrating, confusion, drowsiness, change of behaviour and loss of consciousness develop (Diebel 1999; Banks 2005). These symptoms reflect classic textbook expressions.

In reality, people's symptom experience of hypoglycaemia can be highly subjective. Using the blood glucose level of an individual to determine whether someone has a hypoglycaemic episode does not necessarily manifest itself with the same symptoms. For example, some people with a high average blood glucose level may experience symptoms at a much higher blood glucose level compared to people who are on a strictly controlled insulin treatment regime. People on strictly controlled insulin treatment may experience symptoms at a much lower blood glucose level, or in fact no symptoms at all ('hypoglycaemia unawareness', see section 2.9; Briscoe and Davis 2006; Frier 2007a). This phenomenon is also known as 'relative hypoglycaemia', due to the brain's adjustment to certain levels of blood glucose and subsequent action of 'counterregulatory' hormones; that is hormones which have a protective effect against hypoglycaemia (Briscoe and Davis 2006).

## 2.9 Hypoglycaemia unawareness

Hypoglycaemia unawareness, which is also known as impaired hypoglycaemia awareness, is a risk factor for severe hypoglycaemia. It is defined as the inability to recognise the onset of hypoglycaemia due to an absence or reduced intensity of (mild) symptoms (Clarke et al. 1995, Frier 2007a; Graveling and Frier 2010; Elliott and Heller 2011). This phenomenon seems to be caused by repeat mild hypoglycaemia, which in turn can trigger a readjustment of the threshold of sensitivity of a glucose sensor in the central nervous system (Amiel 1994). Hence, people who are affected by hypoglycaemia unawareness can find themselves in a situation in which they may not recognise impending hypoglycaemia until it is too late to be prevented (Diebel 1999; Gerich 2000).

Hypoglycaemia unawareness has been associated with (a long duration of) insulin treatment, which is mostly the case with type 1 diabetes (Frier 2007a). However, people with type 2 diabetes who are treated with insulin also experience hypoglycaemia unawareness, as shown in a study by Henderson et al. (2003). Henderson and colleagues found a prevalence rate of 8%, but as their data was based on self-report, actual prevalence may be higher. Schopman et al. (2010) used both questionnaires and blood glucose monitoring to investigate hypoglycaemia unawareness in insulin-treated type 2 diabetes, and found a slightly higher prevalence rate of 9.8%. A reduction or gradual loss of warning signs (i.e. mild symptoms) affects about 25% of all people treated with insulin (Frier 2007a), rising to almost 50% after 25 years or more of insulin-treated diabetes (Prumming et al. 1991). Treatment strategies for hypoglycaemia unawareness include frequent blood glucose monitoring, taking

regular snacks and avoidance of hypoglycaemic episodes for a period of time (Graveling and Frier 2010).

## **2.10 Management of hypoglycaemia**

The majority of hypoglycaemic episodes are managed within the community, by the individual and/or family members, friends and colleagues, as most hypoglycaemic episodes occur within the home environment, workplace or during leisure activities (Strachan 2007). Recommendations for treatment of hypoglycaemia depend on whether the individual is conscious or unconscious. For mild and usually self-treated hypoglycaemic episodes (individual is conscious), treatment consists of ingesting 15-20g fast-acting carbohydrates (e.g. glucose tablets, fruit juice, sugary soft drinks) followed by eating 10-20g slow-acting carbohydrates (e.g. a slice of bread or a few biscuits), depending on when the next meal will be taken (Watkins et al. 2003).

If the person with diabetes is unconscious or unable to swallow, which is usually the case during a severe hypoglycaemic episode, an intramuscular glucagon injection or intravenous glucose should be administered (Williams and Pickup 2004). The intramuscular glucagon injection can be given by a family member/carer (glucagon injection kits are available upon prescription) if they have been taught how to do this. Paramedics or medical staff in the hospital can also administer the intramuscular glucagon injection as well as giving intravenous glucose treatment, if emergency services are called (Watkins et al. 2003). Once the person regains consciousness, he/she should be given a drink containing glucose and a snack rich in carbohydrate. Additionally, the individual's blood glucose level should be monitored to ensure full recovery (Watkins et al. 2003; JRCALC Guidelines 2006).

Since hypoglycaemia can occur quite unpredictably, people with diabetes are advised to always carry some fast-acting carbohydrates (glucose) with them, in case a hypoglycaemic emergency occurs (Craigie and Lamb 2008).

### **2.10.1 Use of emergency services**

Most hypoglycaemic episodes occur outwith a medical/hospital setting (Strachan 2007; also see previous section). When hypoglycaemic episodes get to the severe stage (where external help is indicated, see section 2.7), ambulance or hospital services may be required. Interestingly, only a small proportion of people experiencing hypoglycaemic episodes are treated by emergency and/or hospital services (Frier 1993; Leese et al. 2003). Leese and colleagues analysed routinely collected datasets within NHS Tayside in Scotland to investigate the incidence of severe hypoglycaemia requiring medical, emergency or hospital assistance (including primary care, inpatient care, accident and emergency services, and ambulance services). They found that 7.1% of people with type 1 diabetes and 7.3% of people with type 2 diabetes, who were treated with insulin required emergency assistance due to a severe hypoglycaemic episode (Leese et al. 2003).

Although the proportion of people who require emergency services is relatively small (237,468 people with diabetes living in Scotland, compared to approximately 7000 calls made to the SAS per year, which are categorised as hypoglycaemic emergencies), within the group of people who use emergency services there is a significant number of repeat callers (The Scottish Government 2010; Scottish Diabetes Survey 2010). Considering the incidence of severe hypoglycaemia (between one and two cases per individual per year (Frier 2008)), Strachan (2007) observed that “the distribution is

heavily skewed, such that many individuals are unaffected [...], while a small number experience recurrent episodes (p.75).

A study conducted by Brackenridge et al. (2006) investigated the use of emergency services due to hypoglycaemia in two general hospitals in Surrey. They confirmed the finding that a minority of people with diabetes require emergency services. However, within the group of people using emergency services, 20% do not receive any treatment suggesting that they may call the emergency services inappropriately (Brackenridge et al. 2006). Brackenridge and colleagues conclude that the ambulance service is used as a 'lifeline' by some people, who would call out the ambulance before taking any treatment themselves. However, explanations for use and non-use of emergency services have not been explored from the patient's perspective.

### **2.11 Risk factors for hypoglycaemia**

A study conducted by the Diabetes Control and Complications Trial Research Group (DCCT 1997) found that people with diabetes who receive intensive insulin treatment as opposed to conventional therapy have a threefold increase in the risk of experiencing a severe hypoglycaemic episode. Intensive insulin treatment encompasses flexible multiple daily injections of insulin or use of an insulin pump and frequent blood glucose testing in order to achieve tight blood glucose control (Jermendy 2012; Switzer et al. 2012). Conventional therapy involves up to three daily insulin injections at set times and much less blood glucose testing (DCCT 1997, Meetoo et al. 2012).

There is also evidence that tight glycaemic control can reduce the risk for diabetes-related long-term complications (Diebel 1999). As Amiel (1994) pointed out, there is need to balance priorities: on the one hand minimising the risk of long-term complications, while on the other hand not underestimating the immediate impact of hypoglycaemia. Therefore, strict glycaemic control is a risk factor for hypoglycaemia and needs to be taken into consideration when prescribing treatment.

A further risk factor for hypoglycaemia is recurrent hypoglycaemic episodes in the past, and the age of the person. The risk for hypoglycaemia increases with the duration of diabetes, older age, severity, and frequency of previous hypoglycaemic episodes (Briscoe and Davis 2006; Frier 2008; Graveling and Frier 2009). Physical exercise, nutrition and alcohol consumption also influence the incidence of hypoglycaemia. Physical exercise affects blood glucose levels in two ways; one, insulin absorption can be increased and two, the need for insulin diminishes as the body uses more glucose during exercise (Diebel 1999). This links closely with nutrition since an increased carbohydrate intake can counteract the lowering effects of exercise on blood glucose levels (Frier 2008). Additionally, (excessive) alcohol consumption can contribute to causing hypoglycaemia as ethanol, a component of alcoholic drinks, blocks the release of glucose from the liver (Diebel 1999).

Hypoglycaemia unawareness is another risk factor for developing severe hypoglycaemia (section 2.9). It is defined as the inability to recognise the onset of hypoglycaemia due to an absence or reduced intensity of (mild) symptoms (Clarke et al. 1995, Frier 2007a; Graveling and Frier 2010; Elliott and Heller 2011). Therefore, people who are affected by hypoglycaemia unawareness can find themselves in a

situation in which they might not identify impending hypoglycaemia until it is too late to be prevented (Diebel 1999; Gerich 2000).

Nocturnal hypoglycaemia or hypoglycaemia during sleep is a very common complication in insulin-treated diabetes, and sleep has been identified as a risk factor for hypoglycaemia (Frier 2008). Nocturnal hypoglycaemia is particularly dangerous because it often goes without symptoms, can cause cognitive impairment and 'sudden death' (especially in young people with type 1 diabetes). 'Sudden death' or 'dead in bed' syndrome happens as a result of a fatal hypoglycaemic episode during sleep (Tattersall and Gill 1991).

There is also a high risk for nocturnal hypoglycaemia to develop into severe hypoglycaemia; this is because the body's normal release of anti-insulin hormones when blood glucose levels fall is impaired during sleep and while lying down (Heller 2007). A further concern regarding nocturnal hypoglycaemia is its contribution to the development of hypoglycaemia unawareness – in other words; someone who experienced a hypoglycaemic episode during the night is less likely to have early warning symptoms of hypoglycaemia during the day (Heller 2007).

Yale (2004) has pointed out that nocturnal hypoglycaemia is caused by the inadequacy of externally administered insulin to imitate the body's own insulin secretion during the night. Another important aspect is the effort to reduce morning hyperglycaemia by increasing the evening dose of insulin. As a result of this and intensive insulin therapy, the risk for nocturnal hypoglycaemia increases (DCCT 1997).

## **2.12 Hypoglycaemia in type 1 and type 2 diabetes**

There are a number of differences relating to frequency and severity of hypoglycaemic episodes when comparing type 1 and type 2 diabetes. For example, severe hypoglycaemia tends to be more common in type 1 diabetes, compared to type 2 diabetes. This seems to be as a result of intensive insulin treatment in type 1 diabetes and also different physiological responses to falling blood glucose levels (Gerich 2000). In type 2 diabetes, people's (physiological) responses range from increasing release of anti-insulin hormones to developing an awareness of warning symptoms and taking preventive action. Additionally, people with type 2 diabetes often show some degree of insulin resistance and decreasing personal insulin secretion as blood glucose levels fall, which can act as a buffer to prevent severe hypoglycaemia (Gerich 2000; Barnett et al. 2010).

In contrast, people with type 1 diabetes tend to have an impaired anti-insulin hormone response to hypoglycaemia: for example, the release of the hormone glucagon from the pancreas no longer occurs. This hormone counteracts the effects of insulin by stimulating glucose release from the liver and muscle tissues (Watkins et al. 2003). Furthermore, recurrent mild, symptomless hypoglycaemia can damage the body's own protective mechanism to release glucose, which also can lead to hypoglycaemia unawareness (see section 2.9).

Hypoglycaemia is less common among people with type 2 diabetes. However, as the condition progresses and insulin treatment may become necessary, incidence and severity of hypoglycaemia increases and appears to be similar to that of people with

type 1 diabetes. Thus, longer duration of diabetes and intensive insulin treatment seem to have an influence on hypoglycaemia rates (Heller 2008).

### **2.13 Conclusion**

This chapter has provided background information about diabetes and hypoglycaemia; the clinical conditions of interest in this study. The first section gave an overview of diabetes; definition, diagnosis and prevalence. Two main types of diabetes were discussed; namely type 1 and type 2 diabetes.

This was followed by a section that discussed complications and health-related risks of diabetes, with a particular focus on hypoglycaemia. The chapter also considered the challenges of defining hypoglycaemia. The final sections described the symptoms, management of hypoglycaemia, use of emergency services, risk factors and the differences between type 1 and type 2 diabetes relating to hypoglycaemia.

The next chapter will review literature, focussing specifically on people's experiences of diabetes and hypoglycaemia. People with diabetes have to manage their condition for 24 hours each day throughout the year. This creates a substantial self-care burden which impacts on their everyday life. Exploring people's perspectives and experiences can contribute to better understanding of self-care processes, as well as personal explanations and coping strategies for hypoglycaemia. This might offer explanations for differences in self-care processes that lead some people with diabetes to rely more on emergency services than others. The purpose of the literature review was to explore what is known about people's experiences of diabetes and hypoglycaemic episodes. It was also to explore what is known about self-care processes, personal

explanations and coping strategies for hypoglycaemic episodes, and to determine whether they offer any explanation for the use of emergency services.

## **Chapter 3 - Literature Review**

### **3.1 Introduction**

This chapter reviews literature relating to people's experiences of living with diabetes and hypoglycaemia. The chapter is in two parts, the first part presents a general overview of literature about living with diabetes, the second focusses more specifically on people's experiences of hypoglycaemia.

### **3.2 People's experiences of living with diabetes**

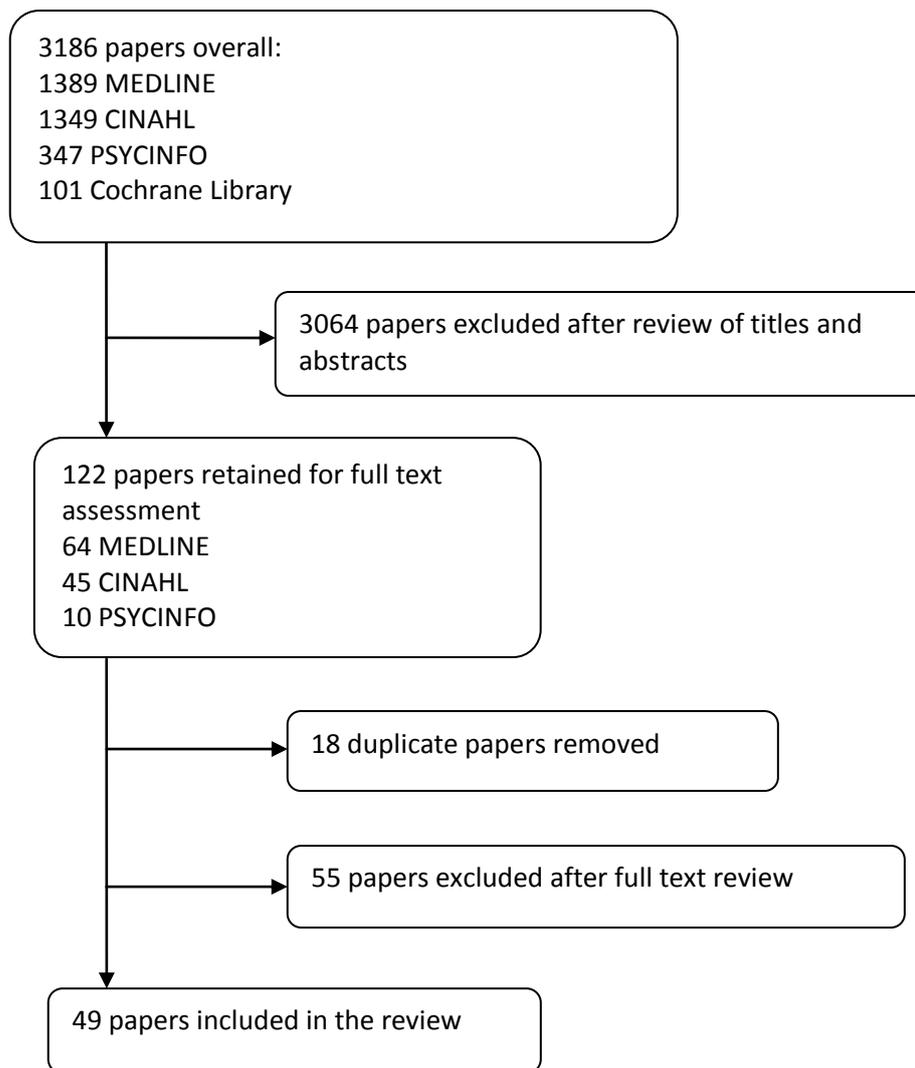
People living with diabetes have to manage their condition constantly. The management of diabetes includes regular monitoring of the individual's blood glucose level, taking diabetes medications (e.g. insulin injections), as well as balancing carbohydrate intake and activity status. This section presents a structured review of published literature relating to people's experiences of living with diabetes. The methods used in the review are described; key themes from the literature are presented and discussed. The aim of the review was to gain a general overview of key themes in the literature around people's experiences of diabetes and to explore how hypoglycaemia has been explored within this literature.

#### **3.2.1 Methods**

A systematic search of online databases CINAHL (Cumulative Index for Nursing and Allied Health Literature), PsycINFO and MEDLINE was carried out. Additionally, reviews from the Cochrane Library's Consumer and Communication Group and Metabolic and Endocrine Disorders Group were searched for relevance. Two facets were developed: Patients' point of view: (patient\*, client\*, people\*, man\*, men\*, male\*, woman\*,

women\*, female\*, consumer\*, subject\*, participant\* or person\*) and experience: (well\*being, quality of life, self\*care, self\*management, experience\*, perspective\*, fear\*, affect\* or impact\*) and illness (diabet\*). Subject headings and text words within each facet were combined using the Boolean operator “OR” and the resultant facets were then combined using the Boolean operator “AND”. These facets were then applied to publication titles.

After limiting search results to English language publications in the 10 years (March 2000 - March 2010), the search yielded 3186 results. These were screened for relevance and whether they were directly related to people’s perspectives of living with diabetes, including experience of hypoglycaemia. Papers that reported primary or secondary research or reviewed literature were included, while publications focussing on interventions were excluded. This was because the focus of the current review was on people’s experiences of living with diabetes rather than the effectiveness of interventions. 122 papers met the inclusion criteria during initial screening and were retrieved for full text assessment.



**Figure 3.1: Flow diagram of structured search process (experiences of diabetes)**

### 3.2.2 Results

After reviewing the full text version of potentially relevant papers, 44 primary research studies and five reviews were identified as relevant. In keeping with good review methods (Popay et al. 2006), twenty percent of papers (n=9) were checked for inclusion/exclusion criteria with the supervisory team, and agreements were high (agreements for n=7, two papers were further discussed regarding inclusion/exclusion (Green et al. 2000; Persson et al. 2009)). Following discussion, both these papers were included as they had some relevance to the aim of this review. Of the 44 primary

research studies, 30 studies used qualitative methods, 11 studies applied a quantitative approach, while the remaining three were multi-method studies. In terms of the included reviews, there were some limitations relating to quality (see section 3.2.3).

Following the identification of relevant papers, key data (e.g. authors, study design, study aim and key findings) were extracted into a summary table (see table 3.1 below). Papers were analysed in-depth to identify key findings and these were compared across included papers. This process generated a set of abstract themes which were further refined and synthesized through critical discussion with the supervisory team. These are presented in section 3.2.3. Salience of extracted information was reached by independent assessment of ten percent of papers (n=5) regarding identified themes.

In terms of quality, most of the included papers provided a wide ranging overview of people's experiences of living with diabetes; however, several gave only limited information on their methodological processes. For example, in a study by Koopmanschap (2002), which looked at the impact of diabetes from the perspective of people living with type 2 diabetes, other than the criteria of having been diagnosed with type 2 diabetes, there was limited information on sample characteristics. It is important to note that despite its limitations the study brought to the fore people's perspectives of the effect of type 2 diabetes. Another key strength of the study was its ability to draw on data from a large sample (n=4189) cutting across five European Countries (Koopmanschap 2002).

A study conducted by Peel et al. (2004) in Scotland investigated participants' views of blood glucose monitoring. While the study highlighted a range of positive and negative

aspects of blood glucose monitoring, it also had a few limitations. For example, the study sample was drawn from adults who were newly diagnosed with type 2 diabetes. The study further excluded people who were treated with insulin. These limitations could mean that this study may have missed out on aspects affecting people's blood glucose monitoring in the longer term, as well as issues impacting on blood glucose monitoring in people treated with insulin/those with type 1 diabetes.

There was a broad scope of issues considered within the literature that related to living with diabetes; ranging from issues around self-care experiences, dealing with complications, having an 'invisible' illness to more specific problems such as regular monitoring of blood glucose levels. Hypoglycaemia was only mentioned in the context of diabetes complications (Frier 2008) and challenges of diabetes management (Debono and Cachia 2007). There was no in-depth exploration of people's experiences of living with hypoglycaemia, and the impact of hypoglycaemia on people's everyday life. Other reviews did not detail their search protocol, quality appraisal methods and overview of included papers (Debono and Cachia 2007; Wild et al. 2007; Frier 2008). As a result, criteria of transparency and reproducibility could not be fully met in many of the included reviews.

Two of the included reviews (Spenceley and Williams 2006; Pun et al. 2009) focussed on people's experiences of self-care. Spenceley and Williams (2006) explored barriers and facilitators of self-care from the patients' perspective, but limited their review to type 2 diabetes. While their focus on self-care and treatment adherence provided details about the demand of diabetes care; for example, fears relating to injections, it

may have missed out on issues around the wider impact diabetes can have on everyday life.

Pun et al. (2009) reviewed literature relating to barriers to diabetes self-care from both patients' and health professionals' perspectives; however, the focus of this review was also limited to type 2 diabetes and only investigated barriers to diabetes self-care. It did not cover the range of people's experiences of living with diabetes.

**Table 3.1: Overview of included papers (experiences of diabetes)**

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
Aalto et al. (2000), Disease-related distress among insulin-treated diabetic patients: Associations with health status, psychosocial factors and self-care practices, Finland	Quantitative (questionnaire incl. ATT 39(measures emotional adjustment to diabetes) ), 423 participants, 20-64 years, 53% male	Measuring diabetes-related distress among insulin-treated persons with diabetes	No scale for measurement of fear of hypoglycaemia was included
Currie et al. (2006), Multivariate models of health-related utility and the fear of hypoglycaemia in people with diabetes, UK	Quantitative (postal surveys) using HFS (hypoglycaemia fear survey) and EQ5D (measures health-related utility), 1305 participants, type 1 and type 2 diabetes	Measuring the impact of hypoglycaemia on patients' health-related utility, investigating how severity, frequency and fear of hypoglycaemia affect patients' health status	Difficulty of recall of hypoglycaemic events
Di Battista et al. (2009), Type 1 diabetes among adolescents: Reduced diabetes self-care caused by social fear and fear of hypoglycemia. Australia (Fieldwork in USA/Canada)	Quantitative (Survey incl.DQoL (Diabetes Quality of Life Measure) and HFS (Hypoglycaemia Fear Survey)), 76 adolescent (13-18 years) participants, type 1 diabetes, 33 boys/43 girls	Investigating the association between social anxiety, fear of hypoglycaemia, adherence to diabetes treatment regimen and perceived quality of life	Small sample size (acknowledged by authors). Sample limited to adolescents
Hanberger et al. (2009), Health-related quality of life in intensively treated young patients with type 1 diabetes, Sweden	Quantitative (DISABKIDS questionnaire, EQ-5D), 400 children and adolescents (191 girls; mean age 13.2 years) and their parents	Investigating the impact of type 1 diabetes on health-related quality of life in intensively treated young patients	No controls without diabetes
Huang and Hung (2007), Quality of life and its predictors for middle-aged and elderly patients with type 2 diabetes mellitus, Taiwan	Quantitative (cross-sectional design), 131 participants (57.3% male), 41-88 years, type 2 Diabetes	Exploring quality of life and its predictors among adults (>40 years of age) with type 2 diabetes	Participants recruited from only one medical centre
Kalda et al. (2008), Predictors of quality of life of patients with type 2 diabetes, Estonia	Quantitative (questionnaire including SF-36), 200 participants (69% female, 31% male), mean age 64.7 years,	Investigating the factors which have most influence on quality of life of people with type 2 diabetes	Results influenced by using a special questionnaire designed by authors which included multiple choice

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
	type 2 diabetes		questions about knowledge and awareness about diabetes, its risk factors and complications
Koopmanschap (2002), Coping with Type II diabetes: the patient's perspective, Netherlands	Quantitative (EQ-5D scale), 4189 participants with type 2 diabetes in 5 European Countries	Exploring the impact of type 2 diabetes from the patients' perspective	Limited information about participants (other than diagnosed with type 2 diabetes)
Lloyd et al. (2001), Impact of long-term complications on quality of life in patients with type 2 diabetes not using insulin, UK	Quantitative (questionnaire including SF-36), 1233 patients with type 2 diabetes (709 male/524 female), aged over 35, type 2 diabetes, not treated with insulin	Assessing the impact of diabetic complications on health-related quality of life in patients with type 2 diabetes	Exclusion of patients treated with insulin (who may experience more complications)
Paddison et al. (2008), Psychological Factors Account for Variation in Metabolic Control and perceived Quality of Life Among People with Type 2 Diabetes in New Zealand, New Zealand/UK	Quantitative (survey), 615 participants, 27-90 years/mean age 63 years, 47% female, type 2 diabetes	Examining the association between psychological variables, metabolic control and quality of life among adults with type 2 diabetes in New Zealand	Use of a single item from the ADDQoL (Audit of Diabetes-Dependent Quality of Life) to measure QoL
Shiu and Wong (2000), Fear of hypoglycaemia among insulin-treated Hong Kong Chinese patients: Implications for diabetes patient education, China	Quantitative (structured interviews), 120 participants, adults, insulin-treated type 1 and type 2 diabetes, 1 <sup>st</sup> phase study	Identifying the extent of fear of hypoglycaemia and its impact on diabetes self-management	Participants were recruited from patients who attended a diabetes clinic (misses out on those who did not attend)
Tierney et al. (2008), Living with cystic fibrosis-related diabetes or type 1 diabetes mellitus: A comparative study exploring health-related quality of life and patients' reported experiences of hypoglycaemia, UK	Quantitative (cross-sectional comparative study) using questionnaires incl. EHS (Edinburgh Hypoglycaemia Scale) and DQoL (Diabetes Quality of Life Measure), 107 participants (55 with type 1 diabetes (T1DM)/52 with cystic fibrosis-related diabetes (CFRD))	Gaining an insight into the experience of hypoglycaemia and the impact of diabetes on health-related quality of life. Comparing perceptions of people with T1DM and CFRD	Low response rate T1DM patients were older than CFRD patients and had a longer duration of diabetes. This may increase occurrence/severity of hypoglycaemia.

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
Abdoli et al. (2008), The empowerment process in people with diabetes: An Iranian perspective, Iran	Qualitative (in-depth interviews), 16 participants, (11 people with diabetes and 5 healthcare professionals), aged 21-73 years	Exploring the concept of empowerment process (from diagnosis to learning to live with diabetes) among Iranian diabetes patients	Details about type of diabetes were not given. Assumption that every diabetes patient will go through the same phases.
Barton et al. (2005), The diabetes experiences of aboriginal people living in a rural Canadian community, Canada	Qualitative (interviews), 8 participants (5 female/3 male), type 2 diabetes, Aboriginal background	Exploring experiences of living with type 2 diabetes from Aboriginal people's perspective	Very specific population group
Carbone et al. (2007), Diabetes self-management: Perspectives of Latino patients and their healthcare providers, USA	Qualitative (focus groups), 37 migrant Latino patients with type 2 diabetes, 15 healthcare practitioners	Exploring experiences and attitudes of Latino patients and their healthcare practitioners regarding diabetes self-management. Refining culturally appropriate self-management interventions.	Highly specific sample population might limit relevance of findings to other populations Sample was drawn from only one medical centre
Choe et. al (2001), Quality of life for patients with diabetes in Korea--I: The meaning of health-related quality of life, South Korea	Qualitative (interviews), 22 participants (11 male/11 female), type 2 diabetes	Exploring the meaning of HRQoL and factors affecting it from the perspective of diabetes patients in Korea	Potential misinterpretation of meaning due to translations (interviews conducted in Korean, analysis carried out in English) Interviews were conducted in hospital waiting room (possible privacy issues)
Coyne et al. (2004), The impact of diabetic retinopathy: Perspectives from patient focus groups, USA	Qualitative (focus groups), 15 participants with diabetic retinopathy	Exploring symptom experience, impact on everyday life and HRQoL of patients with diabetic retinopathy	Focus on only one diabetes complication
Dickinson and O'Reilly (2004), The lived experience of adolescent females with type 1 diabetes, USA	Qualitative (interviews), 10 participants, type 1 diabetes, aged 16-17 years, all female	Exploring female adolescents' perspectives of living with type 1 diabetes	Participants were recruited from a diabetes training camp, which may have influenced findings
Everett (2001), Qualitative study of the impact of type 1 diabetes on everyday life, UK	Qualitative (Interview), 21 participants, 18-40 years, type 1 Diabetes	Exploring impact of type 1 diabetes on everyday life	Limited to people with type 1 diabetes
Frandsen and Kristensen (2002),	Qualitative (focus groups), 123	Identifying barriers relating to	Exclusion of insulin-treated patients

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
Diet and lifestyle in type 2 diabetes: The patient's perspective, Denmark	participants, 45-60 years, type 2 diabetes, treated with oral hypoglycaemic agents (groups were conducted in Germany, France, Spain, UK and USA)	adherence to diabetes treatment (diet, lifestyle, medication) and gaining an insight into the patients' perspective	
Garcia de Alba et al. (2007), "Diabetes is my companion": lifestyle and self-management among good and poor control Mexican diabetic patients, Mexico	Qualitative (interviews), 62 participants (31 good diabetes control/31 poor control patients)	Comparison of poor and good glycaemic control patients (determined by HbA1c values) regarding attitudes towards lifestyle and self-management activities. Identification of views associated with better glycaemic control	Participants recruited from only one clinic setting
Gazmararian et al. (2009), Perception of barriers to self-care management among diabetic patients, USA	Qualitative (focus groups), 35 participants, African Americans	Exploring individual, educational and system barriers to low income diabetes patients' self-care management	Limited generalisability of findings due to very specific group of participants
Hayes et al. (2006), Understanding diabetes medications from the perspective of patients with type 2 diabetes: Prerequisite to medication concordance, USA	Qualitative (focus groups), 138 participants, type 2 diabetes	Investigating patients' perspectives and experiences with diabetes medications	Limited description of data analysis process
Kay et al. (2009), An exploration of the experiences of young women living with type 1 diabetes, UK	Qualitative (semi-structured interviews), 9 female participants, 18-24 years, type 1 diabetes	Exploring young female adults' perspectives of living with type 1 diabetes	Sample limited to one diabetes clinic, no inclusion criteria relating to socioeconomic or educational background
Keeratiyutawong et al. (2003), Self-care experiences of Thai patients with type 2 diabetes, Thailand	Qualitative (in-depth interview), 8 participants (5 female/3 male), 38-75 years, type 2 diabetes	Gain an understanding of self-care experiences of Thai patients with type 2 diabetes who have difficulty controlling their blood glucose	Focus was only on patients who have difficulty controlling their blood glucose level Small sample size
Lin et al. (2008), Diabetes self-	Qualitative (focus groups), 41	Gain an understanding of self-	Authors provide limited information

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
management experience: A focus group study of Taiwanese patients with type 2 diabetes, Taiwan	participants with type 2 diabetes (19 female, 22 male), 42-81 years	management experiences of Taiwanese patients with type 2 diabetes	about sampling strategy, age/gender within different focus groups
Moser et al. (2008), Self-management of type 2 diabetes mellitus: A qualitative investigation from the perspective of participants in a nurse-led, shared-care programme in the Netherlands, Netherlands	Qualitative (in-depth interviews), 15 patients with type 2 diabetes over 55 years	Exploring patients' understanding of self-management processes in type 2 diabetes and relating this to concept of autonomy	Participants were selected by nurse. Patients who did not attend follow-up meetings/did not adhere to prescribed treatment were not included in sample
Mulvaney et al. (2008), Self-management in type 2 diabetes: The adolescent perspective, USA	Qualitative (focus groups), 24 adolescents with type 2 diabetes, 13-19 years	Exploring barriers and facilitators of diabetes self-management from the patients' perspective	Limited generalisability due to participants recruited from only one paediatric clinic
Nafees et al. (2006), How diabetes and insulin therapy affects the lives of people with type 1 diabetes, UK	Qualitative (focus groups), 11 participants, type 1 diabetes, adults	Exploring patients' experiences of living with diabetes and being on insulin therapy. Further topics discussed were hypoglycaemia, understanding of blood glucose control and treatment preferences.	Small sample size (acknowledged by authors), recruitment method (responding to newspaper advertisement) was self-selected
Peel et al. (2004), Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: A qualitative study of patients' perspectives, Scotland/UK	Qualitative (repeat interviews), 40 adults newly diagnosed with type 2 diabetes who were not treated with insulin	Investigating positive and negative aspects of blood glucose monitoring as perceived by newly diagnosed patients with type 2 diabetes	Focus of study was limited to newly diagnosed patients and excluded those being treated with insulin
Peel et al. (2007), Self-monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives, Scotland/UK	Longitudinal qualitative study (in-depth interviews), 18 adults with type 2 diabetes	Gain an insight into patients' attitudes to blood glucose self-monitoring over time	Patients' medical records/HbA1c values not available to researchers
Penckofer et al. (2007), The psychological impact of living with diabetes: Women's day-to-day	Qualitative (focus groups), 41 female participants, 41-68 years, type 2 diabetes, 42% of sample African	Exploring women's everyday experiences of living with type 2 diabetes and psychological impact of	Discussion guide for focus groups was specifically addressing particular emotions

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
experiences, USA	Americans, 58% white Americans	the condition	
Persson et al. (2009), 'From stun to gradual balance'- women's experiences of living with gestational diabetes mellitus, Sweden	Qualitative (interviews), 10 pregnant women living with gestational diabetes mellitus (GDM)	Exploring women's experiences of living with GDM	In contrast to type 1 and type 2 diabetes, GDM is a temporary experience
Phillips (2007), Experiences of patients with type 2 diabetes starting insulin therapy, UK	Qualitative (in-depth interviews), 4 men and 4 women with type 2 diabetes, aged 49-72	Exploring the experience of patients with type 2 diabetes changing to insulin therapy	Small sample size (acknowledged by author)
Rayman and Ellison (2004), Home alone: The experience of women with type 2 diabetes who are new to intensive control, USA	Qualitative (interviews), 14 women, type 2 diabetes, 35- 75 years	Gaining an understanding of women's experiences of daily diabetes self-management. Focus on women who were new to intensive control.	Focus was only on women who were new to intensive diabetes control
Shiu and Wong (2002), Fears and worries associated with hypoglycaemia and diabetes complications: Perceptions and experience of Hong Kong Chinese clients, China	Qualitative (semi-structured interviews), 13 participants, insulin-treated type 1 & type 2 diabetes, adults, 2 <sup>nd</sup> phase study, using a sub-sample of 1 <sup>st</sup> phase (quantitative) study	Investigating patients' (Hong Kong Chinese) perspectives of living with hypoglycaemia, fear of hypoglycaemia (and other complications) as well as coping strategies	Sampling strategy focussed on particular sub-group of patients who expressed higher level of fear and worry relating to hypoglycaemia and other diabetes complications.
Utz et al. (2006), "Working hard with it": Self-management of type 2 diabetes by rural African Americans, USA	Qualitative (focus groups), 73 African Americans (42 female/31 male) with type 2 diabetes	Exploring the experience (barriers and facilitators) of self-management among African Americans with type 2 diabetes living in rural areas	Sample limited to participants who actively sought to discuss their experience of diabetes self-management
Vermeire et al. (2003), The adherence of type 2 diabetes patients to their therapeutic regimens: A qualitative study from the patient's perspective, Belgium	Qualitative (focus groups), 46 participants (21 male/25 female), over 40 years old, type 2 diabetes	Examining type 2 diabetes patients' health beliefs, communication with healthcare providers and problems related to treatment adherence	Patients were selected for participation, potential bias towards more conversant patients with fewer complications
Weiler and Crist (2009), Diabetes self-management in a Latino social environment, USA	Qualitative (semi-structured interviews) with 10 migrant Latino adults, type 2 diabetes	Exploring the social context and sociocultural influences among migrant Latino adults	Specific sample may limit generalisability of findings to other populations

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
Yamakawa and Makimoto (2008), Positive experiences of type 2 diabetes in Japanese patients: An exploratory qualitative study, Japan	Qualitative (interviews), 17 participants, 50-78 years, type 2 diabetes	Exploring positive experiences of living with diabetes from the patients perspective	Limited focus on positive experiences
Everett and Kerr (2005), Measuring the impact of type 1 diabetes from the patient's perspective, UK	Multi-method: first phase qualitative (semi-structured interviews), 31 participants, quantitative BIDS scale (Bournemouth Impact of Diabetes), 237 participants, type 1 diabetes	Developing a tool to measure impact of type 1 diabetes on lifestyle	Sample consisted of many well motivated and self-managing patients, less patients with complications and difficulty controlling their diabetes
Puavilai and Stuijbergen (2000), Quality of life for Thai women with diabetes, Thailand	Multi-method (1 <sup>st</sup> phase quantitative/Self-Anchoring Striving Scale, 57 participants; 2 <sup>nd</sup> phase qualitative/18 participants) aged 20-59 years	Exploring aspects affecting quality of life among Thai women living with diabetes	Small sample size for quantitative part of the study (lack of justification) Limited information provided about response rate
West and McDowell (2002), The distress experienced by people with type 2 diabetes, Scotland/UK	Multi-method, quantitative (using PAID (problem areas in diabetes) questionnaire), 57 participants (35 female/22 male), qualitative (focus groups), subsample of 10 participants (5 female/5 male)	Investigating distress related to type 2 diabetes, potential gender differences in the impact of type 2 diabetes and views regarding dietary management	Small sample size
Green et al. (2000), Fears and phobias in people with diabetes, UK	Case study, 35 year old male with type 1 diabetes (since 15 years)	Investigating how fear of hypoglycaemia and phobic disorders affect people with diabetes	Limited generalisability Descriptive (rather than exploratory) methodology
Debono and Cachia (2007), The impact of diabetes on psychological well-being and quality of life. The role of patient education, UK	Review, search Strategy not given/no information about number of included papers /50 references in bibliography, not a systematic review	Reviewing evidence of impact of diabetes on psychological well-being and quality of life of people living with diabetes	Search strategy and overview of included papers are not provided; quality assessment of included studies was not carried out

<b>Author/s, date, title, country</b>	<b>Study design/Sample size</b>	<b>Study Aim/Focus</b>	<b>Limitations/Weaknesses</b>
Frier (2008), How hypoglycaemia can affect the life of a person with diabetes, Scotland	Search Strategy not given/no information about number of included papers/28 references in bibliography, not a systematic review	Investigating how hypoglycaemia affects the everyday life of people living with diabetes	Search strategy and overview of included papers were not provided; quality assessment of included studies was not carried out
Pun et al. (2009), Barriers to the self-care of type 2 diabetes from both patients' and providers' perspectives: literature review, China	Searching Ovid Medline, CINAHL, Cochrane Library and British Nursing Index, search terms: type 2 diabetes mellitus, self-care, patient compliance, patient adherence and barriers to diabetes self-care, published between 1986 and 2007, 16 studies included	Reviewing the literature about barriers to diabetes self-care from patients' and health professionals' perspectives, focus on type 2 diabetes	Good quality review that included details of search strategy and overview of included papers. Quality assessment of included papers was not carried out.
Spenceley and Williams (2006), Self-Care from the Perspective of People Living with Diabetes, Canada	Focus on self-care experience, patients' perspective, English language, published between 1993 and 2003, 16 studies included	Gaining an understanding of self-care experience (identifying barriers and facilitators) from the patients' perspective	Broad search strategy included studies about both type 1 and type 2 diabetes, thematic focus on self-care did not allow to explore the impact diabetes can have on everyday life
Wild et al. (2007), A critical review of the literature on fear of hypoglycemia in diabetes: Implications for diabetes management and patient education	Reviewing research on fear of hypoglycaemia, English language, published between 1985 and 2007, 34 papers included	Gaining an overview of existing research into fear of hypoglycaemia and analyse its impact on diabetes management and patient education	Overview/table of included papers was not included, not much information about included papers given (e.g. grouping, methodology, etc.)

### **3.2.3 Identified themes: Experience of living with diabetes**

#### **3.2.3.1 Constant presence of diabetes**

Diabetes is a 'constant presence' in people's lives (Hayes et al. 2006; Moser et al. 2008). The theme of 'constant attention' of diabetes care was frequently apparent in the literature: diabetes care is not just a complex balancing act of managing medication/blood glucose monitoring, diet and exercise, but this has to be done on an on-going basis (Frandsen and Kristensen 2002). It is therefore not surprising that some studies reported that people felt overwhelmed by their diabetes care (Everett 2001; West and McDowell 2002; and Nafees et al. 2006). For example, participants in a number of studies reported feelings of stress and hopelessness and not being able to control their diabetes (Aalto et al. 2000; Choe et al. 2001; Everett 2001; Nafees et al. 2006; Huang and Hung 2007; Gazmararian et al. 2009).

Taking a temporary 'break' from all self-care activities was found to be a coping strategy in response to the constant demand of diabetes care (Penckofer et al. 2007). Some papers report that people with diabetes want to take a holiday from their condition (Shiu and Wong 2002; Rayman and Ellison 2004). This could range from intentionally omitting medication, eating any choice of food without worrying about the effect on blood glucose level, or completely 'forgetting about' diabetes for some time (Shiu and Wong 2002; Rayman and Ellison 2004).

### **3.2.3.2 Conflict of perspectives**

Another theme that was evident within the literature is the 'conflict of perspectives' between patients and health professionals, their family and the wider society (Debono and Cachia 2007).

Keeratiyutawong et al. (2003) conducted qualitative in-depth interviews with 8 people with type 2 diabetes in Thailand looking at self-care experiences. In this study, participants reported that if they felt fine, they might not adhere to their prescribed treatment regime. Also, some participants admitted to having personal goals for their diabetes care, which might not necessarily reflect those of their healthcare providers. Additionally, patients felt misunderstood by health professionals; while they have to live with and manage their diabetes 24 hours a day throughout the year, health professionals (those with expert knowledge) spend only a short time with patients during consultations (Keeratiyutawong et al. 2003). This is also reflected in the findings of an ethnographic study conducted by Hinder and Greenhalgh (2012), who concluded that people with diabetes spend 99% of their time managing their diabetes on their own.

There are however a few limitations to Keeratiyutawong et al. (2003). For example, their study only included people with type 2 diabetes who had difficulty controlling their blood glucose level. While this provides useful insight about this particular sample, it could mean that the experiences of other people with diabetes may have been missed. Another limitation relates to the small sample size. Keeratiyutawong et al. (2003) findings are based on data from only 8 participants.

Keeratiyutawong et al. (2003) also noted conflicting priorities between health professionals' and patients' perspectives in relation to diabetes care. In their study, health professionals tended to be more concerned about meeting treatment targets and reducing long-term complications of diabetes, while patients were more focussed on the immediate impact of their condition as well as their quality of life.

Similarly, Vermeire et al. (2003) reported that patients placed much higher importance on immediate effects of diabetes treatment as opposed to potential long-term complications. This finding was also evident in relation to fear of hypoglycaemia where patients were more concerned about immediate, rather than long-term effects (Wild et al. 2007).

Two qualitative studies highlighted another aspect of conflicting perspectives between patients and health professionals: treatment adherence. One of the studies was carried out in Taiwan (Lin et al. 2008) and the other in Canada (Barton et al. 2005). They both found that participants tended to try alternative therapies/traditional medicine first, before accepting to take their diabetes medication. For example, Lin et al. (2008) conducted focus groups with 41 participants with type 2 diabetes investigating self-care experiences, while Barton et al. (2005) used qualitative interviews with 8 participants to explore participants' experiences of living with type 2 diabetes. The Barton et al. (2005) study only included people with type 2 diabetes from an Aboriginal background, which may not reflect the experiences of other people with diabetes.

Further qualitative studies from the USA and Canada conducted with minority ethnic groups have shown that conflicts can extend to members of the community, family

relations and social occasions (Carbone et al. 2007; Weiler and Crist 2009). For example, Weiler and Crist (2009) carried out semi-structured interviews with 10 Latino adults. They found that a major cause for conflict was people's negative perception of diabetes, a reluctance to openly talk about a diabetes diagnosis and difficulties when attending social events (also see Mulvaney et al. 2008). These difficulties included performing diabetes self-care activities in public and the sharing of (traditional) foods, which could impact on diabetes care, e.g. diet recommendations (Barton et al. 2005; Garcia de Alba et al. 2007; Mulvaney et al. 2008).

### **3.2.3.3 Invisibility of diabetes**

Diabetes is an invisible illness. Its presence may not be apparent to others, unless an obvious complication is present or a (hypoglycaemic) emergency arises. A number of studies report that revealing one is diabetic can be challenging, given the stigma and embarrassment that can be attached to a diagnosis of diabetes, as well as the awkward social environment an emergency can create (see Utz et al. 2006; Abdoli et al. 2008; and also Lin et al. 2008). For example, a qualitative focus group study conducted by Lin et al. (2008) found that diabetes was perceived to be an infectious and self-inflicted condition caused by overeating. Another aspect of the stigma attached to diabetes relates to the need to inject insulin and carrying needles; this could be confused with illicit drug use (Shiu et al. 2003).

Closely related to the difficulties in social environments is the question of whether someone with diabetes actually wishes to disclose their condition. For example, a qualitative study using focus groups with 24 adolescents found that for many participants, having diabetes makes them feel different from everyone else (Mulvaney

et al. 2008). According to Rayman and Ellison (2004), a person with diabetes can also feel a loss of their former lifestyle; or even feel alone with a condition that is not comprehended by society and people around them (Debono and Cachia 2007).

The issue of invisibility of diabetes is particularly prominent among adolescents and young adults who express the desire to fit in with their peers and do not want to stand out (Dickinson and O'Reilly 2004; Kay et al. 2009). While people living with diabetes might perceive its invisibility as positive as it allows them to hide their condition, this approach can complicate an open discussion about a diagnosis of diabetes and might impact on an individual's adherence to their diabetes treatment. The complexities arising from the invisible nature of diabetes have further been confirmed by a qualitative study investigating the experiences of women who were diagnosed with gestational diabetes (Persson et al. 2009). Persson and colleagues interviewed 10 women with gestational diabetes and found that as diabetes is an invisible illness, many social situations can involve having to disclose that an individual has been diagnosed with diabetes and that this includes taking diabetes medication and possibly following a special diet.

Another dimension of the invisibility of diabetes is the tangibility of diabetes to people living with it. A study underlining the complexity of having an 'invisible illness' has been conducted by Peel et al. (2004). They explored participants' perspectives regarding blood glucose monitoring and found that they liked the visibility of their blood glucose values when measuring the same. Some of their findings included that low blood glucose values were associated with a feeling of success and being in control, while high readings could trigger an adjustment in diet/medication (Peel et al.

2004). This finding was confirmed by a study carried out by Shiu and Wong (2002). Also, these findings suggest that a diagnosis of diabetes might not even be tangible to people themselves unless there is a clear blood glucose reading or unequivocal symptoms of the condition.

#### **3.2.3.4 Multiple challenges of living with diabetes**

In addition to the three prominent themes of 'constant presence of diabetes', 'conflict of perspectives', and 'invisibility of diabetes', the review identified a variety of challenges that people living with diabetes face, and the wide ranging impact diabetes can have on different aspects of everyday life.

##### *Diabetes impacts on all aspects of life*

Puavilai and Stuijbergen (2000) conducted a multi-method study involving 57 Thai women to explore aspects affecting quality of life. The first phase (quantitative) included completing a life satisfaction survey and collecting personal information, and the second phase (qualitative) employed in-depth interviews with a sub-sample of 18 women. The authors identified that many participants viewed their lives as a 'holistic unit'. Hence, diabetes was seen as having an impact on all aspects of life (Puavilai and Stuijbergen 2000). For example, having diabetes can have an impact on people's quality of life, on their physiological and psychological well-being, as well as on social relationships. It is not only the presence of diabetes complications that reduces individuals' perceived quality of life, but also the demand and complexity of diabetes care (Aalto et al. 2000).

Everett (2001) carried out a qualitative study involving 21 participants with type 1 diabetes in the UK. She investigated the impact of diabetes on everyday life, and found that many participants set themselves the target of controlling and normalising their diabetes. This was as a result of participants comparing themselves to what they perceived as the 'perfect diabetic'. In explaining the findings, Everett (2001) introduced a concept called 'cost of normalisation', which was used to describe the effort required by people living with diabetes to maintain a near normal lifestyle. The cost of normalisation includes managing all aspects of diabetes on a daily basis (e.g. blood glucose monitoring, taking medication), as well as controlling hypoglycaemic episodes.

### *Balancing Act*

According to Shiu and Wong (2002) and Moser et al. (2008), living with diabetes seems to be a balancing act between reducing the risk of long-term complications, avoiding short-term complications and emergencies, while aiming to achieve a good quality of life. For example, both Vermeire et al. (2003) and Nafees et al. (2006) found that in the bid to deal with the multiple challenges of managing diabetes, people often value the immediate effects of treatment on their well-being over the possibility of suffering some long-term complications in the future. This finding of balancing multiple challenges of living with diabetes is further supported by a review undertaken by Debono and Cachia (2007).

### *Fear of complications*

It was evident in the literature that people's fears and worries about diabetes complications can have a massive effect on psychological well-being; even without the presence of any complications. This fear can be triggered by previous personal experiences, other people's depiction or simply knowledge about potential complications (Puavilai and Stufbergen 2000; Choe et al. 2001; Phillips 2007). A number of papers have shown that in many cases people's fear about complications is an important driver in improving treatment adherence, as people learn to adopt a more positive and co-operative approach (Vermeire et al. 2003; Spenceley and Williams 2006; Kay et al. 2009).

The DAWN study (Diabetes Attitudes, Wishes, and Needs), a large international study, investigated people's perspectives about diabetes care (Funnell 2006), and found that psychosocial difficulties and worries were very common among people with diabetes, especially around the time of diagnosis. However, problems of living with diabetes seemed to continue even many years after diagnosis. This included complexity and burden of diabetes care, e.g. monitoring blood glucose level, taking diabetes medications, constant monitoring of carbohydrate intake (see section 3.2.3.1), as well as fears and worries about complications (Funnell 2006).

### *Positive Outlook*

While this review identified that there are a number of studies focussing on the challenges of diabetes management (e.g. Hayes et al. 2006; Penckofer et al. 2007; Mulvaney et al. 2008; Gazmararian et al. 2009), it is important to note that a few other

studies have looked at positive aspects of living with diabetes (Abdoli et al. 2008; Yamakawa and Makimoto 2008).

Yamakawa and Makimoto (2008) conducted a qualitative study in Japan that specifically investigated positive aspects of living with diabetes. They carried out interviews with 17 adults with type 2 diabetes. Participants identified a number of positive aspects of living with diabetes, including the privilege of regular medical checks and changing to a healthier lifestyle. Also, having diabetes meant an opportunity to gain new social networks (e.g. other people with diabetes, exercise groups) and to improve relationships through shared responsibility of diabetes care (Yamakawa and Makimoto 2008). Similarly, Abdoli et al. (2008) described the 'empowerment process' of learning to live with and manage diabetes. They discovered that after overcoming initial challenges associated with a new diagnosis of diabetes, participants worked hard to achieve treatment targets and to develop the ability to control their diabetes (Abdoli et al. 2008).

### *Misconceptions*

Paddison et al. (2008) carried out a quantitative survey in New Zealand, involving 615 adults with type 2 diabetes. They examined the association between psychological factors/beliefs about diabetes, quality of life and metabolic control. Findings showed that despite the growth in research, education and prevalence of diabetes, misconceptions still persist (Paddison et al. 2008). There were generally negative representations and misconceptions about diabetes. These included a belief that diabetes is temporary, and a belief that it has immediate, serious health implications (i.e. it is uncontrollable). These misconceptions were associated with lower quality of

life and poorer metabolic control (Paddison et al. 2008). This shows the importance of self-confidence and attitude towards diabetes in the successful management of the condition.

### *Social Dimension*

Another dimension that can be affected by diabetes is people's social life. This extends from interactions with partners/family, friends and colleagues to social and recreational activities. A large quantitative study involving 4189 participants from five European countries (Belgium, Italy, The Netherlands, Sweden and Spain) has investigated the impact of type 2 diabetes from the participant's perspective. It found a reduction in social functioning due to the impact of long-term complications, which can lead to feelings of social isolation (Koopmanschap 2002).

An important aspect of how diabetes can influence people's social life has been highlighted by some qualitative studies conducted in the USA (Samuel-Hodge et al. 2000; Carbone et al. 2007; Penckofer et al. 2007). While Carbone and colleagues pointed out that participants in their study perceived family and social networks as a main source of support regarding diabetes self-management, the opposite was the case in the Samuel-Hodge et al. (2000) and Penckofer et al. (2007) studies. In these two studies the 'multi caregiver' role of many women and the responsibility and time implications of looking after their families impacted on the resources (e.g. motivation, energy, time and finances) they had left to look after themselves and their own diabetes care.

Interestingly, evidence from a qualitative study that focussed on a minority ethnic population in the USA highlighted that participants tended to seek advice and support relating to their diabetes management from family and their wider social network rather than health professionals (Weiler and Crist 2009). This further highlights the important role of people's social network in supporting them in their diabetes management. The phenomenon of seeking advice and support from non-professional sources (e.g. family members/relatives, friends, acquaintances) is also known as 'lay referral' (Suls et al. 1997). The issue of 'lay referral' is further discussed in sections 4.4 and 4.5.

#### *Impact of complications on diabetes self-care*

The literature showed that the 'knock-on' effect of diabetes complications can be very devastating for people living with diabetes. For example, diabetic retinopathy and neuropathy can have adverse effects on diabetes management (Coyne et al. 2004; Garcia de Alba et al. 2007). This can include impact on planning and performing of diabetes self-care activities (Coyne et al. 2004), and diet and physical exercise (Garcia de Alba et al. 2007). According to Coyne et al. (2004), reduced vision through diabetic retinopathy can complicate testing blood glucose levels, reading medication instructions and administering insulin injections (Coyne et al. 2004).

Donald et al. (2012) carried out a 5-year cohort study involving 3951 participants, which focussed on the everyday experiences of people living with diabetes, in Queensland, Australia. They found that despite most participants being actively involved in the management of their illness, a significant number of the people; in fact,

two in every three reported having at least one complication linked to their illness, which impacts on their self-management abilities (Donald et al. 2012).

### *Impact of hypoglycaemia*

Hypoglycaemia is one of the most serious diabetes complications. According to Shiu and Wong (2000), many people with diabetes have experienced at least one hypoglycaemic emergency since they were diagnosed. Moreover, the literature suggests that even the presence of mild complications can reduce people's perceived quality of life (Lloyd et al. 2001; Hayes et al. 2006). As hypoglycaemic emergencies make diabetes publicly visible and frequently require the assistance of another person, the tendency towards avoidance of hypoglycaemic episodes by decreasing treatment adherence and intentionally keeping blood glucose levels high has been widely reported in the literature (Shiu and Wong 2000; Nafees et al. 2006; Di Battista et al. 2009). This strategy of avoiding hypoglycaemic episodes is further considered in section 3.3.4.2.

Although the general literature about people's experiences of living with diabetes does not consider the impact of hypoglycaemic episodes on people's everyday life in detail, it is evident that hypoglycaemic episodes are one of the challenges people face in managing their diabetes. The literature that more specifically addresses the impact of hypoglycaemia and people's experiences of living with hypoglycaemia are further considered in section 3.3.

### **3.2.4 Summary**

The first part of this chapter has emphasised that living with diabetes has far reaching consequences for the individual: diabetes is a chronic condition and its care is an on-going and constant process. While this review focussed on people's experiences of living with diabetes, identified themes highlighted various other factors, e.g. the invisibility of diabetes, as well as misconceptions and stigma about diabetes.

In terms of diabetes treatment, there seems to be an underlying tension between patients' perspectives and the perspective of health professionals, signalling different priorities. For example, a number of studies (Keeratiyutawong et al. 2003; Vermeire et al. 2003; Wild et al. 2007), indicate that while people with diabetes are much more concerned about the immediate impact of medication and maintaining a better quality of life, health professionals tend to place higher importance on longer-term treatment targets.

Managing diabetes can be a complex task with the need to balance medication, diet, lifestyle and physical activity. The theme of 'constant attention'/constant presence in the management of diabetes has also been well documented in the literature (Everett 2001; Frandsen and Kristensen 2002; Hayes et al. 2006). For example, Moser et al. (2008) explored people's understanding of self-management, and found that self-management is perceived as a complex, on-going process involving routine tasks, managing 'off-course' events (e.g. hypoglycaemia) and taking preventative actions.

This review highlighted that the invisible nature of diabetes is another challenge that people face in everyday life. This entails the reluctance of people to make their

condition noticeable whenever in a social environment (Mulvaney et al. 2008), which is further exacerbated by the complexity of diabetes care (Aalto et al. 2000). In a study by Utz et al. (2006) participants expressed unwillingness to discuss their diabetes condition as a result of perceived social stigma. Thus, there could be a danger that people feel socially excluded and may decline participation in social activities.

Overall, diabetes impacts on people's entire life. This includes: quality of life, relationships, psychological, and physiological well-being (Puavilai and Stuijbergen 2000). Also, a person with diabetes requires a substantial amount of skill and effort to achieve a 'near normal' life (Everett 2001), as well as the problem of balancing seemingly conflicting interests (Campbell et al. 2003; Debono and Cachia 2007); all these emphasise the intricacies of living with diabetes and illustrate the challenges of successful diabetes self-management.

#### *Limitations of this review*

This review was challenging as it included papers that used a variety of research methods as well as publication types. This made synthesis of the results difficult. To address this challenge, a thematic analysis of findings was undertaken. However, looking at more recent research relating to the thematic area, there seems to be agreement with the findings of this review; that, living with diabetes has far reaching consequences for the individual (Donald et al. 2012); that managing diabetes is a complex and on-going process (American Diabetes Association 2012), and that many people with diabetes worry about possible complications (Ridge et al. 2012).

Search terms combined people's perspectives; experience and diabetes (see section 3.2.1). The search terms were applied to publication titles only due to the large number of results when including abstracts in the search. Limiting the search results this way might have missed out on some relevant papers. However, the purpose of this review was not to achieve a definitive review covering all research about living with diabetes; rather, to gain an understanding of the key themes in diabetes research relating to people's lives and experiences. Another aim was to find out how much of the general diabetes literature has investigated people's experiences of hypoglycaemic episodes.

Wild and colleagues (2007) investigated research into fear of hypoglycaemia and possible implications this has for diabetes management. They provide a summary of negative outcomes associated with fear of hypoglycaemia, especially the impact it can have on the 'balancing act' of avoiding both acute complications of hypoglycaemic episodes, as well as long-term complications resulting from hyperglycaemia. However, Wild et al. (2007) fail to offer an overview of included papers. The limitations of the included reviews highlight that there is a need for good quality reviews looking at the impact of hypoglycaemia.

The first part of this chapter has highlighted various challenges people face in the day to day management of their diabetes. It has shown that hypoglycaemia is a considerable problem for many people with diabetes (Shiu and Wong 2000). The next section provides an in-depth, structured review, specifically exploring the literature on people's experiences of living with hypoglycaemia.

### **3.3 People's experiences of living with hypoglycaemia**

Despite improvement in the treatment and management of diabetes over the years, hypoglycaemia is still one of the most feared complications in insulin-treated diabetes. Hypoglycaemia occurs as a potentially dangerous side effect of some diabetes medications. It is caused by inappropriately high insulin levels, which can lead to low blood glucose values (Hicks 2010). Symptoms of hypoglycaemia range from sweating, headache, difficulty in concentrating, to confusion, change of behaviour, and eventually loss of consciousness (Banks 2005; also see section 2.8).

Beyond clinical implications, hypoglycaemia can have a huge impact on the well-being of people living with diabetes, impinging on their ability to perform 'normal' everyday activities, participate in employment, and even engage in social activities (Frier 2004). Lundkvist et al. (2005) summarise that "the effects of [...] hypoglycaemia are twofold. First, well-being may be affected in people with frequent hypoglycaemia, both directly from the effects of hypoglycaemia and indirectly from concern about recurrent events. Second, apart from the distressing acute symptoms, hypoglycaemia may also impair the person's health in the long term; fear of an event may additionally prevent people from taking their anti-diabetic treatment" (p.197).

As highlighted in chapter 2, hypoglycaemia is the most common complication in insulin-treated type 1 and type 2 diabetes (Wild et al. 2007). For example, in people with type 1 diabetes, the annual incidence for severe hypoglycaemia is between one and two cases per individual, which can further increase when other risk factors (e.g. intensive insulin treatment, exercise, past history of frequent and severe hypoglycaemic episodes, etc.) are present. However, mild and usually self-treated

hypoglycaemia is even more common, occurring on average about twice a week (Frier 2008; see section 2.6.2).

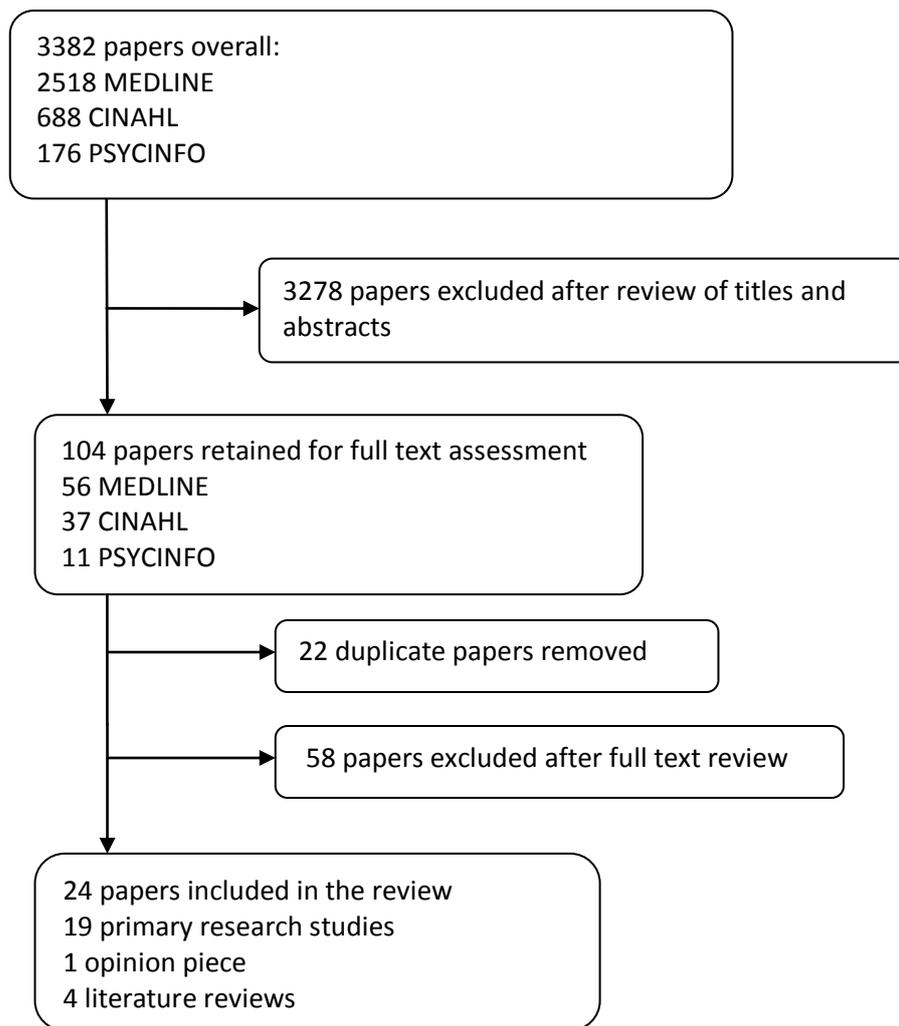
Severe hypoglycaemia is less common in people with type 2 diabetes than in those with type 1 (UKPDS 1998). Though, people with type 2 diabetes who are treated with insulin experience similar rates of severe hypoglycaemia compared to people with type 1 diabetes, particularly when the duration of insulin treatment was 5 years or more (Heller 2008). These further underline the impact hypoglycaemia has on people living with diabetes, but especially those treated with insulin. The initial review (section 3.2) revealed a lack of systematic literature reviews focussing on people's experiences of living with hypoglycaemia. Therefore, the following section presents a review around people's perspectives and experiences of living with hypoglycaemia.

### **3.3.1 Methods**

The aim of this review was to gain an understanding of people's experiences of living with hypoglycaemia. A systematic search of online databases CINAHL (Cumulative Index for Nursing and Allied Health Literature), PsycINFO and MEDLINE was carried out. Two facets were developed: Experience: (experience\*, perspective\*, perception\*, well\*being, quality of life, self\*care, self\*management, fear\*, affect\* or impact\*) and illness: (hypoglyc\*). Additionally, the facet 'diabetes' was applied in an all text search to ensure focus on hypoglycaemia in the context of diabetes. Subject headings and text words within each facet were combined using the Boolean operator "OR" and the resultant facets were then combined using the Boolean operator "AND". These facets were then applied to publication titles and abstracts.

After excluding research carried out with animals, and limiting search results to English and German language publications (due to my language skills) within the last 20 years (since March 1991), the search yielded 3382 results. These were screened for relevance and whether they were directly related to people's experience of hypoglycaemia. Papers that reported primary or secondary research, opinion pieces and literature reviews were included, while publications evaluating interventions were excluded. This was because the focus of the current review was on people's experiences of living with hypoglycaemia rather than the effectiveness of interventions. 104 papers met the inclusion criteria during initial screening and were retrieved for full text assessment. A flow diagram of the structured search process is shown in figure 3.2 below.

Following the identification of relevant papers, key data (e.g. authors, study design, study aims, and themes) were extracted into a summary table (see table 3.2 below). Papers were analysed in-depth to identify key findings and these were compared across included papers. This process generated a set of abstract themes which were further refined and synthesized through critical discussion with my supervisors. Salience of extracted information was reached by independent assessment of ten percent of papers regarding identified themes.



**Figure 3.2: Flow diagram of structured search process (experiences of hypoglycaemia)**

### 3.3.2 Quality assessment

Quality appraisal was conducted using adapted NICE public health guidance (2009) quality appraisal tools and checklists (also see Crombie 1996). Each included paper was assessed for relevance and quality and was given a score following quality appraisal. Papers were then independently checked with my supervisors, and their quality scores discussed.

### 3.3.3 Results

After reviewing the full text version of potentially relevant papers, 19 primary research studies, one opinion piece and four literature reviews were identified as relevant (see figure 3.2). Twenty percent of papers (n=5) were checked for inclusion/exclusion criteria with my supervisors, and agreements were high (agreements for n=4, one paper was further discussed regarding inclusion/exclusion (Crace 1991)). This process is well established and has been used previously by Popay et al. (2006) and Kolehmainen et al. (2010). Of the 19 primary research studies, four studies used qualitative methodology; two studies were based around a single case study, and 13 studies applied a quantitative approach. An overview of included papers is presented in table 3.2 below, along with a list of key themes identified in each paper.

This review faced a challenge of including papers that used a variety of research methods as well as publication types (reviews, primary research studies, etc.). This also brought with it a difficulty of comparing results. To address this challenge, a thematic analysis of findings was undertaken. The review may have missed out on some relevant papers as reference lists of relevant papers or relevant journals were not searched.

The quality of reviews included was poor. For example, some reviews lacked detailed search protocols, overview of included papers and quality appraisal (Gold et al. 1997; Wild et al. 2007; Frier 2008). Frier's review outlines possible implications of hypoglycaemia on people's everyday lives; including travel, driving, physical activities, working life and relationships. But whilst this review gives an interesting and broad overview, it is unclear whether it reflects the perspective of people living with

diabetes. There was a lack of information on the research upon which these conclusions were reached and on the selection of included research studies.

This review has identified only four studies using qualitative methods, with three of them being carried out in the nineties (Richmond 1996; Rajaram 1997; Ritholz and Jacobson 1998). This means that findings could be out of date with changes in treatment (e.g. different types of insulins) and diabetes management approaches. Two of the qualitative studies were conducted in the USA (Rajaram 1997; Ritholz and Jacobson 1998) and one in England (Richmond 1996). The fourth study was carried out in China (Shiu and Wong 2002). Studies which are not conducted in the United Kingdom may have limited relevance to the UK system. Richmond's (1996) study was based on semi-structured interviews with only seven participants and was reported 16 years ago. This suggests that there is a lack of recent, qualitative studies investigating people's experiences of living with hypoglycaemia. In terms of the Scottish context, the literature searched to date has been unable to locate any qualitative studies that have looked at people's experiences of living with hypoglycaemia.

**Table 3.2: Overview of included papers (experiences of hypoglycaemia)**

Author/s, date, title, country	Study Design/Sample Size (n)	Study Aim/Focus	Quality score	Theme(s)
Anderbro et al. (2010), Fear of hypoglycaemia in adults with type 1 diabetes, Sweden	Quantitative, Swe-HFS, using worry and aloneness subscales, 764 adults with type 1 diabetes, mean age 43.3 years	Investigating the associations between fear of hypoglycaemia and disease-specific/demographic variables	++	1
Belendez and Hernandez- Mijares (2009), Beliefs about insulin as a predictor of fear of hypoglycaemia, Spain	Quantitative, Beliefs about medicines questionnaire, fear of hypoglycaemia survey and other questionnaires, 81 adults (18-58 years) type 1 diabetes, 56% female	Investigating how concerns about insulin treatment influences fear of hypoglycaemia	-	1
Costea et al. (1993), Fear of hypoglycaemia in type 1 (insulin-dependent) diabetic patients, Romania	Quantitative (interview and questionnaires) to measure frequency of hypos, evaluation of anxiety, 224 patients with type 1 diabetes, divided into 2 groups (frequent hypos vs. occasional hypos)	To investigate the relationship between frequency and severity of hypoglycaemia, anxiety and compliance behaviours	+	1,2,3
Currie et al. (2006), Multivariate models of health-related utility and the fear of hypoglycaemia in people with diabetes, UK	Quantitative (postal surveys) using HFS (Hypoglycaemia Fear Survey) and EQ5D (measures health-related utility), 1305 participants, type 1 and type 2 diabetes	Measuring the impact of hypoglycaemia on patients' health-related utility, investigating how severity, frequency and fear of hypoglycaemia affect patients' health status	++	1,5
Davis et al. (2005), Impact of hypoglycaemia on quality of life and productivity in type 1 and type 2 diabetes, UK	Quantitative (postal survey) using EQ-5D and SF-36, 861 respondents (response rate= 28%)	To investigate impact of hypos on quality of life, productivity, health related utility	+	2,5
Di Battista et al. (2009), Type 1 Diabetes among adolescents- reduced diabetes self-care caused by social fear and fear of hypoglycaemia, Australia (Fieldwork in USA/Canada)	Quantitative (Survey incl.DQoL (Diabetes Quality of Life Measure) and HFS), 76 adolescent (13-18 years) participants, type 1 diabetes, 33 boys/43 girls	Investigating the association between social anxiety, fear of hypoglycaemia, adherence to diabetes treatment regimen and perceived quality of life	+	1,2,5
Irvine et al. (1992), Fear of Hypoglycemia: Relationship to physical	Quantitative, HFS and other questionnaires, 69 participants with type 1 diabetes (41 female/28 male),	Investigating the impact of hypoglycaemia on fear, self-care behaviour and	+	1,2

<b>Author/s, date, title, country</b>	<b>Study Design/Sample Size (n)</b>	<b>Study Aim/Focus</b>	<b>Quality score</b>	<b>Theme(s)</b>
and psychological symptoms in patients with insulin-dependent diabetes mellitus, USA	mean age 33.4 years	psychological symptoms		
Leiter et al. (2005), Assessment of the impact of fear of hypoglycemic episodes on glycemic and hypoglycemia management, Canada	Quantitative, HFS-98 and other questionnaire items, 235 adults with type 1 and type 2 diabetes, insulin-treated, (171 male/164 female)	Investigating the impact fear of hypoglycaemia has on glycaemic control, lifestyle and hypoglycaemia management	+	1,2
Myers et al. (2007) Fear of hypoglycemia and self-reported posttraumatic stress in adults with type 1 diabetes treated by intensive regimens, USA	Quantitative (questionnaires incl. HFS, posttraumatic diagnostic scale (PDS), Beck Depression Inventory and other demographics questions, 90 participants (65 female/25 male), adults with type 1 diabetes, intensive insulin treatment	Investigating the relationship between fear of hypoglycaemia and posttraumatic stress in people with type 1 diabetes	-	1
Nordfeldt and Ludvigsson (2005), Fear and other disturbances of severe hypoglycaemia in children and adolescents with type 1 diabetes mellitus, Sweden	Quantitative, 74 participants, 4-18 years, type 1 diabetes, person most in charge of treatment filled in questionnaire (incl. parents/carer), participants divided into 2 groups: those who experienced severe hypoglycaemic episodes with unconsciousness and those without unconsciousness	Investigate the occurrence and extent of fear of hypoglycaemia in young people experiencing severe hypoglycaemic episodes	+	1,2,3
Polonsky et al. (1992), Correlates of hypoglycaemic fear in type 1 and type 2 diabetes mellitus, USA	Quantitative, HFS and other anxiety and fear scales, 232 participants, insulin-treated type 1 and type 2 diabetes, 13-85 years old	Investigating whether fear of hypoglycaemia is a response to prior experience of hypoglycaemic episodes, or associated with general anxiety levels?	+	1
Shiu and Wong (2000), Fear of hypoglycaemia among insulin-treated Hong Kong Chinese patients: implications for diabetes patient education, China	Quantitative (structured interviews), 120 participants, adults, insulin-treated type 1 and type 2 diabetes, 1 <sup>st</sup> phase study	Identifying the extent of fear of hypoglycaemia and its impact on diabetes self-management	+	1,2
Tierney et al. (2008), Living with cystic fibrosis-related diabetes or type 1	Quantitative (cross-sectional comparative study) using questionnaires incl. EHS (Edinburgh Hypoglycaemia Scale)	Gaining an insight into the experience of hypoglycaemia and the impact of diabetes	++	5

Author/s, date, title, country	Study Design/Sample Size (n)	Study Aim/Focus	Quality score	Theme(s)
diabetes mellitus: a comparative study exploring health-related quality of life and patients' reported experiences of hypoglycaemia, UK	and DQoL (Diabetes Quality of Life Measure), 107 participants (55 with type 1 diabetes/52 with CFRD (Cystic Fibrosis-Related Diabetes)	on health-related quality of life. Comparing perceptions of people with type 1 diabetes and CFRD		
Crace (1991), Experiences with hypoglycaemia, Sheffield/UK	Opinion piece, experience report/story by patient with type 1 diabetes	Describing personal experiences of living with hypoglycaemia	N/A	2,3,4
Green et al. (2000), Fears and phobias in people with diabetes, UK	Case study, 35 year old male with type 1 diabetes (since 15 years)	Investigating how fear of hypoglycaemia and phobic disorders affect people with diabetes	N/A	1,2
Luthra and Donaldson (1997), Severe hypoglycaemia in insulin-dependent diabetes mellitus (IDDM)- living to tell the tale, USA	Case study, 62 year old male with type 1 diabetes	Giving a retrospect account of a severe nocturnal hypoglycaemic episode	N/A	1,3
Rajaram (1997), Experience of hypoglycemia among insulin dependent diabetics and its impact on the family, USA	Qualitative (interviews with 23 people with type 1 diabetes and their partners), partners were interviewed separately	To explore experience of hypoglycaemia, its management and impact on everyday life from both patients and partners' points of view	++	3,4
Richmond (1996), Effects of hypoglycaemia: patients' perception and experience, UK	Qualitative, semi-structured interviews, 7 participants (3 males/4 females), adults (20-72 years)	Exploring people's experiences of insulin-treated diabetes in relation to hypoglycaemia	+	2,3,5
Ritholz and Jacobson (1998), Living with hypoglycaemia, USA	Qualitative, in-depth, semi-structured interviews, 20 participants (aged 21-30 years), type 1 diabetes, 10 male/10 female	Exploring young adults' experiences of hypoglycaemia and its impact on everyday life	+	3,4
Shiu and Wong (2002), Fears and worries associated with hypoglycaemia	Qualitative (semi-structured interviews), 13 participants, insulin-treated type 1 and type 2 diabetes, adults, 2 <sup>nd</sup>	Investigating participants' (Hong Kong Chinese) perspectives of living with	++	1,2,3

Author/s, date, title, country	Study Design/Sample Size (n)	Study Aim/Focus	Quality score	Theme(s)
and diabetes complications: perceptions and experience of Hong Kong Chinese clients, China	phase study (sub-sample of 1 <sup>st</sup> phase (quantitative) study)	hypoglycaemia, fear of hypoglycaemia (and other complications) as well as coping strategies		
Frier (2008), How hypoglycaemia can affect the life of a person with diabetes, Scotland/UK	Review, Search Strategy not given/no information about number of included papers/28 references in bibliography → not a systematic review	Investigating how hypoglycaemia affects the everyday life of people living with diabetes	-	1,2,3
Gold et al. (1997), Hypoglycaemia and non-cognitive aspects of psychological function in insulin-dependent diabetes mellitus (IDDM), UK	Review, 35 references	3 main aims are review of: 1- impact of acute hypoglycaemia on mood and behaviour 2- investigation of fear of hypoglycaemia 3- effects of recurrent hypoglycaemia on mood, behaviour and personality	-	1,4
Wild et al. (2007), A critical review of the literature on fear of hypoglycaemia in diabetes: Implications for diabetes management and patient education, UK	Reviewing research on fear of hypoglycaemia, English language, published between 1985 and 2007, 34 papers included	Gaining an overview of existing research into fear of hypoglycaemia and analyse its impact on diabetes management and patient education	+	1,2
Zhang et al. (2010), The burden of hypoglycaemia in type 2 diabetes: a systematic review of patient and economic perspectives, UK	Review of research investigating personal and economic impact of hypoglycaemia in people with type 2 diabetes treated with oral diabetes medications, included 17 studies for economic review and 11 for patient reported outcomes	Gaining an overview of literature focussing on personal and economic impact of hypoglycaemia in people with type 2 diabetes treated with oral diabetes medications	+	1,2,5

(Themes: 1= fear of hypoglycaemia, 2= balancing risk, 3= loss of control, 4= impact on identity, 5= impact on quality of life)

Many of the included papers focus on research around fear of hypoglycaemia. It is the most common theme in both reviews and quantitative studies; however, only one qualitative study mentions the 'fear of hypoglycaemia' theme. Among the included qualitative studies, the most frequent theme is the 'loss of control' theme. This suggests that fear of hypoglycaemia has generally been studied using quantitative methods.

Even though the quantitative studies investigating fear of hypoglycaemia and factors influencing it gave an indication about the extent to which people with diabetes are affected by such fear, they tell us little about people's perspectives and experiences of hypoglycaemia. The search strategy identified few qualitative studies (n=4) focussing on experience of hypoglycaemia. Only one qualitative study was conducted in the UK (Richmond 1996). However, this study had a very limited sample size (7 participants). None of the included studies used a longitudinal approach, which indicates a further gap in the literature exploring the impact of hypoglycaemia over time.

The quality of included studies and reviews varied within and between study types. Among the quantitative studies, few were rated as very good quality papers (e.g. Tierney et al. 2008; Anderbro et al. 2010); however, the majority of quantitative studies (n=8) received an average quality score. The main limitations in these studies related to a low response rate (Davis et al. 2005) and a small sample size (e.g. Irvine et al. 1992; Nordfeldt and Ludvigsson 2005; Di Battista et al. 2009). In contrast, qualitative studies appeared to be of a higher quality, with half of the included studies (n=2) receiving a very good quality score. Quality rating of included reviews (n=4) was generally poor to average. One of the main shortcomings was not following a

transparent and rigorous process; for example, two of the reviews did not include an overview of their methodology (Gold et al. 1997; Frier 2008).

### **3.3.4 Identified themes: Experience of living with hypoglycaemia**

Four main themes were identified in this review: fear of hypoglycaemia; balancing risk; impact on identity; and loss of control. These themes suggest that people living with diabetes carry a considerable burden as they have to constantly manage their condition, and directly experience the impact of their diabetes on everyday life. They also have the additional burden that hypoglycaemic episodes can bring and that this also requires substantial management, which may not always be within their control.

#### **3.3.4.1 Fear of hypoglycaemia**

18 papers examined this theme (11 quantitative studies, 1 qualitative study, 4 reviews and 2 case studies)
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With regard to quality of included papers looking at fear of hypoglycaemia, five were rated as very good. These were three quantitative papers (Currie et al. 2006, Tierney et al. 2008, and Anderbro et al. 2010); and two qualitative papers (Rajaram 1997; Shiu and Wong 2002). The rest of the papers, including the reviews, achieved either an average or poor quality score (see quality scores in table 3.2). There was no study that looked at fear of hypoglycaemia in relation to concerns and worries relating to long-term complications.

The theme of 'fear of hypoglycaemia' frequently emerged within the literature. Many people with diabetes are afraid or worry about possible hypoglycaemic episodes. As hypoglycaemia is accompanied by unpleasant, frightening symptoms and can

potentially be life threatening, it is not surprising that many people with diabetes develop a fear of hypoglycaemia. Fear of hypoglycaemia is generally measured using the Hypoglycemia Fear Scale (HFS), which includes a behaviour and worry subscale. The behaviour subscale addresses diabetes self-care behaviours that are adopted to avoid hypoglycaemia, while the worry subscale assesses aspects of hypoglycaemia that cause anxiety (Wild et al. 2007).

There is strong evidence that fear of hypoglycaemia can increase with more severe and more frequent episodes of hypoglycaemia (Gold et al. 1997; Shiu and Wong 2000; Currie et al. 2006; Hanberger et al. 2009). Severe hypoglycaemia occurs more often in people treated with insulin, which includes people with type 1 diabetes. Consequently, people with type 1 diabetes tend to have higher levels of fear of hypoglycaemia (Belendez and Hernandez-Mijares 2009). Interestingly, a study conducted by Tierney et al. (2008) found that frequency of hypoglycaemic episodes seems to have a lesser impact on health-related quality of life compared to severity of hypoglycaemic episodes. This suggests that more severe and disruptive symptoms can cause more distress and fear in people experiencing hypoglycaemia.

Davis et al. (2005) examined associations between occurrence of hypoglycaemia, quality of life, productivity and primary care resource use. Not surprisingly, they found that with increasing frequency and severity of hypoglycaemic events, primary care resources were used more frequently, while both quality of life and productivity reduced. They conclude that “hypoglycaemia clearly has a major impact on people’s lives in terms of physical, mental and social functioning” (Davis et al. 2005:1483). These findings are very relevant as there is evidence that severity of hypoglycaemic

episodes in particular has a considerable effect on fear of hypoglycaemia (Anderbro et al. 2010).

Many people with insulin-treated diabetes worry about possible hypoglycaemic emergencies. Fears and worries about hypoglycaemia seem to be associated with personality (general level of anxiety and self-efficacy), previous experience of (severe) hypoglycaemia and social environment (see Polonsky et al. 1992; Shiu and Wong 2000). Even though it is not clear how many people with diabetes experience fear of hypoglycaemia, the literature suggests that where fears and worries about hypoglycaemia are present, they should be addressed by the diabetes care provider in the context of designing treatment options (Shiu and Wong 2002; Funnell and Anderson 2004).

#### **3.3.4.2 Balancing risk**

14 papers examined this theme (7 quantitative studies, 2 qualitative studies, 3 reviews, 1 case study and 1 opinion piece)
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With the exception of one qualitative study (Shiu and Wong 2002), which received a very good quality score, the remainder of the included papers discussing this theme received an average quality score (see table 3.2).

As a chronic condition, diabetes requires constant balancing and prioritising of medications, food intake, physical activities, and monitoring of blood glucose values. Many people living with diabetes feel caught in between the risk of hypoglycaemia and hyperglycaemia (high blood glucose levels), as well as potential long-term complications (Shiu and Wong 2002). When it comes to balancing these risks, there is

a tendency that immediate effects (e.g. hypoglycaemic episodes) are more salient for people living with diabetes.

Wild et al. (2007) review of research on fear of hypoglycaemia confirms that for people living with diabetes the immediate effects of hypoglycaemia are often more important than longer term effects when trying to balance risks. This may lead to a higher priority of avoiding hypoglycaemia by keeping a higher blood glucose level. This does not seem surprising; given the huge impact hypoglycaemia can have on people's lives, and also the range of negative emotions associated with hypoglycaemia, including feelings of losing control, anger and anxiety (Green et al. 2000; Everett 2001). Unfortunately, this behaviour comes at the cost of worse glycaemic control and risk of potential long-term complications later in life (Richmond 1996).

Overall, several factors influence how people balance risk. For example, risk avoidance behaviour can be linked to previous negative experience of hypoglycaemic episodes (Shiu and Wong 2000; Di Battista 2009). This does not just refer to individual experience and physical symptoms of hypoglycaemia, but also the perceived reaction of people present during hypoglycaemic episodes. There is a perceived stigma and embarrassment associated with a diagnosis of diabetes, and having hypoglycaemia is often considered as being incompetent in the self-management of diabetes, especially when in a public place (Rajaram 1997). Richmond (1996) illustrated this with the following quote from one of her study participants: "I can't do exactly what I want. I feel trapped and people blame me for not getting it right" (p.1684).

The research exemplified the need for people experiencing hypoglycaemia to balance risks. On the one hand, they need to manage their diabetes and hypoglycaemic

episodes when they occur, while on the other hand they also have to consider their 'public image', (interaction with society/people around them). The possible impact of hypoglycaemia on people's identities and interaction with society is discussed in the next section.

### **3.3.4.3 Impact on identity**

4 papers examined this theme (2 qualitative studies, 1 review and 1 opinion piece)
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The theme 'impact on identity' was mentioned by only four papers, which were published either in the UK (Crace 1991; Gold et al. 1997) or in the USA (Rajaram 1997; Ritholz and Jacobson 1998). The two qualitative studies were rated as good (Rajaram 1997) and average (Ritholz and Jacobson 1998), while the review (Gold et al. 1997) was rated as poor quality.

Diabetes is an invisible illness. Unless an obvious complication is present or a (hypoglycaemic) emergency arises, other people would not know whether someone has been diagnosed with diabetes (Peel et al. 2004). This dilemma is further exacerbated by a perceived stigma and embarrassment to openly communicate about diabetes and the risk of hypoglycaemia (Rajaram 1997).

A study conducted by Ritholz and Jacobson (1998) found that people feel different from their normal self when experiencing hypoglycaemia. One of their study participants is quoted as follows: "I think one thing that sort of bothers me about it [hypoglycaemia] is just how stupid I can feel, and it's like losing a major part of your person" (p.801). There is a sense that some people with diabetes are worried about being defined by their illness.

Another dimension is added by Costea et al. (1993), who introduced the concept of “post-hypoglycaemic syndrome”. They claimed that even after a hypoglycaemic episode has been treated, feelings of depersonalisation and depression can remain for up to a couple of days. This illustrates that hypoglycaemia can also affect the identity and sense of self of the person experiencing it, (see section 4.8).

#### **3.3.4.4 Loss of control**

9 papers examined this theme (2 quantitative studies, 4 qualitative studies, 1 review, 1 case study and 1 opinion piece)
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The quality of included papers within the ‘loss of control’ theme varied. For example, half of the qualitative studies (n=2) were rated as very good (Rajaram 1997; Shiu and Wong 2002), while the other two qualitative studies as well as the two quantitative studies received an average quality score (Costea et al. 1993; Richmond 1996; Ritholz and Jacobson 1998; Nordfeldt and Ludvigsson 2005). The review (Frier 2008) received a poor quality score.

One major challenge of hypoglycaemia is its unpredictability. Hypoglycaemia often happens suddenly and unexpectedly. People with diabetes can find themselves in a risky situation, where they either need to take action or depend on someone else to take control (Rajaram 1997). A case study by Luthra and Donaldson (1997) describes the experience of a severe nocturnal hypoglycaemic episode of a man with type 1 diabetes. It confirms the finding that hypoglycaemic episodes are frightening and distressing for the individuals involved, especially when it occurs suddenly without any prior warning signs.

Caroline Crace, who is living with type 1 diabetes, published an opinion paper elucidating her individual experiences of hypoglycaemia (1991). She explains that hypoglycaemia can have a considerable effect on diabetes self-management and confidence levels, as she may feel exhausted and low following a hypoglycaemic episode.

In a review of the literature about how hypoglycaemia can impact on the everyday life of people with diabetes, Frier (2008) describes a range of areas hypoglycaemia can affect: from driving/travelling, to employment, personal relationships and leisure activities/exercise. Moreover, one theme overarches all these aspects, the feeling of 'powerlessness' when hypoglycaemia occurs. This is particularly true for episodes of severe hypoglycaemia, which can cause major disruption (Frier 2008).

#### **3.3.4.5 Impact on quality of life**

6 papers examined this theme (4 quantitative studies, 1 qualitative study and 1 review)
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The quality of included papers within the 'impact on quality of life' theme was generally average, with two quantitative studies rated as very good (Currie et al. 2006; Tierney et al. 2008). Interestingly, all the papers that examined this theme had been conducted in the UK (with the exception of Di Battista et al. (2009), who carried out their study in the USA and Canada). The impact diabetes and hypoglycaemia can have on quality of life has mostly been investigated using a quantitative approach. This review identified only one qualitative study that did mention the impact on quality of life (Richmond 1996).

The literature has emphasised negative impacts of hypoglycaemia on people's quality of life. For example, Richmond (1996) noted that worrying about possible hypoglycaemic episodes and avoiding social and physical activities for fear of embarrassment and loss of control all contribute to reduce quality of life among people with diabetes. People's situation is further worsened as a result of demands by healthcare providers for tight control of blood glucose levels, which may lead to an increased risk of hypoglycaemia (Diebel 1999). While a near-normal blood glucose level minimises the risk of long-term complications, a higher risk of hypoglycaemia can have potentially devastating impact on the person's everyday life. Furthermore, using optimal glycaemic control as the only indicator to measure good self-management practices may overlook the impact of diabetes treatment regimen on emotional well-being and quality of life (Shiu and Wong 2002; Debono and Cachia 2007).

Davis et al. (2005) carried out a postal survey in the United Kingdom to investigate the impact of hypoglycaemia on quality of life, primary care resource use and productivity. They found a direct correlation between increase in frequency and severity of hypoglycaemia and a reduction in quality of life and productivity. Additionally, primary care resource use increased with more severe cases of hypoglycaemia. While this study had some limitations in terms of a low response rate and timeframe (hypoglycaemic episodes over a period of three months), it gave an indication of the huge impact hypoglycaemia can have on people with diabetes. In conclusion, the authors recommended that every effort should be geared towards achieving good glycaemic control, reducing the risk of hypoglycaemia and addressing the impact treatment has on people's quality of life.

Another study which was conducted by Richmond (1996) explored the effects hypoglycaemia has on young people aged 16-30 years. Richmond described that people may find themselves in a 'Catch-22' (no-win) situation. That is, they either face an increased risk of hypoglycaemia by aiming at a tight blood glucose control, or they intentionally run higher blood glucose levels to avoid hypoglycaemia, which also carries with it the potential for future complications. According to Richmond (1996), people with diabetes constantly need to take action to manage their condition. They need to balance the risk of complications, decide whether to adhere to the prescribed treatment and weigh possible implications this decision has on their well-being and quality of everyday life.

### **3.3.5 Summary**

Many people with diabetes have experienced a hypoglycaemic emergency since they were diagnosed (Shiu and Wong 2000). There is evidence that fear of hypoglycaemia, including nocturnal hypoglycaemia, increases with more severe and more frequent episodes of hypoglycaemia (Shiu and Wong 2000; Currie et al. 2006). Given the unpleasant symptoms of hypoglycaemia, it is not surprising that some people reveal a tendency towards avoidance of hypoglycaemia by decreasing their treatment adherence and intentionally keeping blood glucose levels high (Shiu and Wong 2000; Wild et al. 2007).

As highlighted in the summary of the initial review (see section 3.2.4), people with diabetes face the challenge of living with an invisible condition. This includes the reluctance of people to discuss their diabetes whenever in a social situation (Mulvaney et al. 2008), due to perceived social stigma (Utz et al. 2006). Thus, there could be a

danger that people feel socially excluded. However, hypoglycaemic emergencies make diabetes publicly visible as they require the assistance of another person. In such a situation, the individual does not have a choice of whether to disclose their condition to people around. Rajaram (1997) conclude that “chronic illness is seldom a personal matter; the experience of the illness is shaped and transformed by the ill person’s interactions with others” (p.287).

Overall, experiencing hypoglycaemia impacts the entirety of people’ lives. This includes impact on quality of life, relationships, psychological and physiological well-being (Puavilai and Stuijbergen 2000). It also includes the problem of balancing risks of hypoglycaemia and hyperglycaemia, as well as managing various challenges of diabetes self-management (Wild et al. 2007). Some people with diabetes have expressed how hypoglycaemia affects their sense of self and causes fear of being defined by their diabetes (Ritholz and Jacobson 1998). All these challenges emphasise the intricacies of managing hypoglycaemic episodes and illustrate the challenges of successful diabetes self-care.

Hypoglycaemia can have a devastating impact on everyday life. Therefore, a range of negative emotions are associated with hypoglycaemia, including feelings of losing control, anger and anxiety (Green et al. 2000). Even the thought of hypoglycaemia, as well as its actual occurrence can interfere with people’s independence and could trigger feelings of powerlessness. There is evidence that many people alter their treatment to avoid having a hypoglycaemic episode (Shiu and Wong 2000). Whilst avoiding the unpleasantness of a hypoglycaemic episode, such behaviour is likely to

compromise future quality of life due to the increased risk of long-term complications as a result of worse glycaemic control (Nordfeldt and Ludvigsson 2005).

The impact of hypoglycaemia can be perceived in two ways: first, the actual hypoglycaemic episode with its physiological implications and impending threat to health and second, fears and worries about hypoglycaemia (see Nafees et al. 2006). The latter might even manifest itself with symptoms like anxiousness and avoidance behaviour, e.g. intentionally keeping a higher blood glucose level to avoid hypoglycaemia (Wild et al. 2007; Patton et al. 2008).

More importantly, fears and worries about hypoglycaemia possibly affect the individual for a longer period of time than those particular instances during which hypoglycaemic episodes occur. Additionally, fears and worries about hypoglycaemia can pose a major barrier to achievement: they might even lead to avoidance of some social situations and life opportunities (Richmond 1996).

Frier (2008) suggests that hypoglycaemia can impact on many aspects of life; including travel, driving, physical activities, working life and relationships. However, it is unclear whether Frier's review reflects the perspective of people living with diabetes. There is a lack of information on the research upon which these conclusions are reached and the selection of included research studies.

### **3.3.6 Rationale for this study**

To date, diabetes research has paid little attention to people's experiences of hypoglycaemia. Although hypoglycaemia has been mentioned in the literature in the context of diabetes complications, there are few studies that focus on people's

experiences of hypoglycaemia in particular. Much of the research about hypoglycaemia has used a quantitative approach, and clusters around 'fear of hypoglycaemia' and its impact on diabetes self-management (e.g. Shiu and Wong 2000; Leiter et al. 2005; Currie et al. 2006; Belendez and Hernandez-Mijares 2009; Anderbro et al. 2010).

The review looking at people's experiences of living with hypoglycaemia has identified only four studies using qualitative methods, with three of them being carried out in the nineties (Richmond 1996; Rajaram 1997; Ritholz and Jacobson 1998). This means that findings could be out of date with changes in treatment (e.g. different types of insulins) and diabetes management approaches. Only one of the qualitative studies was conducted in the UK (England; Richmond 1996). Studies which are not conducted in the United Kingdom may have limited relevance to the UK system. This suggests that there is a lack of recent, qualitative studies investigating people's experiences of living with hypoglycaemia. In terms of the Scottish context, the literature searched to date has been unable to locate any qualitative studies that have looked at people's experiences of living with hypoglycaemia. It is therefore not possible to use current literature to explain differences relating to self-care processes that lead some people with diabetes to rely more on emergency services than others.

There is some evidence in the literature that hypoglycaemia has potentially far reaching consequences for individuals with diabetes (Richmond 1996; Currie et al. 2006; Wild et al. 2007). For example, impact on social life, future expectations (Frier 2007b), driving, ability to perform 'normal' everyday activities (Frier 2004), psychological well-being (Everett 2001) and even diabetes care (Nafees et al. 2006).

However, the consequences and impact of living with hypoglycaemia have not been sufficiently investigated. In particular, the studies completed to date have focussed mainly on fear of hypoglycaemia as if this is a universal experience, and have been exclusively cross-sectional in design. This study explores the perspective of people living with diabetes and hypoglycaemia.

None of the studies included in the review used a longitudinal approach, which suggests a gap in the literature exploring the impact of hypoglycaemia and how this might change over time or in relation to different episodes. As hypoglycaemia is a complication related to a long-term condition, it may be that people's experiences change over time.

On average, mild hypoglycaemia occurs about twice a week, while cases for severe hypoglycaemia range between one and two incidents per individual annually (Frier 2008). However, some people living with diabetes experience hypoglycaemic episodes much more often, depending on circumstances and risk factors (e.g. strict glycaemic control, history of hypoglycaemia, physical exercise; Heller 2008). Many people manage hypoglycaemic episodes independently, though some need external support. A proportion of this support is delivered by the Scottish Ambulance Service (SAS). Each year, about 7000 calls relating to diabetes are made to the SAS, which includes a considerable number of repeat callers (The Scottish Government 2010).

The Scottish Government published the 'Diabetes Action Plan' in 2010, which states "reducing diabetes emergencies" as one of its targets (p.44). The Diabetes Action Plan also indicates that the SAS aims to reduce episodes of repeat severe hypoglycaemia. Understanding the underlying reasons and people's experiences of hypoglycaemic

episodes would help to address the problem of recurrent hypoglycaemia as well as designing appropriate policy responses. Therefore, it is important to investigate why some people repeatedly rely on emergency services in response to hypoglycaemia (SAS participants) and others appear to self-manage or engage the help and support of others (non-SAS participants; also see section 2.10.1). This may help offer insights into how the management of hypoglycaemic episodes or their impact can be better supported (by healthcare professionals or others) to enable better self-care practices.

Given the findings of the review and the quality of existing research, there was a need for good quality research to investigate people's experiences of hypoglycaemia within their overall experience of diabetes. This study explored the perspectives of people living with diabetes to address: participants' experiences of hypoglycaemic episodes; including the experience of hypoglycaemic emergencies (i.e. when an ambulance is called to attend a person experiencing a hypoglycaemic episode). It investigated participants' perspectives regarding why hypoglycaemic episodes occur, how they are avoided and how they are managed over time. In this context, it was important to establish reasons why participants made use of emergency services, and also why some people did not. Therefore, this study adopted a sample that allowed for comparison of two groups of people with diabetes: those who had recently used emergency services to manage a hypoglycaemic episode (Scottish Ambulance Service (SAS) participants), and a group of people primarily recruited via Diabetes UK who self-identified as not having recently used the SAS.

This study used a longitudinal approach to explore participants' perspectives and experiences of recurrent hypoglycaemia over time. It employed a multiple methods

approach, with qualitative semi-structured interviews forming the basis of the investigation, and quantitative data being collected on participants' daily blood glucose readings and recording of hypoglycaemic episodes to capture episodes and understand how participants' responses to low blood glucose levels may vary. This approach helped to explore participants' experiences of living with diabetes and hypoglycaemia, thus giving an insight into people's life worlds (Hawkes et al. 2009). It also helped understand people's individual explanations for hypoglycaemic episodes as they happened, and their coping strategies, as well as how hypoglycaemic episodes affected their everyday life.

The research questions for this study were:

1. What are the experiences of recurrent hypoglycaemia of those who were emergency service users (SAS participants) and those who were not (non-SAS participants)?
  - a) How does hypoglycaemia affect participants' everyday life?
  - b) What is the impact of hypoglycaemia on participants' family and wider social network?
2. What are participants' explanations for having recurrent hypoglycaemia?
  - a) What coping strategies do participants adopt to deal with recurrent hypoglycaemia?
  - b) How (if at all) does recurrent hypoglycaemia influence diabetes self-management behaviours?

3. Are there any changes over time in relation to experience, possible explanations and management of recurrent hypoglycaemia? What influences these? Are there any differences between participant's various hypoglycaemic episodes (within case)?
4. Are there any similarities or differences between SAS participants and non-SAS participants?
  - a) Are the SAS group having more severe hypoglycaemic episodes than those who do not use emergency services?

### **3.4 Conclusion**

Diabetes is a chronic condition, and its care is an on-going process. This chapter has provided a review of existing literature investigating people's experiences and perspectives of living with diabetes and hypoglycaemia. The literature was reviewed in two parts, covering experience of living with diabetes, as well as hypoglycaemia.

Key themes from the first review showed that a substantial part of the burden of managing diabetes is borne by the people living with it; and that they face multiple challenges in trying to navigate their everyday life. Sometimes treatment goals between health professionals and patients can conflict.

The second review emphasised the impact of hypoglycaemia on the everyday life of people living with diabetes, their quality of life, as well as issues around fear of hypoglycaemia, impact on identity and loss of control. The final sections discussed the review and concluded that there was a lack of research investigating people's experiences of hypoglycaemic episodes, especially in the context of use/non-use of

emergency services. This then provided a rationale for the current study undertaken as part of this PhD.

## **Chapter 4 - Theoretical perspectives within illness experience**

### **4.1 Introduction**

This study is a piece of applied health research which has been informed by a number of sociological theories. According to Fathalla (2004), applied health research “has potential to improve health or quality of life” (p.27). This chapter discusses some sociological theories that could apply to this field of research. It highlights theories of illness experience, help-seeking and self-care, and discusses their potential relevance to this study. These theoretical perspectives are considered in relation to study findings in the final discussion chapter.

### **4.2 The role of theory**

Theories of illness experience are concerned with how people interpret the social and psychological aspects of living with chronic illness. They contribute to a better understanding of health, help-seeking, and healthcare provision. Freund et al. (2003) state that the “interpretation of illness is an on-going process. People reinterpret their situation at various stages of their illness. They look back at earlier experiences and actions and reinterpret them to make sense of subsequent events and new beliefs” (p.173). This thesis focusses on the social aspects of illness experience.

The role of theory in health research has been well documented (Alderson 1998; Brazil et. al 2005; Reeves et al. 2008; Kelly 2010). For example, Reeves et al. (2008) have suggested that using theories may “propose explanations of the underlying causes or influences of observed phenomena” (p.633). Therefore, in health research theory can help explain why a phenomenon happens and in interpreting data. This section

highlights a number of theories that are potentially useful for the interpretation of the study data. There is first a mention of biomedical and sociological models of health, given the nature of diabetes.

### **4.3 Biomedical versus sociological model**

Illness can be viewed and defined from various perspectives, for example, biomedical and sociological. Between these two, the biomedical model has been the more dominant model of health and illness in western medicine (Freund et al. 2003).

The foundation of the biomedical model is the belief that illness is confined to the body; that is, illness is understood as the presence of biological abnormality. Medical interventions and treatments are tools to halt or reverse the disease process (Armstrong 2000; Taylor 2007). The health of society is considered to be largely dependent on medical knowledge and medical resources, due to the narrow focus of the biomedical model (Freund et al. 2003).

Helman (2007) suggests that to some extent, modern medicine has adopted a reductionist approach, moving beyond the individual, and concentrating only on specific 'diseased' parts of the body. This has resulted in many medical doctors specialising in a small area of medicine. Even though this reductionist approach has been useful in advancing medical knowledge, Freund et al. (2003) noted that it could miss out on the wider dimensions affecting people's health status.

Medical advancements have been remarkable, helping to achieve greater accuracy of diagnosis, as well as finding causes and targeting cures for diseases. However, a major limitation of the biomedical model is its exclusive focus on the physical body, ignoring

the social, emotional, cultural and psychological dimensions of ill health (Helman 2007).

In contrast to the biomedical model, the sociological model emphasises the environmental, social and economic causes of and/or 'construction' of illness. In terms of terminology, the sociological model uses 'illness' rather than 'disease', signalling wider implications, including people's perspectives and interpretations of illness (Helman 2007).

The sociological model underlines prevention, health promotion and the social construction of health and illness, rather than relying on medical treatment (Freund et al. 2003). It considers where the prevention or halting/reversing of illness might be at a societal level by looking at structural issues, as well as the individual level (Taylor 2007).

As highlighted above, the biomedical model has been dominant in modern medicine. This may have some implications for this study, for example, participants may be used to focussing on physical symptoms, and placing more emphasis on how they feel physically in relation to their diabetes and experiences of hypoglycaemic episodes. However, the biomedical world or 'illness' is only one part of people's daily life and may not dominate.

#### **4.4 The sick role**

Parsons' sick role theory is one of the most influential sociological theories of illness experience. Since its introduction in 1951, it has yielded volumes of research (see Freidson 1960; Twaddle 1973; Hahn 2001). The sick role theory defines illness

behaviour as a social role that disrupts normal, everyday life. Parsons views the sick role as temporary and deviant behaviour that is medically sanctioned (Cockerham 2000). The sick person is exempt from normal social roles and everyday responsibilities during the period of illness. However, the legitimisation of being exempt from usual duties brings with it the expectation to view sickness as undesirable and to seek help.

Further key characteristics of Parsons' sick role theory include the assumption that patients are not responsible for their illness and that they are motivated to get well (Young 2004). According to Parsons (1951) the 'help' would generally be in the form of professional medical help, and the patient would be compliant with the advice given.

Despite the influence of Parsons' sick role theory over the years, it has continued to divide academic opinions as well as receive criticism. One critic of Parsons' work is Freidson (1960), who argues that Parsons overemphasised the consensus between the patient and the health professional. He points out that potential discrepancies between professional beliefs and lay perceptions could lead to conflicts between patients and professionals. Freidson (1960) introduces the 'lay referral system', that is a network of "potential consultants, from the intimate and informal confines of the nuclear family through successively more select, distant, and authoritative laymen, until the 'professional' is reached" (p.377).

Further criticisms of Parsons sick role theory are in the works of Twaddle (1973) and Hahn (2001). Twaddle's main criticism relates to the assumption that illness is viewed as deviant, while Hahn (2001) was concerned about the challenges arising in the doctor- patient relationship, and the part symptoms play in confirming the sick role.

More recently, Rier (2010) has highlighted a few grey areas of the sick role theory, e.g. when there is no official diagnosis (yet); or when the patient has an illness/symptoms that are not accepted by either the health professional or people around.

Another major criticism relates to the applicability of Parson's theory to long-term or chronic illness, given that the theory is based on acute, short-term illness (Taylor 2007). Where someone is suffering from a long-term illness, the notion to get well and 'leave' the sick role is difficult to achieve (Cockerham 2000). Parsons recognised this and modified his theory in 1975 to accommodate chronic illness, and the 'getting well' component of his original conceptualisation was considered equivalent to managing the chronic illness/following medical advice (Parsons 1975).

The sick role theory views the patient as a passive recipient of care, rather than active participant, lacking autonomy. This passivity of the patient in the sick role theory limits its relevance to this study, as patients living with a chronic illness such as diabetes tend to play an active role in the management of their illness.

#### **4.5 Suchman's illness experience model**

Suchman's illness experience model is another sociological model that has been used in health research (Suchman 1965b; Andersen and Aday 1978; Pescosolido 1992; Cockerham 1995; Young 2004). It explains the different stages of illness experience, starting with symptom experience, response to symptoms, using self-care and lay advice to alleviate symptoms, through to interactions between the patient and health professional (Young 2004). In his model, Suchman (1965a) shows that in addition to physiological factors, cultural and social aspects play key roles in determining how

individuals respond to illness, and whether they seek medical help or not. Building on Parsons' sick role theory, it goes further to explain delays in seeking medical care, highlights issues around self-care and lay referral, and interruptions of care (Young 2004).

According to Suchman (1965a), there are five stages of illness experience:

- The first stage is symptom experience, where the patient recognises that something is wrong. If the symptoms are interpreted as indication of an illness, the patient assumes the sick role.
- In the second stage, and within their sick role, patients seek symptom alleviation by consulting their social network for lay advice or by applying self-care/self-medication.
- When professional medical care is being sought, the person has moved to the third stage. At this stage, legitimisation for the sick role is being sought.
- The fourth stage is acceptance of professional treatment and thereby assuming a dependent-patient role.
- Finally the recovery and rehabilitation stage, which includes a return to normal function (Suchman 1965a; Cockerham 1995).

At each stage of this experience, a decision has to be made, which determines either the continuation or interruption of the process. Suchman's model is useful in understanding the "relationship between severity of symptoms, seriousness of symptoms, and degree of incapacitation with the level of concern and physician

contact; the greater the severity, seriousness, and incapacitation, the greater the level of contact with the physician” (Young 2004:12).

Since the original work (Suchman 1965a), Suchman’s model has been widely applied. For example, in his survey study of social patterns of illness and medical care, Suchman (1965b) used his own model to investigate social group influences on individual medical responses within a multi-ethnic background. He found that an individual’s medical orientation can be highly influenced by the social organisation within which that individual associates. Some other works that have used and/or discussed Suchman’s illness experience model include: analysis of the influence of culture/ethnicity on symptom recognition and interpretation (Zola 1966), a critical re-examination of Suchman’s model (Geertsen et al. 1975), benefits of self-help groups in the context of chronic illness (Trojan 1989) and social dimensions of help-seeking (Pescosolido 1992).

Limitations of Suchman’s model are similar to those of Parsons’ sick role theory, even though Suchman’s model includes lay referral through people’s social network as well as self-care activities to treat symptoms (Young 2004). A key criticism relates to the fact that Suchman’s model is limited to the microsociological level, and does not consider environmental factors, population characteristics and the influence of healthcare institutions (Andersen and Aday 1978).

Geertsen et al. (1975) re-analysed Suchman’s original data and compared it to new data. They concluded that Suchman did not include a number of aspects that may impact on the illness experience, e.g. cultural, structural and socio-economic aspects, as well as individual lifestyle characteristics.

## 4.6 Help-seeking theory

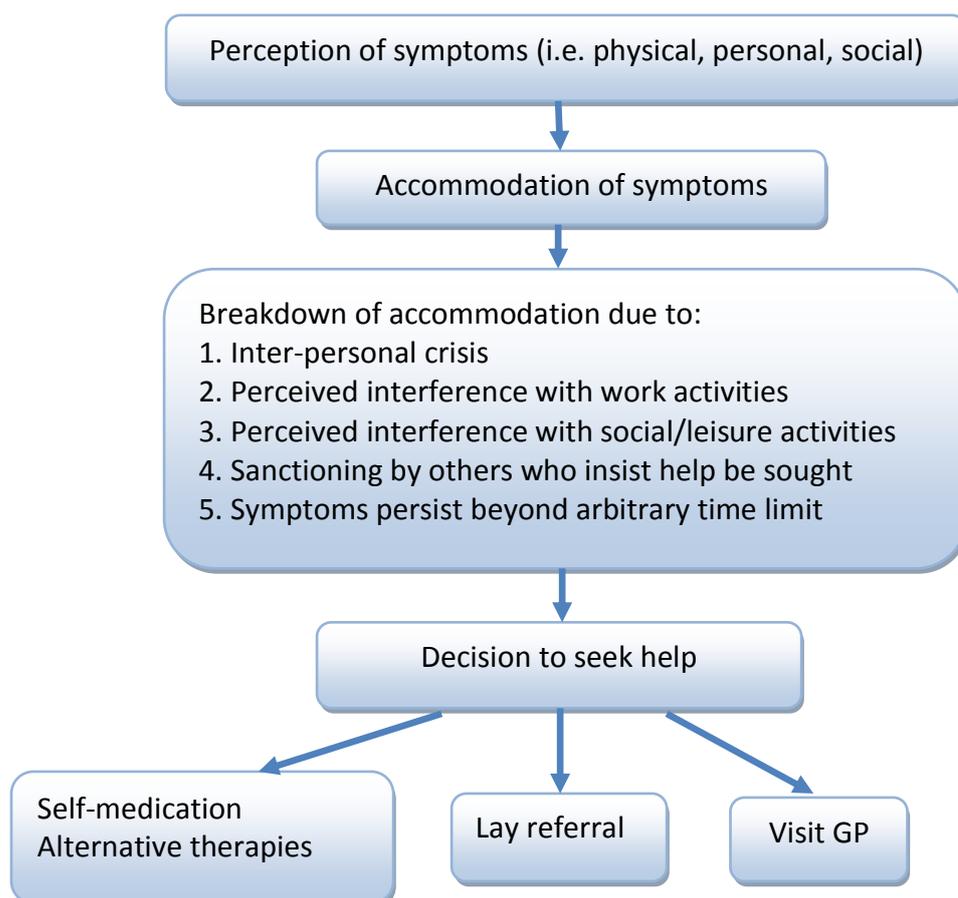
Another theory that might be relevant for this study is Mechanic's general theory of help-seeking (Mechanic 1966; Mechanic 1968; Mechanic 1995). Mechanic posits that illness behaviour is based on perception, recognition and interpretation of symptoms. That is, people's response to symptoms can vary enormously. Mechanic (1995) claims that patients are more likely to seek medical help when symptoms interfere with their ability to carry out everyday activities. He adds that stress is also a factor that can trigger help-seeking. In explaining variations in patients' responses to symptoms, Mechanic (1995) suggests that individual's attitude, coping, use of medical care and social functioning are hugely dependent on perception of their health status.

Mechanic further suggests that illness behaviour results from interaction of cultural assumptions, socially conditioned responses, and individual psychological factors (see Mechanic 1995; also Cockerham 1995). This interplay is illustrated in a study by Verbrugge and Ascione (1987), who used health diaries to investigate people's responses to symptoms. The study found that professional medical care was only sought on five percent of days on which participants experienced symptoms. The authors conclude that "for most symptoms of daily life, people opt to do something on their own without medical help" (Verbrugge and Ascione 1987:549).

On an everyday basis, people have to make a decision as to whether to treat themselves, consult family or friends – what Zola (1973) terms 'lay referral', or to seek medical help. In this context, the challenge is to interpret symptoms adequately; that is, to seek medical help where symptoms are serious and medically treatable, and not to bother medical professionals with unimportant ailments (Freund et al. 2003). This

highlights that help-seeking theory places more importance on patients' agency and autonomy.

Zola (1973) agrees with Mechanic that patients interpret symptoms variably, and that social factors play a major role in patients' decision to seek medical help. Zola has devised a 'help-seeking model' (see below) that highlights five different 'triggers' or crises that can prompt patients to seek medical help.



**Figure 4.1: Zola's Help-Seeking Model (1973)**

According to this model, the first trigger is the occurrence of an inter-personal crisis, for example, losing a job or going through family breakdown. For Zola (1973) this can cause a person to consider their symptoms in a different light. Further prompts are the

perceived interference with work and social activities. For example, a painful back might prevent someone from taking part in social activities or might result in the person feeling unable to carry out daily work properly.

Another trigger relates to 'sanctioning', which means that another person either legitimises the need to, or even insists on seeking medical help. Finally, if symptoms persist beyond an arbitrary time limit set by the individual, a decision to seek help might be facilitated.

Interestingly, the decision to seek help does not necessarily lead to a visit to the GP; patients can also rely on what is termed a 'lay referral' system; that is other people around them including family and friends. In times of increasing availability of medical information, people also tend to engage in 'self-medication'. For example, researching their symptoms on the internet and getting hold of drug treatments over the counter (Crimson 2007). Nettleton (2006) sums this up with the following words: "Seeking help is an on-going social process, rather than a straightforward response to physical symptoms" (p.77).

#### **4.7 Labelling theory**

Having an illness can often be stigmatising. Goffmann's work (1968) has been fundamental in the context of stigma. His work is based on the assumptions of symbolic interactionism, that is, people act based on their interpretations of social situations, which takes place in the context of social interactions (Mead 1967).

Goffmann describes stigma as reactions resulting from the discrepancy between people's 'virtual social identity' (the way people should be if they did not have an

illness) and their 'actual social identity' (the way people are with an illness), referring to this as 'spoiled identity'. If people's illness or disability is visible, they are more likely to experience stigmatised reactions from others. This actual experience of being stigmatised is also known as 'enacted stigma' (Taylor 2007).

In contrast, a different form of stigma, called 'felt stigma', considers people's fear of being stigmatised. The distinction between enacted and felt stigma has been particularly coined by Scambler and Hopkins (1986), who conducted a study into the impact of epilepsy on patients' lives, with a specific focus on stigmatising experiences. Interestingly, they found that felt stigma was much more disruptive to people's lives than enacted stigma (Scambler and Hopkins 1986).

The concept of legitimacy as discussed by Freidson links in well with labelling theory. He claims that there are three categories of legitimacy: conditional legitimacy, unconditional legitimacy and illegitimacy (Cockerham 1995). The difference between conditional and unconditional legitimacy is that the exemption from usual obligations is temporary or permanent, respectively. In contrast, illegitimacy frees individuals from some of their duties on a permanent basis, but this may come at a cost of stigmatisation (Freidson 1970). This is often the case with chronic illness.

In the case of diabetes, illegitimacy could mean that people with diabetes may be expected to perform less well or take more time off work due to diabetes (complications), compared to people who do not have diabetes. According to Cockerham (1995), how people with a particular condition are viewed depends on the context and attitude of people around them (i.e. the concept of legitimacy is relative).

A major criticism of labelling theory is based on its limitation in relation to an explanatory stance. Labelling theory does not explain the reasons for illegitimacy; rather it focusses on the social reaction to it (Cockerham 2000). Another limitation of labelling theory relates to its variability/relativity as to what and who gets stigmatised. This depends on the societal, cultural and historic context (Young 2004).

#### **4.8 Biographical disruption**

Bury (1982) introduced the concept of 'biographical disruption', following a study with rheumatoid arthritis patients. His investigations focussed on the early stages of diagnosis and adjusting to the chronic illness. Bury claims that chronic illness disrupts everyday life in three ways:

First, chronic illness interferes with everyday activities, it disorganises behaviours and routines that have been taken for granted. This impact on everyday life includes uncertainty in the face of fluctuating and unpredictable symptoms.

Second, the disruption extends to people's explanatory systems, which prompts a re-thinking of identity and self-concept. Bury illustrates this point using the example of young women who were diagnosed with rheumatoid arthritis. Since this condition was perceived as an illness of 'aging' or older people, a diagnosis of rheumatoid arthritis for people in their twenties or thirties was upsetting in relation to their perceived 'normal trajectory' (Bury 1982).

The third point is concerned with people's response to the disruption and the way they adjust to changing circumstances. This includes how people identify and use

resources (e.g. social network) as well as how they deal with the risk of social isolation and dependency (Bury 1982).

There have been a number of criticisms of Bury's concept of biographical disruption relating to timing/age and context of a chronic illness (Lawton 2009). Bury (1982) based his concept on findings that highlight the impact of chronic illness on a relatively healthy population (young women). However, the relevance of his concept is limited in older populations who may already have multiple health problems, and therefore may not perceive the onset of a new illness as biographically disruptive; instead, it may have been anticipated due to older age (Pound et al. 1998).

Williams (2000) has published a paper reviewing Bury's work. He pointed out that it is important to take the broader historical, social and political context into consideration when assessing the usefulness and relevance of the concept of 'biographical disruption'. The criticisms levied against the biographical disruption concept highlight one major flaw of the concept: it is based on the assumption that a life has been free from illness and any other complexities when chronic illness occurs (Lawton 2009).

#### **4.9 Loss of self**

Charmaz (1983) looked at the 'loss of self' as a key feature in the management of chronic illness. Her study was based on data from a qualitative study that included 57 chronically ill people. The 'loss of self' happened as a result of four dilemmas that people who have a chronic illness may face: the first dilemma was living a 'restricted life'. The restrictions could either be a direct result of accommodating the chronic illness, or self-imposed in order to avoid embarrassment. Following these restrictions,

the second dilemma of social isolation may occur. For example, as people socialise less due to fear of embarrassment or unpredictability of symptoms, they risk becoming more isolated (Charmaz 1983).

The third dilemma refers to 'being discredited'. This is directly linked to people's identity and sense of self, and takes place in the context of interaction with others. How people around view and act towards the person with a chronic illness has a direct impact on the person's sense of self. The extent of the discrediting depends on the individual's perception in terms of magnitude, who the gesture is coming from, and the specific situation.

Interestingly, the discrediting or stigmatising includes those people with 'invisible' impairments like diabetes, resulting in decreased participation in the normal world (Charmaz 1983). Similarly, Field and Kelly (2007) argue that a chronic illness will always impact on a person's identity, independent of whether or not others know about it, as it requires actions to manage the illness.

Taylor (2007) supports this view as he points out the impact chronic illness can have on people's identities: it can change people's sense of self or self-image. Living with a chronic illness can affect people's feelings of control over their lives as well as their sense of autonomy. Taylor shows that illness is not only an attack on the integrity of the body, but also on people's identities. He states: "The sick person's place in the world and sense of who they are can become compromised or even lost" (Taylor 2007:39).

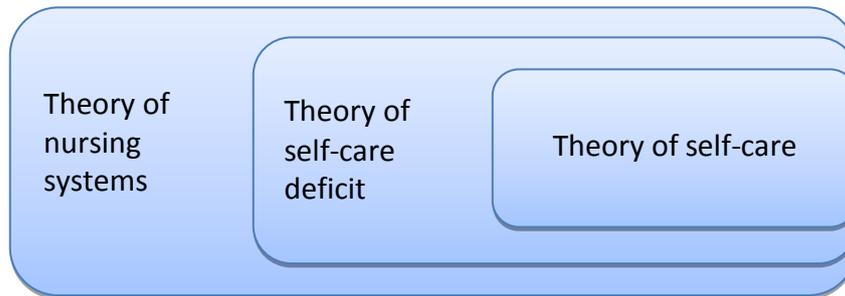
A final point Charmaz raises is that of 'being a burden' to others. This links in well with the 'loss of control' theme from the diabetes literature (e.g. Rajaram 1997). As people with a chronic illness lose their independence, they rely on others to support them (e.g. social network, healthcare system). Again, the feeling of 'becoming a burden' has an effect on the person's sense of self, potentially limiting the role/s the person can fulfil. All four factors summarised here contribute to the loss of self. This brings with it the need to re-negotiate self-image and identity (Dewar and Lee 2000; Rasmussen et al. 2007).

#### **4.10 Theory of self-care**

Orem developed a theory of self-care, based on her definition of a universal human need for self-care. That is the "need for self-care action and the provision and management of it on a continuous basis in order to sustain life and health, recover from illness or injury, and cope with their effects" (Orem 1959:3). This quote shows that according to Orem, self-care does not just relate to treating illness, but also expands to activities required to maintain life and health.

Orem (1991) defined self-care as "the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health and well-being" (p.117). Every individual has the ability to perform self-care and take responsibility for their health (Masters 2011). Orem maintains that healthy adults would willingly care for themselves, while others such as children, the elderly, sick and disabled people would either require complete care or assistance with self-care activities.

In explaining how and why people care for themselves, Orem has developed a theory of self-care. This comprises of three composite theories: theory of self-care, theory of self-care deficit, and theory of nursing systems (Orem 1991; 1995).

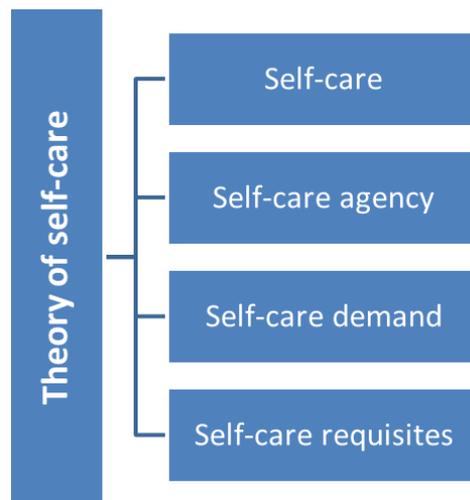


**Figure 4.2: Orem's self-care deficit theory of nursing (adapted from Orem 1995; 2001)**

The theory of self-care outlines the care which an individual requires in order to stay healthy or get better from illness. The theory of self-care deficit goes a step further, explaining when medical care is required, that is, when patients and their family members/carers are not or no longer able to care for the individual. Finally, the theory of nursing systems refers to actions a nurse/medical professional undertakes to help meet a person's self-care needs. It also describes the nurse's responsibilities, roles of the nurse and the patient, as well as the nurse-patient relationship (George 1995).

Given that this study investigated participant's experiences, and not those of health professionals, or interactions between health professionals and patients, the first two composites of Orem's theory (theory of self-care and theory of self-care deficit) may be potentially relevant, and will be further explored.

## *Theory of self-care*



**Figure 4.3: Theory of self-care (adapted from Orem 1991; 1995)**

Orem's theory of self-care includes four main components: self-care, self-care agency, self-care demand and self-care requisites. The purpose of self-care is to achieve human functioning and development. Self-care agency is the ability of the individual to engage in self-care activities (Orem 1991). Self-care demand is the self-care actions needed to meet an individual's self-care requirements, while self-care requisites are actions required to provide self-care (Orem 1991).

According to Orem (1991), there are three categories of self-care requisites, namely: universal, developmental and health deviation. Universal self-care requisites are common to all human beings varying with age, development and environment. They are linked to basic human functioning and well-being. Developmental requisites relate to processes and conditions that occur during various stages of the life cycle, e.g. pregnancy, adverse events, etc. Health deviation self-care requisites are concerned with genetic and constitutional defects, as well as human structural and functional deviations and their treatment (Orem 1991).

### *Theory of self-care deficit*

The theory of self-care deficit is a vital component of Orem's theory as it helps to identify the reason why people require nursing, and also explains when nursing is needed. When patients are not able to meet self-care requisites due to limitations relating to their self-care agency/ability to carry out self-care activities, nursing may become necessary (Orem 2001).

There are a few limitations to Orem's theory of self-care and self-care deficit. Despite widespread use of Orem's theories in nursing practice and research (Zarkowska and Clements 1994; Moore and Pichler 2000; Berbiglia 2002; Taylor 2002), it has been criticised for its use of terminology (Fitzpatrick and Whall 2004). The authors have noted that the multiple terms can be confusing, thus question the clarity of the theory.

Orem's theory is broad and comprehensive, touching important aspects of self-care (George 1995). However, according to Fitzpatrick and Whall (2004), it is not dynamic enough, potentially lacking to explain various levels of need. Despite these limitations, Orem's theory may have some relevance for this study, as it could potentially help explain participants' ability to perform self-care actions and the circumstances under which external help and intervention would be sought or needed.

#### **4.11 Conclusion**

This chapter has introduced some potentially relevant theories from the fields of chronic illness experience and help-seeking behaviour. For example, the biomedical model could be relevant to this study, given its emphasis on the physical body; that is, diabetes as a metabolic disorder that impacts on the functions of a healthy physical

body. Participants may be used to focussing on physical symptoms, and placing more emphasis on how they feel physically in relation to their diabetes and experiences of hypoglycaemic episodes. However, the medical management of illness is only one part of how people understand and cope with illness. The biomedical model tends to be reductionist, and may miss that people experience symptoms differently (Helman 2007).

Various aspects of theories introduced in this chapter may be relevant for this study, for example, the impact diabetes and the experience of hypoglycaemia can have on people's identity and sense of self (Charmaz 1983). Charmaz highlights issues around being discredited or becoming a burden to others. This may be useful to explain the dynamics of seeking external help to treat hypoglycaemic episodes or to carry out diabetes self-care activities.

Further, the concept of biographical disruption (Bury 1982) may be relevant for this study, as it could help to explain how participants respond to hypoglycaemic episodes, and adjust to living with diabetes. However, as highlighted in section 4.7, Bury's concept focussed on the early stages of diagnosis and adjustment, which may limit its relevance to this study. Given that most participants in this study have lived with diabetes for many years, and therefore tend to be 'expert patients', that is, they have some experience of managing their diabetes and are used to hypoglycaemic episodes happening recurrently (Paterson and Thorne 2000).

Help-seeking theory (Mechanic 1968; Mechanic 1995) could be relevant for the analysis and interpretation of data. This study looked at participants' responses to symptoms of hypoglycaemia, as well as the phenomenon of hypoglycaemia

unawareness. In this context, Mechanic's focus on perception, recognition and interpretation of symptoms could be very useful. Help-seeking theory affords more autonomy to the patient and may therefore be helpful for this thesis, since people living with a chronic illness tend to play an active role in the management of their illness, as opposed to being passive recipients of healthcare (Nettleton 2006).

Also, labelling theory may have relevance to this study, in particular issues around the potential for people with diabetes to experience stigma (see section 4.7). Stigma may be an issue for people living with chronic illness. In terms of diabetes, the thought of hypoglycaemic episodes happening in public could cause embarrassment, fear or could lead to increased felt stigma. Labelling theory could therefore help to inform our understanding around the impact diabetes and the experience of hypoglycaemia could have on people's sense of self and identity (Charmaz 1983; Taylor 2007).

Another theoretical framework introduced in this study that could inform analysis and interpretation of findings is Orem's theory of self-care and self-care deficit. It may help to explain participants' ability to perform self-care actions, as well as highlight where people are not able to meet self-care demand and where external help is required. Orem's theory may also help to explain how people with diabetes are required to modify their self-care activities in order to lead a normal life ('maintain life and health') and navigate the complexities of managing a long-term condition (Orem 1991; 1995).

In this context, diabetes self-management may be considered a health deviation self-care requisite. For example, people with diabetes have to carry out a variety of self-care activities (monitor blood glucose level, inject the appropriate amount of insulin at

regular intervals, etc.) to cope with their illness. In any situation when an individual is not able to meet these self-care requirements, external help may be required. This is usually the case when the person experiences a severe hypoglycaemic episode.

This chapter has discussed theories with potential relevance and usefulness to this study. Theory is important in helping to understand why a phenomenon happens and in interpreting data (Kelly 2010). This thesis discusses the study findings in relation to these theoretical explanations (see section 9.3.1).

The next chapter describes the primary research study undertaken for this PhD thesis. This includes a description of the aims and research questions, the study design and methods used. It also highlights challenges of the approaches employed as well as their operationalisation.

## **Chapter 5 - Methods**

### **5.1 Introduction**

The purpose of this research study was to explore participants' perspectives and experiences of recurrent hypoglycaemia over time. The study employed a multiple methods approach, with qualitative semi-structured interviews forming the basis of the investigation. In terms of theoretical positioning, this study is a piece of applied health research which has been informed by a number of sociological theories. For example, this study explored participants' social construction of illness (see Conrad and Barker 2010), and whether they had developed their own understanding of what hypoglycaemia is rather than relying on medical definitions (see section 7.2.4).

This chapter aims to provide a detailed account of the development, design, methods, implementation and analysis of the study. The chapter begins with an overview of study aims and research questions, and gives a rationale for the methodological approach that was selected. It further presents details of the methods used in conducting the research, including sampling strategy, access to participants, recruitment process, ethical considerations, and practicalities around data collection. Finally, the chapter outlines the approach used for analysis of both qualitative and quantitative components, as well as synthesis of data.

### **5.2 Aim of the study**

There was a scarcity of studies that focus on people's experience of hypoglycaemic episodes, as well as a lack of research in this area using a longitudinal approach (see section 3.3.6). Therefore, the overall study aim was to investigate participants'

experiences, possible explanations and management of recurrent hypoglycaemia over time (in the context of chronic illness experience). This was undertaken with two different participant groups: those who had recently used emergency services (SAS participants) and those who had not recently used emergency services (non-SAS participants, primarily recruited through Diabetes UK Scotland).

### **5.3 Research questions**

The research questions were:

1. What are SAS and non-SAS participants' views of experiencing recurrent hypoglycaemia?
  - a) How does hypoglycaemia affect participants' everyday life?
  - b) What is the impact of hypoglycaemia on participants' family and wider social network?
2. What are participants' explanations for having recurrent hypoglycaemia?
  - a) What coping strategies do participants adopt to deal with recurrent hypoglycaemia?
  - b) How (if at all) does recurrent hypoglycaemia influence diabetes self-management behaviours?
3. Are there any changes over time in relation to experience, possible explanations and management of recurrent hypoglycaemia? What influences

these? Are there any differences between participant's various hypoglycaemic episodes (within case)?

4. Are there any similarities or differences between those who were emergency service users (SAS participants) and those who were not (non-SAS participants)?

a) Are the SAS group having more severe hypoglycaemic episodes than those who do not use emergency services?

Addressing the above questions will provide better understanding about the contributing factors to recurrent hypoglycaemia. It will also explore specific explanations for recurrent hypoglycaemia from the participants' perspective, as well as highlight potential ways of reducing the number of emergency call-outs due to hypoglycaemia.

## **5.4 Study design**

### **5.4.1 Multiple methods research**

Multiple methods research, also referred to as mixed methods research, has become increasingly popular within social and health science research (Johnson and Onwuegbuzie 2004; Greene 2007; Creswell et al. 2011). This can be attributed to the advancements in methodology, made possible by the various opportunities for training available to researchers using multiple methods approaches (Brannen 2005a).

According to Tashakkori and Creswell (2007), mixed methods research has been defined as "research in which the investigator collects and analyses data, integrates

the findings, and draws inferences using both qualitative and quantitative approaches and methods in a single study or programme of inquiry” (p.3). It has also been referred to as ‘multi-strategy research’ (Bryman 2001), which entails the application of different research strategies to the investigation of a complex set of research questions (Brannen 2005b).

In terms of terminology, various terms have been used to describe mixed methods research (e.g. multi-method research, combined methods, mixed methods or multiple methods), and there has been some debate over the appropriate definition of each terminology (Gurtler et al.2007; Creswell 2011). Some authors have suggested using the term ‘multiple methods’ rather than ‘mixed methods’ when multiple sources of mainly one type of data (qualitative or quantitative) has been used (Morse and Niehaus 2009).

This study used multiple methods to investigate people’s experiences and individual explanations of recurrent hypoglycaemic episodes. Greene (2007) has considered this approach as “multiple ways of seeing and hearing, multiple ways of making sense of the social world, and multiple standpoints on what is important and to be valued” (p.20). This type of combination and integration of findings also helps to investigate similarities and differences between various aspects of human behaviour (Bernardi et al. 2007).

Additionally, there has also been much debate relating to theoretical perspectives. The debate has largely focussed on the different epistemological and ontological assumptions and paradigms associated with qualitative and quantitative research (Sale et al. 2002). Bryman (2007) argues that qualitative and quantitative research differs in

far more than the use of words or numbers; differences extend to the very foundations of each research approach: its epistemological, ontological and paradigmatic stance.

Quantitative research approaches have traditionally been associated with 'positivism', which holds the position that there is an objective reality. This objective reality is considered independent of human perception and social interaction, and can be measured and reported as 'facts' (Sale et al. 2002; Bryman 2007). The positivist perspective originated from the natural sciences, using quantitative methods to measure phenomena and test hypotheses. Quantitative research typically adopts a deductive approach, where hypotheses are developed based on theory and then data is collected to test the hypotheses (Carr 1994; Buckingham and Saunders 2004).

In contrast, qualitative research is usually based on an interpretivist paradigm which is concerned with meaning and action within the social world. It seeks to interpret how individuals experience and make sense of the world around them (Mason 1996; Sale et al. 2002; Bryman 2008). Rather than taking an objectivist view, qualitative research generally follows a constructionist ontological position which incorporates the assumption that realities are constructed by individuals, influenced by social interaction, and that there are multiple realities (Lincoln and Guba 2000). Another important aspect of the interpretivist epistemology is the role of interaction between the researcher and participants, which could influence the research process (Mason 1996). Qualitative research is inductive in terms of how theory develops; it describes social phenomena as they occur naturally, and data is used to develop concepts and theories (Bradley et al. 2007; Lapan et al. 2011).

While the debate over philosophical stance continues (Bryman 2006; Creswell and Plano Clark 2007), the appropriateness of the different paradigms depends on the focus of the specific study design. For example, Howe (2004) has introduced the term 'mixed methods interpretivism' in which qualitative research is the dominant method, and quantitative methods play a secondary role. This study was underpinned by such a 'mixed methods interpretivist' paradigm, as its focus was on understanding people's perspectives and their interpretations of the social world using qualitative methods as its dominant method (Snape and Spencer 2003).

This study used multiple methods and multiple types of data collection to capture the depth and multiplicity of participants' experiences of recurrent hypoglycaemic episodes. While the qualitative method was the dominant method, quantitative data was used to record actual hypoglycaemic episodes and a range of blood glucose readings surrounding these episodes. The quantitative data added a precise measure of phenomena in the following ways: first, it helped to relate blood glucose readings to actual hypoglycaemic episodes collected via the hypoglycaemia diary. This was useful to establish whether actual blood glucose readings fell below the agreed threshold of hypoglycaemia (4.0 mmol/l, see section 2.7), and whether participants recorded a hypoglycaemic episode when their blood glucose reading did fall below 4.0 mmol/l. Therefore, quantitative data was also relevant in investigating hypoglycaemia unawareness, an important phenomenon that can contribute to the use of emergency services (see section 6.5.3).

Second, quantitative data allowed for comparison of perceived severity scores of hypoglycaemic episodes across study groups (SAS and non-SAS participants). And

third, quantitative data provided an opportunity to compare the number of hypoglycaemic episodes across study groups. Hence, findings from quantitative data addressed the research question relating to similarities and differences between those who had recently used emergency services (SAS participants) and those who had not recently used emergency services (non-SAS participants, primarily recruited through Diabetes UK Scotland).

The qualitative data was particularly useful to gain an understanding of participants' experiences and explanations of recurrent hypoglycaemic episodes. It helped to address the impact hypoglycaemia can have on participants' everyday life and their support network, as well as what coping strategies participants adopted. Further benefits of using qualitative semi-structured interviews and telephone interviews can be found in sections 5.7.3 and 5.7.5. Combining the findings from both quantitative and qualitative data helped to provide a fuller overall account of participants' experiences of recurrent hypoglycaemia. Findings from qualitative data shed light on participants' experiences of and possible explanations for recurrent hypoglycaemic episodes. The unique multiple methods, longitudinal design of this study used findings from quantitative data to inform findings from qualitative data.

Table 5.1 below shows a summary of research questions and relevant data used to answer the research questions.

<b>Research questions (RQ's)</b>	<b>Relevant data</b>	<b>Data type</b>
1. What are SAS and non-SAS participants' views of experiencing recurrent hypoglycaemia?	Face to face interviews, follow-up telephone interviews	Qualitative
a) How does hypoglycaemia affect participants' everyday life?	Face to face interviews, hypoglycaemia diaries (narrative around hypoglycaemic episode)	Qualitative
b) What is the relationship between participants' management of hypoglycaemia and their support network?	Face to face interviews	Qualitative
2. What are participants' explanations for having recurrent hypoglycaemia?	Hypoglycaemia diaries (individual explanations), face to face interviews	Qualitative
a) What coping strategies do participants adopt to deal with recurrent hypoglycaemia?	Face to face interviews, follow-up telephone interviews and hypoglycaemia diaries	Qualitative
b) How (if at all) does recurrent hypoglycaemia influence diabetes self-management behaviours?	Face to face interviews, follow-up telephone interviews, hypoglycaemia and blood glucose diaries	Qualitative
3. Are there any changes over time in relation to experience, possible explanations and management of recurrent hypoglycaemia? What influences these? Are there any differences between participant's various hypoglycaemic episodes (within case)?	Hypoglycaemia and blood glucose diaries, follow-up telephone interviews	Qualitative
4. Are there any similarities or differences between those who were emergency service users (SAS participants) and those who were not (non-SAS participants; more likely to engage in self-care)?	Hypoglycaemia and blood glucose diaries (blood glucose readings and perceived severity score)	Quantitative
a) Are the SAS group having more severe hypoglycaemic episodes than those who do not use emergency services?	Hypoglycaemia diaries (perceived severity score)	Quantitative

**Table 5.1: Research questions and relevant data**

### **5.4.2 Challenges of multiple methods research**

There are, however, a number of challenges in using a multiple methods approach. The major challenge relates to integration of qualitative and quantitative data due to the use of different data collection instruments, which generate different types of data. There has been an argument that the epistemological positions underlying qualitative and quantitative methods are conflicting (Bryman 2008) and cannot be merged. However, considering that there are huge variations within each research methodology, the position that there is a single epistemological and ontological stance attached to a research method is difficult to maintain (Bryman 2008).

Onwuegbuzie and Leech (2005) recognise that there are overwhelming similarities between qualitative and quantitative perspectives, as both methodologies use observations to address research objectives, and attempt to develop explanations through the interpretation of their data. Hence, rather than being opposites, Newman and Benz (1998) consider qualitative and quantitative research as an 'interactive continuum', as neither tradition is fully independent of the other, nor can either approach cover the whole research process. Thus, using multiple method approaches can provide a more complete understanding of phenomena (Johnson and Onwuegbuzie 2004; Bryman 2007; Creswell et al. 2011).

### **5.4.3 Longitudinal approach**

Ruspini (1999) claims that there are a number of potential benefits when using a longitudinal design: researchers may gain fuller information and a more complete picture of the issues under investigation. A longitudinal approach allows for investigating changes over time, since data collection is carried out at two or more

points in time over an extended period. This can range from a few weeks to many years, but is mainly constrained by resources and time available to researchers (Menard 2002). A longitudinal approach is considered particularly useful for a study using multiple methods as it can help to gain a more accurate picture of the phenomena under investigation (Mingione 1999).

Previous research into experiences of living with diabetes and managing hypoglycaemic episodes has largely been cross-sectional (Richmond 1996; Rajaram 1997; Ritholz and Jacobson 1998). While these studies provide a general insight into people's experiences of hypoglycaemic episodes and impact on everyday life, they may miss out on issues relating to change over time, and in understanding potential differences between hypoglycaemic episodes, the context in which they occur and how they are subsequently managed. Considering that diabetes is a chronic condition, it is important to look at hypoglycaemic episodes over time.

This study applied a longitudinal design to capture a variety of hypoglycaemic episodes over time. Participants were asked to keep a personal blood glucose and hypoglycaemia diary over a period of six months. The longitudinal approach facilitated the investigation of recurrent hypoglycaemia in a number of ways. First, it enabled prospective data collection, allowing access to actual hypoglycaemic episodes in the context of participants' everyday life (Polit and Beck 2003). Second, the longitudinal approach also helped describe what happened in-between, in the run-up to, as well as following different hypoglycaemic episodes.

Third, it explored whether there were differences between various hypoglycaemic episodes. And fourth, it investigated any changes (relating to the research questions)

that might have occurred over time (also see Menard 2002). Finally, the longitudinal approach can help to explore participants' specific situations at various points in time and thus provide many options for analysis and inferences (Ruspini 2000).

#### **5.4.4 Challenges of longitudinal approach**

A major challenge in using a longitudinal approach is the issue of attrition; that is participants deciding to drop-out of the study at different time points (Polit and Beck 2012). The main concern with attrition is that those who stay in the study may differ in important aspects from those who decide to leave the study (Bryman 2008), hence impacting on the representativeness of the sample and validity of study findings (Ruspini 2000; Polit and Beck 2012). It is therefore important to address this by identifying any differences between participants who leave the study and those who stay in the study. Details of this are discussed in section 5.8.

Further consideration needs to be given to the time lag between data collection points, as a longer time lag can contribute to attrition (Robson 2011). In this study, data collection was on-going during the six month follow-up phase, and I kept in regular contact with participants. In order to make study participation as straightforward and easy as possible, participants were provided with clear information about the study and given the opportunity to ask questions both before and during the study.

## **5.5 Population**

### **5.5.1 Sampling strategy and sample size**

Developing a sampling strategy is a very important stage in the research design, and there are a number of approaches to sampling. A major distinction can be made between probability and non-probability sampling, which are associated with quantitative and qualitative research designs, respectively (Ritchie et al. 2003a; Bryman 2008). While probability sampling is mainly concerned with a statistically representative sample, non-probability sampling has traditionally been used in qualitative approaches. The choice of sampling strategy depends primarily on the research aim and research questions.

As this study is guided by a qualitative approach to sampling, the two main approaches to sampling in qualitative research will briefly be outlined. First, theoretical sampling has been associated with grounded theory (Glaser and Strauss 1967), and, as the name suggests, is driven by the potential to develop theory. Theoretical sampling evolves in an iterative process: the researcher selects an initial sample, analyses the data, and decides on a further sample that helps to develop and refine emerging categories and theory (Charmaz 2000; Ritchie et al. 2003a; Hodkinson 2008).

Another approach is purposive sampling, where participants are selected based on specific characteristics and criteria they possess (Mason 1996). This is also referred to as 'symbolic representation' by Ritchie et al. (2003a), because participants are chosen to both 'represent' and 'symbolise' certain features that are relevant to the study. As Gilbert (2008) put it, "the focus is on gaining insight and understanding by hearing from representatives from a target population" (p.512). The inclusion criteria are

strategically developed to ensure focus and relevance on research aim and research questions (Bryman 2008). The main difference between purposive and theoretical sampling is the stage at which criteria are defined: in purposive sampling the criteria are developed before data collection takes place, while within theoretical sampling the criteria evolve during the data collection period (Ritchie et al. 2003a).

In sampling for qualitative research, consideration needs to be given to variety within the sample. This increases the chances to capture the full range of factors that are associated with a phenomenon, as well as allowing for comparison within the sample (Mason 1996; Ritchie et al. 2003a; Bryman 2008).

A purposive approach to sampling was selected for this study as it was most appropriate in addressing the research aim and research questions. The study used a sample that allowed for comparison of recent emergency service users (SAS participants) and those who had not recently used emergency services (non-SAS participants, primarily recruited through Diabetes UK Scotland). It was assumed that both participant groups were likely to experience a number of hypoglycaemic episodes; however SAS participants were more likely to reflect the sub-set of the diabetes population who contacted emergency services (frequently). In order to get a clear classification of the two population groups, non-SAS participants who had called the SAS due to a hypoglycaemic episode in the three months prior to recruitment were excluded from participation (based on self-report).

The sample included both male and female participants to investigate potential differences and similarities between genders. While some studies have focussed on specific population groups or only one gender (e.g. Kay et al. 2009; Weiler and Crist

2009), this study included both male and female participants as well as various age groups. This ensured a variety of people living with diabetes were included in the study.

Inclusion criteria were:

- adults (>18 years)
- diagnosed with either type 1 or type 2 diabetes
- residing in the central belt of Scotland
- treated with insulin therapy
- experience a hypoglycaemic episode at least once a month

Exclusion criteria were:

- individuals aged below 18 years
- inability to communicate in English language
- where participants lack capacity to consent
- Indication of alerts (e.g. end of life issues, complications), particularly in the SAS group.

These criteria were selected because the vast majority of people with diabetes who experience hypoglycaemia are treated with insulin (Wild et al. 2007). The lower age limit was 18, to ensure that only adults who can give consent were included in the study. The geographical limitation was a practical consideration. It covered the majority of the Scottish population and was affordable in terms of travel. The experience of at least one hypoglycaemic episode per month had been chosen

because it captured individuals who experience hypoglycaemic episodes regularly and recurrently and therefore addresses the research aim.

### 5.5.2 Sampling framework

Sample group	Non-SAS			SAS		
Age group	18 – 40	41 – 60	> 60	18 - 40	41 – 60	> 60
Male	4	4	4	4	4	4
Female	4	4	4	4	4	4

**Table 5.2: Target sampling framework**

For each cell of the table, the target was to recruit 4 individuals. The study adopted a naturalistic approach to sampling, and a record of geographical area (postcode) was kept. This was used to identify deprivation categories using the Scottish Index of Multiple Deprivation (SIMD) codes (The Scottish Government 2009). The number of participants per cell was set at four for the following reasons:

- Trying to get variation/different perspectives within each cell
- Collecting a manageable amount of data that is sufficient for the purpose and achievable within the time frame of the study
- Minimising the impact of attrition over time. Due to the longitudinal nature of the study, keeping diaries and conducting follow-up telephone interviews, it was expected that a number of participants would drop out.

However, during the fieldwork, a number of factors contributed to a smaller sample size (see actual sample in table 5.3 overleaf). As mentioned above, high target numbers were set to allow for a degree of attrition. However, the major challenge during data collection was not attrition but recruitment. Overall, there was a limit to what could be achieved within the time frame.

Once recruitment and operationalisation were under way, I realised that the effort required in keeping track of participants was more time consuming with repeated contacts during the follow-up period. During data collection, and especially during the recruitment phase, my workload was very high, given the number of people contacted (particularly in recruitment for the SAS group, see details below) and the amount of information collected. Participants wrote a lot more diary entries than initially expected. The inclusion criteria stated that participants should experience at least one hypoglycaemic episode a month (see section 5.5.1); however, some participants completed up to 62 diary entries over the six month follow-up period. There were a number of concurrent activities to manage during the data collection period, including; on-going recruitment of study participants, arranging and conducting initial semi-structured interviews, staying in touch with existing participants, reading through diary entries, transcribing and reading interview transcripts in preparation for further telephone interviews and finally carrying out repeated follow-up telephone interviews.

Delays in securing NHS ethical approval (detailed below) also reduced the time available to this study for recruitment. There were also some challenges during the recruitment process, mainly a slow response rate in the non-SAS group, and a time consuming method of recruiting SAS participants, which are described in more detail

in section 5.5.4.2. Despite these challenges, the actual sample achieved allowed for comparison between the two participant groups, as a total of 13 SAS and 17 non-SAS participants were involved in the study. These included 11 participants in the 18-40 age group, 11 in the 41-60 age group and 8 in the over 60 age group; there were 14 male and 16 female participants, which gave a good spread (see table 5.3 below). Overall, a total of 30 participants took part in the study with multiple data collection points.

Sample group	Non-SAS (n=17)			SAS (n=13)		
	18 – 40	41 – 60	> 60	18 - 40	41 – 60	> 60
Age group	18 – 40	41 – 60	> 60	18 - 40	41 – 60	> 60
Male	4	3	1	1	3	2
Female	4	3	2	2	2	3

**Table 5.3: Actual sampling framework**

### 5.5.3 Inclusion of carer/family member

Carers/family members have substantial knowledge about dealing with hypoglycaemic episodes. They play an important role in supporting the person living with diabetes (see Trief et al. 2003); they are also the first point of help/calling emergency services when hypoglycaemia occurs. Therefore, it was thought to be important to include carers/family members if requested. It was emphasised that carers and family members were only included when participants actively requested this, which suggested that participants were comfortable with their carer's presence during the

interview. I knew from a previous study conducted in the NMAHP Research Unit that it was likely that participants would ask their carers to join them in the interview, and that carers would offer information during that process. If such a request was made by the participant, I allowed their carer to attend the interview(s). During the data collection period, this was the case with 5 participants within the SAS group. Interestingly, there was no request made to include a carer/family member in the non-SAS group.

Separate consent forms were signed by carers as they contributed within the interview(s) and gave consent to their views and opinions being recorded and used anonymously in reports and publications. Consent was taken immediately prior to the interviews (see Appendix 6). There were not any specific questions for carers; however, if they had knowledge about participants' hypoglycaemic episodes, they were invited to tell me about it. This meant that the focus of the study remained with the participant.

## **5.5.4 Recruitment process**

### **5.5.4.1 Recruitment of non-SAS participants**

The recruitment strategy for non-SAS participants was discussed with key staff at the Diabetes UK (Scotland) office in Glasgow in the first instance. Colleagues there were very keen to support the study and agreed to send out study advert flyers (see Appendix 10) with the regular Diabetes UK newsletter, they also posted a study advert on both their Facebook page and Twitter account. This was re-posted regularly for a period of three months. Potential participants then got in touch with me.

Once potential participants got in touch, they were sent detailed information about the study (including participant information sheet (PIS), see Appendix 1). They were then asked to fill in a simple form with their contact information (see Appendix 9) and return it to me if they were still interested in taking part. Following this, a suitable date and time for the first interview was arranged. Immediately before the interview, participants were given the opportunity to ask further questions and asked to sign the consent form (see Appendix 4).

Due to the low recruitment achieved by the above method, I also used snowball sampling techniques (Streeton et al. 2004; Denscombe 2007), which led to a post on a blog type website called "Shoot up or put up" including a written interview about my research study as well as an advertisement for the study. The snowball sampling technique also resulted in further distribution of study advert flyers within some Diabetes UK support groups. Overall, this technique generated another four participants. Despite the efforts to publicise the study advert both online and through flyers, the recruitment rate through Diabetes UK was quite slow and resulted in only 21 enquiries, out of which 12 people eventually took part in the study.

It was decided to seek an amendment to the initial ethical approval (which was granted through the School of Nursing Midwifery and Health Ethics Committee in November 2011) to advertise for the current study within the University of Stirling. People recruited through the University would likely be similar to participants recruited through Diabetes UK Scotland in terms of engagement in diabetes self-care. An advertisement on the University of Stirling internet portal generated another 14 enquiries out of which 5 people finally took part in the study.

#### **5.5.4.2 Recruitment of SAS participants**

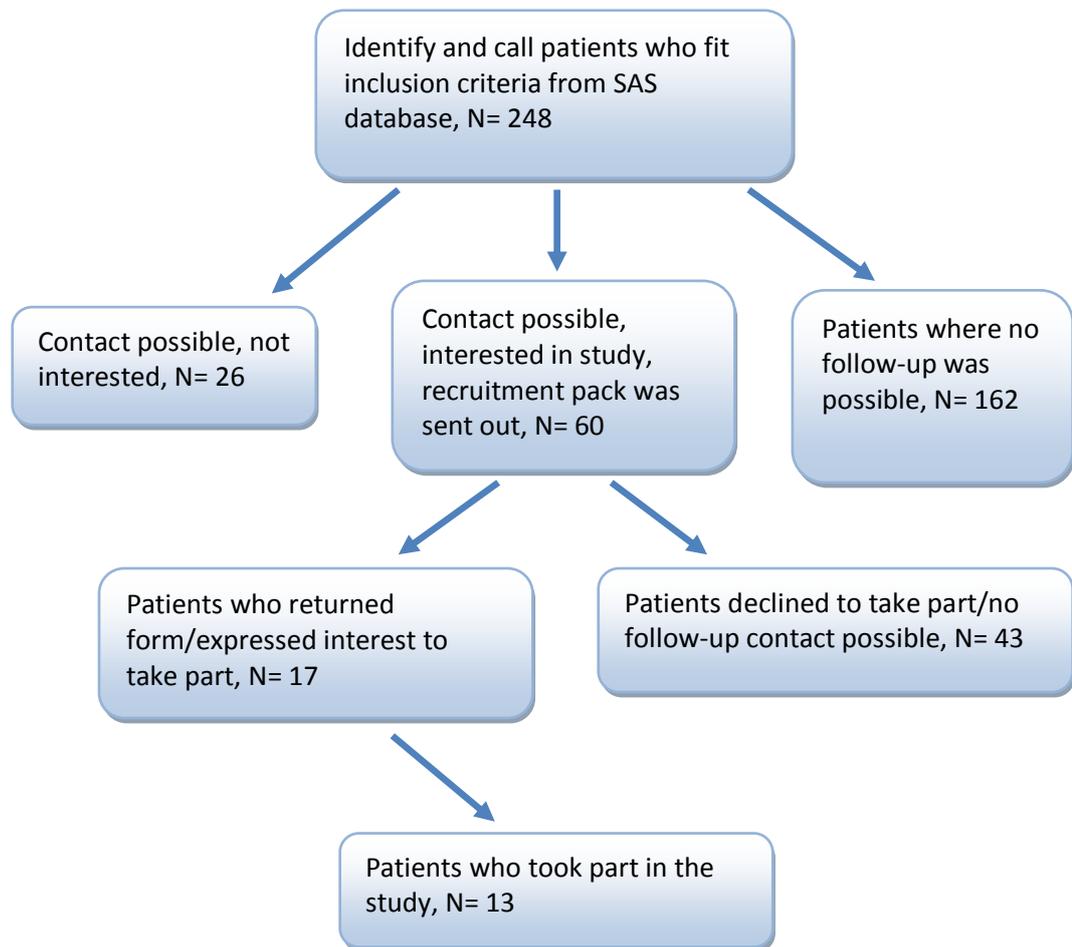
SAS patients who had experienced a hypoglycaemic emergency in the preceding week were identified via the SAS electronic patient record system. SAS patients were initially contacted by phone and sent information about the study if they expressed an interest in knowing more about the study (this included participant information sheets and consent forms, see Appendices 2 and 5). Potential participants were then asked to confirm their interest in the study by returning a simple form or by phoning me. Similar procedures of identifying and contacting patients had been used successfully before in other SAS research within the NMAHP Research Unit. Caldicott Guardian approval was applied for and subsequently granted in order to access patient information for recruitment purposes. Further ethical issues that were relevant in the recruitment of SAS patients are discussed in more detail below (section 5.6).

Once potential participants got in touch with me, a suitable date and time for the first interview was arranged. Before the interview, participants were given the opportunity to ask further questions and asked to sign the consent form (see Appendix 5).

The process to gain access to SAS patients was lengthy since a number of permissions were required, including getting the appropriate Disclosure Certificate, Research Passport, Caldicott Guardian Approval, and setting up an NHS email account. Following this, a system was set up to be sent data relating to emergency call-outs due to a hypoglycaemic episode via a weekly email.

Challenges in the recruitment of SAS patients included calling large numbers of patients (overall 248 patients were contacted) with very few people expressing an

interest in taking part in the study. At least two attempts (at different times) were often required to reach patients on the phone. Sending out study information and receiving participants' expressions of interest forms through the post worked well, however, overall, the process was slow which led to delays in relation to the study timetable. Further details of the recruitment process through the SAS can be found in the flow diagram below (figure 5.1). It shows that there was no follow-up possible for many patients (n=162). This was because the telephone numbers available in the electronic patient record system were the telephone numbers that the emergency call was made from, which was not necessarily the patient's telephone number (n=47). Another reason was that it was not possible to reach patients on the phone within two attempts (n=115). The slight discrepancy in numbers of patients who returned the form and those who finally took part in the study was either due to patients not meeting all inclusion criteria (n=2), or patients willing to take part, but not being well enough (n=2).



**Figure 5.1: Recruitment process for SAS participants**

## 5.6 Ethical considerations

This study was conducted in accordance with ethical approval received through both the School of Nursing, Midwifery and Health Research Ethics Committee, University of Stirling (in March 2011, see Appendix 20) and the NHS Fife and Forth Valley Research Ethics Committee (in August 2011, REC reference number 11/AL/0330, see Appendix 21). Involvement in the study was on an opt-in basis and informed consent was ensured by providing participants with information sheets as well as giving them the opportunity to ask questions.

The main ethical concerns were about accessing confidential patient data (e.g. names, addresses, telephone numbers) and contacting SAS patients by telephone following their hypoglycaemic emergency episode without prior consent by the patient. Relevant permissions were obtained (see section 5.5.4.2), and I was granted limited access to the SAS electronic patient record system due to its sensitive and confidential nature. An NHS email account was set up, that allowed me to be sent data relating to emergency call-outs due to a hypoglycaemic episode via a weekly email.

A few possible scenarios of contacting SAS patients were considered (see below); however, making contact by telephone was deemed the most appropriate option as it would best maintain patient confidentiality.

Following advice from the Fife & Forth Valley Research Ethics Committee, a scripted telephone protocol (see Appendix 7) was devised to ensure patient confidentiality when making initial contact by telephone to confirm patients' postal addresses. The purpose of the telephone call was to ask if potential participants would be willing to receive information regarding the study and to ascertain the correct address to send this to. It was proposed that I would make the telephone call to potential participants, using the scripted telephone protocol (see Appendix 7). This approach was preferable to other options (discussed below) as it would best maintain patient confidentiality by ensuring that no information was divulged to anyone other than the patient. It is important to emphasise that I did not attempt to consent patients during this phone call. The aim was solely to ask if patients would be willing to receive information about the study, and if so, to record their postal address for this purpose. Similar calls to patients had been made in this manner before, and there were neither incidents

where I felt patient confidentiality was at risk, nor complaints about this procedure by any party.

The following options were also considered following discussion with the Fife & Forth Valley Research Ethics Committee, but after lengthy consideration and consultation with other senior researchers and senior managers within the SAS, I came to the conclusion that they were unfeasible and/or unethical. The reasons for this are outlined in the following sections.

The Fife & Forth Valley Research Ethics Committee suggested that the telephone call could be made by a SAS employee. Unfortunately, there were no funds to support this option. Furthermore, the SAS have limited capacity and were unlikely to be able to deliver this even if funds were available. Additionally, getting a SAS employee to make the telephone call would not in itself solve the challenge of patient confidentiality. I did ensure however, that I had the appropriate permissions and disclosure to contact SAS patients for the purposes of this study.

Another option that was considered was to ask ambulance clinicians to give study information leaflets to people when attending hypoglycaemic emergencies. This method would have significant ethical implications for the patient, as it would require paramedics to pass study information to people when they are in an emergency care situation and would potentially be unconscious or confused. Furthermore it would have been very challenging to ensure that all ambulance vehicles had the appropriate paperwork and paramedics would have been likely to forget to give out such leaflets when attending an emergency situation. If this method was used, it would be impossible to know who had actually received study information, and the likelihood of

achieving the study target numbers would dramatically reduce. For all these reasons, this method of distributing study information was considered to be both impractical and unethical.

A further potential method of recruitment would be to send study information to addresses that are recorded in the SAS database (these are addresses where hypoglycaemic events occurred). However, the location of the hypoglycaemic emergency may well not have been the patient's own home address; and this method would therefore not address the issue of patient confidentiality. Further, this method of contacting people was also likely to decrease the response rate/number of potential recruits, and consequently lengthen the study time. Due to these reasons this method was not considered to be either practical or ethical.

### **5.6.1 Informed consent**

It was important to gain informed consent from all participants who took part in the study, as well as ensuring participants entered into the study freely and willingly, knowing and understanding what they agreed to. When people expressed an interest in participating in the study, they were provided with a copy of the participant information sheet (see Appendices 1 and 2). Information sheets were designed to outline the key points of the study, its overall purpose and to highlight potential risks and benefits of participation. They also included details about participants' rights to withdraw from the study at any point (Mason 1996).

If participants still expressed an interest to take part in the study once they had read the participant information sheet, a suitable time was arranged for the initial face to

face interview. Before commencing the interview, each participant was given the opportunity to ask any questions and then asked whether they were happy to take part in the study and, if so, to sign two copies of the consent form (see Appendices 4 and 5), one copy of which they were given to keep. It was made clear to all participants (both verbally and in the information sheets and consent forms) that they were free to withdraw from the study at any time, without giving any reason and that their medical care or legal rights would not be affected by this. Participants were also informed how data would be used.

### **5.6.2 Confidentiality and anonymity**

Each interview was audio recorded using a digital recorder. As soon as possible after each interview, the recording was uploaded onto a password protected computer and deleted from the hand-held digital recorder. Typed notes of interviews were assigned a participant number with no names or other identifiable information included in the notes. A list of names of participants and their numbers was kept electronically, separate from the interview notes themselves. Interviews were also anonymised, with personal and place names removed (see Bryman 2008). It was ensured that quotes were not attributable to participants. Anonymity was guaranteed to all participants with descriptors being carefully used to describe participants (e.g. female, SAS, age group 1). Only I had access to personal details of participants. Transcriptions of interviews (both face to face and telephone interviews) did not contain any identifiable information as they were all anonymised. The diaries were also anonymised before analysis. Completed consent forms were stored in a locked cabinet separate from all other data.

On completion of the study, all written data was securely archived. All paper data will be destroyed 6 months after completion of the PhD thesis. According to University of Stirling regulations, this data will then be held in electronic format for a period of 10 years. Provision for electronic storage was made through the Nursing, Midwifery and Allied Health Professions Research Unit (NMAHP RU). All data was securely archived in keeping with the NMAHP RU guidelines.

### **5.6.3 Potential risks and safeguarding against risk**

The research was carried out in accordance with the University of Stirling 'Code of Good Research Practice' (2009). The rights, safety and well-being of participants were the primary concern throughout the study.

The overall burden on participants was minimised by ensuring that telephone interviews and diary requirements were brief. In summary, each participant was asked to take part in one semi-structured interview (lasting about 60 minutes), keep a hypoglycaemia and blood glucose diary over a period of six months (recording blood glucose values no more or less often than they would usually do and writing diary entries about hypoglycaemic episodes as they occurred), as well as take part in six monthly telephone interviews each lasting about 15 minutes. The frequency of telephone interviews was later reduced to bi-monthly (see section 5.7.5). Overall, monthly participation time was about 30 minutes.

There was no physical/medical risk to participants via participation in this study. However, I explored private worlds and experiences of study participants, which "might sometimes evoke strong emotional responses and sometimes pursuing

thoughts that might otherwise never be revealed” (Cowles 1988:163). Actual or potential distress may be revealed through interviews or diary entries; this could include emotional stress experienced through recounting hypoglycaemic events, as well as problematic diabetes self-care, etc. Consideration was given to the impact this might have on the participant and researcher. Risks were balanced with ensuring participant confidentiality and the limitations of the researcher role.

Participants were able to stop the interview at any point. If participants were to become distressed, the interviewer would suggest a break or offer to terminate the interview. It was emphasised that participants had the right to withdraw from the study at any time. Given my training and experience in social work, I would have been able to sensitively deal with situations where participants were getting distressed.

Additionally, I proposed to refer participants to their GP in the event that they became unduly distressed during the interview which might not necessarily have been related to the interview. If specialist counselling services were required, the GP could refer participants to this service. In case participants did not feel comfortable contacting their GP with any concerns they had, contact details of an alternative free service (Diabetes UK helpline, if Diabetes related; or Breathing Space, if mental health related) were provided on the participant information sheet (see Appendices 1 and 2). In this case, it was left to the participant to decide whether further action needed to be taken with regards to any concerns the interview may have raised. There were no incidents of participants becoming distressed or stopping the interview during data collection. Any issues arising for me were discussed with supervisors who offered support as required.

Due to the approach chosen to contact SAS patients, there was a risk that potential SAS participants might be unwell or might have died at the point of or following initial contact. Further exclusion criteria were imposed to limit the chances of this happening. SAS patients who resided in nursing homes were excluded, and where there was a clinical alert of end of life issues, the person was also excluded (clinical alerts were recorded in the SAS database). During the recruitment process, a small number of patients who I attempted to contact, were unwell or had died. In those cases, I tactfully apologised for calling and expressed my sympathy to the person who answered the telephone call. There was one person who got upset about being contacted, in which case I apologised and removed the person's name from the list of potential study participants.

I was working as a lone worker when conducting interviews. For this reason, I provided a contact person (either one of my supervisors, or the NMAHP Research Unit secretary) with the address of the interview location and prior to entering the location/beginning the interview, contacted the contact person. I then phoned the contact person immediately after leaving the interview location. If there had not been any communication after one and a half hour from commencement of the interview, the safety protocol was as follows:

1. The contact person phoned me.
2. If I was still with the participant, and in the event that I had concerns for my or the participants' safety a code word (pre-arranged with the contact person) was used, after which the police would be called by the contact person who would raise their concerns and inform the police of my location.

3. If the contact person was unable to make contact with me when they called then the police were contacted as above.
4. I would stop any interview in which I had concerns for my safety and inform the contact person that I had done so immediately upon leaving the interview.

Additionally, during some of the interviews, I used a personal security device ('GEMshield') which was provided by a company called 'Skyguard'. The main feature of the GEMshield device was the alarm function which could be activated by pressing the SOS button. Once activated, an alarm message containing the user's identity and location would be sent to Skyguard's Incident Management Centre (IMC) and a voice call would be initiated. Following this, Skyguard's controllers would assess the incident and follow pre-arranged emergency procedures (i.e. contact the police and a named contact person). The GEMshield device used GPS tracking to ensure accurate location information (see <http://www.skyguardgroup.com> for further details, accessed 29<sup>th</sup> November 2012).

#### **5.6.4 Potential benefits for study participants**

There was no direct healthcare benefit to participants. However, it was hoped that, indirectly participants would be able to help shape future emergency care, improve the safety of current diabetes care and help people with diabetes by ensuring that they receive appropriate advice and care. At the end of the study, each participant received a £10.00 gift voucher to thank them for their participation, which they were not aware of at the point of recruitment.

## **5.7 Data collection**

During the data collection period, face to face semi-structured interviews, blood glucose and hypoglycaemia diaries and telephone interviews were used. Participants were asked a number of questions relating to the overall research aim (see section 5.2). During this first meeting, participants were provided with a 'Hypoglycaemia and blood glucose' diary (see Appendices 13 and 14). The format of the diary was explained and any questions answered. Interviews were recorded using a digital voice recorder. During the period of diary keeping (six months), I stayed in regular contact with participants and conducted a brief telephone interview monthly (see Appendix 15). The frequency of telephone interviews was later reduced to bi-monthly (see section 5.7.5).

### **5.7.1 Schedule for data collection**

Data collection took place between July 2011 and July 2012. It consisted of four phases: the piloting phase, the recruitment phase, the data collection phase and the follow-up phase. Piloting for the current study was conducted in July 2011. The recruitment phase was carried out from August 2011 until February 2012.

The main phase of data collection using semi-structured face to face interviews was conducted from August 2011 until February 2012, and the follow-up phase was ongoing, starting after the first interview was conducted in August 2011, until the last participant finished with the blood glucose and hypoglycaemia diary, in July 2012.

### **5.7.2 Piloting**

Piloting is an important stage in any research project as it can help to fine-tune procedures and identify concerns, which need to be addressed in preparation for the main study (Robson 2002). This includes issues relating to data collection instruments, adequacy of instructions, and practicalities of daily management of the study during its conduct (Robson 2002; Bryman 2008).

Participants' views were sought in relation to acceptability and relevance of data collection tools, especially the interview guide (see Appendix 12), participant information sheet (see Appendix 1) and blood glucose and hypoglycaemia diary (see Appendices 13 and 14). The piloting was conducted with three volunteers recruited through the Diabetes UK (Scotland) Head office in Glasgow. While piloting was limited to participants recruited through Diabetes UK (Scotland), there was a range of age groups (from 24 to 67 years) and both genders represented (n=2 female, n=1 male). It was not possible to include participants recruited through the SAS in the piloting study because of delays in obtaining NHS Ethics Approval and in getting all appropriate permissions to access the target population.

The participants in the piloting study gave very valuable and useful feedback that helped refine data collection tools. In particular, participants highlighted the phenomenon of overcompensating when having a hypoglycaemic episode, that is, taking more glucose or food than is required to bring blood glucose levels back to a normal range. Another interesting point was that there can be considerable variations when it comes to the blood glucose level people start feeling symptoms of hypoglycaemia, both on an individual level as well as between different people. These

themes were very relevant and were confirmed during the main data collection (see sections 7.2.4 and 8.2.5).

Further, practical issues relating to the content of the interview guide and blood glucose and hypoglycaemia diary were emphasised during the piloting phase.

Following feedback from participants, a space for recording the blood glucose value after a hypoglycaemic episode was included in the diary, and the number of pages to record hypoglycaemic episodes increased from 6 to 24 (as many people were experiencing more than one hypoglycaemic episode a month). Two of the questions on the 'hypo diary' page (see Appendix 13) focussed on the impact hypoglycaemic episodes can have on people; the question asking about how long the particular hypoglycaemic episode lasted and the question relating to perceived severity of hypoglycaemia episodes ('From your perspective, how bad was the hypo?'). One of the participants in the piloting phase felt it was challenging to answer those two questions, as she did not like to focus on how hypoglycaemic episodes affected her everyday life. This was taken into consideration when introducing participants to the diary during the main data collection phase.

The interview guide was also refined during the piloting phase. The question asking to describe a 'typical day' was removed, while the 'Do hypos affect your daily activities?' question was kept. As many people in the study have lived with diabetes for many years, they might not necessarily remember the first hypoglycaemic episode they have experienced; instead, very 'bad' hypoglycaemic episodes seemed to be more salient for people. Therefore, the initial question asking about first experience of

hypoglycaemic episodes was replaced by a question asking about particularly bad hypoglycaemic episodes people have had.

Additionally a set of questions investigating how people felt after a hypoglycaemic episode, as well as how people managed (the risk of having) a hypoglycaemic episode in a work environment was included after taking into consideration feedback from participants during the piloting process, and further reflections and discussions with my supervisors.

### **5.7.3 Qualitative semi-structured interviews**

The first stage of the main data collection for the current study used semi-structured interviews to gain understanding into participants' perspectives of recurrent hypoglycaemia. Using qualitative interviews to collect data can provide a unique insight into participants' life worlds; it gives the researcher an opportunity to explore participants' perspectives and experiences. Interviews are ideal to gain an in-depth account, allowing the researcher to capture nuances within participants' experiences (Arksey and Knight 1999).

According to Patton (1990), "the purpose of interviewing is to find out what is in and on someone else's mind [...], to access the perspective of the person being interviewed [...], to find out from them those things we cannot directly observe" (p.278). Semi-structured interviews are therefore appropriate in addressing some of the research questions, particularly the research questions relating to participants' experiences of recurrent hypoglycaemia and impact on everyday life.

While qualitative semi-structured interviews can provide rich and in-depth data relating to the experience of participants, there are a number of drawbacks when using this approach. First, arranging and conducting semi-structured face to face interviews is both time consuming and costly (Opdenakker 2006; Flick 2009). In the current study, I interviewed participants at their home, which had cost and time implications in relation to travelling.

Second, in order to collect good quality data, the researcher's skillset is vital. This includes interpersonal skills that are important in developing rapport with research participants, e.g. creating a relaxed and friendly atmosphere, listening skills, interpreting body language, etc. (DiCicco-Bloom and Crabtree 2006). Another competency relates to research method. The researcher needs to have the ability to carry out a study within a flexible and adaptive qualitative research design, for example, asking the right questions, and constantly reflecting about and analysing data which may lead to creation of future questions or adaptation of existing ones. As Rubin and Rubin (2005) put it, "research design and questioning must remain flexible to accommodate new information, to adapt to the actual experiences that people have had, and to adjust to unexpected situations" (p.35).

#### **5.7.3.1 Interview guide**

The interview topic guide (see Appendix 12) was designed in a semi-structured format to allow for flexibility, while providing a general structure to ensure focus on the research questions (Flick 2009). The flexibility of the interview guide relates to time spent on each topic of discussion, wording of questions and the order questions were posed (Robson 2011). The content of the interview guide was developed using

findings from the literature review, feedback obtained during piloting and focus on the research aims and research questions.

In terms of topics, the interview guide covered participant's individual history of diabetes, previous experiences of hypoglycaemic episodes as well as differences between various hypoglycaemic episodes. It also explored participants' personal explanations for various hypoglycaemic episodes. The interview guide investigated the impact hypoglycaemic episodes have on participants' everyday life (e.g. work, social life, family, driving) and how hypoglycaemic episodes might influence diabetes management. Further topics included coping strategies people adopted and individual views in relation to the future of living with hypoglycaemia.

A few questions were added to the interview topic guide during the course of conducting the interviews. The issue of (having) children was introduced to the interview, this can be considered an extension to the initial question exploring the impact hypoglycaemic episodes can have on family. The discussion around children highlighted participants' concerns about whether their children would inherit diabetes, whether they would be able to look after their children in case of complications (both long-term and short-term), their children caring for them (one participant's daughter was registered his official carer) and issues around pregnancy.

Participants recruited through the SAS were also asked whether they were a member of Diabetes UK. This helped to establish whether there was any overlap between the two groups of participants. During recruitment, I confirmed whether non-SAS participants had required the assistance of emergency services due to a hypoglycaemic episode recently (within the three months prior to recruitment).

## **5.7.4 Blood glucose and hypoglycaemia diaries**

In addition to semi-structured interviews, diaries were used to keep a record of hypoglycaemic episodes and blood glucose values over time. Participants were asked to keep a diary over a period of six months. This added another dimension to the data collection process; for example, participants could make notes of their reflections and generate further ideas in response to questions asked during the interview and cues given with the diary instructions (e.g. describing the different hypoglycaemic episodes as they occurred).

The diary consisted of two parts: one section to keep a record of blood glucose readings and another section to describe experiences with hypoglycaemic episodes. Participants were instructed to carry out plotting of blood glucose values no more or less often than they would normally do; they were simply asked to keep a record of their blood glucose values when these were measured (this would usually be carried out on a daily basis).

The frequency of filling in the hypoglycaemia diary varied depending on the number of hypoglycaemic episodes participants experienced during the diary time. Therefore, the hypoglycaemia diary was written intermittently rather than daily.

### **5.7.4.1 Structure of diaries**

A brief description of every hypoglycaemic episode was written when they occurred. It was expected that keeping the diary would not take more than 30 minutes per month of participation time. Using diaries was beneficial for addressing the research questions in the following ways: it helped gain longitudinal insights into participants'

lives, as well as exploring individual explanations for different hypoglycaemic events (Elliott 1997). Another advantage of using diaries is the “opportunity for the recording of events and emotions in their social context” (Hawkes et al. 2009:211).

There are, however, a few potential drawbacks in using diaries. Keeping a diary requires some literacy skills and commitment from participants (see Hawkes et al. 2009). To address this, the diary format was clearly explained and any questions addressed to support people keeping the diary and to minimise attrition rates. Diary entries were also brief and included a plotting of blood glucose levels (see Appendix 14) and a section for participants to enter a brief narrative about the situational context (e.g. lifestyle, exercise, illness) surrounding their experiences of hypoglycaemia (see Appendix 13). The diaries were designed in a format that was attractive and easy to use. Additionally, pre-paid envelopes were provided to return completed diary entries, as this has been known to increase response rate (Hawkes et al. 2009).

Looking at results from blood glucose diaries, there can be some inaccuracies, as highlighted in a study by Kazlauskaitė et al. (2009). The authors suggest that the blood glucose meter memory (which usually saves a couple of months’ worth of blood glucose readings) should be checked and compared with participants’ written diary entries to increase reliability of results (Kazlauskaitė et al. 2009). While it was not possible to access blood glucose meter memory in this study, limitations of self-reported blood glucose diary entries should be taken into consideration when analysing diary results.

In terms of the hypoglycaemia diaries, limitations were mainly related to its self-reported nature. For example, participants had to make a decision on what they

identified as a hypoglycaemic episode, and whether to write a diary entry. Completion rates can be influenced by time participants had to complete the diary, commitment and literacy skills of participants (Burman 1995; Hawkes et al. 2009). Therefore, participants may not have written a diary entry every single time they experienced a hypoglycaemic episode. Also, some participants may fail to record sufficient detail of their hypoglycaemic episodes (Bryman 2008). However, I did not specify any expected number of hypoglycaemic episodes participants may experience, rather participants were asked to keep a record of all the hypoglycaemic episodes they had during the period they kept the diary. A major advantage of the hypoglycaemia diary was the fact that it enabled prospective recording of actual hypoglycaemic episodes as they happened, giving an insight into people's life worlds (Hawkes et al. 2009).

### **5.7.5 Semi-structured telephone interviews**

During the period of diary-keeping a short telephone interview was conducted monthly (later reduced to bi-monthly) to follow-up with participants to:

1. Explore any changes that might have occurred in participants' experiences of hypoglycaemia;
2. Gain an understanding of different individual explanations for various hypoglycaemic episodes;
3. Investigate whether participants perceived any link between hypoglycaemic events and variation of blood glucose levels; and
4. Encourage participants to maintain their engagement in the study and completion of diary forms.

Telephone interviewing is a practical and time efficient way to collect data (Opdenakker 2006).

During the course of the follow-up phase the frequency of follow-up telephone interviews was reduced from monthly to bi-monthly. This decision was made in consultation with the supervisory team following a few practical considerations. All participants returned their completed diaries via pre-paid envelopes in the post, which meant that there was a slight delay between the time participants completed their diaries, posted them to me and the time I received them. Further, arranging a suitable time for a telephone interview could take up to another week or more, depending on participants' other commitments (e.g. work, family) and holidays/travel plans.

Consideration was also given to the fact that after receiving the diaries, I needed time to study and review the entries, in order to prepare for the telephone interview. Finally, and very importantly, participants wanted to be able to feedback new information to me during follow-up telephone interviews, so reducing the frequency of telephone interviews from monthly to bi-monthly worked better, and provided enough time to explore and discuss the diary.

Conducting telephone interviews bi-monthly was therefore deemed more practical and reduced the burden on both participants and researcher. Most importantly, reducing the number of telephone interviews from six to three per participant did not appear to adversely affect the collection of data required to answer the research questions.

In addition to the scheduled telephone interviews, I was still available for any questions or support in keeping the diary, as required by participants. I contacted participants when they returned their diaries (some did this every month while others preferred to send in their diaries every two months), or I got in touch when I did not hear anything from participants within 6 weeks.

#### **5.7.5.1 Structure of telephone interviews**

The structure of the telephone interviews was based on findings from the semi-structured face to face interviews and literature (see Appendix 15). I asked participants to describe their experiences of writing the diary, and to discuss the hypoglycaemic episodes that had been recorded. The telephone interviews provided an opportunity to investigate issues around symptoms, individual explanations for hypoglycaemic episodes, perceived severity of hypoglycaemic episodes, as well as coping strategies, including whether participants required external or emergency help. During the regular telephone contacts, participants were also asked whether they needed any support in keeping the diary.

Generally, where participants decided to stay in the study during the follow-up phase, they were very keen to share their experiences of hypoglycaemic episodes during the diary time. Some participants even claimed that keeping the hypoglycaemia and blood glucose diary for this study helped them to understand patterns and causes of hypoglycaemic episodes better, and helped to improve their diabetes control.

The topic guide for the telephone interview was applied flexibly. On the one hand, I allowed participants to expand on their experiences of hypoglycaemic episodes freely

as long as there was a focus on the research questions. On the other hand, prompts and questions were used to investigate specific areas of interest.

Some participants (n=2) who lived locally preferred to meet in person at the University of Stirling rather than being interviewed over the phone. I agreed to this, while making sure that the same structure for the follow-up/telephone interview was used with all participants.

A small number of questions were added to the telephone interview topic guide during the follow-up phase, following interim analysis of data. These were in relation to coping strategies and people's perceived severity of their hypoglycaemic episodes. Initial findings from face to face interviews and participants' diaries showed that there were different views relating to the subjective, perceived severity of hypoglycaemic episodes. While for some participants, symptoms were the most important indicator in relation to severity, others tended to judge this purely based on blood glucose readings. Therefore, I included a question about the 'perceived severity' in the telephone interview topic guide.

Another issue that came up during the face to face interviews was that of health literacy/health education. This seemed particularly relevant in the context of hypoglycaemia unawareness. For this reason, the topic of health education and training was included in the telephone interview topic guide.

### **5.7.6 Managing data collection**

A number of issues were important in managing the data collection. First, I had to pay particular attention to minimise the burden of participation on participants. This was

achieved by clearly explaining what study participation involved and answering any questions participants had. Second, recruitment rates were monitored on a monthly basis and reviewed with my supervisors. Third, an accurate record of what stage in the study participants were at (e.g. dates of face to face interviews, progress with the blood glucose and hypoglycaemia diary, dates of follow-up telephone interviews) was kept throughout the data collection and follow-up phase. This was important to ensure that (telephone) interviews were conducted and diaries completed at the appropriate time. And finally, I attempted to keep a record of reasons why people either refused to take part in the study or decided to withdraw from the study at a later point. All these were important for establishing the accuracy and relevance of study findings as well as helping to inform the design of future research.

Overall, the data collection yielded 30 interview recordings lasting between 15 and 72 minutes (most interviews lasted 30-55 minutes/average 44 minutes), 20 personal diaries of participants covering between 1- 6 months (77 months of diary keeping) and 48 telephone interviews.

### **5.7.7 Rigour and quality of the qualitative data**

According to the Oxford Dictionary (2012), rigour is defined as the “quality of being extremely thorough and careful” (para.1). The issue of rigour is important when assessing quality of qualitative research. In order to convince the audience of trustworthiness and credibility of findings, it is vital that the research process is clearly described, and that methods, data analysis and presentation are transparent (Yardley 2007).

Rigour allows reproducibility of a study based on accurate representation of the sample and good quality account of study design and method, ensuring consistency over time (Thomas and Magilvy 2011). Mays and Pope (1995) suggest that to guarantee rigour, researchers should “create an account of method and data which can stand independently so that another trained researcher could analyse the same data in the same way and come to essentially the same conclusions; and to produce a plausible and coherent explanation of the phenomenon under scrutiny” (p.110).

Credibility can be achieved by presenting an accurate description and interpretation of participants’ experiences that is recognisable by people who share the same experience (Krefting 1991). Another aspect of credibility relates to the representativeness of data, which can be accomplished by reviewing interview transcripts to establish similarities across and within individual participants (Thomas and Magilvy 2011).

Reflexivity of the researcher is an important quality criterion in the context of transparency of the research process, including data analysis and interpretation. Reflexivity means that the researcher considers how his/her personality and assumptions may influence the research outcomes (Thomas and Magilvy 2011). In order to address this, I wrote field notes immediately after each interview, including reflections on new insights and personal biases. During interviews, I attempted to stay neutral and not steer participants towards responses that they may not have previously thought about (see Thomas and Magilvy 2011).

To ensure rigour, this study provides a detailed account of the processes through which the research was undertaken, as well as how the research questions were

developed, details of research design, sampling strategy, data collection, potential biases, etc. In terms of approach to data analysis, a link is established between the objectives of the study, choice of method, and the research findings, so that both the findings and processes are recognisable, transparent, and can be replicated.

## **5.8 Potential for bias**

Bias may have been introduced into the study in a number of ways. For example, bias in relation to sampling can be a limitation (Groger et al. 1999). The non-SAS participants might not be entirely representative of people with diabetes who do not use emergency services. There might also be differences between those SAS patients who took part and those who refused to take part. This study only included people who resided in the central belt of Scotland, who might have different views and experiences of hypoglycaemic episodes compared to people who live outwith the region. However, the sample did cover two different groups (SAS and non-SAS participants), a good spread of ages (ranging from 21 to 82 years), as well as male and female participants (see section 5.5.2).

Another factor that may influence participants' responses is the way in which interviews and diaries are introduced. Participants' require sufficient information about the study and what participation involves in order to make an informed decision about their willingness to participate. However, the information provided has to be carefully selected to minimise the level of bias in participants' reporting.

It is possible that participants decide to leave the study at various points (as highlighted in section 5.4.4), which can introduce bias to the study. It is therefore

important to investigate any differences between participants who stay in the study and those who decide to leave the study during the follow-up phase.

Finally, the interviews and diaries may have revealed that some participants' self-care activities or diabetes control were either problematic or inappropriate. I acknowledged the limitation of my role as a researcher, and only referred participants to seek medical advice and help when they expressed concern. Further limitations of this study are discussed in section 9.4.

## **5.9 Data analysis**

There are a number of approaches in analysing qualitative data and their appropriateness is influenced by the stance of the researcher (participant or observer), data type and what research aims to achieve. This section briefly introduces a few ways of analysing qualitative data and gives details about the method of data analysis chosen for this study.

Two similar approaches are conversation analysis (CA) and discourse analysis (DA), both of which place much importance on language. Bryman (2008) states that "language is depicted in discourse analysis as constituting or producing the social world" (p.500). Discourse analysis (DA) emphasises the way versions of the world, of society and events are produced in discourse; it is particularly interested in the use of language (Fairclough 2003; Bryman 2008). According to Morgan (2010), it represents the umbrella term for the many approaches used to analyse discourse.

Discourse analysis can be useful in addressing key research questions and topics in health research and policy. For example, topics that emphasise promoting health,

reducing health inequalities, as well as improving health services (Morgan 2010). An example of a study that applied discourse analysis is O'Connor and Pearson (2005). They investigated the discourse used in palliative care for older adults living in Australia. Interestingly, their findings showed that there were two distinct approaches to palliative care: One stated that palliative care represented a highly specialised and complex practice. This was prominent in healthcare institutions and in the literature. The other discourse regarded palliative care as an addition to usual nursing practice, and did not associate it with any specialised knowledge. The latter view was primarily adopted within nursing homes (O'Connor and Pearson 2005).

The emphasis of DA on language means that it could have been useful in looking at participants' use of language in this study, for example to investigate whether all participants adopted a biomedical discourse of their illness. However, this study places less emphasis on participants' use of language, as its main interest is about the content and themes of participants' accounts of their experiences.

Another approach is the 'grounded theory' method of data analysis, which was developed by Glaser and Strauss. The central feature of grounded theory is the "discovery of theory from data" (Glaser and Strauss 1967:2). This is achieved by an iterative and systematic process of data collection, data analysis and reflection (see Bryman 2008). Strauss and Corbin (1998) highlight that a grounded theory is one that is inductively derived from the study of the phenomenon it represents, while Creswell (1998) points out that the researcher has to set aside theoretical ideas to allow a 'substantive' theory to emerge. According to Strauss and Corbin (1998), grounded theory is most appropriate in research areas where little or no theories exist.

Egan (2002) advises that although grounded theory research is commonly accepted to be holistic, naturalistic, and inductive in maintaining the traditional stages of research; that is, planning, data collection, analysis, and reporting, its creation is not wholly a linear process. For example, a key characteristic of grounded theory is theoretical sampling (Birks and Mills 2011), which means that further recruitment and data collection is based on emerging concepts from initial data analysis (Egan 2002). This study used a purposive sampling approach; with some pre-conceived assumptions of the study populations (see section 5.5.1). Thus, a pure grounded theory approach would not be appropriate.

However, there are some less 'purist' ways of applying a grounded theory approach in data analysis, whereby the researcher uses grounded theory principles as well as some background theory (Birks and Mills 2011). The background theories can then be further developed during data analysis. In relation to this study, it did not follow a pure grounded theory approach; however, some techniques of grounded theory have been used (e.g. constant comparison method).

The main method chosen to analyse qualitative data in this study was thematic analysis using a framework analysis approach (see section 5.9.1). Framework analysis is a structured approach to thematic analysis of qualitative data developed by Ritchie and Spencer (1994). It was explicitly designed to generate findings relevant to practice and policy (Ritchie and Spencer 1994). This fits in very well with the current study design, in terms of findings being relevant to (future) design of SAS emergency care as well as general diabetes care. Framework analysis also offered a structured approach to develop models of illness behaviour (the HEBC model, see section 7.3 and the HEHS

network, see section 8.3). These models were generated from the data with reference to existing evidence.

Additionally, framework analysis links in well with the interpretivist approach this study was following in terms of its constructionist ontological position. It is also very useful in addressing pre-specified questions (Furber 2010). Another benefit of framework analysis is its systematic and transparent approach to data analysis, giving people other than the primary researcher access to the analytic process (Ritchie et al. 2003b).

A major difference between framework analysis and grounded theory is that framework analysis preserves the integrity of individual participant's accounts through a process of summarising and classifying data within a thematic framework, in contrast to the intentional 'fragmentation' of data during the analytic process when using grounded theory (Green and Thorogood 2009). Again, this feature of framework analysis underlines its relevance to this study, facilitating a clear and transparent approach during each step of data analysis.

### **5.9.1 Stage 1: Analysis of qualitative data**

As highlighted above, the analysis of qualitative components of this study was guided by principles of framework analysis (Ritchie and Spencer 1994). The framework approach is very appropriate as the objectives of the investigation are set in advance and it offers a practical and systematic way of analysing large amounts of qualitative data (Pope et al. 2000).

The main stages of the framework approach to qualitative data analysis are:

- Familiarisation (with all collected data)
- Identification of a thematic coding framework
- Indexing (i.e. applying the thematic framework to data)
- Charting data according to their thematic reference (which includes some abstraction and synthesis of data)
- Mapping and interpreting the data as a whole

### **Familiarisation**

The first stage in framework analysis is familiarisation with all data. All interviews in this study were audio recorded and transcribed verbatim. After each interview, recordings were listened to and transcripts read several times in order to become closely familiar with the data and to gain an overview of the range and diversity of data (Ritchie and Spencer 1994). During this stage, a list of key ideas and emerging themes was developed (Ritchie et al. 2003b).

### **Identification of a thematic coding framework**

Following the familiarisation stage, a thematic coding framework was identified (see Appendices 16 and 17). This was guided by key themes generated by reading through and coding five transcripts. The five transcripts were selected to ensure that a variety of participants' experiences was included based on the following criteria: different age groups (n=1 aged 18-40, n=2 aged 41-60 and n=2 aged over 60), genders (n=3 female

and n=2 male), and participant groups (n=2 SAS and n=3 non-SAS). The initial thematic coding framework was cross checked with both my supervisors and further refined and developed through critical discussion (see Appendix 18). At this stage, coding was conducted manually, as it is suggested that this is sufficient to gain an overview of key themes (Arksey and Knight 1999).

The development of the thematic coding framework was an iterative process, moving back and forth between the coding framework and the transcripts, continuously refining and revising the coding framework and re-coding the transcripts (see Appendix 18). At this stage, my supervisors were involved in co-coding and checking of data analysis.

### **Indexing and charting data according to their thematic reference**

Once the thematic coding framework had been identified, it was applied systematically to the whole (qualitative) data. I used a qualitative analysis software package, Nvivo (Version 9) to facilitate this process. Following indexing, the data was re-arranged according to their thematic reference and charted to the appropriate part of the thematic framework (see Appendix 18). During this process, data was summarized, abstracted and synthesized (Pope et al. 2000).

### **Mapping and interpreting the data as a whole**

Finally, the charts, abstracts and summaries were used to develop and refine concepts and to establish associations between themes (Pope et al. 2000). I followed a pragmatic approach, developing charts for selective themes (those of particular interest to the study). This helped to develop the hypoglycaemic episode balancing

continuum (HEBC; see section 7.3) and the hypoglycaemic episode help-seeking network (HEHS network; see section 8.3). The process of mapping and interpreting the data as a whole was informed by the research aims, research questions and by themes from the data. This was also beneficial as it allowed for looking at phenomena across individual cases.

### **5.9.2 Stage 2: Analysis of quantitative data**

The quantitative data from the hypoglycaemia diary and the plotting of blood glucose values was entered into a quantitative analysis software package, SPSS (Version 19). Following this, the data set was checked for errors to ensure the accuracy of the data set, as suggested by Buckingham and Saunders (2004). This was done by double checking for errors and mistakes.

Quantitative data was analysed using descriptive statistics. It investigated:

- count of hypoglycaemic episodes, comparison across the SAS and non-SAS group
- consistency in perceptions of hypoglycaemic episodes (correlating the lowest blood glucose level with recording of hypoglycaemic episodes)
- perceived severity scores, comparison across the SAS and non-SAS group.

### **5.9.3 Stage 3: Data integration**

Data integration is an important step in studies adopting mixed methods approaches (Kroll and Neri 2009). The process of triangulation is generally used to integrate qualitative and quantitative findings, and is known to increase validity of results and

provides a more complete picture to answer the research questions (Jones and Bugge 2006; Doyle et al. 2009). Triangulation involves using multiple perspectives to address a set of research questions, as well as comparing results from qualitative and quantitative methods (Patton 2002). This study used the technique of triangulation to integrate all data, following the separate analysis of qualitative and quantitative elements.

Data integration was carried out at the interpretation stage. Results from qualitative and quantitative data were compared across the two participant groups (SAS and non-SAS participants, see section 9.2.1), as well as looking at particular themes (e.g. the issue of hypoglycaemia unawareness; see Hussein 2009). This study used a parallel analytic approach (Östlund et al.2011), and findings from quantitative data were used to inform findings from qualitative data. For example, socio-demographic factors identified from the quantitative data (see section 6.2) were used to help understand findings from the qualitative data (e.g. the issue of health literacy, see sections 7.4.4 and 7.5). The quantitative data on participants' blood glucose readings was used to inform findings from qualitative data; for example, it helped to investigate hypoglycaemia unawareness, an important phenomenon that can contribute to the use of emergency services (see sections 6.5.3 and 7.4.3).

## **5.10 Summary**

This study employed a longitudinal, multiple data collection approach, to explore participants' perspectives and experiences of recurrent hypoglycaemia over time. This chapter has provided an overview of methods chosen in this study, including details on study aims, research questions, sampling strategy and issues around access to

participants and recruitment. It has highlighted ethical considerations, phases of data collection and the approach chosen for data analysis.

The following chapters present findings from the analysis of the semi-structured interviews, hypoglycaemia and blood glucose diaries and telephone interviews. Chapter 6 presents the demography of the sample, characteristics of participants who completed the hypoglycaemia and blood glucose diary and then focusses on results from the quantitative data. It points out a number of differences between the SAS and non-SAS participants. These are further picked up on and analysed in chapter 7 (see for example section 7.5).

Chapter 7 focusses on findings in relation to participants' experiences and perceptions of recurrent hypoglycaemic episodes. Chapter 8 includes findings about participants' management of hypoglycaemic episodes within their overall diabetes care.

## **Chapter 6 - Study sample and comparison of diary results**

### **6.1 Introduction**

This chapter reports details about sample demography (section 6.2), including information about the sub-sample who completed the hypoglycaemia and blood glucose diary (section 6.3), and highlights possible differences between those who completed the diary and those who did not (section 6.4). It also considers similarities and differences between SAS and non-SAS participants in terms of numbers of hypoglycaemic episodes, perceived severity ratings and recording of hypoglycaemic episodes in the hypoglycaemia and blood glucose diary (section 6.5.1).

All quotes from participants are marked with their participant ID number, which provides basic information about the participant. The first part of the ID number shows which group participants belong to: AS= Scottish Ambulance Service (SAS) group and NS= non-SAS group. The number following the group code indicates people's age group: 1= 18 to 40 years, 2= 41 to 60 years and 3= over 60 years of age. The letters M or F stand for male or female, and the number at the end of each participant's ID number is simply a count of participants, from 01 to 30. For example, NS1\_M23 would be a male non-SAS participant, age group 1 with participant number 23.

## 6.2 Demography of the sample

The following table reports on the demographic characteristics of the sample.

Participants in sample (n=30)	Frequency	Percentage
<b>Group</b>		
Scottish Ambulance Service (SAS)	13	43%
Non-Scottish Ambulance Service (non-SAS)	17	57%
<b>Age</b>		Range:
Mean (All participants)	50 years	21-82 years (SD=17.2)
Mean (Non-SAS)	44 years	28-66 years (SD=13.87)
Mean (SAS)	58 years	21-82 years (SD=18.55)
18-40 years	11	37%
41-60 years	11	37%
>60 years	8	26%
<b>Gender</b>		
Male (6 SAS/8 non-SAS)	14	47%
Female (7 SAS/9 non-SAS)	16	53%
<b>Type of diabetes</b>		
Type 1 (9 SAS/15 non-SAS)	24	80%
Type 2 (4 SAS/2 non-SAS)	6	20%
<b>Duration of diabetes</b>		Range:
Mean (All participants)	24 years	2-65 years (SD=16.0)
Mean (Non-Scottish Ambulance Service)	21 years	2-51 years (SD=16.68)
Mean (Scottish Ambulance Service)	28 years	6-65 years (SD=15.39)
<b>Scottish Index of Multiple Deprivation (SIMD) Deprivation category</b>		
1	7	23%
2	4	13%
3	2	7%
4	7	23%
5	10	34%
Mean (All participants)	3.3	-
Mean (Non-Scottish Ambulance Service)	4	-
Mean (Scottish Ambulance Service)	2.4	-

**Table 6.1: Demographic characteristics of the sample**

All participants in this study were diagnosed with either type 1 (80%) or type 2 (20%) diabetes and were treated with insulin. The method of insulin administration was either through insulin pump (n=3, all from within non-SAS group) or injection (n=27). It was expected that the majority of participants would be diagnosed with type 1 diabetes as insulin therapy is the only treatment for type 1 diabetes (and being treated with insulin therapy was one of the inclusion criteria for this study). Treatment for

type 2 diabetes ranges from diet control and exercise, to oral diabetes medications and insulin therapy.

Participants ranged in age from 21 to 82 years, with the mean age being 50 years. The mean age for SAS participants was 58 years, while it was 44 years in the non-SAS participant group. Slightly more females (53%) than males (47%) took part in the study. There were more non-SAS participants (57%) than SAS participants (43%). This was due to challenges in the recruitment of SAS participants (see section 5.5.4.2).

Looking at the duration of diabetes for all participants, the mean was 24 years. SAS participants had a longer duration of diabetes (28 years), compared to non-SAS participants (21 years).

The Scottish Index of Multiple Deprivation (SIMD) was used to assess participants' socio-economic backgrounds. Deprivation categories are based on scores from seven domains (income, employment, education, housing, health, crime, and geographical access), and can be identified using people's postcodes (The Scottish Government 2009). This study used the SIMD quintile scores which range from 1 to 5 (1 being most deprived). There was a spread across all five deprivation categories among study participants; however, there was clustering of participants on both ends of the deprivation scores. For example, 57% of the sample belonged to deprivation category 4 or 5 (very little deprivation), while 36% were in the deprivation categories 1 or 2 (higher levels of deprivation). Interestingly, 14 of the 17 non-SAS participants were in deprivation categories 4 or 5, which is reflected in a mean score of 4. SAS participants tended to live in more deprived areas, with a mean deprivation score of 2.4.

### **6.3 Sub-sample who completed the hypoglycaemia and blood glucose diary**

Of the 30 participants who took part in the semi-structured face to face interviews, 67% (n=20) completed at least two months' worth of diary time. 11 participants (9 non-SAS/2 SAS) completed the full six months of diary time. Looking at the two groups, 71% of non-SAS participants took part in the diary stage, and 53% completed the hypoglycaemia and blood glucose diary for the full six months. In the SAS group, 62% of participants wrote some diary entries, but only 15% completed the full six months. Further details can be found in table 6.3 (see section 6.5.1). All participants who took part in the diary stage completed both hypoglycaemia and blood glucose diary during that time. Table 6.2 (see overleaf) shows an overview of missing data across all participants.

**Table 6.2: Overview of missing data across all participants**

Participant ID	N= days diary kept	N= missing days pre diary*	N= missing days within diary	N= missing days post diary (drop-out)**
NS2_F01	170	10	0	0
NS2_F02	168	12	0	0
NS1_F03	92	0	0	88
NS2_M04	160	20	0	0
NS3_F05	178	2	0	0
NS1_F06	0	N/A	N/A	N/A
NS1_M07	177	0	3	0
NS1_F08	0	N/A	N/A	N/A
AS1_F09	180	0	0	0
NS3_F10	112	0	68	0
AS1_M11	62	0	0	118
NS1_F12	0	N/A	N/A	N/A
AS2_F13	54	7	0	119
AS3_M14	0	N/A	N/A	N/A
NS2_M15	180	0	0	0
NS1_M16	0	N/A	N/A	N/A
NS3_M17	180	0	0	0
NS1_M18	61	0	0	119
NS2_M19	84	0	7	89
AS3_M20	0	N/A	N/A	N/A
NS2_F21	178	2	0	0
AS1_F22	109	0	4	67
NS1_M23	0	N/A	N/A	N/A
AS3_F24	179	0	1	0
AS2_M25	0	N/A	N/A	N/A
AS3_F26	0	N/A	N/A	N/A
AS2_M27	110	7	5	58
AS2_M28	77	8	5	90
AS3_F29	77	9	58	36
AS2_F30	0	N/A	N/A	N/A

\*missing days pre diary indicates that the participant did not start diary on 1<sup>st</sup> of the month (Participants usually started the diary the day following the face to face interview)

\*\*missing days post diary indicates that the participant stopped writing any further diary entries and dropped out from the study

#### **6.4 Potential differences between participants who completed the diary and those who did not**

There were 10 participants (five in each group) who did not write any diary entry following the initial interview. It was difficult to establish the reasons why participants decided to drop out of the study after the initial interview. This was because during

follow-up telephone calls or emails, participants did not directly state that they wished to drop out of the study, instead they responded to reminders by saying that they would try to write some diary entries.

Comparing the ages of participants who decided to drop out, it can be noted that the mean age of non-SAS participants leaving the study was 32 years (with a range from 28 to 35 years), while it was 68 years in the SAS group (with a range from 51 to 82 years). Even though the mean age was higher in the SAS group (see section 6.2), this difference still seems remarkable. There are some possible explanations for this difference: non-SAS participants might have been too busy with work or family responsibilities to commit to writing the diary, and SAS participants might have had further health problems that could have made diary completion difficult. For example, one of the SAS participants (82 year old male) had a stroke a few weeks after the semi-structured interview, which is why he dropped out of the study.

### **6.5 Differences between SAS and non-SAS participants who completed the diary**

As one of the inclusion criteria was either having called out the ambulance service in the week preceding recruitment (SAS participants) or not having required the assistance of emergency services due to a hypoglycaemic episode in the three months prior to recruitment (non-SAS participants), a major difference between non-SAS and SAS participants was whether or not they required external help to deal with hypoglycaemic episodes. One of the non-SAS participants explained why he had never needed the ambulance service or A&E due to a hypoglycaemic episode:

*I've never once been hospitalised or had to call an ambulance with my hypos because I know how to treat them now and I know when they're going to start. (NS2\_M19, face to face interview)*

Issues around needing external help are investigated in more detail in section 7.2.5. Further differences between SAS and non-SAS participants are discussed throughout the findings chapters (see for example section 7.5).

### 6.5.1 Frequency and perceived severity of hypoglycaemic episodes by participant group

	Participant ID	Age	Years since diagnosis	Group	N=days diary kept	N=number of hypos recorded	N=times BG<4 mmol/l	Percentage*	Mean perceived severity
1	NS1_F03	28	1.5	Non-SAS	92	17	20	85.00	4.31
2	NS1_M18	24	10	Non-SAS	61	20	20	100.00	3.10
3	NS1_M07	40	4	Non-SAS	177	31	53	58.49	4.03
4	NS2_F01	54	51	Non-SAS	170	62	58	106.90	4.86
5	NS2_F02	59	11	Non-SAS	168	18	18	100.00	3.11
6	NS2_F21	45	19	Non-SAS	178	61	78	78.21	5.64
7	NS2_M04	56	51	Non-SAS	160	52	58	89.66	1.91
8	NS2_M15	43	26	Non-SAS	180	46	74	62.16	2.51
9	NS2_M19	50	7	Non-SAS	84	5	4	125.00	7.40
10	NS3_F05	66	51	Non-SAS	178	47	69	68.12	2.93
11	NS3_F10	62	24	Non-SAS	112	17	15	113.33	2.06
12	NS3_M17	64	6	Non-SAS	180	50	51	98.04	6.65
	Mean	49	22	Non-SAS	145	35.5	43.17	82.23	4.04
13	AS1_F09	40	27	SAS	180	13	62	20.97	4.23
14	AS1_F22	21	7	SAS	109	2	23	8.70	3.00
15	AS1_M11	34	15	SAS	62	1	5	20.00	5.00
16	AS2_F13	58	35	SAS	54	1	5	20.00	8.00
17	AS2_M27	53	17	SAS	110	5	27	18.52	5.00
18	AS2_M28	58	41	SAS	77	1	27	3.70	Missing
19	AS3_F24	78	65	SAS	179	9	48	18.75	5.00
20	AS3_F29	70	30	SAS	77	0	23	.00	Missing
	Mean	52	30	SAS	106	4	27.5	14.54	5.04

\*Percentage = Percentage of times BG below 4 mmol/l and a hypo was recorded

**Table 6.3: Overview of results from quantitative data**

Table 6.3 (above) provides an overview of frequency and perceived severity of hypoglycaemic episodes by participant group. These are results from the sub-sample of participants (n=20) who completed the hypoglycaemia and blood glucose diary. The table shows that SAS participants who completed the diary were slightly older (mean age 52 years) than non-SAS participants (mean age 49 years), and had lived with diabetes for a longer time (mean duration= 30 years), compared to a mean of 22 years in the non-SAS group.

In terms of time the diary was kept, it ranged from 54 to 180 days. Comparing the mean data for SAS and non-SAS participants, non-SAS participants kept the diary for a longer time (mean=145 days) than SAS participants (mean=106 days). Participants also varied in relation to diligence and accuracy in completing the blood glucose diaries. For example, one SAS participant (AS1\_F22, who was pregnant when taking part in the study) completed her blood glucose diary very diligently, and interestingly, her blood glucose readings were always within the target she had been given by her diabetes specialist (see Appendix 14). This highlights that participants could be more motivated to maintain appropriate blood glucose levels when pregnant, or there could potentially be an issue of participants trying to portray themselves in terms of what they thought was more desirable (Adams et al. 1999; Fielding and Thomas 2008).

There were considerable differences regarding the overall number of hypoglycaemic episodes that were recorded. Non-SAS participants recorded an average of 35.5 hypoglycaemic episodes, while SAS participants only recorded an average of 4. These were the number of self-reported hypoglycaemic episodes. Taking into consideration

that on average SAS participants kept the diary for a shorter length of time, the difference between the two groups still seems striking.

The differences between the two groups are further highlighted when results from the blood glucose diary are considered. The blood glucose diary allowed me to analyse blood glucose readings surrounding hypoglycaemic episodes. SPSS was used to get a frequency count of low blood glucose readings (BG<4 mmol/l), and found that non-SAS participants had a higher number of times when their actual blood glucose readings were below 4 mmol/l (mean= 43.17). However, when correlating the number of hypoglycaemic episodes that each participant recorded with the number of times a low blood glucose reading was taken, there were considerable differences between the SAS and non-SAS group.

In the SAS group, participants only wrote an entry in the hypoglycaemia diary in 14.54% of the cases when their blood glucose readings were below 4.0 mmol/l. This contrasts to 82.23% in the non-SAS group. Some of these differences can be explained with different levels of record-keeping: perhaps participants in the SAS group found it more challenging to take a note of every hypoglycaemic episode they experienced during the diary time. Another possible explanation could be different levels of health literacy (also see section 7.4.4), and maybe a better understanding about what a hypoglycaemic episode is in the non-SAS group.

The differences between the SAS and non-SAS group in relation to recording of hypoglycaemic episodes when their blood glucose level was below 4.0 mmol/l may also have been influenced by hypoglycaemia unawareness (see section 6.5.3).

Overall, 18 hypoglycaemic episodes required SAS support during the study. These incidents were all reported by SAS participants. Given the comparatively short time SAS participants kept the hypoglycaemia and blood glucose diary and the potential for underreporting as a result of self-reported methodology (McGregor and Makkai 2003; Myers et al. 2007), these numbers are considerable.

### **6.5.2 Severity of hypoglycaemic episodes**

Participants were asked to give a severity rating for each hypoglycaemic episode they recorded in the diary. The severity rating was purely subjective, as perceived by each individual. It was based on a 1 to 10 scale (10 being most severe). Mean scores ranged from 1.91 to 8.0. There was a slight difference in the mean scores for the two groups. Non-SAS participants gave a mean score of 4.04, while SAS participants perceived their hypoglycaemic episodes to be slightly more severe with a mean score of 5.04. There was more variation when comparing severity scores within each group; especially in the non-SAS group where scores ranged from 1.91 to 7.4. The variety of perceived severity scores were further considered when looking at results from the qualitative data, (see section 7.3/table 7.1), especially in relation to attitudes towards hypoglycaemic episodes.

### **6.5.3 Possible hypoglycaemia unawareness**

The (low) percentage of times a hypoglycaemic episode was recorded in participants' diaries when their blood glucose level was below 4.0 mmol/l highlights another possible phenomenon: hypoglycaemia unawareness. Despite having a blood glucose level below 4.0 mmol/l, some participants might not have recognised that they were having a hypoglycaemic episode due to a lack of symptoms. Hypoglycaemia

unawareness is associated with a higher risk of experiencing severe hypoglycaemic episodes (Gerich 2000). This could be a particular problem in the SAS group, and might explain why the percentage of recorded hypoglycaemic episodes when the blood glucose level was below 4.0 mmol/l was so low. The results from the qualitative data further helped explain possible differences relating to hypoglycaemia unawareness between the SAS and the non-SAS group (see sections 7.4.3 and 7.5).

## **6.6 Summary**

This chapter presented details of sample demography (section 6.2), as well as information relating to the sub-sample who completed the hypoglycaemia and blood glucose diary (section 6.3). SAS participants tended to live in more deprived areas and have had diabetes for longer than non-SAS participants.

The results from the quantitative data have shown some differences between the SAS and non-SAS participants. For example, non-SAS participants recorded more hypoglycaemic episodes compared to SAS participants. This could in part be due to higher levels of hypoglycaemia unawareness in the SAS group (see section 6.5.3). In terms of perceived severity scores, SAS participants rated their hypoglycaemic episodes slightly more severe than non-SAS participants (section 6.5.2). Further differences between the two groups were explored as they occurred in the qualitative analysis and are discussed in the following chapters (see for example section 7.5).

## **Chapter 7 - Participants' experiences and perceptions of recurrent hypoglycaemic episodes: Re-conceptualisations of balancing the risks**

### **7.1 Introduction**

This chapter focusses on participants' experiences and perceptions of recurrent hypoglycaemic episodes and the impact hypoglycaemic episodes can have on their everyday life. It is structured into four sections.

The first describes how the variation and unpredictability of hypoglycaemic episodes can affect participants (section 7.2). This includes worries about hypoglycaemic episodes happening (section 7.2.1), as well as difficulties such as feeling confused when participants were experiencing hypoglycaemic episodes (see section 7.2.3). It highlights that there can be a lack of association between blood glucose levels and symptoms participants experience, both on an individual level as well as across participants (section 7.2.4). This could have potential implications for clinical practice, for example, recommendations given to patients. It may be useful to include information that hypoglycaemia unawareness can affect people at various times and that blood glucose levels can fail to predict onset of hypoglycaemic episodes (see section 9.5.1).

The second section presents the 'hypoglycaemic episode balancing continuum' (HEBC; section 7.3) which has been developed based on the findings of this thesis. The HEBC is a framework for understanding how participants adopted different stances towards hypoglycaemia, and that they varied in the way they balanced risks of long-term complications, the immediate impact of hypoglycaemic episodes and achieving

appropriate diabetes control. For example, the HEBC demonstrates that those participants who had a fearful perception of hypoglycaemia tended to keep a higher blood glucose level in an attempt to avoid hypoglycaemic episodes happening.

The third section highlights participants' individual explanations for recurrent hypoglycaemic episodes (section 7.4). This included participants' awareness of the factors contributing to hypoglycaemic episodes, underlining the importance of health literacy. Findings show that participants' understanding of the factors that can cause hypoglycaemic episodes varied considerably.

The fourth and final section of this chapter presents the differences between participant groups. Findings show that SAS participants tended to experience more severe hypoglycaemic episodes, compared to non-SAS participants. One contributing factor was that they seemed to be less able to manage hypoglycaemia unawareness (section 7.5).

## **7.2 Variation and unpredictability of hypoglycaemic episodes**

The following sections highlight various issues that were identified in relation to the variation and unpredictability of hypoglycaemic episodes participants experienced. For example, participants' fears and worries about hypoglycaemia: this seemed to vary between different participants (section 7.2.1). In relation to the unpredictability of hypoglycaemic episodes, findings also showed participants' feelings of being confused and not in control when experiencing a hypoglycaemic episode (sections 7.2.2 and 7.2.3).

A surprising finding was the lack of association between blood glucose level and symptoms experienced: individuals spoke about experiencing symptoms of hypoglycaemia at various blood glucose levels. There was no consistency of symptoms at particular blood glucose levels. In fact, sometimes participants were still able to solve a difficult puzzle at very low blood glucose levels, while at other times they would struggle to even treat their hypoglycaemic episode at exactly the same blood glucose level, (see section 7.2.4).

There was variation relating to participants' experiences of needing external help (section 7.2.5). Major differences were evident between SAS and non-SAS participants: seeking external help was a lot more prominent in the SAS group, and this help was more often provided by the ambulance service. Requiring external help also seemed to be associated with hypoglycaemia unawareness.

### **7.2.1 “Hypos are scary”: fears and worries about hypoglycaemia**

Fears and worries about hypoglycaemia were mentioned by many participants. This included both fear when hypoglycaemic episodes actually occurred, as well as worries about potential hypoglycaemic episodes happening.

*When you start having all the hypos it's quite scary. (NS1\_F06, telephone interview)*

*I get very impatient if I can't have something to eat, not only because I know that I'm quite low [referring to blood glucose], but because I'm scared stiff that I'm going to go too low and I'm out. (NS3\_M17, face to face interview)*

*I've never collapsed or anything, but I know that that can happen and that's a hugely worrying thing to live with. (NS2\_F02, face to face interview)*

For some participants, fear of hypoglycaemic episodes influenced their diabetes self-management, resulting in them keeping a higher blood glucose level in order to avoid hypoglycaemic episodes happening (also see section 8.2.7.3). The following quote illustrates the dilemma of a female non-SAS participant who was very frightened of hypoglycaemic episodes.

*Some of the reasons why I stopped taking my insulin was because I was scared of hypos – I know it sounds really, really daft, but because of the way they make me feel, I'm scared to take too much insulin if it's going to bring on a hypo, and sometimes that makes my blood go high. So I can't win [laugh]! (NS1\_F12, face to face interview)*

One SAS participant spoke about experiencing a severe hypoglycaemic episode while travelling to another country. She described her anxiety of whether someone would know how to treat hypoglycaemic episodes and help her, and whether she would be able to explain that she had diabetes, and was experiencing a hypoglycaemic episode. She stated:

*It's scary, hypos are scary in the fact that you feel vulnerable [...] it's the feeling of not feeling safe, that's scary. (AS1\_F09, face to face interview)*

Another SAS participant explained her fear and confusion when she needed external help due to a severe hypoglycaemic episode:

*I just get scared when the paramedics are standing there, am I coming or am I going? [...] I just don't know what I'm doing. (AS2\_F30, face to face interview)*

A number of participants also mentioned experiencing depression/low mood as a result of the burden of managing diabetes and hypoglycaemic episodes. The following participant explained how experiencing hypoglycaemic episodes and managing diabetes brought on depression.

*I know it sounds a daft thing but with the hypos and the diabetes, right, that's what's causing my depression as well. But a lot of people don't realise this and it's hard to try and get over to people, right, that depression is linked with diabetes now. [...] it does get you down and that's why I'm now on 40mg of anti-depressants a day as well now, right, because you do... don't get me wrong when I first got diagnosed with diabetes, right, at one point I was getting suicidal. (NS2\_M19, face to face interview)*

One of the SAS participants described how experiencing a hypoglycaemic episode in the morning can impact on the rest of the day causing her to feel depressed.

*If I experience a hypo in the morning, say, like I won't do anything for the rest of the day because I know that it's going to be like that. It's going to go up and down all day, and if I do go out I'll just take my sugar gels with me, but I don't like going out if I know that my blood sugar's been low in the morning... it puts a downer on it, I know that's... they say don't let it do that but it does. You can't help it, it makes you feel all down and depressed when it goes like that. (AS1\_F22, face to face interview)*

This section has underlined the huge strain hypoglycaemic episodes can have on people's life: feeling scared when hypoglycaemic episodes are actually happening, as well as worrying about potential hypoglycaemic episodes occurring at any point in time. For some participants, the experience of hypoglycaemic episodes and the demands of managing diabetes can cause feelings of depression. This could have a knock-on effect on their diabetes management; for example, trying to avoid hypoglycaemic episodes (also see section 8.2.1).

### **7.2.2 “Not being in control”: issues around losing control**

When describing their experiences of recurrent hypoglycaemic episodes, participants often expressed the wish to be in control, to be able to take care of themselves. Hypoglycaemic episodes are sometimes perceived as a threat to achieving this, especially when help from another person becomes necessary. The following quote highlights that the feeling of losing control seemed to be associated with increased fears and worries about hypoglycaemia.

*“When you start having all the hypos it's quite scary, just because you almost lose control, you know, you always want to be in control but you're almost losing control then.” (NS1\_F06, telephone interview)*

The following participant reflected about the concept of (not) being in control in light of her experience of hypoglycaemic episodes over time.

*“You become conscious of the fact that you are not in control [when having a hypoglycaemic episode], it's not that I'm a control freak, but it's just I like to be in control of what I'm doing, I don't mind about*

*anybody else, but that would be a serious loss for me.” (NS2\_F01, face to face interview)*

Another participant described a conflict when a situation arose where external help was required, but she was reluctant to accept any help. This underlined her strong desire to be independent and ‘in control’.

*“I think it’s hard because that’s when you’re feeling your most confused [refers to situation when blood glucose level is very low] and you don’t want anyone else taking control over you, well I probably wouldn’t like that anyway, you know, that’s part of the problem is that you don’t want any help.” (NS2\_F21, face to face interview)*

Participants’ fear of losing control appeared to be a major concern in relation to how hypoglycaemic episodes disrupted their everyday lives, as well as the impact this could have on their ability to treat hypoglycaemic episodes themselves effectively. Interestingly, the issue of losing control was not just about physical control, but perhaps more importantly mental capacity: experiencing hypoglycaemic episodes could impact on people’s mental ability, as illustrated below.

*“Hypos are not nice things to have, it’s a horrible, horrible feeling. Apart from feeling drained and tired, it’s this business of not being in control; your mind isn’t working the way it should and that bothers me, that really worries me. You lose your rationale on things and you start to think ‘am I confused, am I thinking straight, what should I be doing?’” (NS3\_F10, face to face interview)*

### 7.2.3 “I’m so confused by them”: issues around confusion and struggles

A number of participants viewed hypoglycaemic episodes as a major challenge in the management of diabetes. Some participants seemed to generally struggle to manage hypoglycaemic episodes. Participants also reported feeling confused and sometimes finding it challenging to treat hypoglycaemic episodes. Such confusion was a major factor that can impact on treatment, e.g. cause a delay in taking appropriate action or necessitate external help. Another important factor was people’s attitude towards diabetes and hypoglycaemic episodes. The following quote highlights one participant’s struggle:

*It’s an on-going battle every day in the big war that you never win! That’s what it feels like [...] it’s very hard work, it’s quite exhausting and you feel like your whole life is just sort of taken over by it, although it isn’t, but that’s just... everything that you do is sort of impacted by it. (NS1\_F08, face to face interview)*

Some participants reported that hypoglycaemic episodes can cause confusion, which can interfere with treatment. The following participant spoke about situations when she felt so confused that she ‘forgot’ what she was about to do, or how to treat the hypoglycaemic episode:

*Now I’m so confused by them [i.e. hypoglycaemic episodes] I don’t... I know once or twice I’ve even sat thinking ‘there’s something I really need to do, I must do it but I’ve no idea what it is?’ (NS2\_F01, telephone interview)*

*I was just a bit confused, obviously because I was having a hypo!  
(NS1\_M07, telephone interview)*

One SAS participant recalled a severe hypoglycaemic episode where she lost consciousness:

*I woke up and it's like all confused and everything, it's like didn't know what was happening. See when I woke up the last time with the ambulance here, I woke up and I thought I was actually just dreaming because the ambulance was there and I was like 'what's going on?'  
(AS1\_F22, face to face interview)*

This highlights an important problem in the treatment of hypoglycaemic episodes: when people get confused, external help may become necessary. This help is often provided by family members or friends, and in more severe cases the ambulance may be called. In situations when the individual is confused, the ability of the person's support network to identify, help treat or call out an ambulance is vital. Section 8.2.7.4 takes a closer look at the role of people's support network.

#### **7.2.4 “No rhyme nor reason”: the lack of association of blood glucose levels and symptoms of hypoglycaemia**

Several participants spoke about discrepancies between their blood glucose level and the symptoms they experienced. For example, some of the non-SAS participants could feel 'perfectly normal' even though their blood glucose level was very low. The following quotes illustrate this:

*I can still be doing a Sudoku diabolical puzzle at 1.8 and I'm still okay! But the other thing is I have different feelings; I can be 1.8/1.9/2 and I'm feeling okay, but sometimes at 3.4 I think 'wait a minute, I need sugar here...' So it varies and I just can't put rhyme nor reason to that. (NS2\_M04, face to face interview)*

*I've checked my blood and I've been 1.6 [mmol/l]. I'm completely normal [...], I've been socialising with folk and it's all fine, [...] but there's none of the symptoms, but also at the same time I can be 4.5 [mmol/l] and all the symptoms are all over the place. (NS1\_M23, face to face interview)*

The above quotes illustrate that there were variations in relation to when symptoms of hypoglycaemia were felt. Some participants reported the absence of symptoms in situations when their blood glucose level would be classed as hypoglycaemic (below 4.0 mmol/l, see section 2.7). But participants also reported that they could feel symptoms when their blood glucose level was well above 4.0 mmol/l. The following participant confirmed this:

*I can feel as though I'm having a hypo and my blood sugar is still over 5 [mmol/l]. (NS2\_F01, face to face interview)*

Several SAS participants described similar experiences. Interestingly, the experience in the SAS group appeared to be mainly related to low blood glucose levels where participants did not experience any symptoms, which is also known as hypoglycaemia unawareness, (see section 2.9). This may suggest that hypoglycaemia unawareness is a more prominent problem in the SAS group, compared to the non-SAS group. Results

from the quantitative data (see sections 6.5.1 and 6.5.3) also confirmed that hypoglycaemia unawareness appeared to be a major problem in the SAS group.

*See sometimes I test and say I'm 2.6 [mmol/l] and I'm perfectly alright, I'm not hypo [...] other times at two point something I probably would be hypo, so it doesn't always happen at the same level as far as I'm aware. (AS3\_F24, face to face interview)*

*I'll check my blood and see what it is, and I might look at it and say 'oh it's a two point something' and I still feel normal, I feel okay, I'm not going to fall down, I don't feel any different, but maybe ten minutes later or even less than that you could just fall down, but this is you just finding out cause you've checked your blood. (AS2\_M25, face to face interview)*

These quotes highlight that the lack of association between blood glucose levels and symptoms of hypoglycaemia is strongly associated with hypoglycaemia unawareness. The above quote illustrates that the participant's sense of balance was not affected at a specific blood glucose level. However, a short time later he found himself in a situation where his sense of balance was affected and he was then likely to require external help. A similar experience is reflected in the following quote by a female SAS participant:

*There's been a time when I check my sugars and I'm conscious and they're down at 1.2, and then another time they'll be at 1.6 and the paramedics are having to bring me round. I can't explain that. (AS1\_F09, face to face interview)*

Another important aspect of the issue of lack of association of blood glucose levels and symptoms of hypoglycaemia is a potential conflict between participants' responses to certain blood glucose levels (in terms of symptoms of hypoglycaemia) and health professionals' recommendations. For example, one SAS participant described his experience of having a severe hypoglycaemic episode while in hospital. Before the hypoglycaemic episode became severe, he had felt symptoms and called for a nurse asking for glucose. However, no action was taken and the participant ended up unconscious.

*I was in the hospital, and during the night I felt I wasn't right, you know, so I pressed the buzzer and one of the nurses came up and she said 'what's the matter?' and I had my own check for my sugar and I said 'my sugar is 4.6', 'oh...' she said '...that's alright yet' I said 'but it's not alright with me, my sugar is not alright at 4.6, it's dangerous, it can go right over the edge very quick'. But anyway, she never bothered and it was only when they were going off the shift this other nurse had to get blood off me or something off me, and she couldn't waken me up and she couldn't get nothing in my mouth. I was away; I was away into a coma. Finally they got sugar into me, this stuff, you know, it's Glucogel aye, and they managed to get that into me and they finally got me round, but it was a dangerous situation. (AS3\_M14, face to face interview)*

#### **7.2.4.1 Gradual versus quick onset hypoglycaemic episodes**

Participants' accounts of various hypoglycaemic episodes showed one important difference between these episodes: how a particular hypoglycaemic episode started and at what point it was noticed. For example, one of the non-SAS participants (NS1\_M16) distinguished quick onset and gradual onset hypoglycaemic episodes.

### *Quick onset hypoglycaemic episodes*

He explained that the quick onset hypoglycaemic episodes were much more noticeable because the symptoms were stronger and more present.

*If it [BG level] rapidly drops down then that to me is much more noticeable. So, for example, if you over-bolus [i.e. take too much insulin] for a meal and it comes crashing down very rapidly then you really notice that, so it sort of depends on the speed, the rate of descent as it were, that makes how noticeable it is and how strong the symptoms are I think. (NS1\_M16, face to face interview)*

One of the SAS participants described how his hypoglycaemic episodes can happen so quickly that it was very challenging for him to treat the hypoglycaemic episode on time.

*I've been at the point where I'm going below four going into a hypo, and I say to myself 'right, I'm going into a hypo here' and say to myself 'right I need to take something quick' but there are some points that it just drops... fast I don't know, I know I'm going into it but...I've not got time to react sort of thing. (AS1\_M11, face to face interview)*

While both participants referred to their hypoglycaemic episode happening rapidly, the non-SAS participant talked about having strong symptoms. He made no mention of not being able to treat himself. However, the SAS participant's account of a quick onset hypoglycaemic episode provided details about difficulties in treatment due to the short time available 'to react' before the hypoglycaemic episode got worse. This highlights a potential link to hypoglycaemia unawareness. The reason the above SAS

participant talked about a short time available to treat himself could be an absence of early warning signs.

#### *Gradual onset hypoglycaemic episodes*

According to some participants, 'gradual onset' hypoglycaemic episodes tended to come on when the person was sedentary (i.e. working on the computer, watching TV). These hypoglycaemic episodes were much less noticeable until the blood glucose level had dropped further. The following quote refers to a situation where the participant was playing a computer game:

*Your blood glucose might just trickle down whilst you're doing that [playing computer game] and you might get quite low really without noticing, so you might sort of... might get up from doing that or whatever and you think 'mmm, better check' and you don't feel too bad but you might be sort of, you know, down in the low threes. (NS1\_M16, face to face interview)*

Another participant described a similar scenario when he watched TV. The absence of early symptoms caused him to worry.

*If I've just been sitting watching TV for instance, and I then decide to go to bed, I always take my blood sugar before I go to bed anyway, and it can often be low enough which suggests to me I'm actually having a hypo, but because I'm not doing anything, just sitting and watching telly, I don't have the symptoms. So that's quite worrying I think [...] It [blood glucose level] can be down as low as 2.5 which is really dangerously low in a way, isn't it? (NS3\_M17, telephone interview)*

There might be an association between what participants referred to as gradual onset hypoglycaemic episodes and hypoglycaemia unawareness. In fact, the 'gradual onset' could be a misinterpretation of a lack of warning signs/early symptoms.

### **7.2.5 “It happens just like that”: the experience of needing external help**

Some participants talked about situations where they needed external help to get out of a hypoglycaemic episode. This issue was mentioned by all SAS participants, and mostly external help was provided by Scottish Ambulance Service paramedics. One of the SAS participants spoke about his experience of recurrent hypoglycaemic episodes when he needed the paramedics frequently.

*At some points I was taking two and three a day, that's how bad things had got. [...] the biggest majority of them have been where the paramedics have been out and had to bring me back, blood sugars below zero... below 1.1 and all that, this is how bad it had got. You get the paramedic out in the morning and get them back out at night time again. (AS2\_M25, face to face interview)*

Needing external help seemed to be associated with hypoglycaemia unawareness, which has been identified as a contributing factor for severe hypoglycaemic episodes (Frier 2007a; Clarke et al. 1995). For example, some participants mentioned that their hypoglycaemic episodes come on quickly leaving them little time to identify the hypoglycaemic episode and treat themselves. This is one of the characteristics of hypoglycaemia unawareness, that is, the absence of early warning signs (Briscoe and Davis 2006; Frier 2007a). The following quotes illustrate where participants needed external help because of hypoglycaemia unawareness.

*Lately it has been, what, about three times hasn't it I've been into the... with the ambulance, you know. It [hypos] just happens just like that and if you're not onto it right away you're in trouble. (AS3\_M14, face to face interview)*

*The last couple of times it's happened, I've actually been sleeping and I haven't known anything about it until the paramedics woke me up. (AS2\_M27, face to face interview)*

In comparison to SAS participants, non-SAS participants spoke about the theme of needing external help much less. In fact, none of the non-SAS participants needed ambulance service care during the study. When they did need external help, this was often provided by family, friends or colleagues. SAS participants also referred to their support network, e.g. one participant's daughter either phoned or visited him on a daily basis to make sure he was alright. However, SAS participants tended to have more hypoglycaemic episodes where external help was required from the ambulance service rather than other sources. This suggests that their hypoglycaemic episodes may differ in speed of onset and severity, such that their immediate support network may not be able to respond, (also see section 8.3). The role of people's support network is further discussed in section 8.2.7.4.

### **7.2.6 Severity of hypoglycaemic episodes**

The extent to which hypoglycaemic episodes impact on participants' everyday life depends on the severity, as well as response (whether treatment was taken quickly) and how long recovery takes, (see section 8.2.6). There was considerable variation regarding the severity of hypoglycaemic episodes participants experienced. For

example, for many non-SAS participants, hypoglycaemic episodes were a ‘minor inconvenience’ that they usually treated themselves.

*It is an interruption, but it's not a major thing really for me with my lifestyle. I know how to get over it, know how to deal with it, I do that quickly as I can and move on. So it's not a huge thing for me really, a nuisance though, I get annoyed [laugh]! (NS3\_F10, face to face interview)*

When hypoglycaemic episodes were more severe, the impact on participants' everyday life was a lot more far reaching. For example, one 82 year old SAS participant who experienced a severe hypoglycaemic episode had to spend two weeks in hospital following the event.

*I got the ambulance right away and they took me straight into hospital, you know, and I was in there for a fortnight. (AS3\_M14, face to face interview)*

Comparing the two groups, SAS participants tended to have more severe hypoglycaemic episodes. This was based on severe hypoglycaemic episodes being defined as requiring external help to effect treatment (DCCT 1997). In terms of participants' perceived severity scores, there was only a slight difference in the mean scores for the two participant groups, (see sections 6.5.1 and 6.5.2). Non-SAS participants gave a slightly lower score compared to SAS participants. It is important to note that perceived severity and actual severity (based on symptoms, blood glucose reading, and whether external help was required) can differ greatly.

For example, one of the non-SAS participants (NS3\_F05) recorded a perceived severity score of 5 when her blood glucose reading was 3.1 mmol/l, while she judged the severity as 2 when her blood glucose reading was 2.9 mmol/l on another occasion. When asked about this variation during a follow-up telephone interview, she stated that the difference in perceived severity was a result of how she felt during each hypoglycaemic episode. This experience was shared by many participants.

### **7.2.7 The longitudinal impact of recurrent hypoglycaemic episodes**

This section looks at the longitudinal impact of recurrent hypoglycaemic episodes. It highlights changes over time in relation to participants' experiences of hypoglycaemic episodes. Many participants spoke about technological improvements relating to diabetes treatment, for example, better blood glucose monitoring using a precise blood glucose monitoring machine rather than urine test strips and a colour chart. The following participant explained how she used urine tests to monitor her blood glucose level over fifty years ago when she was first diagnosed with diabetes.

*The testing was with gathering urine, putting five drops into a test tube, adding five drops clean water, putting in a tablet which then went [fizzing sound] and then looking and you were left with a colour, and if it was blue that meant you were okay [...] but you didn't really have any indication, there were no blood glucose tests. (NS3\_F05, face to face interview)*

The experience of another participant illustrates that there has been considerable development and improvement relating to blood glucose monitoring. He described

how his blood glucose monitor would even recommend whether he should eat some carbohydrates.

*The blood testing kit I've got is a great wee gizmo because it actually... it's one of the new systems, it actually... I've pre-programmed it with some settings and stuff so it takes in my insulin to carbohydrate ratios, so I do a blood test, it tells me what it is and then it'll recommend the amount of carbohydrate to take. (NS1\_M23, face to face interview)*

While these improvements in blood glucose monitoring may help to precisely determine an individual's blood glucose level, and therefore classify whether the person is experiencing a hypoglycaemic episode, challenges to identify and treat hypoglycaemic episodes remain, (see sections 7.2.3 and 7.2.4).

The following section focusses particularly on changes relating to frequency, severity and symptoms of hypoglycaemic episodes. A number of participants identified changes relating to their symptoms of hypoglycaemia. The changes in symptoms were often associated with hypoglycaemia unawareness, which in turn was linked to frequency and severity of hypoglycaemic episodes.

### *Frequency*

In terms of frequency of hypoglycaemic episodes, participants reported changes relating to both an increase as well as a decrease in hypoglycaemic episodes. The issue of changes in frequency was mentioned by both SAS and non-SAS participants, however only very few non-SAS participants spoke about this issue. Compared to SAS participants, the non-SAS participants that did identify changes in frequency stated

that they were experiencing less hypoglycaemic episodes than previously. This decreased frequency of hypoglycaemic episodes was associated with better diabetes control, which was a result of better health education and learning from experience.

*I'm more aware of it now than there's maybe... I probably think I had more hypos five years ago because I was taking higher amounts of insulin, whereas I don't think I'm having as many and I know how to deal with them now more than what I did five years ago. Whereas before I was just in a bit of denial about it all, and it's just helped being more regulated, sort of, in the past couple of years about things, so I know what's going to happen and if I get one I can explain it, whereas back then I probably couldn't explain what was happening. (NS1\_F08, face to face interview)*

In contrast, all SAS participants who mentioned changes in frequency concluded that they were experiencing more hypoglycaemic episodes than previously. Common reasons for this were a reduced ability to control diabetes (related to age/co-morbidities), hypoglycaemia unawareness and duration of diabetes. Interestingly, looking at the age groups of participants who mentioned changes in frequency, all non-SAS participants were younger than 40 years (age group 1), while all SAS participants were older than 40 years (age groups 2 and 3).

One SAS service participant explained that recently he was experiencing more hypoglycaemic episodes. He suggested that these might be associated with his inability to recognise them on time: *"I seem to be having more hypos. It's probably because I'm not detecting the signs soon enough"* (AS2\_M28, face to face interview).

According to a 78 year old female SAS participant, the increased frequency of hypoglycaemic episodes was caused by a long duration of diabetes and hypoglycaemia unawareness:

*I might have had more since I retired, erm... maybe that's because of the length of time I've had diabetes, I don't... I think you get less warning the longer you have it. Less warning of a hypo. (AS3\_F24, face to face interview)*

Another SAS participant linked the increase in hypoglycaemic episodes she experienced to the type of insulin she had been prescribed. During the interview, she mentioned challenges of changing to new types of insulin. The challenges related to different levels of effectiveness, i.e. faster impact on blood glucose level.

*See I never used to get, I never used to get as many [hypos] as that.*

*INT: So do you think anything has changed at all?*

*RES: Aye definitely that Actrapid, it's definitely down to that, mm hmm. (AS2\_F13, face to face interview)*

### *Severity*

Changes in severity of hypoglycaemic episodes were closely linked to changes in symptoms. Interestingly, it was an absence of early symptoms that could lead to more severe hypoglycaemic episodes, resulting from hypoglycaemia unawareness, (also see section 2.9).

Those participants that did talk about a change in severity stated that their hypoglycaemic episodes had become more severe. One feature of this was a quicker onset of the hypoglycaemic episode, as described by the participant below.

*When I was younger, I could feel a hypo coming on when I was out in the garden, and I had time to walk into the kitchen and get something to eat. I wouldn't actually risk doing that now. They are much quicker than that [now], and using that kind of energy could well be what pushed it too far. (NS2\_F01, face to face interview)*

The wife of an 82 year old SAS participant confirmed the challenge of a quicker onset of hypoglycaemic episodes in the context of changes over time.

*Well when you were younger... it never seemed to come onto you as fast as it does now. It seems as if it comes upon you faster now than what it did then, you know, you seem as if your body could take it on better than it could now, you know. (Wife of AS3\_M14, face to face interview)*

Another aspect that was identified in relation to an increased severity was that recovery might take longer.

*When I do have a hypo they are worse now. Like, it takes me longer to come out of it, whereas before it used to be just... a wee, like, ten minutes and I'd feel fine kind of thing. (NS1\_F12, face to face interview)*

### *Symptoms*

In terms of symptoms, the most reported change was an increase in hypoglycaemia unawareness, that is, on the one hand, loss of early warning signs, and on the other

hand, a quicker onset of hypoglycaemic episodes. Both of these contributed to more severe hypoglycaemic episodes.

The following participant spoke about losing her warning signs over time. She also described how she did not feel any symptoms of hypoglycaemia when she was pregnant.

*When I used to be able to feel it was like two-ish [refers to blood glucose] and that's when I was, like, getting really tingly lips and stuff like that, that's when I knew it was really down low. The lowest I've... when I've actually been pregnant, the lowest I've been is, like, 1.5 I think it was, it was really low, but I didn't have any warning with that one, it was quite low and not to get warning. (AS1\_F22, face to face interview)*

One of the non-SAS participants reported a change in symptoms being caused by the type of insulin, which gave her less symptoms when her blood glucose level was low, as well as a quicker onset of hypoglycaemic episodes.

*The new insulins, the human insulins make the reactions a little bit less and much quicker, so you haven't got a lot of time to muck about, you know finding is this high, is this low, is this whatever. So I generally, if I'm feeling odd at all, I'll test my blood, sometimes I'm testing about 10 times a day, but it's just to be sure, you've got the blood glucose monitoring equipment, it's silly to guess when you don't need to. (NS2\_F01, face to face interview)*

### 7.3 The hypoglycaemic episode balancing continuum (HEBC)

A number of participants referred in one way or another to managing diabetes as being a 'balancing act', which involved maintaining an appropriate blood glucose level, in order to avoid complications relating to a low or high blood glucose level. One participant described how she tried to keep her blood glucose levels balanced:

*You know, you feel split between two things: you want to get your blood glucose, your HbA1C, you want to get that down but you don't want to get it so down that it's giving you more hypos, so my HbA1C has been running round about seven, up to eight at one point, but it's back down to about seven just now. I would rather it was a bit lower but on the other hand if it was I'd have more hypos. So it's just that balancing act that you've got to do. (NS2\_F02, face to face interview)*

Another factor that was identified in terms of the balancing act was weight management, as highlighted by the following participant. He explained that he had to make a decision about how he could balance achieving a 'good' HbA1c reading while avoiding hypoglycaemic episodes and putting on weight.

*I did improve slightly the last time [referring to HbA1c result] but at the expense of having a lot of hypos, so my average was lower but I was having a lot of hypos for it and having a lot of hypos meant I was eating more carb rich foods/sugary foods to bring myself back up so I put on weight. So the trade-off was a lower HbA1c level but more hypos and I was getting fat! So I sort of decided to accept that my blood levels can be around the eight mark, I would rather it was running around that level which isn't too bad than I was getting really unhealthily fat and having a lot of hypos. (NS2\_M15, face to face interview)*

Another participant mentioned that exercise influenced the balance of keeping an appropriate blood glucose level. He stated that he needed to eat (more) to treat his hypoglycaemic episodes, and then do more exercise/physical activity to help with weight management.

*My coping strategy [for hypos] tends to be eat; then it also means that I'm always worried that I'm eating too much, putting on weight or any of those kind of things, so it's the balancing act which is why I tend to run quite a lot for fitness because that means that I can eat whenever I want [laugh] and not put on too much weight. (NS1\_M07, face to face interview)*

Examining the data around the issue of 'balancing act' more closely showed some patterns in relation to how people balance the various risks surrounding diabetes management (e.g. short-term and long-term complications). Participants seemed to take different views about the hypoglycaemic episodes they experienced. Depending on what attitude people adopted, this could have various implications on their diabetes self-management. For example, some people may try to avoid hypoglycaemic episodes if these episodes were perceived as very negative ("I wouldn't like to take another one [i.e. hypoglycaemic episode]. That was terrible." AS3\_F29), while others aimed to avoid long-term complications by keeping a very strict blood glucose control ("I would rather have a hypo than go blind!" NS1\_M07).

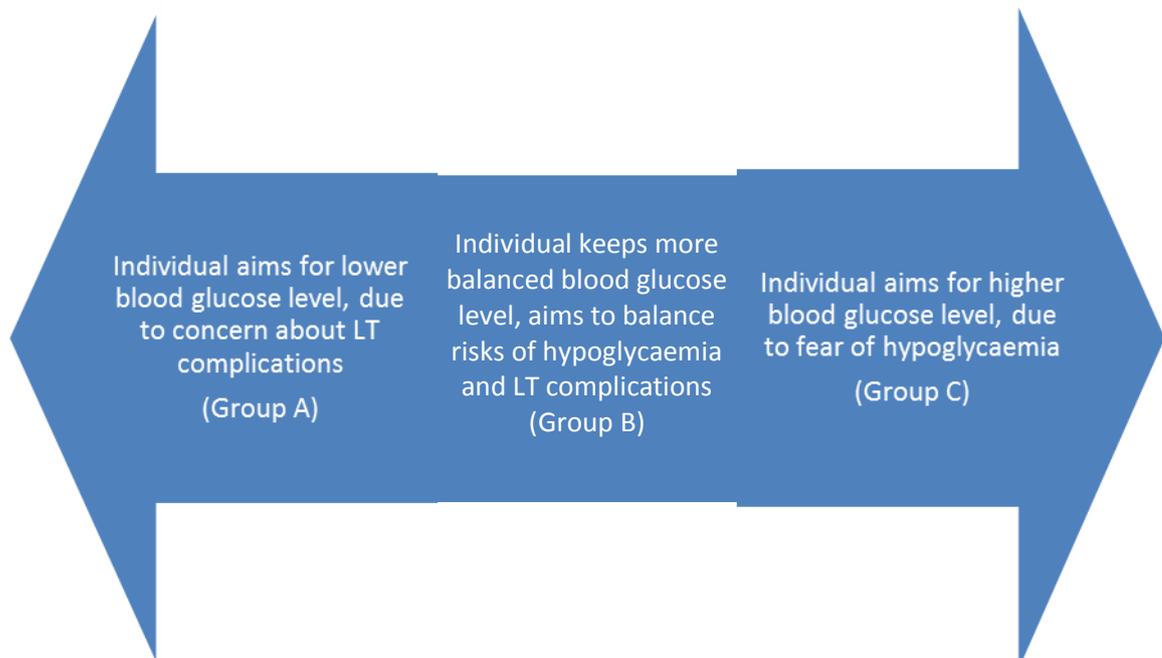
On the basis of these findings, I have developed the concept of a hypoglycaemic episode balancing continuum (HEBC). The HEBC is a framework for understanding how participants adopted different stances towards hypoglycaemia, and that they varied in

the way they balanced risks of long-term complications, the immediate impact of hypoglycaemic episodes and achieving appropriate diabetes control. It helps to explain how participants balanced risks of having (more) hypoglycaemic episodes when keeping a strictly controlled blood glucose level, as against reducing the number of hypoglycaemic episodes by keeping a higher blood glucose level and increasing their risk of experiencing long-term complications in the future.

The hypoglycaemic episode balancing continuum was based on the assumption that people possess self-care agency, which is defined as the human ability to engage in self-care (Orem 2001). In the context of this study, self-care agency means that people make a conscious decision about how they view hypoglycaemic episodes and the possibility of long-term complications, and how these short (i.e. hypoglycaemic episodes) and long-term complications are prioritised. Another aspect of self-care agency is people's ability to influence their condition and to make decisions regarding their diabetes self-management (e.g. adjusting the doses of insulin they are taking, regularly monitoring their blood glucose level and discussing treatment options with health professionals).

Another assumption was that people have a certain level of health literacy and awareness about long-term complications. According to Ratzan and Parker (2000), health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic information and services needed to make appropriate health decisions" (as quoted in Nielsen-Bohlman et al. 2004:32). While this definition includes both an understanding of health information as well as health services, for the purpose of this study, the term 'health literacy' is used to capture people's

understanding of health information as well as their health knowledge. This includes different types of knowledge: lay knowledge, experiential knowledge and medical knowledge. Lay knowledge is understood as knowledge passed on by non-professionals through narratives (Popay et al. 1998), experiential knowledge is individual knowledge learned through personal experience (Storkerson 2009) and medical knowledge is defined as knowledge of medical information. This can be obtained through health professionals, textbooks or the internet (Seale 2001).



**Figure 7.1: Hypoglycaemic episode balancing continuum (HEBC)**

It is important to note that the HEBC is a continuum and that participants can move along the continuum based on their experiences and perception of the risks of hypoglycaemia and long-term complications at any given time. Among the study participants, there were different management approaches towards hypoglycaemic episodes. People differed in the attitude they adopted towards having a hypoglycaemic episode: some people accepted hypoglycaemic episodes as a normal

part of living with diabetes (=not fearful), while other people felt very fearful about experiencing hypoglycaemic episodes (=fearful). The classification whether a person was 'fearful' or 'not fearful' was made based on participants' accounts in the interviews and diaries (see table 7.2 overleaf). Similarly, the classification into 'concerned' or 'not concerned' about long-term complications (LT) was also based on evidence from the interviews and diaries. Examples from the data are given in the discussion of the different groups.

As shown in table 7.1 below, participants' perceived severity scores varied a lot. Participants' perceived severity scores may be associated with their attitude to hypoglycaemic episodes (fearful or not fearful). Table 7.1 shows that there was a tendency for higher perceived severity scores in group C, while lower scores tended to be in group A.

Group A			Group B			Group C		
Participant	Number of hypoglycaemic episodes per month	Perceived severity	Participant	Number of hypoglycaemic episodes per month	Perceived severity	Participant	Number of hypoglycaemic episodes per month	Perceived severity
1	11	4.86	2	3	3.11	3	6	4.31
4	10	1.91	9	10	4.23	6*	4-5	N/A
5	11-12	2.93	15	12	2.51	8*	10-12	N/A
7	9	4.03	17	8-9	6.65	10	3	2.06
16*	4-5	N/A	18	10	3.10	11	2.5	5.00
21	13	5.64	20*	5	N/A	12	6	N/A
26*	8	N/A	23*	6	N/A	13	2-3	8.00
28	9	N/A	24	8	5.00	14*	2-3	N/A
			25*	30	N/A	19	1	7.40
			27	7	5.00	22	6	3.00
						29	8	N/A
						30*	4-5	N/A

\*Did not write any hypoglycaemia/blood glucose diary, number based on information provided during recruitment and interview

**Table 7.1: Number of self-reported hypoglycaemic episodes**

In order to determine whether participants had 'many' or 'few' hypoglycaemic episodes, data from the hypoglycaemia and blood glucose diary was used. The number of hypoglycaemic episodes was counted as self-reported hypoglycaemic episodes in the hypoglycaemia diary, as well as number of times participants recorded a blood glucose level below 4.0 mmol/l. This is the commonly accepted threshold for hypoglycaemia (JRCALC 2006; Diabetes UK 2008). The number of times participants recorded a low (below 4.0 mmol/l) blood glucose level was only added to the overall number of hypoglycaemic episodes if the individual did not write an entry in the hypoglycaemia diary for that day. The number of hypoglycaemic episodes people recorded varied considerably, ranging from one to thirty per month. The cut-off point for classifying whether someone had many hypoglycaemic episodes was set at five. This was because experiencing five or more hypoglycaemic episodes per month meant that the person had more than one hypoglycaemic episode a week, which was considered 'many' hypoglycaemic episodes for the purpose of classifying frequency of hypoglycaemic episodes. Where participants did not write any entries in the hypoglycaemia diary (due to dropping out of the study), evidence from the interviews was used.

There were some anomalies within group A and group C. Participant 8 reported considerably more hypoglycaemic episodes compared to other participants in group C, while participant 16 reported much less hypoglycaemic episodes than other participants in group A. The number of self-reported hypoglycaemic episodes for both participant 8 and participant 16 were based on verbal reporting in interviews, which

might over- or underestimate the number of hypoglycaemic episodes people experienced.

Table 7.2 (see overleaf) shows an overview of HEBC groups within the sample.

HEBC group	Participant group	Participant number	Gender	Age	Fearful	Not fearful	Many hypoglycaemic episodes	Few hypoglycaemic episodes	Concern LT	Not concern LT
A	Non-SAS	1	F	54		X	X		X	
A	Non-SAS	5	F	66		X	X		X	
A	Non-SAS	7	M	40		X	X		X	
A	Non-SAS	4	M	56		X	X		X	
A	Non-SAS	16	M	34		X		X	X	
A	Non-SAS	21	F	45		X	X		X	
A	SAS	26	F	73		X	X		X	
A	SAS	28	M	58		X	X		X	
B-1	Non-SAS	2	F	59	X			X	X	
B-1	Non-SAS	17	M	64	X		X		X	
B-2	Non-SAS	15	M	43		X	X			X
B-2	Non-SAS	18	M	24		X	X			X
B-2	Non-SAS	23	M	35		X	X			X
B-1	SAS	9	F	40	X		X		X	
B-1	SAS	20	M	79	X		X		X	
B-1	SAS	24	F	78	X		X		X	
B-2	SAS	27	M	53		X	X			X
C-B	Non-SAS	8	F	35	X		X			X
C-B	SAS	22	F	21	X		X			X
C-B	SAS	30	F	57	X			X	X	
C	Non-SAS	3	F	28	X		X			X
C	Non-SAS	6	F	29	X			X		X
C	Non-SAS	10	F	62	X			X		X
C	Non-SAS	12	F	28	X		X			X
C	Non-SAS	19	M	50	X			X		X
C	SAS	11	M	34	X			X		X
C	SAS	13	F	58	X			X		X
C	SAS	14	M	82	X			X		X
C	SAS	29	F	70	X		X			X
*	SAS	25	M	51		X	X			X

\*low self-care agency

**Table 7.2: Overview of HEBC groups within the sample**

People's views of hypoglycaemic episodes appeared to relate directly to how they prioritised risks of having long-term complications in the future versus the immediate impact a hypoglycaemic episode can have on everyday life. In terms of the HEBC, I have categorised the sample into three groups. It is important to note that the HEBC is a continuum and that participants can move along the continuum based on their experiences and perception of the risks of hypoglycaemia and long-term complications at any given time.

**Group A:** People who are in group A experienced many hypoglycaemic episodes. They were not very scared of hypoglycaemic episodes and accepted them as a normal part of living with diabetes. People in this group expressed a high level of concern about having potential long-term complications, and tried as much as possible to keep a low blood glucose level (sometimes even lower than the recommended target set by health professionals). Having a high blood glucose level was associated with physical discomfort/feeling unwell. They accepted having more hypoglycaemic episodes, if this reduced the (perceived) risk of long-term complications.

Hypoglycaemia unawareness was more common in this group than in group B or C. Frequent previous hypoglycaemic episodes and a strict glycaemic control have been identified as risk factors for hypoglycaemia unawareness (Amiel 1994; DCCT 1997).

Some quotes from people in group A are:

*To me, a hypo is going to happen as naturally as getting up and going to bed again, you know, it just happens. (NS2\_F01, face to face interview)*

*I always tend to err on the side of having a hypo and bulk up with sweets rather than taking less insulin and running high on my glucose, because I would rather have a hypo than go blind! (NS1\_M07, face to face interview)*

*I think it's more the higher blood sugars that I would be more concerned about. No... yeah as I said, I think that I need to have some hypos, not that I need to have some, but it shows that I'm on the right track and managing my blood sugar. (NS2\_F21, face to face interview)*

*I get more upset about having high blood sugars than I do about having low blood sugar, I think the low blood sugar's easy to alter and to rectify, whereas a high blood sugar you're toiling. (NS3\_F05, face to face interview)*

**Group B:** People in group B were aware of the risks of both having recurrent hypoglycaemic episodes as well as the potential for long-term complications when keeping a high blood glucose level. They tried to balance risks by aiming for a 'good' HbA1c without increasing the number of hypoglycaemic episodes they had. In relation to the HEBC, people in group B could be fearful of both, hypoglycaemic episodes and long-term complications (group B-1). Another possible combination for group B was that people were fearful of neither hypoglycaemic episodes, nor concerned about long-term complications (group B-2).

Quotes from people in group B:

*You feel split between two things: you want to get your blood glucose, your HbA1C, you want to get that down but you don't want to get it so down that it's giving you more hypos, so my HbA1C has been running round about seven, up to eight at one point, but it's back down to about*

*seven just now. I would rather it was a bit lower but on the other hand if it was I'd have more hypos. So it's just that balancing act that you've got to do. (NS2\_F02, face to face interview)*

*You do worry about the long-term effects but then the short-term effects will affect you right now, so yes you do worry about that, yes. It's just always a balancing act. (AS1\_F09, face to face interview)*

**Group C:** People who were in group C were very fearful of hypoglycaemic episodes and tried to avoid them 'at all costs'. They tended to run a higher blood glucose level (and thus have higher HbA1c readings). By keeping a high blood glucose level, they decreased the risk of having (recurrent) hypoglycaemic episodes, while increasing the risk of having long-term complications. People in this group had lower rates of hypoglycaemia unawareness.

Quotes from people in group C:

*They always show 5.8 on the meters as being the paragon, you know, and I think 'well, if I was at 5.8 all the time I would be on the verge of a hypo constantly' [...] I couldn't live like that day in/day out, I wouldn't want to. That is just not a good life experience [laugh], so I avoid that I suppose, although I try as hard as I can. If I could keep my sugar levels about seven or eight I'd be happy with that, never mind the 5.8, seven or eight or even... anything below ten, but unfortunately I don't even do that a lot of the time, but I would never want to be so low that I would be risking, constantly risking a hypo. (NS3\_F10, face to face interview)*

*I don't have the best control and I'm the first to admit that I like getting on a wee bit higher because I would rather avoid hypos if I can. I feel if my blood sugar's better controlled getting a hypo is almost guaranteed*

*and they'll be more frequent and they'll be more often and I almost think 'well, are they going to get worse?' (NS1\_F06, telephone interview)*

People could experience hypoglycaemic episodes no matter at what point on the HEBC they were. However, hypoglycaemic episodes appeared to happen a lot more frequently in group A. People could move between groups depending on how they viewed hypoglycaemic episodes at any given time. A major aspect that influenced people's attitude towards hypoglycaemic episodes was their experience of the same. For example, when a person experienced a severe hypoglycaemic episode impacting hugely on their everyday life, this could cause a shift on the HEBC from group A (less fearful) to group B or even group C (fearful).

*The first time I had one [i.e. hypoglycaemic episode] I thought I was dying, right, until I realised it was a hypo. (NS2\_M19, face to face interview, group C)*

*It's quite scary because when you start shaking and going cold but you're sweating sort of thing and it's quite scary. (AS1\_M11, face to face interview, group C)*

It was not just the actual experience of hypoglycaemic episodes that could influence people's attitude, but also their awareness about what might happen if they had a severe hypoglycaemic episode, as highlighted in the following quote.

*I've never collapsed or anything but I know that that can happen and that's a hugely worrying thing to live with. (NS2\_F02, face to face interview, group B-1)*

Another important factor that may influence people's balancing of priorities was the occurrence of long-term complications. For example, where a person used to keep a high blood glucose level due to fear of hypoglycaemia, when retinopathy or early signs of neuropathy were diagnosed, this could trigger a shift in priorities and move towards a more balanced approach (group B). The following participant explained why she preferred to keep a higher blood glucose level than recommended. She also stated that when her average blood glucose readings were 'bad' or when there was indication of a long-term complication starting, that would make her think again.

*I do worry about the complications that you can have with diabetes, not constantly, and I often think that's why I don't stick with my control as well as I should because it's always way into the future rather than something immediate, you know, if it was something that as soon as you did the wrong thing you got an immediate reaction, that would be more inclined to me to say 'well I'm not going to do that again' you know, [...]. So there's nothing immediate but each time you get a bad report [i.e. high HbA1c result] or some complication that seems to be starting or something like that, it does pull you up and you do worry about it.*  
(NS3\_F10, face to face interview, group C)

There were some examples in the data (participants 8 and 22), where people had moved from group C to group B. In both cases, it was related to pregnancy, either the desire to become pregnant (participant 8), or the participant getting pregnant (participant 22). It is important to note that health professionals emphasise the target of keeping blood glucose levels within a tight range when planning for a baby or when pregnant (Mulholland et al. 2007; Mersereau et al. 2011). This clearly had influenced both participants to keep their blood glucose level more controlled.

A similar shift can theoretically happen from group A to group B. When people experience more severe hypoglycaemic episodes this might cause a change in their attitude towards having hypoglycaemic episodes. In turn, they might alter their behaviour resulting in keeping a higher blood glucose level in order to avoid (severe) hypoglycaemic episodes. In terms of the HEBC, people then move from group A to group B or even group C. However, there were no examples for a move from group A to group B in the data.

#### **7.4 Participants' individual explanations for recurrent hypoglycaemic episodes**

Participants offered various explanations for the hypoglycaemic episodes they experienced, ranging from an imbalance of insulin and carbohydrate intake, to exercise, alcohol consumption and even the weather. In some cases participants were not able to explain what caused a specific hypoglycaemic episode. This could either be due to multiple factors being involved that made it difficult to identify a single reason, or people's lack of understanding about what influenced their blood glucose level to drop. The following quotes illustrate the complexities surrounding people's blood glucose control:

*It's a very difficult balance, really is and the more you go into it, sometimes the worse it gets because it isn't analysable totally, it just isn't. It's subject to all sorts of vagaries. You know, when you start saying that things like stress or worry or... depression or anything like that starts to affect you as well, it's very difficult to... it's bad enough if it was only food and understanding your intake and everything, that is complex enough, but when you start to, you know, exercise and all the other things that are going on in your body, and then of course you get a*

*cold or any illness, that has a different impact again. So it's extremely difficult, well I find it so anyway [laugh]! (NS3\_F10, face to face interview)*

This participant had an awareness of factors that could influence her blood glucose level (e.g. food intake, exercise, stress or an illness). However, she expressed difficulty in identifying the exact reason for a particular hypoglycaemic episode and keeping everything in balance. The following participant took explanations for hypoglycaemic episodes a step further, stating that complexities around social interaction as well as the weather influenced her blood glucose level. She felt that she had no control over many factors that influenced her blood glucose level.

*Every single day is different and everything that goes on around you 24 hours a day, 7 days a week affects your sugars. The weather affects your sugars, people affect your sugars, the situation you're in affects your sugars, driving, every single thing you do and the people you come into contact with affect your sugars. You have no control over the majority of it. (AS1\_F09, face to face interview)*

In contrast to the above participant, other participants believed that they could control their diabetes. For example, one of them, who had lived with diabetes for 51 years, claimed that he was in control of his diabetes.

*My philosophy is that I control my diabetes, not diabetes controls me and that has held me in good stead for many, many years. (NS2\_M04, face to face interview)*

Issues around control in relation to hypoglycaemic episodes have also been discussed in section 7.2.2.

#### **7.4.1 Imbalance of insulin taken and carbohydrate intake**

Some participants showed a very clear understanding of how the amount and type of insulin they injected affected their blood glucose level, depending on their carbohydrate intake. When completing the hypoglycaemia diary, participants cited reasons for their hypoglycaemic episodes such as “missed lunch” (AS1\_M11), “not eating enough” (AS2\_M27), “high blood sugar before dinner and too much insulin taken to compensate” (NS1\_M07), “overdid insulin at lunch” (NS2\_F21). This shows that many participants had awareness of the key factors that could contribute to their blood glucose level going high or low (e.g. insulin dose, carbohydrate intake).

Many participants understood that on the one hand, the insulin they injected could cause a hypoglycaemic episode if their carbohydrate intake was not proportionate to the amount of insulin taken. On the other hand, their blood glucose level could go high if the amount of insulin was not sufficient for the amount of carbohydrate intake.

#### **7.4.2 Exercise/activity**

Many participants spoke about the impact exercise or activity could have on their blood glucose level: it could reduce it quite substantially and thereby trigger a hypoglycaemic episode.

*If I exercise in the evening, I mean we have a wee exercise machine in the house and if I use that then I'm guaranteed to have a hypo during the night. (NS1\_F06, Telephone interview)*

*If I've been for a run and I've taken too much NovoRapid in the morning, gone for a run at lunchtime, then that can obviously trigger a hypo because there's too much insulin in your system. (NS1\_M07, face to face interview)*

Similar to the participant above, another participant also described how a combination of exercise and taking insulin caused him to have hypoglycaemic episodes. As he was able to identify the problem, he made some slight adjustments in relation to the timing of taking his insulin injection.

*I tend to find I have hypos if I exercise when I've got insulin in my system. If I have my lunch, an injection for my lunch, and then I go for a walk, instantly I'm needing to have glucose tablets; it seems to be a problem, so now if I'm doing that, we go out to lunch, we have the walk and then I inject. So I've learned to sort of move things around a wee bit. (NS2\_M15, face to face interview)*

In comparison to the non-SAS group, SAS participants spoke about the impact of exercise/activity much less; only half of the SAS participants did mention situations where exercise/activity brought down their blood glucose level. Fewer SAS participants reporting about the effects of exercise/activity may suggest either a lack of awareness or less active lifestyles. One of the SAS participants explained the impact gardening had on his blood glucose level:

*If you're doing something... exerting yourself, it could go faster, you know, to a hypo. When I used to be up in the garden and doing the garden, I used to be digging the garden, I used to have to leave it in there and come down and everything was going black in front of my*

*eyes, you know, by the time I got into the house, you know. (AS3\_M14, face to face interview)*

### **7.4.3 Hypoglycaemia unawareness**

Hypoglycaemia unawareness seemed to affect many participants at some point in their life. While hypoglycaemia unawareness can be a contributing factor for severe hypoglycaemia (Frier 2007a), in many cases, recurrent mild hypoglycaemia went unnoticed, unless a blood glucose test was carried out. In terms of awareness of hypoglycaemia unawareness, participants varied considerably. Some participants concluded that, if they did not have any symptoms and their blood glucose reading was below 4.0 mmol/l, they did not have a hypoglycaemic episode. When prompted for reasons/explanations for a low blood glucose reading, some participants could not see any reason why their blood glucose reading was low. As illustrated by the quotes below, hypoglycaemia unawareness also brought with it a level of unpredictability.

*I haven't got a clue. I just hope that it does not go any lower than that. (AS3\_F29, telephone interview)*

*I don't get any warning with the hypos, it just shoots me and that's it, that's it. (AS2\_M25, face to face interview)*

*No, there's not always rhyme or reason and that's frustrating, that's really annoying, [...] and that makes it worse. (NS3\_F10, telephone interview)*

Other participants were more aware about hypoglycaemia unawareness: they knew that hypoglycaemia unawareness meant a loss of early warning signs which necessitated closer monitoring of blood glucose levels.

*Over the last few years [...] I certainly think that my awareness of hypos has deteriorated hugely, because I used to be very aware, and it didn't stop me in anyway. Now I am wholeheartedly reliant on my blood glucose monitoring. (NS2\_F01, face to face interview)*

*I've got hypoglycaemia unawareness. (NS3\_F05, face to face interview)*

The quote above shows that the participant treated hypoglycaemia unawareness like having another diagnosis. This may legitimise behaviours that might normally not be acceptable, especially in relation to feeling in control, (also see section 7.2.2). If participants had been told by health professionals that they 'had' hypoglycaemia unawareness, this could offer them an explanation/'excuse' for situations when they were not able to control a hypoglycaemic episode.

Interestingly, there was a noticeable variation of people's response to hypoglycaemia unawareness. Some participants (like NS2\_F01, see above) would monitor their blood glucose level more closely, others would try and be prepared in case a hypoglycaemic episode occurred, (see section 8.2.2), and some participants simply accepted that they may experience hypoglycaemic episodes without prior warning signs and that they would require external help. The latter view was more common where people did not have a clear understanding of the concept of 'hypoglycaemia unawareness'. This was characteristic of the SAS group.

While hypoglycaemia unawareness was common in both groups, the knowledge of hypoglycaemia unawareness was much higher in the non-SAS group compared to the SAS group. This could have potential implications for diabetes management in the SAS group: experiencing hypoglycaemia unawareness over a period of (many) years increases the likelihood of having severe hypoglycaemic episodes (Gerich 2000; Briscoe and Davis 2006; Frier 2008). The issue of knowledge of hypoglycaemia unawareness is further discussed in section 9.3.1.

#### **7.4.4 Health literacy**

Participants' individual explanations of recurrent hypoglycaemic episodes seemed to be associated to their diabetes health literacy: that is, how much they knew about the various factors that could influence their blood glucose level and how these interrelated. One participant spoke about learning how the liver's activity could influence her blood glucose level:

*I have only just recently learned that there's an impact on hypos from your liver's activity too, and apparently when you go hypo, whether you take sugar or not, your liver will release some [glucose] in natural state of affairs, but what I didn't know was that it will actually take some back too, later, to put back in its store, so you can have a hypo because of that. I had no idea about that. (NS2\_F01, face to face interview)*

For many participants, learning about how to live with their diabetes and manage hypoglycaemic episodes was an on-going process.

*I'm learning every day with diabetes. (NS1\_F03, face to face interview)*

Some participants took time to study and learn about their condition in order to be better informed. There were also some circumstances in which participants described having to develop their own knowledge, when other sources of health information only took them so far.

*I then got loads of books out the library and went on the internet and such like, and learnt what foods were bad for me and what were good for me and what I shouldn't eat and what I could eat and really that was fine until my next worry was going to a restaurant and judging what I could eat there. (NS3\_M17, face to face interview)*

Most participants got some information about managing diabetes when they were diagnosed, either directly through conversations with their doctor or diabetes nurse, or indirectly in the form of information leaflets.

*They [i.e. health professionals] give you all these wee pamphlets, like, the one they've given me, the wee things is showing you where you take one jag in the morning, as soon as you get out your bed you take this jag and this one keeps your blood sugars all kind of levelled out. (AS2\_M25, face to face interview)*

In terms of sources of information about diabetes management, these ranged from family members/friends who also had diabetes, to reading books, the internet, taking part in education courses to discussions with health professionals and reading information leaflets provided by the GP or hospital. Comparing health literacy between the SAS and non-SAS group, the non-SAS group were generally more knowledgeable about their condition and its management, or described more

information seeking activities. For example, almost half of the participants in the non-SAS group reported having completed a structured education course (e.g. DAFNE 'dose adjustment for normal eating'; DAFNE online 2010; Owen and Woodward 2012), while none of the participants in the SAS group had taken part in such a course.

As highlighted above, the amount of diabetes education participants had received varied. General diabetes education is currently delivered on a one-to-one basis within primary care, where written material is also available. This includes diabetes education leaflets on various aspects of living with and managing diabetes, e.g. exercises, hypoglycaemia, coping with illness, diabetes and alcohol, driving and employment, diabetes and travel, etc. (NHS Forth Valley 2009).

There are recommendations that every individual diagnosed with diabetes should be offered to take part in structured diabetes education (NICE 2003; The Scottish Government 2010). However, this target may not always be achieved and it is also left to the individual to decide whether or not to engage in any educational activities.

## **7.5 Differences between SAS and non-SAS participants**

Participants' individual explanations for hypoglycaemic episodes reveal a great deal about people's understanding of their condition and their health literacy. The previous sections (7.4.1 – 7.4.4) have highlighted that there were various differences between SAS and non-SAS participants in relation to individual explanations for recurrent hypoglycaemic episodes. While most participants had a basic understanding about the requirement to balance the amount of insulin taken with the carbohydrate intake

(section 7.4.1), differences between the two groups became apparent when looking at participants' health literacy (section 7.4.4).

Health literacy captures people's understanding/knowledge about diabetes management, as well as factors that contribute to occurrence of hypoglycaemic episodes (Schillinger et al. 2002; Powell et al. 2007). Participants' diabetes health literacy influenced their knowledge about the impact exercise/physical activity can have on their blood glucose level (section 7.4.2), as well as awareness about hypoglycaemia unawareness (section 7.4.3). In terms of explaining hypoglycaemic episodes and achieving appropriate self-management responses, participants' diabetes health literacy was key. Section 7.4.4 has shown that non-SAS participants were generally more knowledgeable about their condition and its management, resulting in a better awareness of hypoglycaemia unawareness (section 7.4.3). This could have been a result of non-SAS participants being younger than SAS participants, and likely to be more computer literate (Poynton 2005; Choi and DiNitto 2013). Another factor that may have influenced people's health literacy and knowledge about their condition is their socio-economic background. SAS participants tended to live in more deprived areas compared to non-SAS participants (see section 6.2), which may have contributed to lower levels of health literacy (Brown et al.2003).

This chapter has highlighted a number of differences between SAS and non-SAS participants in relation to participants' experiences of recurrent hypoglycaemic episodes and impact on everyday life. While issues with confusion (section 7.2.3) and fear of hypoglycaemia (section 7.2.1) were common in both groups, there were some differences with regards to how people balanced risks of experiencing hypoglycaemic

episodes and having long-term complications in the future (section 7.3). In terms of the HEBC, the overview of groups within the sample (table 7.2) has shown that there was a spread of HEBC groups across both participant groups. However, in comparison to SAS participants, there were slightly more non-SAS participants in group A. This may suggest that non-SAS participants were more aware of the risks of long-term complications, or more concerned about them.

The issue of lack of association between blood glucose levels and symptoms experienced (section 7.2.4) has emphasised that participants experienced symptoms of hypoglycaemia at different blood glucose levels. Sometimes participants reported experiencing no symptoms despite a low blood glucose level. Comparing the two study groups, the experience in the SAS group appeared to be mainly related to low blood glucose levels where participants did not experience any symptoms, which is also known as hypoglycaemia unawareness (section 2.9). This suggests that hypoglycaemia unawareness was more common in the SAS group. In fact, results from the quantitative data (see sections 6.5.1 and 6.5.3) confirmed that hypoglycaemia unawareness appeared to be a major problem in the SAS group.

All SAS participants mentioned the issue of needing external help (section 7.2.5). In most cases, external help was provided by SAS paramedics. It is important to note that needing external help was associated with hypoglycaemia unawareness (see previous paragraph). In comparison to SAS participants, non-SAS participants spoke about the issue of needing external help much less. In fact, none of the non-SAS participants needed help provided by the SAS during the study. When they did need external help, this was often provided by family, friends or colleagues.

In terms of severity of hypoglycaemic episodes (section 7.2.6), there were some differences between SAS and non-SAS participants. For many non-SAS participants, hypoglycaemic episodes were a 'minor inconvenience' that they usually treated themselves, while SAS participants tended to have more severe hypoglycaemic episodes. This was based on severe hypoglycaemic episodes being defined as requiring external help to effect treatment (DCCT 1997). A factor that may have contributed to SAS participants experiencing more severe hypoglycaemic episodes is duration of diabetes (see section 6.2). There is evidence to suggest that a longer duration of diabetes is associated with more severe hypoglycaemia (Briscoe and Davis 2006; Graveling and Frier 2009). In terms of participants' perceived severity scores, there was only a slight difference in the mean scores for the two groups (see sections 6.5.1 and 6.5.2). Non-SAS participants gave a slightly lower score compared to SAS participants. It is important to note that perceived severity and actual severity (based on symptoms, blood glucose reading, and whether external help was required) can differ greatly.

## **7.6 Summary**

The findings reported in this chapter relate to participants' experiences and perceptions of recurrent hypoglycaemic episodes, as well as impact on everyday life. They particularly highlighted that it is the variation and unpredictability of hypoglycaemic episodes that impact on participants' everyday life and present a major challenge in diabetes self-management. Many participants described struggling with confusion and the feeling of losing control when hypoglycaemic episodes occurred. However, it was not only the actual hypoglycaemic episode affecting participants'

everyday life, but also fears and worries about possible hypoglycaemic episodes happening (section 7.2.1).

The findings presented in this chapter also highlighted the problem of hypoglycaemia unawareness, which was associated with the lack of association between blood glucose levels and symptoms experienced (see section 7.2.4). Many participants spoke about situations where their blood glucose level was below 4.0 mmol/l (the threshold for hypoglycaemia), without experiencing any symptoms. Hypoglycaemia unawareness also appeared to be linked to needing external help (section 7.2.5). The issue of needing external help was more prominent in the SAS group.

The section on the longitudinal impact of recurrent hypoglycaemic episodes identified changes relating to frequency, severity and symptoms of hypoglycaemic episodes (section 7.2.7). It was noted that only SAS participants described an increase in frequency of hypoglycaemic episodes. This was mainly associated with a reduced ability to control diabetes, hypoglycaemia unawareness and duration of diabetes.

A number of participants reported changes in symptoms (less early warning signs) relating to increased hypoglycaemia unawareness (section 7.2.7). This was associated with frequency and severity of previous hypoglycaemic episodes. Frequent previous hypoglycaemic episodes have been identified as a contributing factor for hypoglycaemia unawareness, while hypoglycaemia unawareness could cause more severe hypoglycaemic episodes (Amiel 1994; Gerich 2000; Briscoe and Davis 2006; Frier 2007a).

This chapter introduced the concept of a hypoglycaemic episode balancing continuum (HEBC), which conceptualised how participants took different stances towards hypoglycaemia. The HEBC explained how participants balanced the risk of long-term complications, immediate impact of hypoglycaemic episodes and achieving appropriate blood glucose control, depending on their fears in relation to hypoglycaemic episodes and long-term complications (section 7.3). It found that the focus of participants' fear determined where they sat on the HEBC. The continuum has demonstrated that those who exhibited fear of hypoglycaemia would be more likely to keep a higher blood glucose level in an attempt to avoid hypoglycaemic episodes happening, or to reduce the number of hypoglycaemic episodes they experienced. Those who did not express a similar degree of fear were more likely to keep their blood glucose level within a lower range, and were more likely to be concerned about long-term complications.

The findings reported in this chapter have shown that participants' individual explanations for recurrent hypoglycaemic episodes ranged from an imbalance of insulin taken and carbohydrate intake, to the effects of exercise and the impact of hypoglycaemia unawareness. While most participants showed a basic understanding about the requirement to balance the amount of insulin taken with the carbohydrate intake (section 7.4.1), differences between the two groups were apparent when looking at health literacy (section 7.4.4). Non-SAS participants tended to be more knowledgeable about their condition and its management compared to SAS participants, resulting in a better awareness of hypoglycaemia unawareness (section 7.4.3).

This chapter also presented differences between SAS and non-SAS participants (section 7.5). For example, findings showed that SAS participants tended to experience more severe hypoglycaemic episodes, and consequently required external help more often. It is important to note that needing external help was associated with hypoglycaemia unawareness, especially when the individual did not have much knowledge about the phenomenon. While both groups experienced hypoglycaemia unawareness, it appeared to be a more serious problem in the SAS group. Non-SAS participants seemed to be more knowledgeable about hypoglycaemia unawareness and better prepared in case a hypoglycaemic episode occurred. This contributed to non-SAS participants being able to better manage hypoglycaemia unawareness.

The following chapter focusses on participants' strategies to manage hypoglycaemic episodes (section 8.2), as well as participants' coping strategies (section 8.2.7). It also introduces the hypoglycaemic episode help-seeking network (HEHS network), which helps to identify the agents involved in the management of participants' hypoglycaemic episodes (section 8.3).

## **Chapter 8 - Managing hypoglycaemic episodes within diabetes care**

### **8.1 Introduction**

This chapter focusses on the management of hypoglycaemic episodes within diabetes care. It presents findings about participants' strategies to manage hypoglycaemic episodes in the context of their everyday lives (section 8.2). This includes issues around always being prepared (section 8.2.2), managing daily life with diabetes (section 8.2.3) and recovery from hypoglycaemic episodes (8.2.6). This chapter also gives an overview of participants' coping strategies (section 8.2.7), for example the tendency to avoid hypoglycaemic episodes by keeping high blood glucose levels (section 8.2.7.3). This is an important finding as it highlights the dangers associated with avoiding hypoglycaemic episodes by altering self-management strategies; that is, an increased risk of experiencing long-term complications in the future.

Another coping strategy participants adopted was denying that they were experiencing a hypoglycaemic episode. This included both self-denial and denial towards others (section 8.2.7.2). This strategy might be risky as it could lead to a delay in treatment, which might cause the hypoglycaemic episode to get worse, thus increasing the likelihood of needing external help.

Most hypoglycaemic episodes were managed by the individual without requiring any external help. However, participants' ability to self-care differed and deficits occurred, resulting in participants being more likely to need involvement of others (family/friends; see section 8.2.7.4). When the capacity of others to help broke down, participants' were more likely to need SAS emergency care. In order to explain how

hypoglycaemic episodes are managed, this chapter presents the hypoglycaemic episode help-seeking network (HEHS network), which has been developed from the data collected in this study (section 8.3). It helps to identify the various agents involved in helping to treat hypoglycaemic episodes. The HEHS network illustrates agents who manage hypoglycaemic episodes, and also points out other factors that can be involved in the management of hypoglycaemic episodes, for example, hypoglycaemia unawareness, health literacy and the participant's or their support network's ability to identify and treat hypoglycaemic episodes.

## **8.2 The management of diabetes and hypoglycaemic episodes**

The following sections report findings in relation to participants' strategies to manage hypoglycaemic episodes in the context of diabetes self-management, as well as participants' overall coping strategies (section 8.2.7). For example, hypoglycaemic episodes can have a huge impact on diabetes self-management, potentially resulting in poorer diabetes control caused by deliberate attempts to avoid hypoglycaemic episodes (section 8.2.7.3).

Participants' strategies to manage daily life with diabetes (section 8.2.3) and recovery from hypoglycaemic episodes (8.2.6) were also explored. Findings showed that some participants tended to avoid certain situations/tasks, and were especially concerned about keeping an appropriate blood glucose level while driving. Additionally, some participants admitted restricting exercise (on their own) or avoiding going out due to fear of hypoglycaemic episodes.

Findings also showed that the risk of having a hypoglycaemic episode caused some participants to try and always 'be prepared' (see section 8.2.2). One aspect of participants' preparations was to make sure food or glucose tablets were within easy reach in case a hypoglycaemic episode occurred. Another aspect was always carrying diabetes 'equipment' and medications (e.g. blood glucose monitor, insulin pens) to monitor the blood glucose level and keep it within an appropriate range.

### **8.2.1 Hypoglycaemia and diabetes self-management**

Diabetes self-management requires the individual to make decisions regarding his/her diabetes care on a daily basis. This includes dosage and timing of insulin injections, monitoring blood glucose levels, carbohydrate intake and exercise. Participants varied in their approaches towards diabetes self-management. For example, many participants adjusted their insulin dosage based on blood glucose levels, while others just followed recommendations given by their diabetes specialist. The following participant described how he adjusted the amount of insulin he took based on his blood glucose reading.

*It [i.e. blood glucose level] goes up and down, aye well if I get high blood sugars I'll take a wee bit extra insulin, sometimes I've seen me maybe after I've had the injection I'm supposed to have for that day, the last one at night, I've seen me coming in at night and maybe taking maybe another ten units or something just to bring my blood down because I've had it maybe away up at maybe 35 and all that. I know when it's as bad as that I need to get my insulin to come back down, so I'll just be lying on the couch and waiting for my blood to start to come down and eventually it'll come down anyway and that maybe followed by a hypo, don't know. (SAS participant, AS2\_M25)*

A female non-SAS participant explained how she worked out how much insulin to take. She showed a good understanding that taking more insulin could bring down her blood glucose level to a more controlled level; however, she was also aware that an increased amount of insulin could lead to (more) hypoglycaemic episodes occurring.

*I will sometimes change my Lantus, my night time insulin, if I'm not getting good results in the morning. In fact I did that just last night because I sort of looked back over the last week and I thought 'these morning results are creeping up a wee bit so it's time to notch up the night time Lantus' so I did that just last night, just going up a couple of units and whether that's going to result in a few more hypos after the next couple of days I'll just have to wait and see, but if it did then I'll put it back down again. (NS2\_F02, face to face interview)*

As the main responsibility of diabetes self-management lies with the individual, the individual has to make decisions and take action to manage diabetes. Sometimes an individual's decision can diverge from health professionals' recommendations as shown in the quote below. The participant admitted that he 'worked out' what amount of insulin was most acceptable for his individual diabetes control.

*Actually when I go to the clinic and they say to adjust my insulin, and I try it for a few days and I'm not happy with it, I tend to revert to what I was on before, I'm a bit stubborn like that [laugh]! [...] Sometimes the doctor tells you to do something and it really doesn't work for you, so you have to work things out for yourself a little bit as well. (NS2\_M15, face to face interview)*

Hypoglycaemic episodes potentially impact on participants' diabetes self-management in two ways. First, adjusting the amount of insulin taken and/or carbohydrates consumed in order to avoid a hypoglycaemic episode (also see section 8.2.7.3); that is, before a hypoglycaemic episode occurs, and second, making changes in relation to insulin/carbohydrate intake following a hypoglycaemic episode. This is illustrated by the following quote:

*If I've had a hypo, I will eat more and cut my insulin down a wee bit, but not too much, and that seems to work for me. (NS1\_F03, face to face interview)*

Generally, adjustments in diabetes self-management were aimed at reducing/avoiding hypoglycaemic episodes. However, as the hypoglycaemic episode balancing continuum (see section 7.3) has illustrated that some participants seemed more concerned about long-term complications, and would therefore accept more hypoglycaemic episodes happening as a result of keeping a lower blood glucose level.

Some participants tended to monitor their blood glucose level more closely following a hypoglycaemic episode. One non-SAS participant described how she would check her blood glucose level more often after she has experienced a hypoglycaemic episode because she did not get any warning signs if she experienced another hypoglycaemic episode in such a situation.

*You check your blood every couple of hours, you've got no choice, there's no other way of doing it. (NS2\_F01, Telephone interview)*

### 8.2.2 “Covering all bases”: participants’ strategies to prepare for potential hypoglycaemic episodes

Many participants mentioned strategies to prepare for potential hypoglycaemic episodes. Preparations ranged from making sure food/glucose tablets were available in case a hypoglycaemic episode occurred, to carrying blood glucose monitors and planning ahead (e.g. timing of meals/snacks, exercise). The following quotes show the strategies some participants adopted in preparation for future hypoglycaemic episodes.

*If I was going to do something, like supposing I was going to go for a long walk, say 10/12 mile walk for instance, then I would make sure I had plenty of food, I would make sure I had my glucose meter with me. (NS3\_M17, face to face interview)*

*I've got everything I could possibly need for my diabetes all in the one bag and I've got to carry this about with me all the time.[...] I have a replica kit in the car as well, right in the glove compartment which has a blood machine, glucose tablets, gluco stop, right, it has everything in there so that if I forget to take that one with me, I've always got one in the car, there's always a kit in my wife's car, right, and there's a kit in my wife's handbag, right, so we're covering all bases, right, in the case of emergency. (NS2\_M19, face to face interview)*

One of the SAS participants spoke about going away (e.g. travelling) less because of the preparation required and the inconvenience of carrying all her diabetes related equipment with her, e.g. blood glucose monitor, insulin pens, something sweet to eat, etc. She described how she would worry about keeping her insulin cool, and that she felt more confident to look after her diabetes when she was at home.

*It [having diabetes] restricts you from quite a lot I think. [...] what if there's a hold up with the traffic and all this, you know, [laugh] oh dear! (AS2\_F13, face to face interview)*

Interestingly, all non-SAS participants made reference to the issue of 'being prepared' (as highlighted in above quotes), while some of the SAS participants did not mention anything about being prepared at all. This suggests that there could be differences between the two groups in relation to diabetes self-care and being prepared for potential hypoglycaemic episodes.

### **8.2.3 “You’ve got to watch”: managing daily life with diabetes**

Many participants described managing diabetes as a balancing act (see section 7.3). The need to balance requirements to manage diabetes with everyday demands is further explored in this section. Two particular scenarios have been identified from participants' accounts: one, participants' tendency to avoid certain situations/tasks, and two, managing diabetes/keeping an appropriate blood glucose level while driving.

A number of participants mentioned situations they preferred to avoid because of the risk of having a hypoglycaemic episode. For example, one non-SAS participant spoke about not going cycling on his own since he was diagnosed with diabetes.

*If you're on a bike, you know, your blood glucose can pretty quickly drop and, you know, if you're ten miles from home or 15 miles from home then it's a bit unnerving if you're down a country road where there's no one around. (NS1\_M16, face to face interview)*

Another participant recalled that he had missed many classes at university:

*This year my diabetes hasn't been that good, well my bloods haven't been that good and I even missed, I'd say, 85% of my tutorials and about 50% or 60% of my lectures because my blood sugars have been down low and I've just not had the energy to do anything. (NS2\_M19, face to face interview)*

Some participants described that they did not go out at all because of fear of having a hypoglycaemic episode while out. This was often coupled with concern that people around would not understand what a hypoglycaemic episode was, and would therefore not be able to offer any help.

*I probably prefer to stay at home in case I went out and I took a more serious one [i.e. hypoglycaemic episode] sort of thing, eh. But I don't know because, like, if I do go out, see trying to explain hypos to people sitting in your company sort of thing they don't really understand. (AS1\_M11, face to face interview)*

One SAS participant (70 year old female) even avoided going to her regular diabetes check-up because of long walks within the hospital to get to the diabetes clinic. She also felt discouraged by the fast pace many doctors used to walk from the patient waiting room to the consultation room.

*You think it's a marathon they're running' and you're trying to keep up with them', I says 'no I'm not doing that anymore, because it knocks you all to pot' see and you've got to watch, ken what I mean, you've got to watch. (AS3\_F29, face to face interview)*

In terms of driving, participants found that keeping a good balance for their blood glucose level was vitally important. Even though participants were aware that keeping their blood glucose level within a tight range would be the target, there seemed to be a shift towards keeping a higher blood glucose level when driving in order to minimise the risk of having a hypoglycaemic episode.

*If I'm doing a lot of driving on a long journey, I must admit I tend to let my blood glucose run a bit high, I'd rather have it a bit high than a bit low. (NS2\_F02, face to face interview)*

#### **8.2.4 Dealing with hypoglycaemic episodes**

Many participants had identified particular foods/drinks to treat hypoglycaemic episodes (e.g. Lucozade, glucose tablets, sweets), which they tried to keep handy in case a hypoglycaemic episode occurred. For example, one SAS participant talked about keeping sweets close to her bed so she did not have to get up to get treatment when she experienced hypoglycaemic episodes during the night.

*Well my bedroom, right next to my bed I've got a bedside cabinet, it's like a snack bar actually, and I used to get the really easy to... they actually melt in your mouth, I find them really quick, you know, the fruit jellies you get? And they're soft and they're coated with sugar, so they're easy to swallow, aye. (AS2\_F13, face to face interview)*

Another SAS participant described how he would always wake up during the night when his blood glucose level was low. He would then carry out a blood glucose test and eat some food or have a sugary drink to treat the hypoglycaemic episode.

*Say I felt not too well during the night, I would say 'my sugar's getting low', so I'd take my sugar level and all of a sudden I see it maybe dropped to 4.5 and I say 'aha aha, sugar!' or a drink of something or other or something to eat, a biscuit, something like that. And then I'll wait a wee while until I see it going back up the scale again, then I say 'right, that'll do me till morning now' you know. (AS3\_M14, face to face interview)*

One of the non-SAS participants spoke about his treatment strategy when he identified a hypoglycaemic episode coming on. His treatment approach was in stages, starting with glucose tablets or a sugary drink, followed by a sandwich if he did not begin to feel better. A final measure would be taking a glucagon injection.

*Glucose tablets are the first line of defence along with maybe a bit of fruit or a can of Coke or a Mars Bar, right, that's what I take. If that doesn't work and there is a sandwich, right, get all that inside me so it's giving me slow release energy and then if that doesn't work it's hit the deck and glucose dope [laugh]! (NS2\_M19, face to face interview)*

This section has shown that many participants had an initial strategy for treating hypoglycaemic episodes, which was often carried out by the individual.

### **8.2.5 The issue of overcompensation**

An aspect closely linked to avoidance of hypoglycaemic episodes was overcompensation when a hypoglycaemic episode occurred. A number of participants described how they would take more sugary foods/drinks than strictly necessary to

treat a hypoglycaemic episode. For example, the following participant spoke about taking more glucose rich foods than necessary to treat the hypoglycaemic episode.

*Once I get a taste of chocolate or something sweet, I tend... when I'm having a hypo, I tend to want more. I think that's fairly common, you have this desperate need for something sweet, you just want to stuff your face with something sweet and you overdo it, you know, you take far more than you actually need [laugh]! (NS3\_F10, face to face interview)*

A younger male participant confirmed the same challenge when treating his hypoglycaemic episodes, referring to it as 'carbohydrate rage'. He also explained how he learned to control food intake better when he was experiencing a hypoglycaemic episode.

*The huge difficulty with a hypo is that in... regulating it once you know that you're having one is that you overshoot because it's an unpleasant thing to have, it's not nice, you know, so what you tend to do is to get it over and done with as quickly as possible, shove as much stuff down your gob as you can and you tend to overshoot, [...]and before you know it you're up at 15/16, you know, 20 minutes later which is tiring [...] What I've learnt to do now is to take a measured amount [...] and live with it in the meantime, try not to do that sort of carbohydrate rage! (NS1\_M16, face to face interview)*

Some participants also made reference to food tasting different or better when they were having a hypoglycaemic episode, which added to the challenge of overcompensation.

*I could eat food that I really don't like when I'm hypo and they'd taste absolutely amazing. It's really strange, although I'll know when I'm eating it that I really don't like this and then I'll try it and go 'oh that tastes absolutely amazing, why do I not like this, I'll have some more of this!' (NS1\_M23, face to face interview)*

Interestingly, it was only non-SAS participants who referred to overcompensation. This suggests that either SAS participants did not experience this challenge, or non-SAS participants were more aware of it.

The following sections describe findings relating to recovery from hypoglycaemic episodes, as well as coping strategies. For example, section 8.2.6 highlights that the time required for participants' recovery from hypoglycaemic episodes and the impact hypoglycaemic episodes had on participants' everyday life varied.

### **8.2.6 Recovering from hypoglycaemic episodes**

Participants' experiences of recovering from hypoglycaemic episodes varied in relation to the impact a hypoglycaemic episode could have on how they felt for the rest of the day and even the following days. Some participants said that they got 'back to normal' within a short time after the hypoglycaemic episode, while others described longer lasting effects. The following quotes illustrate the variety of participants' experiences:

*Sometimes if I've had a hypo, the rest of the day is a washout, so it can just wipe your day out, you just feel rubbish, you feel weak and you can't be bothered with things. (NS2\_F01, face to face interview)*

*After hypos, your body feels exhausted and you just want to sleep. (AS1\_F09, face to face interview)*

*I would be back compos mentis within five minutes at the most.  
(NS2\_M04, face to face interview)*

*I feel like I've maybe ran a marathon or something like that [...] that [hypo] was very scary that day because it probably took me about two days to recover from that, I just felt so awful and I felt emotionally drained and quite depressed. (NS1\_F08, face to face interview)*

The above quotes highlight that the impact of hypoglycaemic episodes on participants' everyday life can go beyond the actual occurrence of the hypoglycaemic episode; it can have an effect for up to a couple of days following the hypoglycaemic episode. The severity of hypoglycaemic episodes influenced recovery time and to what extent the hypoglycaemic episode impacted on the person's everyday life. For example, if participants had experienced a 'bad hypo' they may have injured themselves from falling due to the impact the hypoglycaemic episode had on their sense of balance.

*I've actually injured myself falling out of bed and I've had carpet burns, in fact I've still got one I got about a month ago, should've seen the size of it, it was a great big, big carpet... [...] I've actually hurt my back on furniture too and knocked furniture over, lamps – bedside lamps and things... I've fallen onto the floor, you know, from my bed. (AS2\_M28, face to face interview)*

*I remember the hypo just came on all of a sudden and I just remember falling and hurting my arm and having to go to A&E because I thought I'd fractured it and that's because I had a hypo. (NS1\_F08, face to face interview)*

Participants from both groups mentioned injuries that occurred during a hypoglycaemic episode; however, compared to non-SAS participants, the theme was more prominent in the SAS group. This highlights that SAS participants seemed to experience more severe hypoglycaemic episodes compared to non-SAS participants.

### **8.2.7 Coping strategies**

This section describes various coping strategies that participants adopted in response to hypoglycaemic episodes. Coping strategies included accepting hypoglycaemic episodes as a normal part of living with diabetes ('positive attitude'; see section 8.2.7.1), and denying that one is having a hypoglycaemic episode, particularly in the presence of others (section 8.2.7.2). Avoidance of hypoglycaemic episodes (section 8.2.7.3) and building and educating a support network (section 8.2.7.4) were also identified as coping strategies.

#### **8.2.7.1 Positive attitude/acceptance**

A number of participants adopted a positive attitude about their hypoglycaemic episodes, accepting them as a normal part of living with diabetes. One of the non-SAS participants compared treating hypoglycaemic episodes to blowing her nose when she had a cold: "You've got a hanky in your pocket and you blow your nose, the world doesn't stop while you do it" (NS2\_F01, face to face interview). She went on to describe a situation where she easily and quickly treated a hypoglycaemic episode without anyone around her noticing:

*If I was sitting round an office table, at a meeting, no-one else knew I had a hypo, I would- well, maybe they did, maybe they noticed I was eating glucose, but other than that, nothing happened, you just- I dealt*

*with it, they weren't aware, they didn't need to be aware anyway and life went on. That's how diabetics do treat hypos, they are not the major event that in medicine they are. They are just, they are a routine thing. (NS2\_F01, face to face interview)*

Another non-SAS participant shared a similar perspective. She claimed that she found it easy to treat hypoglycaemic episodes and get back to normal.

*To me it's [i.e a hypo] not a very big risk because it's so easily remedied and so, you know, I don't make a big deal of it. I know that some people feel very unwell when they have a hypo but I'm lucky I just... okay I hit the pits and then I bounce up again, so no, not a problem. (NS3\_F05, face to face interview)*

An interesting aspect of the coping strategy of 'acceptance' was discussed by a non-SAS participant who said that he liked the fact that he could eat (more) food when having a hypoglycaemic episode.

*I quite like being hypo sometimes because it means I get to eat food, I quite like eating food [laugh] I don't deliberately make myself hypo but if I do go hypo I always think 'excellent, another chance to eat food' so I do! [...] I don't think it's a real issue that I am having lower blood levels now and again. (NS1\_M23, face to face interview)*

The issue of having a positive attitude was more common in the non-SAS group. There were only a few SAS participants who made reference to this theme. The following SAS participant described how he kept a positive attitude.

*I'm of the attitude that I control it, it doesn't control me. Obviously I watch what I'm eating and things like that but if I fancy a chocolate biscuit or something I just have one, you know. But I go through all the standard stuff, you know, like, eating sensible and just watch what I'm doing you know, but it's just a way of life now, I don't think about it. (AS2\_M27, face to face interview)*

#### **8.2.7.2 Denial**

Some participants admitted that they tended to deny they were having a hypoglycaemic episode. This could potentially be problematic as it may lead to a delay in treatment, which could cause the hypoglycaemic episode to get worse. External help may then become necessary. Denying that one is having a hypoglycaemic episode could be associated with viewing the occurrence of hypoglycaemic episodes as failure to keep a 'good' blood glucose balance. Therefore, people may be reluctant to admit they are having a hypoglycaemic episode, especially in the presence of others. This perceived 'embarrassment' could be made worse if people around identified the hypoglycaemic episode before the individual did (see second quote).

*You tend to deny you're having a hypo, you deny it oh gosh yes. (AS1\_F09, face to face interview)*

*The guys who were playing [golf] with me they always knew before I do because I was very resistant to taking advice and taking help, obstinate in fact was probably the best term I could use! So I didn't even listen to them and the 12th hole at the golf course is a lot of sand dunes on it and I used to go up and down the sand dunes in my own little dream world carrying my golf bag [laugh]. (NS2\_M04, face to face interview)*

The next quote highlights that some participants may even deny they are having a hypoglycaemic episode to themselves. The participant described how he sometimes ignored (early) symptoms of hypoglycaemia, and thereby risked going into a severe hypoglycaemic episode that would require external help.

*I think it's really a case of all my life I've turned and said 'right, if something doesn't bother me I don't bother it' and maybe when I'm going fuzzy I'm ignoring it... (AS3\_M20, face to face interview)*

### **8.2.7.3 Avoidance**

Hypoglycaemic episodes were associated with a host of challenges and negative emotions, (see sections 7.2.1 and 7.2.2). It was therefore not surprising that many participants spoke about trying to avoid hypoglycaemic episodes by keeping a high blood glucose level. Avoidance could manifest itself following a particular hypoglycaemic episode (see quotes below) or be a general coping strategy in the person's diabetes self-management.

*I think once you've had one [i.e. hypo], you are doing everything you can to avoid another one. I think they make me run my blood glucose levels much higher than they need to be. (NS2\_F01, face to face interview)*

*I probably just let me blood sugars run a bit high over the weekend and probably for the next couple of weeks just because my body was drained, just to stop it happening again because it really frightened me. (NS1\_F08, telephone interview)*

There seemed to be an association between fear of hypoglycaemic episodes and participants' avoidance of these episodes. This is explored in more detail in section 7.3.

Other situations where people tried to avoid hypoglycaemic episodes were when they were driving (see section 8.2.3) or when they had an important task to do (e.g. interview/meeting, leading in a ceremony or presentation). For example, one of the non-SAS participants spoke about keeping her blood glucose level higher in order to avoid a hypoglycaemic episode happening during interviews she was conducting for her work.

*I would eat more than strictly necessary because having a hypo in the middle of an interview is not very clever. (NS3\_F05, face to face interview)*

While this avoidance behaviour can help people cope by reducing the number of hypoglycaemic episodes occurring, it may have a negative impact on diabetes control. The way people tried to avoid hypoglycaemic episodes happening was by keeping a higher blood glucose level, which could have negative implications in relation to long-term complications (Williams and Pickup 2004; American Diabetes Association 2012).

For example, one of the non-SAS participants, who lived on a farm, tried to avoid having hypoglycaemic episodes as a way of coping with the everyday demands of living and helping out on the farm.

*I live on a farm so you're quite busy and the thought of having a hypo when you've got lots to do it kind of... it makes you run that wee bit higher because, you know, you're trying to avoid having hypos. (NS1\_F06, telephone interview)*

#### 8.2.7.4 Support network

Many participants took an active role in building a support network by identifying people they trusted and educating them about diabetes and what to do when a hypoglycaemic emergency occurred. In fact, all participants had at least one person (family member, friend, etc.) who supported them with diabetes management. The support ranged from being actively involved in the participant's daily diabetes management (e.g. giving injections, taking blood glucose readings), to being prepared to help when this was required (e.g. during hypoglycaemic episodes).

Sometimes a very competent member of the support network could intervene and provide support when a hypoglycaemic emergency happened, and thereby not call out emergency services. For example, the husband of one non-SAS participant was confident and competent to treat a hypoglycaemic emergency without calling the ambulance.

*He was actually very very good at dealing with hypos, in fact he was very laid back about it [...] he got some sugar and mixed it in orange juice and he just sat me down on the couch and he poured it down my throat and I was- I came to wearing a tea towel, lots of orange juice, because he had just poured it and- and he'd walk away, in the kitchen and he started peeling spuds or something, and just left me to come round. And I think a lot of people would have panicked and called for an ambulance, but he just thought, 'no no, I've dealt with that, once she gets that sugar in her system, she will be ok' (NS2\_F01, face to face interview)*

However, as has been highlighted in section 7.2.3, when people got confused, external help may become necessary. In this context, participants' support network did not only play an important role in helping to treat hypoglycaemic episodes, they could also help with identifying when the individual was having a hypoglycaemic episode before the individual recognised it. This was of particular importance where the person was affected by hypoglycaemia unawareness.

Some participants described how people close to them were sometimes able to identify a hypoglycaemic episode before they recognised it themselves.

*My daughter and my wife, they know I'm going to have a hypo because my wife will say to me 'you're going to have a hypo' and I went 'how d'you know?' she said 'you've gone grey'. She says 'your face colour's just changed, you've gone grey so I'll go and make you a sandwich just now'. (NS2\_M19)*

However, some participants admitted that they did not always accept another person's opinion identifying their hypoglycaemic episode, and might delay taking food or glucose (see 'being discredited by others', section 9.3.1).

*Somebody might say to me 'You're not looking very... or you're not speaking whatever' and I'd probably be feeling alright but they would notice it before me and try to tell me, 'Are you sure you're okay, you know, you're going pale or whatever?' you know, and I would be stubborn and say 'I'm feeling fine, what are you talking about!' (SAS participant, AS2\_M28)*

*If I'm with friends they're very good at spotting that I'm needing sugar and they'll say... and I ask them afterwards 'how did you know I was needing sugar?' 'well because your eyes were different' you know,*

*something changes in my face [laugh] and, erm, if I'm good I'll obey them and take something... which I usually do when I'm told firmly to take it. But you can be argumentative as well. It just changes your brain somehow or other. (SAS participant, AS3\_F24)*

These quotes show that participants' struggles to manage hypoglycaemic episodes did not only refer to themselves but extended to their interpersonal relationships. While a good support network was important, it might conflict with people's desire to remain independent.

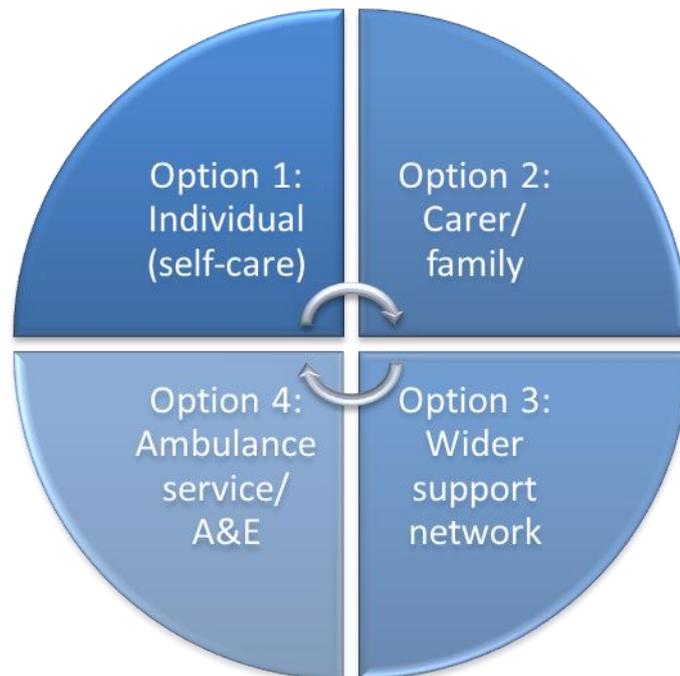
### **8.3 The hypoglycaemic episode help-seeking network (HEHS network)**

A closer look at how participants' managed hypoglycaemic episodes in the context of their everyday life showed a pattern. This pattern provides a number of options in relation to what roles various agents play in controlling hypoglycaemic episodes, and whether external help is required. Data showed that the following agents could potentially play a key part in the management of a hypoglycaemic episode:

- 1) The individual, that is the person experiencing the hypoglycaemic episode
- 2) Their carer or immediate family member(s)
- 3) A member of the individual's wider support network, and/or
- 4) Ambulance clinician(s) or paramedic(s).

In order to explain the relationship between severity of a hypoglycaemic episode, and the role of the agents identified, I have developed the hypoglycaemic episode help-seeking network (HEHS network; see figure 8.1 below). The HEHS network describes the key people/agents involved and the role they play in the management and control

of an individual's hypoglycaemic episode. There are four options in the HEHS network; each option is named according to the agent involved.



**Figure 8.1: A visual representation of the hypoglycaemic episode help-seeking network (HEHS network)**

The HEHS network helps to identify whether an individual is able to control their hypoglycaemic episodes and at what point external help is required. It shows options that are available in managing hypoglycaemic episodes. The HEHS network is based on the assumption that better control is achieved when the individual is able to manage the hypoglycaemic episode. Another assumption is that the higher the option number of the agent/network who controls a hypoglycaemic episode, the more severe it tends to be.

### *Option 1: The individual*

This option presents a situation when the individuals are able to identify and control their hypoglycaemic episodes without requiring any external help. As highlighted previously (section 8.2.4), many participants developed strategies to deal with their hypoglycaemic episodes (e.g. keeping food/sugary snacks/drinks close by). In option 1, the individual could take, for example, a sugary drink/snack or food to treat their hypoglycaemic episode, and is able to recover from the hypoglycaemic episode without help from any other person. There were many examples in the hypoglycaemia diary of when individuals were able to identify and treat their hypoglycaemic episodes (also see table 8.1).

*I treated myself with sweets and fruit juice followed with 2 chocolate digestives. (NS1\_M07, hypoglycaemia diary)*

*I treated myself, had a cup of coffee with 2 sugars + chocolate biscuit. (NS2\_M04, hypoglycaemia diary)*

*I looked after myself, took 100ml Lucozade, then lunch. (NS3\_F05, hypoglycaemia diary)*

An important factor that determined whether a hypoglycaemic episode could be controlled at option 1 (i.e. by the individual experiencing it) was the impact of hypoglycaemia unawareness. When people are affected by hypoglycaemia unawareness, they may not recognise that they are having a hypoglycaemic episode until it reaches a severe stage (see section 7.4.3). At that point, people are much more likely to need external help.

*Option 2: Help from a family member or carer was required*

In some instances, participants were supported by a partner/family member or carer in order to treat hypoglycaemic episodes. The following are examples of when participants were assisted by a partner or family member to treat a hypoglycaemic episode.

*My partner made me toast as I was worried that I was going to pass out.  
(NS3\_M17, hypoglycaemia diary)*

*I needed my wife's assistance to make a snack. My daughter also assisted with glucose tabs + sugary drink. (NS2\_M19, hypoglycaemia diary)*

Participants' hypoglycaemia diaries suggest that option 2 may be a result of people delaying to treat the hypoglycaemic episode, or worrying about the hypoglycaemic episode getting worse (see table 8.1).

*Option 3: Help was provided by a member of the wider support network*

Option 3 of the HEHS network is indicated when help was provided by a member of the wider support network including friends, colleagues and neighbours. For example, a 78 year old female SAS participant recorded a hypoglycaemic episode where she lost her balance, but was able to phone a friend to help her treat the episode.

*I fell on the floor and could not get up. Eventually I rolled over to phone and managed to contact my friend. Just could not reach glucose. She gave me the Lucozade while I was able to drink. (AS3\_F24, hypoglycaemia diary)*

The following is an example where help from both a family member (the participant's mother, option 2) as well as help from a member of the wider support network (a neighbour, option 3) was required:

*I came down for breakfast, I vaguely remember coming down the stairs and then the next thing I remember I'm waking up on the couch... apparently I'd got down, made my cereal, went through to the dining room, sat down and apparently just collapsed off onto the floor and then my mum tried to give me a Glucagon injection but I was fighting her off so she had to... so she ran out into the street in her dressing gown and there was a neighbour getting into his car for work and she said 'can you come and help me I need you to hold my son down while I give an injection bla, bla, bla' so I'd some bloke sitting on me while I got my injection and that kind of stopped me fighting everyone off, and then they managed to get me onto the couch where I think I effectively just either was knocked out or just fell asleep. (NS1\_M23, face to face interview)*

*Option 4: Help was provided by ambulance clinician(s)/paramedic(s)*

In option 4, people required emergency assistance to treat a hypoglycaemic episode. In many situations when emergency assistance was required, it involved actions of other agents/people from various options in the HEHS network. For example, a family member might help by calling the ambulance, and then the ambulance service provided treatment. Another example was one female SAS participant who described a situation where people around noticed that she needed help (option 3), then her father arrived and called the ambulance (option 2), and finally, the ambulance arrived and provided treatment (option 4).

*I had to rush out to an interview and then onto another one at last minute. I got lost and was panicking, had got myself in a terrible state. People noticed me and dad had arrived and phoned paramedics. (AS1\_F09, hypoglycaemia diary)*

Another SAS participant required external help to treat a hypoglycaemic episode while out sweeping leaves at work. Initially, motorists saw him and called an ambulance (option 3), and then eventually the ambulance and a doctor from a nearby health centre arrived and treated the hypoglycaemic episode (option 4).

*There was one time when I was out on City Road, motorists saw me, I'd slipped on wet leaves and I was sort of on my back and I was kicking about, and some motorists saw me and someone obviously called an ambulance, I don't know who it was, but one of the doctors from across in the health centre at the City Road came down to see me too, but I was okay, I came round. (AS2\_M28, face to face interview)*

The individual's or their support network's ability to identify and treat hypoglycaemic episodes on time (i.e. before the hypoglycaemic episode worsened and could no longer be controlled by the individual or their support network) also influenced whether the individual was able to control their hypoglycaemic episodes.

*Good diabetes control means the individual is able to control the hypoglycaemic episode*

In a situation where the individual is able to identify and treat a hypoglycaemic episode on time, better control is achieved without needing external help (option 1 of the HEHS network). This is because external help takes more time to arrive; therefore

it is more likely for the hypoglycaemic episode to get worse in such a situation. One non-SAS participant described a tricky situation where he was driving and he felt a hypoglycaemic episode coming on. He was able to identify that he was experiencing a hypoglycaemic episode; however, he did not have anything with him to treat the episode. He then decided to keep driving to the nearest place where he could get some glucose rich food or drink, rather than stopping the car and waiting for external help to arrive.

*There was an incident when I couldn't... I was about half an hour before I could eat something, and then I got the cold sweat and the shakes and all those kind of things quite badly and I just had to sit for a while and wait until they all calmed down. That was about a month ago and I was in the car and just didn't have anything, I had to wait until I could get to a garage. [...] I was driving, so yes I am aware that that is dangerous, but the traffic was very slow and I didn't have any choice. I had the option of keep on going or pull over and wait until however long it would take for someone to come and help me and I thought that would just be too bad. (NS1\_M07, face to face interview)*

There was a two-way association between severity of hypoglycaemic episode and needing external help: when the individual with diabetes needed external help, the hypoglycaemic episode was likely to be severe. On the other hand, as the person perceived they needed external help, there was a delay in treatment (e.g. from calling the ambulance until it arrived at the scene) which meant the hypoglycaemic episode was likely to worsen before it was treated. Mechanic (1995) has suggested that people are more likely to seek external help when symptoms interfere with their ability to carry out everyday activities (see help-seeking theory, section 4.6). In terms of study

data, when participants experienced a severe hypoglycaemic episode, they required external help, as symptoms did not only interfere with their ability to carry out everyday activities, but also with the ability to treat the hypoglycaemic episode themselves (also see sections 7.2.3 and 7.2.6).

The HEHS network does not represent a linear sequence of when the various agents may be involved in the management of hypoglycaemic episodes; rather, it illustrates who could be involved at different points, and what options were exemplified in the study. For example, in some instances help was provided by paramedics, without anyone being involved at option 2 or 3.

The following table presents data that was used to develop the HEHS network. It was extracted from participants' hypoglycaemia diary entries.

<b>Participant</b>	<b>Diary data (Did you treat yourself?)</b>	<b>Control option</b>
NS2_F01	Treated myself. Always have glucose in pocket. Then got Lucozade from car. Then tested BG. Then ate, and ate and ate until I felt back in control.	1
NS2_F01	Yes, ate glucose sweets (about 13g CHO) Treated myself and returned to sleep.	1
NS1_F03	Treated self Yes, can of juice, chocolate	1
NS1_M07	Treated myself	1
AS1_F09	Yes. I got up and drank Lucozade. I was given a sweet drink + then I took another myself. No ambulance called.	1
NS3_F10	Yes, treated myself. 2 pieces of white chocolate. Didn't get up.	1
AS1_M11	Yes, I treated myself. Treated myself with fiancée present & no ambulance needed	1, 2
AS3_F24	Treated myself - drank Lucozade.	1
NS1_M07	My wife made me tea although I was capable of doing it.	2
AS1_F09	I did at first, but kept delaying myself, so needed father's help. No service was called	2
NS3_F10	I didn't treat myself as I was cooking dinner at the time & thought I could last until dinner was ready. My husband got me some sweets.	2
NS3_M17	Partner made me toast as I was worried that I was going to pass out. Treated by myself & partner	2, 1
NS2_M19	I needed my wife's assistance to make a snack. My daughter also assisted with glucose tabs + sugary drink.	2
AS2_M27	Mother, 2 Glucogel + Jelly babies, ambulance service was not called.	2
AS2_M27	Mother called ambulance, paramedics came.	2, 4
AS2_M27	Mother treated me. No ambulance was called.	2
NS3_F10	Bit of a panic – vending machine not working – had to go to another floor to get Mars bar. Running out of time; colleagues were on hand to help	3
AS3_F24	Neighbour heard me – needed someone. She gave me the Lucozade while I was able to drink.	3
AS3_F24	The other bowlers got the emergency Lucozade out of the Bowling Club fridge & gave me a drink.	3
AS1_F09	People noticed me, dad had arrived & phoned paramedics.	2, 3, 4
AS1_F22	I couldn't get up, midwife helped [participant was pregnant].	4
AS3_F24	Neighbour heard me. She called ambulance.	3, 4

**Table 8.1: Extract of hypoglycaemia diary data used to develop the HEHS network**

## 8.4 Summary

The findings presented in this chapter emphasised different ways in which hypoglycaemic episodes affected participants' diabetes self-management and everyday life, for example, preparations for potential hypoglycaemic episodes (e.g. always having food/glucose tablets available, carrying a blood glucose monitor) and recovery from hypoglycaemic episodes. Some participants admitted that they tended to avoid certain tasks or social situations due to worries about a (severe) hypoglycaemic episode happening. This ranged from never exercising alone to not travelling or going out, (see section 8.2.3).

The chapter also pointed out the potential impact hypoglycaemic episodes can have on participants' diabetes self-management. One of the major ways in which hypoglycaemic episodes can influence diabetes self-management was in shifting participants' self-management strategies towards keeping a higher blood glucose level aimed at avoiding hypoglycaemic episodes; thereby increasing their risk of having long-term complications in the future. On a day to day basis, participants tended to adopt various strategies to deal with hypoglycaemic episodes, e.g. keeping sugary foods within easy reach, (section 8.2.2).

The avoidance of hypoglycaemic episodes was not just an issue in the day to day management of diabetes, but also a coping strategy adopted by many participants. Participants admitted to intentionally altering their diabetes treatment, aiming to keep a higher blood glucose level in order to avoid hypoglycaemic episodes happening, (section 8.2.7.3). This could have a devastating effect on their risk of experiencing long-term complications.

Some participants adopted a positive attitude to cope with hypoglycaemic episodes, and accepted these episodes as normal part of living with diabetes. They also claimed that it was easy to treat hypoglycaemic episodes, (section 8.2.7.1). This attitude was more common in the non-SAS group.

Another coping strategy was that some participants tended to deny that they were having a hypoglycaemic episode. This included self-denial as well as denial towards others, (section 8.2.7.2). This strategy might be risky as it could lead to a delay in treatment, which might cause the hypoglycaemic episode to get worse. Section 8.2.7.4 has highlighted the importance of a support network, whose members can not only help with treatment of hypoglycaemic episodes, but crucially help identify the onset of hypoglycaemic episodes and thereby support people affected by hypoglycaemia unawareness. However, when individuals tried to deny that they were having a hypoglycaemic episode, accepting help from members of their support network might be challenging.

The HEHS network (section 8.3) captured the various agents that may be involved in the management of hypoglycaemic episodes. It helped to identify the various options available to control hypoglycaemic episodes and at what point external help was required. While participants developed strategies to deal with hypoglycaemic episodes as they happened (section 8.2), they sometimes required help from their support network or the ambulance service.

According to the HEHS network, when people were not able to control their hypoglycaemic episodes, they required alternative options (options 2, 3 and/or 4), thus needing external help. This was usually the case when hypoglycaemic episodes

were more severe. The HEHS network suggested that good diabetes control can only be achieved when individuals were able to manage their hypoglycaemic episodes, without needing external help.

The next chapter provides an overview of study findings and discusses these findings with reference to the wider literature and theory. It also highlights strengths and limitations of this study. Finally, it discusses implications for clinical practice and further research.

## Chapter 9 - Discussion

### 9.1 Introduction

This chapter presents a summary of study findings (section 9.2), and discusses these findings with reference to the wider literature (section 9.3). It also examines which theories (see chapter 4) may be helpful in understanding the study findings. In terms of theoretical positioning, this study is a piece of applied health research which has been informed by a number of sociological theories.

The chapter further reflects on strengths and weaknesses of this study, for example, limitations regarding study design, sampling, and the potential influence of the researcher on data generation. Finally, implications for clinical practice and further research are considered.

### 9.2 Summary of study findings

This study investigated participants' experiences and individual explanations of recurrent hypoglycaemic episodes. It found that hypoglycaemic episodes can have a **wide ranging impact** on participants' everyday life. It was not only the actual hypoglycaemic episode that affected participants' everyday life, but also fears and worries about future hypoglycaemic episodes, the preparations that people engaged in to manage potential hypoglycaemic episodes, and the process of recovery, (see section 8.2.6).

The study found that **hypoglycaemia unawareness** was a major problem for many participants living with diabetes. Hypoglycaemia unawareness appeared to be linked with the likelihood of needing external help, (section 7.2.5). While participants in both

groups experienced hypoglycaemia unawareness, a key difference was how participants managed it. SAS participants tended to be less aware and less knowledgeable about hypoglycaemia unawareness, resulting in more severe hypoglycaemic episodes. Consequently, they were more reliant on external help from both the ambulance service, as well as their support network (section 7.5).

Findings of this study call for a re-conceptualisation of the previously recognised 'balancing act' of managing diabetes and hypoglycaemic episodes. This study has introduced the concept of a **hypoglycaemic episode balancing continuum** (HEBC) which enables a deeper understanding of the factors involved in this balancing act: it demonstrates that people balance the various risks differently, depending on whether they prioritise their fear of hypoglycaemia over fear of long-term complications, (section 7.3). Participants' position on the continuum directly affects their management strategies for hypoglycaemic episodes, for example, some participants actively avoided hypoglycaemic episodes more than others.

This thesis found that fear of hypoglycaemic episodes governed some participants' management of diabetes, but for others, the fear of long-term complications was greater. The focus of people's fear determined where they sat on the HEBC. The continuum demonstrates that those who exhibited fear of hypoglycaemia would be more likely to keep a higher blood glucose level in an attempt to avoid hypoglycaemic episodes happening, or to reduce the number of hypoglycaemic episodes they experienced. Those who did not express a similar degree of fear were more likely to keep their blood glucose level within a lower range, and were more likely to be concerned about long-term complications. However, there were times when avoiding

hypoglycaemic episodes was necessary to engage in activities (e.g. driving, physical exercise). Some participants used avoidance of hypoglycaemic episodes as a temporary coping strategy, while other participants adopted avoidance of hypoglycaemic episodes as a permanent coping strategy (see section 9.3.1).

In order to illustrate how hypoglycaemic episodes are managed, this thesis has developed the **hypoglycaemic episode help-seeking network** (HEHS network) from the data, which helped to identify the various agents involved in helping to treat hypoglycaemic episodes (e.g. the individual with diabetes, their carer/family members, members of their wider support network, and ambulance service paramedics/clinicians; section 8.3). The HEHS network suggests that while many participants tried to deal with hypoglycaemic episodes as they happened, they sometimes required help from their support network or the ambulance service. It has illustrated the nature of involvement of the various agents in the management of hypoglycaemic episodes, and why/when they were likely to be involved.

The HEHS network shows that the severity of each hypoglycaemic episode influenced whether external help was required, and that the most severe episodes were likely to be treated by the ambulance service. Another important factor that influenced which agent was involved in the management of the hypoglycaemic episode was the individual's or their support network's ability to identify and treat hypoglycaemic episodes on time. This ability was affected by participants' knowledge about their diabetes and their capacity for its management. When this capacity has been exceeded, e.g. through hypoglycaemia unawareness, then participants were more likely to require SAS involvement.

### **9.2.1 Differences and similarities between the SAS and non-SAS group**

Both the SAS and the non-SAS group experienced hypoglycaemia unawareness, however, it was more common and appeared to be more problematic in the SAS group. One important aspect was people's response to hypoglycaemia unawareness, which seemed to differ in the two groups. For example, non-SAS participants tended to be more prepared (e.g. having food/glucose tablets available; see section 8.2.2) in case a hypoglycaemic episode occurred. This was particularly important when an individual was affected by hypoglycaemia unawareness, as it caused hypoglycaemic episodes to come on a lot more quickly and severely, leaving the person little time to identify and treat the episode.

Another major factor in managing hypoglycaemia unawareness was awareness about the phenomenon itself. This is where participants' health literacy is key; that is a good understanding about what hypoglycaemia unawareness is, what causes it and how it can be addressed. Non-SAS participants tended to be more knowledgeable about their condition and its management than SAS participants, resulting in a better awareness of the potential to develop hypoglycaemia unawareness, (see sections 6.5.3 and 7.4.3). A good awareness of hypoglycaemia unawareness can contribute to better management of it (e.g. being prepared, checking blood glucose level more regularly), or even help to reduce hypoglycaemia unawareness by altering diabetes medications (Frier 2007a). The differences between the two groups may be a reflection of the non-SAS study sample being mainly recruited through Diabetes UK, a population that could represent a group more willing to learn about their diabetes and to take active control of their self-care.

A number of differences between SAS and non-SAS participants have been identified in relation to socio-demographic factors (see section 6.2). For example, SAS participants were older and tended to live in more deprived areas compared to non-SAS participants. These factors may have contributed to lower levels of health literacy in the SAS group, which in turn affected participants' ability to manage hypoglycaemia unawareness (see section 7.4.3).

Hypoglycaemia unawareness is a known risk factor for severe hypoglycaemia, and poor management of hypoglycaemia unawareness makes the situation worse (Clarke et al. 1995, Frier 2007a). As highlighted above, SAS participants' experiences and descriptions of hypoglycaemic episodes would indicate a greater tendency towards hypoglycaemia unawareness compared to non-SAS participants. SAS participants also appeared to be less able to manage hypoglycaemia unawareness. This may help to explain why SAS participants experienced more severe hypoglycaemic episodes where they were unable to treat the episode themselves, and thus required external help, (see section 7.2.5). In contrast, none of the non-SAS participants needed help provided by the ambulance service during the study. They rarely required any help, but when they did, this was often provided by family, friends or colleagues.

In terms of severity of hypoglycaemic episodes (section 7.2.6), there were some differences between SAS and non-SAS participants. For many non-SAS participants, hypoglycaemic episodes were a 'minor inconvenience' that they usually treated themselves, while SAS participants tended to have more severe hypoglycaemic episodes. This was based on severe hypoglycaemic episodes being defined as requiring external help to effect treatment (DCCT 1997). In terms of participants' perceived

severity scores for individual hypoglycaemic episodes, there was only a slight difference in the mean scores for the two groups, (see sections 6.5.1 and 6.5.2). Non-SAS participants gave a slightly lower score compared to SAS participants. It is important to note that perceived severity and actual severity (based on symptoms, blood glucose reading, and whether external help was required) can differ greatly.

Another aspect of severity was the occurrence of injuries happening during a hypoglycaemic episode, as mentioned in section 8.2.6. When comparing the two study groups, injuries were more common in the SAS group. This further underlines that SAS participants seemed to experience more severe hypoglycaemic episodes compared to non-SAS participants.

### **9.3 Discussion of study findings with reference to the wider literature and theory**

#### **9.3.1 Study findings with reference to wider literature and theory**

##### *Wide ranging impact of hypoglycaemic episodes*

Frier (2008) and Barnett et al. (2010) concur with the study finding that hypoglycaemic episodes can have a wide ranging impact on participants' everyday life, including travel, driving, physical activities, employment and relationships. The aspect of fears and worries about hypoglycaemia has also been well documented (Currie et al. 2006; Wild et al. 2007; Tierney et al. 2008; Belendez and Hernandez-Mijares 2009; Hanberger et al. 2009). The study adds to this understanding of people's experiences of hypoglycaemic episodes and how these episodes affect people's everyday life, ranging from preparations for potential hypoglycaemic episodes happening, and issues around being confused and not in control when experiencing a hypoglycaemic episode

to recovery from hypoglycaemic episodes. The findings highlight an important problem in the treatment of hypoglycaemic episodes: when participants get confused, they may not be able to initiate treatment on time, and external help may become necessary. The issue of confusion is also confirmed in the literature (Diebel 1999; Banks 2005).

One aspect this study adds to knowledge of the impact of diabetes on everyday life is the issue of being prepared for potential hypoglycaemic episodes happening, (see section 8.2.2). The degree of preparedness has been found to be one of the differences between the SAS and non-SAS group, which could be a key difference in whether external help was required. A qualitative study involving six participants with type 2 diabetes in Singapore also highlighted that being prepared for potential hypoglycaemic episodes reduces the fear and anxiety associated with hypoglycaemia, and helps to recover from hypoglycaemic episodes more quickly (Tan et al. 2012b).

This study found that hypoglycaemic episodes can impact on participants' everyday life beyond the actual episode, and that full recovery from hypoglycaemic episodes can sometimes take a few days. Participants spoke about feeling exhausted and depressed after experiencing a hypoglycaemic episode, especially if the episode was perceived as severe, (section 8.2.6). This is referred to as 'post-hypoglycaemic syndrome' in the literature (Costea et al. 1993).

In chapter 4, it was suggested that Charmaz' (1983) concept of the impact on identity and sense of self may be relevant for this study. For example, Charmaz points out that people may be discredited by others due to their chronic condition. This study found that both SAS and non-SAS participants sometimes tended to deny they were

experiencing a hypoglycaemic episode, (section 8.2.7.2). This could be due to people not wanting to be discredited by others, or to be viewed as not capable of managing their diabetes and hypoglycaemic episodes, (also see section 8.2.7.4).

Another aspect of Charmaz' concept is 'living a restricted life' to accommodate the chronic condition or to avoid embarrassment. Study findings have highlighted that some participants preferred to avoid certain situations because of the risk of having a hypoglycaemic episode, for example, going out or exercising on their own, (see section 8.2.3).

The issue of 'being a burden to others' (Charmaz 1983) relates to the finding that participants may lose control when experiencing a hypoglycaemic episode. In such situations, people rely on others to help them treat the hypoglycaemic episode. According to Charmaz (1983), all these aspects (i.e. being discredited, living a restricted life, being a burden to others) can lead to a loss of self (section 4.9). This may impact on people's identity and sense of self.

#### *Impact of hypoglycaemia unawareness and importance of health literacy*

This study has identified hypoglycaemia unawareness as a key factor that can impact on the management of hypoglycaemic episodes. For example, when participants did not experience any early symptoms of hypoglycaemia, this left them at risk of both, not being able to identify an impending hypoglycaemic episode, as well as a higher chance for the hypoglycaemic episode to get to the severe stage (also see Gerich 2000; Briscoe and Davis 2006). The wider literature confirms that hypoglycaemia unawareness is a problem that affects many people with diabetes. According to Frier

(2007a), a reduction or gradual loss of warning signs (i.e. mild symptoms) affects about 25% of all people treated with insulin, rising to almost 50% after 25 years or more of insulin-treated diabetes (Pramming et al. 1991). Høi-Hansen et al. (2005) used a continuous blood glucose monitoring system to investigate unrecognised hypoglycaemic episodes. They found that over six days, 90% of 29 participants with type 1 diabetes experienced at least one occasion where their blood glucose level was within a hypoglycaemic range, while only 15% experienced symptoms.

While the problem of hypoglycaemia unawareness has been widely acknowledged in the literature (Clarke et al. 1995; Gerich 2000; Briscoe and Davis 2006; Frier 2007a; Hayes 2008; Gibson 2009; Cove 2011; Elliott and Heller 2011), it is the response to hypoglycaemia unawareness that can be a key difference in how people cope and whether they require external help (Rogers et al. 2012). One of the factors that influenced participants' response to hypoglycaemia unawareness was their knowledge about the phenomenon itself (also see Tan et al. 2012a). For example, non-SAS participants tended to be better prepared in case a hypoglycaemic episode occurred. They also seemed to be more knowledgeable about their condition and its management, resulting in a better awareness and understanding of hypoglycaemia unawareness (section 9.2.1).

The importance of health education and health literacy to achieve good diabetes control has been emphasised in the wider literature (Schillinger et al. 2002; Murata et al. 2004; Powell et al. 2007; Protheroe et al. 2008; Longo et al. 2010; Stiles 2011). For example, Lawton et al. (2013) carried out a longitudinal qualitative study involving 30 participants with type 1 diabetes, who had recently taken part in a DAFNE education

course (DAFNE online 2010). They focussed specifically on self-treatment of hypoglycaemic episodes, and found that education plays a key role in establishing appropriate treatment strategies.

However, the key role health literacy plays in participants' explanations for hypoglycaemic episodes is something this study adds. This is especially important in addressing the issue of hypoglycaemia unawareness. This study found that a good understanding about what hypoglycaemia unawareness is, what causes it, and how it can be addressed can contribute to a more appropriate response and better management of hypoglycaemia unawareness (sections 7.4.3 and 7.4.4).

One of the theories that is potentially relevant for this study is help-seeking theory (Mechanic 1966; Zola 1973; Mechanic 1968; Mechanic 1995). A central element of help-seeking theory is perception, recognition and interpretation of symptoms. This can be applied to the study findings, which have highlighted that experience and appropriate interpretation of symptoms are key in identifying and treating hypoglycaemic episodes. For example, where people were affected by hypoglycaemia unawareness, they did not experience any symptoms at the onset of hypoglycaemic episodes. This absence of symptoms removed any opportunity for self-care or active help-seeking, as there was no indication/detection of an impending hypoglycaemic episode at that stage.

In terms of Zola's help-seeking model (1973), some of the triggers that can cause an individual to seek help/take remedial action (see section 4.6, figure 4.1) apply to the study findings. For example, perceived interference with work, social or leisure activities; findings confirm that when symptoms of hypoglycaemic episodes interfered

with participants' everyday activities, they were more likely to seek help or to treat themselves via self-management strategies. Closely related to the interference with everyday activities is what Mechanic (1968) called 'tolerance for the symptoms'. This tolerance describes people's ability to accommodate symptoms before they take action to treat the hypoglycaemic episode (i.e. treat themselves or seek help). Study findings have shown that there were certain situations in which participants could not afford to accommodate symptoms, e.g. when driving or during an important meeting, (see section 8.2.3). In such situations, participants tended to pre-empt the symptoms with self-management strategies, which might be counterintuitive to good healthcare practice.

According to Zola's model (1973), help-seeking does not only relate to lay referral (i.e. help and advice from family members/carers or friends) and medical help, but it includes self-medication. This is particularly relevant for this study, as participants often treated themselves when they experienced hypoglycaemic episodes.

Mechanic (1995) suggests that people's perception of their health status influences their responses to symptoms. Study findings have shown that it is not just people's perception of their health status; rather, it is their perception of their condition (for example, do they believe diabetes is controllable/not controllable) and ability to manage hypoglycaemic episodes, that influences people's responses to symptoms. This ability determines whether people seek external help. Additionally, sometimes symptoms are not recognised and the biomedical indicators are not always reliable to identify hypoglycaemic episodes (see section 7.2.4).

In relation to social construction of illness (Mechanic 1968; Conrad and Barker 2010), study findings have highlighted that participants relied on their experiential knowledge as opposed to medical definitions of what constitutes a hypoglycaemic episode (see section 7.2.4). Even though diabetes and hypoglycaemia are biomedical conditions (Williams and Pickup 2004), participants placed more importance on how they felt and how hypoglycaemia impacted on their everyday life (see section 8.2.4). This has potential implications for clinical practice (see section 9.5.1).

#### *The hypoglycaemic episode balancing continuum (HEBC)*

This study, like others (Callaghan and Williams 1994; Shiu and Wong 2002; Campbell et al. 2003; Vermeire et al. 2003; Debono and Cachia 2007; Moser et al. 2008; Wu et al. 2011) found that participants described managing diabetes as being a ‘balancing act’, which involves maintaining an appropriate blood glucose level, in order to avoid complications relating to a low or high blood glucose level. This included reducing the risk of long-term complications whilst at the same time striving to avoid short-term complications (e.g. hypoglycaemic episodes), and maintaining a good quality of life.

According to Nafees et al. (2006), people often place a higher priority on the immediate effects of treatment/short-term complications as opposed to long-term complications at some point in the future. Some people may alter their diabetes self-management in order to avoid experiencing hypoglycaemic episodes, due to fear of hypoglycaemia (Wu et al. 2011; Tan et al. 2012a). This is captured in group C of the hypoglycaemic episode balancing continuum (HEBC), as presented in chapter 7. People who are in group C tended to be fearful of hypoglycaemic episodes and tried to avoid them by keeping a higher blood glucose level. In the short term, this decreased their

risk of experiencing hypoglycaemic episodes; however, in the long run, it increased their risk of having long-term complications. Avoidance of hypoglycaemia has also been identified as a coping strategy, (see section 8.2.7.3).

In terms of balancing priorities, this study adds a more differentiated understanding of approaches people adopted. Many authors have focussed on measuring people's fear of hypoglycaemia using a quantitative scale (Choe et al. 2001; Vermeire et al. 2003; Nafees et al. 2006; Tierney et al. 2008; Anderbro et al. 2010); however, they did not consider how this related to people's actual diabetes management, or their concern about long-term complications. The HEBC explains the relationship of people's perception of hypoglycaemic episodes (e.g. fearful of hypoglycaemic episodes/not fearful), occurrence of hypoglycaemic episodes, blood glucose control and attitude towards long-term complications. It clarifies that people adopt various positions towards hypoglycaemic episodes, based on their experiences and understanding of hypoglycaemic episodes, as well as long-term complications. Therefore, the HEBC may offer explanations for differences in self-care processes.

For example, some participants accepted experiencing more hypoglycaemic episodes as a result of strict glycaemic control, in order to reduce the risk of having long-term complications in the future (group A on the HEBC). According to Rogers et al. (2012), people's fear of long-term complications/high blood glucose contributes to low concern about hypoglycaemia unawareness. Even though Rogers and colleagues focussed on hypoglycaemia unawareness, their findings are relevant to the HEBC, as they illustrate that a significant fear and anxiety of high blood glucose levels and long-term complications can reduce people's concern about hypoglycaemia.

The HEBC has also illustrated how some participants took a more balanced approach in managing risks of long-term and short-term complications. This could either be a result of them being fearful of both, hypoglycaemic episodes as well as long-term complications (group B-1), or not being fearful of either and thus not altering their diabetes self-management strategy (group B-2).

The HEBC is an example of people making decisions about their diabetes self-management in the context of their everyday lives, and also illustrates where people's priorities can change, thus drawing on sociological thinking. When hypoglycaemia impacted on participants' social life or their ability to 'function normally' especially when in an important situation (e.g. driving, meeting), they tended to adopt strategies to avoid hypoglycaemic episodes (see section 8.2.7.3).

A qualitative study carried out by Wu et al. (2011) confirmed that people vary in relation to how they balance risks of short-term and long-term complications. Wu et al. (2011) interviewed 17 people diagnosed with type 1 or type 2 diabetes in Taiwan, and found that participants balanced the risks of experiencing hypoglycaemia and having long-term complications in the future, depending on their perception of the threat of hypoglycaemia. They concluded that "regardless of which approach they used to maintain glucose levels, participants recognised the potential risks of hypoglycaemia and hyperglycaemia, while recognising this experience as living with a constant shadow of dilemma" (p.2281).

Murphy and Kinmonth (1995) conducted a qualitative study using in-depth interviews with 46 participants who were diagnosed with type 2 diabetes. They confirmed that participants varied in relation to how they balanced the various risks, and classified

participants into two categories: Those concentrating on avoiding symptoms and those focussing to avoid long-term complications. While Murphy and Kinmonth (1995) did not specifically focus on hypoglycaemia, their findings are relevant to the HEBC, as they demonstrate that people living with diabetes vary in how they view diabetes and how they balance the risk of short-term symptoms and avoiding long-term complications.

#### *Self-care and the hypoglycaemic episode help-seeking (HEHS) network*

Orem's theory of self-care (1991; 1995) could explain participants' abilities to perform self-care actions; as well as situations when people are not able to meet self-care demand, they would require external help (e.g. during a severe hypoglycaemic episode). According to Orem (1959), self-care is a necessity to maintain life and health. Therefore, the need for self-care action can be viewed as a basic human need. Masters (2011) claims that every individual has the ability to perform self-care and take responsibility for their health. People with diabetes have to carry out a variety of self-care actions (e.g. monitor blood glucose level, inject the appropriate amount of insulin at regular intervals, etc.) to cope with their condition, and to maintain life. However, there is the possibility that some people living with a chronic condition may have a limited ability to perform self-care actions, and may require external help.

The HEHS network (section 8.3) illustrates the above interplay, and shows when people are able to carry out self-care actions, and when they would require external help, as well as the various agents that could be involved in managing hypoglycaemic episodes. According to the HEHS network, better control (self-care agency) is achieved when individuals are able to identify and control their hypoglycaemic episodes without

requiring any external help (option 1 in the HEHS network). When people are not able to manage their hypoglycaemic episodes themselves (i.e. meet self-care requisites), external help would be required (options 2, 3 and 4 in the HEHS network). This can be considered a self-care deficit, (see section 4.10). Self-care deficit can be caused by hypoglycaemia unawareness or the person's lack of knowledge about their condition and its management.

In relation to hypoglycaemia unawareness, little knowledge about the phenomenon itself (see section 7.4.3) could mean that people were not able to respond to hypoglycaemia unawareness appropriately; that is, they were not able to meet their self-care demand. The inability to carry out diabetes self-care actions (e.g. blood glucose monitoring, responding to early warning signs/symptoms of hypoglycaemia, being prepared for possible hypoglycaemic episodes, etc.) could also imply a self-care deficit. People who have a self-care deficit usually require external help to meet self-care demand. This was more prominent within the SAS group and explains why more people within this group repeatedly needed external help/emergency services. Orem's theory therefore helps to explain how people with diabetes are required to carry out self-care actions in order to lead a normal life ('maintain life and health') and navigate the complexities of managing a long-term condition. It shows that when people living with diabetes have a self-care deficit, needing external help is inevitable.

#### *Avoidance of hypoglycaemic episodes*

This study has shown that avoidance of hypoglycaemic episodes is a coping strategy many participants adopted at various times. Given many negative experiences associated with the experience of hypoglycaemic episodes (e.g. feelings of losing

control, anger and anxiety) and the potential for embarrassment when having a hypoglycaemic episode in a public place, it is not surprising that people tried to avoid experiencing hypoglycaemic episodes by altering their self-management activities, resulting in a higher blood glucose level (Callaghan and Williams 1994; Rajaram 1997; Green et al. 2000; Everett 2001; Di Battista 2009; Fidler et al. 2011; Sutton and Chapman-Novakofski 2011; Tan et al. 2012a).

This study contributes to a more differentiated understanding of people's avoidance behaviour, going beyond avoidance simply as a response to fear of hypoglycaemia (Irvine et al. 1992; Costea et al. 1993; Shiu and Wong 2000; Leiter et al. 2005; Fidler et al. 2011). The study found that some participants adopted avoidance of hypoglycaemic episodes as an overall approach to diabetes self-management, which can be considered a *permanent coping strategy*. This was often a general trait which may develop in response to fear of hypoglycaemia. In terms of the HEBC, people adopting avoidance of hypoglycaemic episodes as a permanent coping strategy would likely be in group C.

However, some participants tried to avoid hypoglycaemic episodes only in specific situations (e.g. when driving, during an important task/meeting); that is, using it as a *temporary coping strategy*. Participants who adopted avoidance of hypoglycaemic episodes as a temporary coping strategy would likely be in group A or group B of the HEBC. They tended to be more concerned about experiencing long-term complications, and would therefore only try to avoid hypoglycaemic episodes as an exception.

It is important to note the difference as the former approach (i.e. avoidance as a permanent coping strategy) could potentially be more damaging to diabetes control. When avoidance of hypoglycaemic episodes is adopted as a permanent coping strategy, people aim for a higher blood glucose level on a permanent basis resulting in an increased risk of suffering from long-term complications (Watkins 2003; American Diabetes Association 2012).

### **9.3.2 Advancement of theory**

Mechanic's help-seeking theory (Mechanic 1966; Mechanic 1968; Mechanic 1995), which proposes that illness behaviour is based on perception, recognition and interpretation of symptoms, was useful to explain participants' variations in response to symptoms of hypoglycaemia. The study findings have also highlighted that experience and appropriate interpretation of symptoms were key in identifying and treating hypoglycaemic episodes. However, Mechanic's (1995) assumption that the patient takes a decision to seek help, and then actively seeks help underlines a limitation of help-seeking theory (Mechanic 1966; Mechanic 1968; Mechanic 1995) for chronic conditions such as diabetes. It does not clearly address the different roles which an individual can play in the help-seeking process; for example, taking action to seek help, delegating action to seek help or not seeking any help/not being able to seek help.

This study has shown that in relation to participants' experiences of hypoglycaemic episodes, help-seeking was not always an active process participants engaged in; in other words, participants were not always able to make a decision to seek help. For example, participants might not be able to seek help when they experienced a severe

hypoglycaemic episode (due to confusion or even unconsciousness). In such situations, they relied on others to recognise and either help them treat the hypoglycaemic episode or call emergency services. It can be argued therefore, that people may not always seek help when they need help. In such cases, help-seeking can be seen as a transferred responsibility.

While Mechanic (1968) underlines that people's responses to illness situations can be influenced by their social environment, which is referred to as the 'social construction of illness' (Conrad and Barker 2010), he also states that little is known "about how people use their friends and acquaintances in attempting to cope with distress" (Mechanic 1968:135). According to Mechanic (1968), the main focus of help-seeking activity lies with the individual; however, Mechanic also acknowledges that 'others' can be involved in the interpretation of symptoms and advise that medical help should be sought. Though Mechanic addresses other people's involvement in the decision-making stage, he says less about whether others can seek help on the person's behalf, for example, in situations when people are not able to seek help themselves (Mechanic 1968; Mechanic 1995). This study has demonstrated that other people can play a significant role in seeking or providing help in the context of treating hypoglycaemic episodes.

Also, Mechanic (1995) assumes that people understand the signs and symptoms of their condition, emphasising the importance of recognition and interpretation of symptoms. This ability requires people to have adequate knowledge and awareness about their condition. However, findings have shown that participants did not always have sufficient knowledge to make sense of their symptoms (section 7.4.4), and that

confusion could be a symptom that may complicate an appropriate response, (section 7.2.3). This indicates that people may need more support to engage in appropriate help-seeking activities, and to deal with hypoglycaemia unawareness.

Zola (1973) describes that 'sanctioning by others' who advise on medical help being sought can be a trigger that may cause the individual to seek help. This could only be applied to this study to some extent. While study findings highlight that 'others' play an important role in the help-seeking process, they do not just advise on seeking help, but often take an active part in seeking help by either calling the emergency services or providing assistance in treating the hypoglycaemic episode. However, some participants tended to deny they were experiencing a hypoglycaemic episode and openly rejected advice by others, (section 8.2.7.2), which could lead to a delay in seeking help until the hypoglycaemic episode worsened or participants lost control, (section 7.2.2). This could make 'sanctioning by others' more challenging, as participants did not want others to recognise that they were having a hypoglycaemic episode. When others did recognise that the person was experiencing a hypoglycaemic episode, a loss of face or challenge of the person's experiential knowledge may occur. Therefore, help-seeking theory may need to be expanded to accommodate illnesses such as diabetes; in particular, addressing that the individual may not always be the key player in the help-seeking process.

Orem's theory (1995) was useful to explain people's ability to carry out self-care actions. When a person was not able to carry out self-care actions (i.e. had self-care deficits), the help of healthcare professionals would become necessary. Orem (1991) defined self-care as "the practice of activities that individuals initiate and perform on

their own behalf in maintaining life, health and well-being” (p.117). Therefore, Orem (1992) emphasises the ability of the individual to perform self-care and take responsibility for their health (Masters 2011). However, this study has illustrated that in the context of diabetes self-care, it may be useful to consider the role of the individual’s support network, as it can play a vital part in the management of diabetes and hypoglycaemic episodes, and was a link in the process leading to increased use of emergency services.

The HEHS network (section 8.3) incorporates other agents who may provide help, for example, family members and the wider support network. Findings have also shown that while participants developed strategies to deal with hypoglycaemic episodes as they happened (section 8.2); they sometimes required help from their support network or the ambulance service. The agents who may provide help bring with them their own capacity to support the patient, as well as deficits when they are no longer able to offer help.

Therefore, this study adds to Orem’s self-care theory in relation to the involvement of various agents in the management of hypoglycaemic episodes, particularly the role of the individual's support network and family members. Thus, Orem’s theory of self-care may need to be expanded to include the important role that ‘other agents’ may play in the management of chronic conditions such as diabetes.

#### **9.4 Strengths and limitations of this study**

This study attempted to investigate participants’ experiences, possible individual explanations and management of recurrent hypoglycaemic episodes over time.

A longitudinal design combining qualitative semi-structured interviews with blood glucose and hypoglycaemia diaries was employed to obtain a rich and in-depth understanding of participants' experiences of recurrent hypoglycaemic episodes. The longitudinal approach allowed prospective data collection, giving an insight into 'real' hypoglycaemic episodes as they happened (Polit and Beck 2003). A longitudinal approach is considered particularly useful for a study using multiple methods as it can help to gain a more accurate picture of the phenomena under investigation (Mingione 1999). As well as the longitudinal approach, multiple methods research is an important approach for combining qualitative and quantitative findings, and thus provides a fuller overall account, which may not have been achieved using one approach alone (Bryman 2007).

A key strength of the longitudinal approach is that it facilitated the investigation of a variety of hypoglycaemic episodes. This enabled analysis within individual participants, which was very relevant to investigate the lack of association of blood glucose levels and symptoms of hypoglycaemia (see section 7.2.4). The longitudinal aspect of the study also helped to explore what happened in-between, in the run-up to, as well as following different hypoglycaemic episodes. The longitudinal approach allowed an insight into participants' everyday life experiences of hypoglycaemia. For example, it helped to explore participants' strategies to prepare for potential hypoglycaemic episodes (see section 8.2.2), as well as the impact of recovery (see section 8.2.6).

The longitudinal approach was particularly useful to investigate differences between various hypoglycaemic episodes, and factors that influenced whether participants needed external help. Thus, it helped to develop the HEHS network (see section 8.3).

Qualitative semi-structured interviews provided a good understanding of participants' experiences and explanations for recurrent hypoglycaemic episodes. The qualitative approach helped to explore people's attitude towards hypoglycaemic episodes (e.g. whether they were fearful or not fearful) in relation to people's experiences of hypoglycaemic episodes and their overall diabetes management.

#### *Limitations of study design*

A number of limitations were identified in relation to the blood glucose diary. Some of the lowest recorded blood glucose readings may not have been the lowest in the day, due to the fact that some participants did not check/record their blood glucose level during a hypoglycaemic episode. This means there is a potential for missing data around the hypoglycaemic episode.

Another limitation of the blood glucose diary was the absence of time when the blood glucose reading was taken. This made it impossible to analyse the results from the blood glucose diary within their time sequence, to establish whether a reading was taken before or after a meal, and to investigate issues around a potential rise or fall in blood glucose level preceding or following a hypoglycaemic episode. While it was possible to compare results from the blood glucose diary with recording of hypoglycaemic episodes (as recorded in the hypoglycaemia diary), it was not possible to establish whether high blood glucose readings occurred before or after a hypoglycaemic episode. These limitations regarding the blood glucose diary meant that interpretation was limited.

The decision not to include the time the participants took a test of their blood glucose level in the blood glucose diary was taken following consideration of burden on participants, and whether this would have added any value to the study. It was thought that, on an aggregate level, knowing all the different times of day of blood glucose readings across participants would not have yielded much, given that participants also recorded blood glucose readings during and following each hypoglycaemic episode in the hypoglycaemia diary. However, the incompleteness of blood glucose readings in hypoglycaemia diaries might have been mitigated had the timing of daily blood glucose readings been available. Future studies of hypoglycaemia may benefit from the use of technologies that test and record blood glucose readings more accurately.

In terms of the hypoglycaemia diary, recording of hypoglycaemic episodes was subjective. Participants made the decision as to what they regarded as a hypoglycaemic episode and whether to record it in the diary. This may have introduced bias and the potential for missing data. However, one strength of using both the blood glucose and hypoglycaemia diary was that it allowed a comparison of the days hypoglycaemic episodes were recorded with data from the blood glucose diary. It was therefore possible to investigate whether participants recorded a hypoglycaemic episode when their blood glucose level was below 4.0 mmol/l, which is the accepted threshold for hypoglycaemic episodes (JRCALC 2006; Diabetes UK 2008).

#### *Limitations of sample*

There were a number of limitations in relation to sampling (Groger et al. 1999). For example, the non-SAS participants might not be entirely representative of people who

do not use emergency services. There might also have been differences between those SAS patients who took part and those who refused to take part. Unfortunately, it was not possible to investigate differences between those SAS patients who took part and those who did not. The experiences of recurrent hypoglycaemic episodes of those SAS patients who did not take part in this study may have been different from the experiences of those SAS patients who agreed to take part in the study.

One of the inclusion criteria was experience of at least one hypoglycaemic episode a month (based on self-report). However, during recruitment participants did not always know how many hypoglycaemic episodes they had experienced. This was because many participants did not keep a record of their hypoglycaemic episodes, and people's understanding about what constituted a hypoglycaemic episode varied. For example, some participants differentiated between low blood glucose events (less severe) and hypoglycaemic episodes (more severe). During recruitment, many participants appeared to underestimate the number of hypoglycaemic episodes they experienced (compared to the results from the hypoglycaemia diary). This highlights the limitations of participant recall and advantage of prospective data collection.

This study only included people who resided in the central belt of Scotland, who might have different views and experiences of hypoglycaemic episodes compared to people who live outwith the region, and in more rural settings where other issues may become more important.

### *Limitations of study method*

A major limitation in using a longitudinal approach was the issue of attrition; that is participants deciding to drop-out of the study at different time points (Polit and Beck 2012). The main concern with attrition is that those who stay in the study may differ in important aspects from those who decide to leave the study (Bryman 2008), hence impacting on the representativeness of the sample and validity of study findings (Ruspini 2000; Polit and Beck 2012). It is therefore important to address this by identifying any differences between participants who leave the study and those who stay in the study. While it was not possible to establish the exact reasons why some participants decided to leave the study after the initial interview, it was noted that non-SAS participants who left the study were much younger than SAS participants who left the study, (section 6.4). Possible explanations for this were that non-SAS participants might have been too busy with work or family responsibilities, while SAS participants might have had additional health problems that could have made diary completion challenging. It is unlikely that the participants who left the study were different in important aspects from those participants who stayed in the study.

Further consideration was given to the time lag between data collection points, as a longer time lag can contribute to attrition (Robson 2011). In this study, data collection was on-going during the six month follow-up phase, and I kept in regular contact with participants. In order to make study participation as straightforward and easy as possible, participants were provided with clear information about the study and given the opportunity to ask questions both before and during the study. Despite these attempts to minimise attrition rates, some attrition was inevitable due to the

longitudinal approach and the requirement for participants' on-going involvement in the study (Ruspini 2000). In total, ten participants decided to leave the study after completing the semi-structured interview (5 non-SAS/5 SAS), and a further eight participants dropped out during the diary phase (3 non-SAS/5 SAS).

It is important to acknowledge the impact the researcher might have on the research process: the personality, gender, behaviour and background of the researcher does not only influence the way rapport is created with participants, but also the responses given during the interviews and in the diary (Robson 2011). During the recruitment stage of the study, my gender and nationality (non-native English speaker) might have influenced people's willingness to take part in the study. However, this may be a theoretical issue rather than an actual problem that was found in the study; it was not raised as an issue by any participant, though they may have been reluctant to raise such issues directly.

The longitudinal nature of the study meant that I had repeated contact with participants during the course of the study. While this was vital for developing a good rapport with participants, it may have influenced the responses and motivation to participate in the study. Participants may have been steered towards giving answers they anticipate the interviewer wants to hear, rather than expressing their views and perceptions freely (Fielding and Thomas 2008). Additionally, participants may have given responses they perceive as socially desirable in order to present themselves in a favourable light. This includes providing responses that make their condition appear better or worse than it actually is (Adams et al. 1999). These limitations may have been a potential threat to objectivity and validity of the study. However, due to the

longitudinal design of this study, I spoke to participants several times, which gave me the opportunity to check whether there were any discrepancies.

Using a self-completed diary increased the potential for missing data, as well as inaccuracies in reporting (Bryman 2008). For example, participants' level of diligence in recording blood glucose readings may have varied. However, it allowed for prospective collection of data, minimising the impact of participant recall, and revealed how participants wanted to portray themselves in terms of self-image/self-care (Richardson 1994), see Appendix 14 for some examples. The fact that the diaries were structured helped to limit the level of bias.

Another factor that may have influenced participants' responses is the way in which interviews and diaries were introduced. Participants required sufficient information about the study and what participation involved in order to make an informed decision about their willingness to participate. However, the information provided has to be carefully selected to minimise the level of bias in participants' reporting. Another dimension of this is that participants may want to be perceived as 'good patients' and rational beings (Locker 1981; Jadad et al. 2003). I chose not to provide a pre-set definition of hypoglycaemia, and instead explored participants' views as to what constitutes a hypoglycaemic episode, from their individual perspectives.

The interviews and diaries may have revealed that some participants' self-care activities or diabetes control were either problematic or inappropriate. I acknowledged the limitation of my role as a researcher, and only referred participants to seek medical advice and help when they expressed concern.

## **9.5 Conclusion and recommendations**

This thesis has made a unique and original contribution to knowledge with regard to people's experiences and individual explanations of hypoglycaemic episodes. In particular, the study design made it possible to compare the experiences of people who had recently used emergency services with those who had not done so.

A key contribution of this study to knowledge is the development of the hypoglycaemic episode balancing continuum (HEBC), which enables a deeper understanding of the factors involved when an individual balances the risks associated with their diabetes and hypoglycaemia. The HEBC helps to explain how people's priority setting is placed in relation to their risks of hypoglycaemia and long-term complications, and how this can impact on their diabetes self-management (see section 7.3).

### **9.5.1 Implications for clinical practice**

Study findings have shown that participants' experiences of hypoglycaemic episodes varied; specifically that there was a lack of association of blood glucose levels and symptoms of hypoglycaemia. For example, participants could feel fine even though their blood glucose level was very low, or they could experience symptoms of hypoglycaemia when their blood glucose level was above the threshold for hypoglycaemia (section 2.7). It seems important that such variations are included in information given to patients.

Findings from this study have implications for clinical practice. For example, looking at hypoglycaemia unawareness, this study has shown that current understanding may fail

to take account of participants' real experiences, which show hypoglycaemia unawareness to be a fluid phenomenon that can affect people at various times. Blood glucose levels can also fail to predict onset of hypoglycaemic episodes. Clinical practice mainly focusses on blood glucose monitoring to detect and manage hypoglycaemic episodes (Watkins et al. 2003). This may not be helpful from participants' perspectives. This study has shown that some participants placed more importance on how they felt (i.e. whether they had symptoms and how disruptive these symptoms were) rather than on a number that represented their blood glucose level (section 7.2.4).

This study also found that people can be affected by hypoglycaemia unawareness at certain times, while they may not be affected at other times; that is, sometimes they did experience early warning signs, and at other times they did not (see sections 7.2.4 and 7.2.4.1). This may be useful in terms of patient education, especially when (new) patients are given information about hypoglycaemia unawareness.

Findings confirm the burden associated with managing diabetes to prevent or avoid hypoglycaemic episodes. However, they also highlight the unpredictability of hypoglycaemic episodes where 'visual' blood glucose levels are an unreliable predictor of symptoms. Current advice by healthcare professionals may need to take this into account.

Study findings have highlighted that avoidance of hypoglycaemic episodes was a coping strategy that participants adopted on either a temporary or more permanent basis. This may contribute to a deterioration in glycaemic control (De Galan et al. 2006), and thus could be an important issue to address in clinical practice. The HEBC has potential for use in clinical practice, as it could help health professionals explore

how patients feel about hypoglycaemic episodes and how they place their priorities in relation to risk of hypoglycaemia and risk of long-term complications. The HEBC could also help to identify those at greater risk of hypoglycaemic episodes and those at greater risk of long-term complications, and to target advice more specifically to these patient groups. Thus, study findings have underlined that clinical practice needs to take into consideration patients' individual self-management strategies.

This study found that due to a long duration of living with diabetes, some participants experienced less symptoms of hypoglycaemia (i.e. an increased risk of hypoglycaemia unawareness) and more severe hypoglycaemic episodes (see section 7.2.7). Healthcare professionals may need to consider this when providing advice and information to patients who have lived with diabetes for a long time.

As highlighted in section 7.4.4, non-SAS participants appeared to be more knowledgeable about their diabetes and its management compared to SAS participants, resulting in a better awareness of hypoglycaemia unawareness (section 7.4.3). In this regard, it may be beneficial to invite people contacting the SAS to take part in a structured education course/refresher class. The SIGN guideline for the management of diabetes also recommends that people experiencing difficulties with hypoglycaemia should be offered to take part in structured education programmes (SIGN 2010).

To reduce the use of emergency services, more attention has to be paid to hypoglycaemia unawareness and better advice provided about the condition. For example, it could be recommended that patients take part in a structured education programme, such as hypoglycaemia anticipation, awareness and treatment training

(HAATT; Cox et al. 2004). Also, more education should be provided for family members/carers, given the crucial role they play in the management of diabetes and hypoglycaemic episodes, and being a link in the process leading to increased use of emergency services (Sutton and Chapman-Novakofski 2011).

Another potential way to reduce the use of emergency services is the increased monitoring of blood glucose levels, which has been identified as a strategy to manage hypoglycaemia unawareness (Graveling and Frier 2010). The development and use of new technologies to measure blood glucose and provide early feedback might also be helpful.

### **9.5.2 Implications for further research**

The study findings have highlighted that carers/family members play an important role in supporting the person with diabetes. This is particularly the case when the person is unable to identify and treat a hypoglycaemic episode (e.g. due to hypoglycaemia unawareness). This study only included carers/family members when this was requested by the participant (see section 5.5.3). Overall, five carers/family members took part in the face to face interviews. It would be beneficial to carry out further research that focusses more on the role of carers/family members in supporting people experiencing (recurrent) hypoglycaemic episodes. This would also need to explore carer knowledge in more detail to better understand their role in helping to manage hypoglycaemic episodes.

This study found that there may be a link between people's knowledge about their diabetes and its care, and their ability to manage hypoglycaemia unawareness. While

the qualitative approach this study adopted was useful to gain an in-depth account of participants' experiences, a quantitative approach could measure people's level of diabetes health literacy, and investigate how this relates to hypoglycaemia unawareness.

Preparation for potential hypoglycaemic episodes happening (section 8.2.2) was a key difference between the two participant groups, and one of the factors that influenced whether external help would be needed. Further research could develop an intervention for people who are less prepared for potential hypoglycaemic episodes.

Further research could develop the HEBC into a useful 'screening tool' for healthcare professionals to help identify where patients sit in terms of prioritising risks of hypoglycaemia and long-term complications to be able to tailor help to individuals. This could be in the form of a questionnaire.

The HEBC has suggested that there may be a link between people's fear of hypoglycaemia, fear of long-term complications and diabetes self-management. Further quantitative research could investigate any correlations between these factors.

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## Appendices



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### Appendix 1: Participant Information Sheet (non-SAS)

*This information sheet explains the purpose of the study and clearly outlines what participation will involve.*

Version 1.8, June 2011

#### 1. Study title

'Participants' experiences of hypoglycaemia and diabetes'

#### 2. Invitation

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

#### 3. What is the purpose of the study?

The purpose of this research study is to find out about participants' views and experiences of recurrent hypos.

The research questions will be about:

- What are participants' individual explanations for having recurrent hypos?
- What coping strategies do participants adopt to deal with recurrent hypos?
- How (if at all) do recurrent hypos influence diabetes self-management?
- What is the impact of hypos on your family and wider social network?
- How do hypos affect the everyday life of people with diabetes?
- Are there any changes over time? What influences these? Are there any differences between various hypos?

The study is being carried out between July 2011 and July 2012.

#### 4. Why have I been chosen?

We have given you this information sheet as you may fit our study criteria. Study participants should be diagnosed with type 1 or type 2 diabetes and treated with insulin. You should experience at least one hypo in a month. We are looking for people who are over 16 years of age and living in the central belt of Scotland.

If you decide to opt-in, please speak to the researcher who sent you this information sheet. We wish to recruit 48 individuals in total and all those opting in who fit the criteria will be recruited on a 'first come, first served' basis. You may be asked to go on a reserve list in case people who have already agreed to take part leave the study in future.

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

No, participation in this study is completely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, the researcher will set up a time and place for you to meet for an interview. At the time of interview you will be asked to sign two copies of a consent form and given one of the copies to keep. If you decide to take part you are still free to withdraw at any time, without giving a reason and without your medical care or legal rights being affected.

## **6. What will happen to me if I take part?**

Participation in the study is in three parts:

1. If you decide to take part, a suitable date, time and location for an interview will be agreed with the researcher. After giving your consent, you will be interviewed at the arranged time and place with the interview lasting for approximately one hour. The interview will be based around a series of key questions relating to the study topic. Your interview will be audio recorded and notes will be taken from the recording.
2. At the interview you will be shown how to use a 'hypoglycaemia and blood glucose diary' and asked to use this diary to record your hypos and blood glucose values for a period of six months.
3. During the diary time, the researcher will stay in regular contact and arrange to interview you by telephone monthly. This interview will further explore your experiences during the time of keeping the diary. It will last around 10 minutes.

All data collected will be analysed and the findings will be used to help to answer the research questions.

## **7. What do I have to do?**

You have to decide whether you wish to take part in this study. If you do, simply fill in the 'Participants' Details' Form enclosed and return to the researcher. We will then set up a suitable time, date and location to be interviewed.

## **8. What are the possible risks and disadvantages of taking part?**

There are no medical risks involved in taking part in this study.

## **9. What are the possible benefits of taking part?**

By taking part you are helping to provide information that will give the researchers a better understanding of the experiences of hypos of people living with diabetes. A researcher will feed back the findings of the research to you following this study and offer you a summary of the findings. A copy of the full report will be available upon request.

## **10. Will my taking part in the study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. You will be identified by an ID number and any information about you will have your name and address removed so that you cannot be recognised from it. Only the researchers will have access to the data collected in this study. The research report will include a summary of the type of people (e.g. type 1 diabetes, male, 40-60 years old) interviewed and descriptors will be used carefully within the report in relation to participants, ensuring anonymity is maintained.

## **11. What will happen to the results of the research study?**

This study is being undertaken by Theresa Ikegwuonu as part of her PhD. The results of the study will be published in her PhD thesis and other publications. Participants will not be identified. A summary of the findings will be offered to you following completion of this study.

**12. Who is organising and funding the study?**

The study is being organised by the researcher as part of her PhD based at the Nursing, Midwifery and Allied Health Professions' Research Unit (NMAHP RU) at the University of Stirling, funded by the University of Stirling, NMAHP Research Unit and the Scottish Ambulance Service.

**13. Who has reviewed the study?**

The study has been approved by the University of Stirling's Department of Nursing and Midwifery Ethics Committee.

**14. Contact for further information**

Theresa Ikegwuonu  
NMAHP Research Unit  
Iris Murdoch Building  
University of Stirling  
Stirling, FK9 4LA  
Tel: 01786 466 341  
Email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

**This study is supervised by:**

Dr Edward Duncan  
NMAHP Research Unit  
University of Stirling  
Tel: 01786 466 286  
Email: [Edward.duncan@stir.ac.uk](mailto:Edward.duncan@stir.ac.uk)

**15. What if something goes wrong?**

If you would like to speak to someone who knows about this study who is an independent advisor, please contact:

Professor William Lauder  
Head of School of Nursing, Midwifery and Health  
University of Stirling  
Tel: 01786 466 345  
Email: [William.lauder@stir.ac.uk](mailto:William.lauder@stir.ac.uk)

If you have any concerns about your diabetes or your health and emotional well-being, please contact your GP in the first instance. You may also contact:  
Diabetes UK (Scotland) Helpline 0845 120 2960 or [www.diabetes.org.uk](http://www.diabetes.org.uk)  
Breathing Space 0800 83 85 87 or [www.breathingspacescotland.co.uk](http://www.breathingspacescotland.co.uk)

**Study participants will be given a copy of this information sheet and a signed consent form to keep.**

**THANK YOU IN ADVANCE FOR TAKING PART IN THIS STUDY.**

## Appendix 2: Participant Information Sheet (SAS)



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*This information sheet explains the purpose of the study and clearly outlines what participation will involve.*

Version 1.8, 6<sup>th</sup> July 2011

### 1. Study title

'Participants' experiences of hypoglycaemia and diabetes'

### 2. Invitation

My name is Theresa Ikegwuonu and I am undertaking a PhD at the University of Stirling. I am required to undertake a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

### 3. What is the purpose of the study?

The purpose of this research study is to find out about participants' views and experiences of recurrent hypos.

The research questions will be about:

- What are participants' individual explanations for having recurrent hypos?
- What coping strategies do participants adopt to deal with recurrent hypos?
- How (if at all) do recurrent hypos influence diabetes self-management?
- What is the impact of hypos on your family and wider social network?
- How do hypos affect the everyday life of people with diabetes?
- Are there any changes over time? What influences these? Are there any differences between various hypos?

The study is being carried out between July 2011 and July 2012.

### 4. Why have I been chosen?

You are being invited to take part in this research study as you have recently experienced a hypoglycaemic emergency involving the Scottish Ambulance Service and may fit our study criteria. Study participants should be diagnosed with type 1 or type 2 diabetes and treated with insulin. You should experience at least one hypo in a month. We are looking for people who are over 18 years of age and living in the central belt of Scotland.

You have been sent this information sheet as agreed during a telephone call with the researcher. If you decide to opt-in, either speak to the researcher (Theresa Ikegwuonu, see contact details below), or complete and return the enclosed card in the pre-paid envelope provided. We wish to recruit 24 individuals in total and all those opting in who fit the criteria will be recruited on a 'first come, first served' basis. You may be

asked to go on a reserve list in case people who have already agreed to take part leave the study in future.

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

No, participation in this study is completely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, the researcher will set up a time and place for you to meet for an interview. At the time of interview you will be asked to sign two copies of a consent form and given one of the copies to keep. If you decide to take part you are still free to withdraw at any time, without giving a reason and without your medical care or legal rights being affected.

You are able to have someone else present with you during the interview (e.g. partner, family member, carer), if you wish.

#### **6. What will happen to me if I take part?**

Participation in the study is in three parts:

1. If you decide to take part, a suitable date, time and location for an interview will be agreed with the researcher. After giving your consent, you will be interviewed at the arranged time and place with the interview lasting for approximately one hour. The interview will be based around a series of key questions relating to the study topic. Your interview will be audio recorded and notes will be taken from the recording.
2. At the interview you will be shown how to use a 'hypoglycaemia and blood glucose diary' and asked to use this diary to record your hypos and blood glucose values for a period of six months.
3. During the diary time, the researcher will stay in regular contact and arrange to interview you by telephone monthly. This interview will further explore your experiences during the time of keeping the diary. It will last around 10 minutes.

All data collected will be analysed and the findings will be used to help to answer the research questions.

#### **7. What do I have to do?**

You have to decide whether you wish to take part in this study. If you do, simply return the enclosed card or contact the researcher (Theresa Ikegwuonu, see contact details below). We will then set up a suitable time, date and location to be interviewed.

#### **8. What are the possible risks and disadvantages of taking part?**

There are no medical risks involved in taking part in this study.

#### **9. What are the possible benefits of taking part?**

By taking part you are helping to provide information that will give the researchers a better understanding of the experiences of hypos of people living with diabetes. A researcher will feed back the findings of the research to you following this study and offer you a summary of the findings. A copy of the full report will be available upon request.

#### **10. Will my taking part in the study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. The only occasion on which this may be breached is when the researcher has concerns for your safety or the safety of others. In the unlikely situation that this would arise, we would first inform you that we would for ethical and moral reasons be required to contact an appropriate authority.

You will be allocated a study number and any information about you will have your name and address removed so that you cannot be identified from it. Only the

researchers will have access to the data collected in this study. The research report will include a summary of the type of people (e.g. type 1 diabetes, male, 40-60 years old) interviewed and descriptors will be used carefully within the report in relation to participants, ensuring anonymity is maintained. Digital recordings of the interviews will be securely stored and erased on completion of the study. Anonymised paper transcripts will be held securely for a period of 10 years, in accordance with good research practice guidelines. If you wish, you may request a copy of any of your transcripts held.

With your permission, we will inform your GP of your participation in the study.

#### **11. What will happen to the results of the research study?**

This study is being undertaken by Theresa Ikegwuonu as part of her PhD. The results of the study will be published in her PhD thesis and other publications. Direct quotes may be used; however, participants will not be identified. A summary of the findings will be offered to you following completion of this study.

#### **12. Who is organising and funding the study?**

The study is being organised by the researcher as part of her PhD based at the Nursing, Midwifery and Allied Health Professions' Research Unit (NMAHP RU) at the University of Stirling, funded by the University of Stirling, NMAHP Research Unit and the Scottish Ambulance Service.

#### **13. Who has reviewed the study?**

The study has been reviewed by a NHS Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans. In this case, the reviewing Committee was the Fife & Forth Valley Research Ethics Committee who have raised no objections from the point of view of medical ethics.

#### **14. Contact for further information**

Theresa Ikegwuonu  
NMAHP Research Unit  
Iris Murdoch Building  
University of Stirling  
Stirling, FK9 4LA  
Tel: 01786 466 341  
Email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

#### **This study is supervised by:**

Dr Edward Duncan  
NMAHP Research Unit  
University of Stirling  
Tel: 01786 466 286  
Email: [Edward.duncan@stir.ac.uk](mailto:Edward.duncan@stir.ac.uk)

#### **15. What if something goes wrong?**

If you would like to speak to someone who knows about this study who is an independent advisor, please contact:

Professor William Lauder  
Head of School of Nursing, Midwifery and Health  
University of Stirling  
Tel: 01786 466 345  
Email: [William.lauder@stir.ac.uk](mailto:William.lauder@stir.ac.uk)

If you have any concerns about your diabetes or your health and emotional well-being, please contact your GP in the first instance. You may also contact:  
Diabetes UK (Scotland) Helpline 0845 120 2960 or [www.diabetes.org.uk](http://www.diabetes.org.uk)  
Breathing Space 0800 83 85 87 or [www.breathingspacescotland.co.uk](http://www.breathingspacescotland.co.uk)

**Study participants will be given a copy of this information sheet  
and a signed consent form to keep.**

**THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET  
AND FOR CONSIDERING TAKING PART.**

## Appendix 3: Participant Information Sheet (Carers and family members)



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AND HEALTH

*This information sheet explains the purpose of the study and clearly outlines what participation will involve.*

Version 1.0, 6<sup>th</sup> July 2011

### 1. Study title

'Participants' experiences of hypoglycaemia and diabetes'

### 2. Invitation

My name is Theresa Ikegwuonu and I am undertaking a PhD at the University of Stirling. I am required to undertake a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

### 3. What is the purpose of the study?

The purpose of this research study is to find out about participants' views and experiences of recurrent hypos.

The research questions will be about:

- What are participants' individual explanations for having recurrent hypos?
- What coping strategies do participants adopt to deal with recurrent hypos?
- How (if at all) do recurrent hypos influence diabetes self-management?
- What is the impact of hypos on your family and wider social network?
- How do hypos affect the everyday life of people with diabetes?
- Are there any changes over time? What influences these? Are there any differences between various hypos?

The study is being carried out between July 2011 and July 2012.

### 4. Why have I been chosen?

You are being invited to take part in this research study as your partner/family member or the person you care for has requested that you be present when we speak to them about their hypoglycaemic episodes. They have been asked to take part because they have recently experienced a hypoglycaemic emergency involving the Scottish Ambulance Service and may fit our study criteria.

### 5. Do I have to take part?

No, participation in this study is completely voluntary. The decision to participate in the study will initially lie with your family member/the person you care for with diabetes. We will arrange any interviews with them and they should inform you of these dates and times if they still want you to be present. If you decide to take part you are still free to withdraw at any time, without giving a reason and without your legal rights being affected.

## **6. What will happen to me if I take part?**

You and the person you care for will be interviewed together for approximately one hour. You will be asked to sign two copies of a consent form prior to the interview, and you will be given one of the copies to keep. The interview will be based around a series of key questions relating to the study topic. Your interview will be audio recorded and notes will be taken from the recording.

All data collected will be analysed and the findings will be used to help answer the research questions.

## **7. What are the possible risks and disadvantages of taking part?**

There are no medical risks involved in taking part in this study.

## **8. What are the possible benefits of taking part?**

By taking part you are helping to provide information that will give the researchers a better understanding of the experiences of hypos of people living with diabetes. A researcher will feed back the findings of the research to you following this study and offer you a summary of the findings. A copy of the full report will be available upon request.

## **9. Will my taking part in the study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. The only occasion on which this may be breached is when the researcher has concerns for your safety or the safety of others. In the unlikely situation that this would arise, we would first inform you that we would for ethical and moral reasons be required to contact an appropriate authority.

You will be allocated a study number and any information about you will have your name and address removed so that you cannot be identified from it. Only the researchers will have access to the data collected in this study. The research report will include a summary of the type of people (e.g. type 1 diabetes, male, 40-60 years old) interviewed and descriptors will be used carefully within the report in relation to participants, ensuring anonymity is maintained. Digital recordings of the interviews will be securely stored and erased on completion of the study. Anonymised paper transcripts will be held securely for a period of 10 years, in accordance with good research practice guidelines. If you wish, you may request a copy of any of your transcripts held.

## **10. What will happen to the results of the research study?**

This study is being undertaken by Theresa Ikegwuonu as part of her PhD. The results of the study will be published in her PhD thesis and other publications. Direct quotes may be used; however, participants will not be identified. A summary of the findings will be offered to you following completion of this study.

## **11. Who is organising and funding the study?**

The study is being organised by the researcher as part of her PhD based at the Nursing, Midwifery and Allied Health Professions' Research Unit (NMAHP RU) at the University of Stirling, funded by the University of Stirling, NMAHP Research Unit and the Scottish Ambulance Service.

## **12. Who has reviewed the study?**

The study has been reviewed by a NHS Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans. In this case,

the reviewing Committee was the Fife & Forth Valley Research Ethics Committee who have raised no objections from the point of view of medical ethics.

### **13. Contact for further information**

Theresa Ikegwuonu  
NMAHP Research Unit  
Iris Murdoch Building  
University of Stirling  
Stirling, FK9 4LA  
Tel: 01786 466 341  
Email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

### **This study is supervised by:**

Dr Edward Duncan  
NMAHP Research Unit  
University of Stirling  
Tel: 01786 466 286  
Email: [Edward.duncan@stir.ac.uk](mailto:Edward.duncan@stir.ac.uk)

### **14. What if something goes wrong?**

If you would like to speak to someone who knows about this study who is an independent advisor, please contact:

Professor William Lauder  
Head of School of Nursing, Midwifery and Health  
University of Stirling  
Tel: 01786 466 345  
Email: [William.lauder@stir.ac.uk](mailto:William.lauder@stir.ac.uk)

If you have any concerns about your diabetes or your health and emotional well-being, please contact your GP in the first instance. You may also contact:  
Diabetes UK (Scotland) Helpline 0845 120 2960 or [www.diabetes.org.uk](http://www.diabetes.org.uk)  
Breathing Space 0800 83 85 87 or [www.breathingspacescotland.co.uk](http://www.breathingspacescotland.co.uk)

**Study participants will be given a copy of this information sheet  
and a signed consent form to keep.**

**THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET  
AND FOR CONSIDERING TAKING PART.**

## Appendix 4: Consent Form (Non-SAS participants)



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AND HEALTH

### *Participants' experiences of Hypoglycaemia and diabetes*

Name of Researcher:

**Theresa Ikegwuonu**

Tel. 01786 466 341

Email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

**Please initial box**

1. I confirm that I have read and understand the information sheet version 1.8 dated June 2011 for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone else.
4. I agree to take part in the above study.
5. I agree that an audio record of my participation can be made.
6. I give permission for the information I provide to be used for research purposes (including reports, publications and presentations) with strict preservation of anonymity. I understand that direct quotes from my interviews may be used, but I will not be identified through them.
7. I understand that any information I provide will be treated in the strictest confidence. The information will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed, 1 copy for participant; 1 copy for researcher

## Appendix 5: Consent Form (SAS participants)



UNIVERSITY OF  
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SCHOOL OF  
NURSING, MIDWIFERY  
AND HEALTH

### *Participants' experiences of Hypoglycaemia and diabetes*

Name of Researcher:  
**Theresa Ikegwuonu**  
Tel. 01786 466 341  
Email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

**Please initial box**

1. I confirm that I have read and understand the information sheet version 1.8 dated 6<sup>th</sup> July 2011 for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I agree to my GP and diabetes health worker being informed of my participation in this study.   
My GP's contact details are: \_\_\_\_\_  
\_\_\_\_\_
4. I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone else.
5. I agree that an audio record of my participation can be made. I understand that the recording will be securely stored and erased on completion of the study. Transcriptions will be anonymised with personal and place names removed.
6. I give permission for the information I provide to be used for research purposes (including reports, publications and presentations) with strict preservation of anonymity. I understand that direct quotes from my interviews may be used, but I will not be identified through them.
7. I understand that any information I provide will be treated in the strictest confidence. The information (interview transcripts and diaries) will be held securely for ten years and will only be available to the research team. The information will be destroyed after this time.

8. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed, 1 copy for participant; 1 copy for researcher

## Appendix 6: Consent Form (SAS carers/family members)



UNIVERSITY OF  
STIRLING

SCHOOL OF  
NURSING, MIDWIFERY  
AND HEALTH

### *Participants' experiences of Hypoglycaemia and diabetes*

Name of Researcher:  
**Theresa Ikegwuonu**  
Tel. 01786 466 341  
Email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

**Please initial box**

I confirm that I am attending an interview for the above study at the request of \_\_\_\_\_ (insert participant's name).

1. I confirm that I have read and understand the information sheet version 1.0 dated 6<sup>th</sup> July 2011 for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without legal rights being affected.
3. I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone else.
4. I agree that an audio record of my participation can be made. I understand that the recording will be securely stored and erased on completion of the study. Transcriptions will be anonymised with personal and place names removed.
5. I give permission for the information I provide to be used for research purposes (including reports, publications and presentations) with strict preservation of anonymity. I understand that direct quotes from my interviews may be used, but I will not be identified through them.
6. I understand that any information I provide will be treated in the strictest confidence. The information (interview transcripts and diaries) will be held securely for ten years and will only be available to the research team. The information will be destroyed after this time.

7. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed, 1 copy for participant (carer/family member); 1 copy for researcher

## **Appendix 7: Telephone Protocol (SAS recruitment)**

### Part 1: to get the target individual on phone

Researcher: Hello, can I speak to X please?

C: May I ask who is calling?

Researcher: My name is Theresa Ikegwuonu, and I'm calling from the University of Stirling regarding a study of diabetes.

C: Why do you want to speak to X?

Researcher: I believe X is in a position to help with our study. I just want to ask X's permission to send out study information, but I can't do this without getting his/her permission first.

C: How did you get his/her phone number?

Researcher: X has been identified through a previous contact with health services as someone who could help with our study.

If X is not available:

Researcher: Can I call back later or leave my contact details for X to contact me?

If we don't hear anything back within 2-3 days, we would call back.

No more than 2 attempts to contact someone will be made.

### Part 2: Speaking to the target individual

Researcher: Can I please just check I'm speaking to the right person? (verify name, age/DOB)  
My name is Theresa Ikegwuonu, and I'm calling from the University of Stirling. I am currently working on a project with the Scottish Ambulance Service, and I'm very interested in diabetes and hypoglycaemia. I would like to find out about people's experiences of hypos, and to see if anything can be done to help people cope with hypoglycaemia over time.

The reason I'm contacting you is because I understand you have recently contacted the ambulance service due to a hypoglycaemic emergency.

At this stage, I just want to ask if you are willing to receive further information about the study, and if I can send you an information pack?

If you read the information and want to take part, all you need to do is to return the enclosed postcard, or to send me an email or give me a call.

Would you be willing to receive this information?

If yes → Where should I send the information pack to? (confirm address)

If no → Thanks very much for your time. Sorry to have bothered you about this.

If the person asks for further information, the researcher will briefly explain what participation in the study will involve (e.g. taking part in a one to one interview, keeping a hypoglycaemia and blood glucose diary and taking part in brief follow-up telephone interviews). It will be made clear that the reason for the telephone call is just to check whether the person is willing to receive further information about the study.

## Appendix 8: Letter for SAS Participants

Date

Dear Participant,

### **Re: Study about people's experiences of hypos and diabetes**

Following our recent chat over the phone, I am pleased to enclose some further information about the study "Experiences of Hypoglycaemia and Diabetes" (Participant Information Sheet and consent forms).

Please note that you do not need to sign the consent forms at this stage, we would have time to do that before the interview.

If you are interested to participate, could you fill in the form ('Participants' details') and return it to me by fax or post (in the pre-paid envelope provided)?

If you've got any questions about the study, please do not hesitate to contact me (email/phone/post).

Looking forward to hearing from you!

Best regards,  
Theresa

Theresa Ikegwuonu  
PhD Research Student  
NMAHP Research Unit  
Iris Murdoch Building  
University of Stirling  
STIRLING, FK9 4LA  
email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)  
Phone: 01786 466 341

## Appendix 9: Participant's Details Form



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AND HEALTH

### Research Study

## “Participants’ Experiences of Hypoglycaemia and Diabetes”

### Participant’s details

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Age/DOB: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

### **Additional information**

Type of diabetes: \_\_\_\_\_

Diagnosed since: \_\_\_\_\_

Treatment: \_\_\_\_\_

How often do you have hypos? \_\_\_\_\_

Did you ever call the emergency services/ambulance as a result of a hypo? If yes, when was the last time you contacted them? \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Please return this form to Theresa Ikegwuonu by email ([ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)) or post: NMAHP Research Unit, Iris Murdoch Building, University of Stirling, Stirling, FK9 4LA

## Appendix 10: Hypoglycaemia Study Project Flyer

An investigation of people's experiences of hypoglycaemia and diabetes.

---

### ***Volunteers wanted...***

#### **Would you be willing to take part in the above research study?**

We are very interested in finding out about people's views and experiences of having hypos, and the impact hypos have on everyday life. Participation will include a one-to-one interview, keeping a blood glucose diary and taking part in brief follow-up telephone interviews. Interested?

We would like to involve people who:

- Are over 18 years of age
- Are treated with insulin
- Normally have at least 1 hypo every month
- Have not used the emergency services (due to their hypoglycaemia) in the last 3 months

For more information, please contact:

Theresa Ikegwonu

Tel. 01786 466 341 or email: [ti1@stir.ac.uk](mailto:ti1@stir.ac.uk)

NMAHP Research Unit, University of Stirling, FK9 4LA



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Nursing, Midwifery and Allied  
Health Professions Research Unit

## Appendix 11: Letter to participant's GP

Date

Dear Dr ...,

**Ref: Study Investigating Patients' Experiences of Hypoglycaemia and Diabetes**

Re: (Patient's name, DOB, address)

We are undertaking a research study which aims to investigate patients' experiences of/and possible explanations for recurrent hypoglycaemia over time. The study is being funded by the Scottish Ambulance Service and the University of Stirling, and is being undertaken as part of a PhD at the University of Stirling. The study has been given Research Ethics Approval by the Fife & Forth Valley Research Ethics Committee (11/AL/0330).

As part of this study we contact patients with diabetes who have recently required ambulance service assistance for a hypoglycaemic emergency. Patients are invited to take part in face to face interviews, keep a hypoglycaemia and blood glucose diary for a period of six months, and take part in brief follow-up telephone interviews.

As the above patient's General Practitioner we are informing you they have agreed to take part in this study. Consent was given by the patient prior to sending you this letter.

If you have any further questions, please do not hesitate to contact me, or my supervisor Dr. Edward Duncan (Tel. 01786 46 6286).

Kind regards

Theresa Ikegwuonu (PhD Research Student)  
Tel. 01786 46 6341  
Email. [Theresa.ikegwuonu@stir.ac.uk](mailto:Theresa.ikegwuonu@stir.ac.uk)

## Appendix 12: Interview Topic Guide

Tell me about living with diabetes. What is it like?  
How long have you been diagnosed?

Tell me about your experiences with hypos (hypoglycaemia).  
Do you remember your worst hypo? Could you tell me about it?  
(Do you know...) What level do you go hypo at?

RQ1&RQ3: hypo  
experience +  
change over time

Do you ever experience hypos in the night/during sleep?  
What did you do the day before?

How do you know when you are about to have a hypo?  
(→ Hypoglycaemia unawareness)  
What happens after you've had a hypo?  
How does your body feel?

General hypo experience

Do hypos affect your daily activities?  
Driving...?

RQ1a: impact on everyday life

Do you have any particular strategies to deal with hypos?

RQ2a: Coping strategies

How (if at all) do hypos influence your family and  
friends?  
Do you talk about hypos with your family and friends?  
How do you educate them? (→support network)

RQ1b: impact on  
social network

Do hypos influence your social life? Going out?

What about work? Do hypos influence your work life?

For many people with diabetes, hypos are not  
just a one-off event, but can happen quite regularly.  
In your opinion, what are the reasons for repeat hypos?  
Are there any differences between hypos?

RQ1&RQ2:  
experience& individual  
explanations of  
recurrent hypos

If you think about the last 5 years (or the time since  
you had diabetes), do you think that anything  
(relating to diabetes/hypos) has changed at all?

RQ3: change  
over time

Do you think that anything might change in the future?

Do you think hypos influence your diabetes management?

RQ2b: diabetes  
self-management

-----  
Is there anything else you wish to tell me?

Thank you very much for sharing your thoughts  
and for your openness.

Conclusion

(END OF INTERVIEW)

RQ= research question

## Appendix 13: Example Page from the Hypoglycaemia Diary

### Hypo Diary

Name: NS2\_F01

Date & time of hypo	Where were you?	How long did hypo last?	BG value (if recorded)	
			(during hypo)	(after hypo)
24/08/2011 3.10pm	Kitchen	40 mins	3.6	11.3
<b>Who was around?</b> Alone		<b>What were you doing?</b> Housework	<b>Number of days since last hypo?</b> <1	
<b>What do you think might have caused this hypo?</b>  Activity? Low BG at lunchtime not adequately covered.				
<b>What symptoms did you have?</b>  Shaky, poor concentration, confusion Aware something was wrong, but struggled to remember what to do.		<b>From your perspective, how bad was the hypo? (on a scale of 1-10, with 10 being very bad)</b>  4		
<b>Did you treat yourself? Did you need someone's assistance (if so, please give relationship (e.g. wife/husband, friend, sister)? Was the ambulance service called?</b>  Sorted it myself				
<b>Treatment of hypo? (e.g. glucose tablets, sweets, glucagon injection)</b>  Lucozade, then biscuit				
<b>Any other comments?</b>  Didn't feel any early warnings, and was busy, so wasn't watching for them.				
Please be as open as you can, remember all entries are strictly confidential.				





## Appendix 15: Telephone Interview Topic Guide

---

How did you get on with your diary?

Was this period quite normal for you in terms of hypos? Any more, less?

The following questions were used to discuss an example of a hypoglycaemic episode that occurred during the diary time:

What led up to the hypoglycaemic event?

What could have been done differently? (before/during/after event)

What happened during the hypoglycaemic event?

How severe was it? How bad (on the scale of 1-10) would it have to be before you would seek external help?

How did you cope?

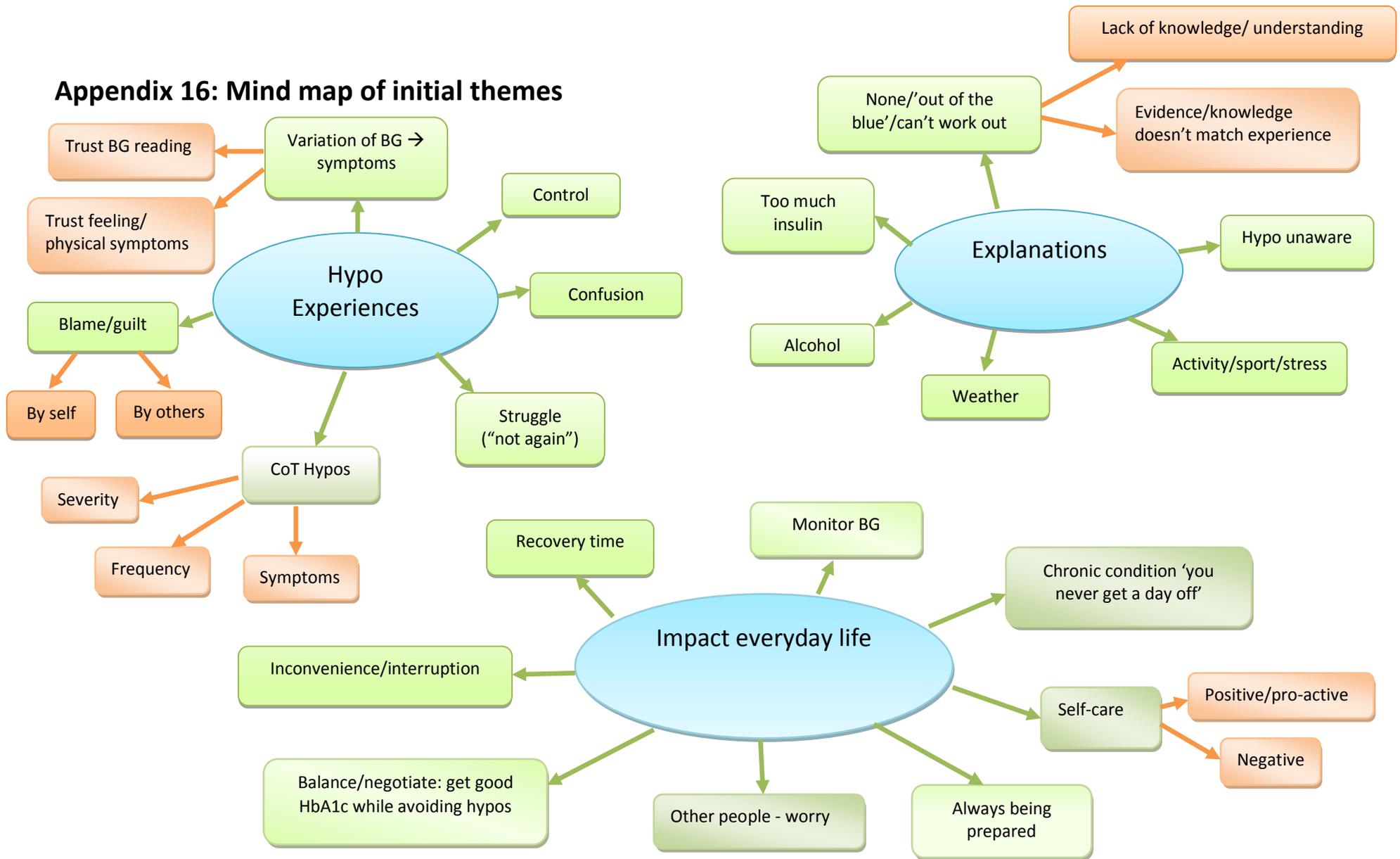
Did you change anything after this hypoglycaemic episode?

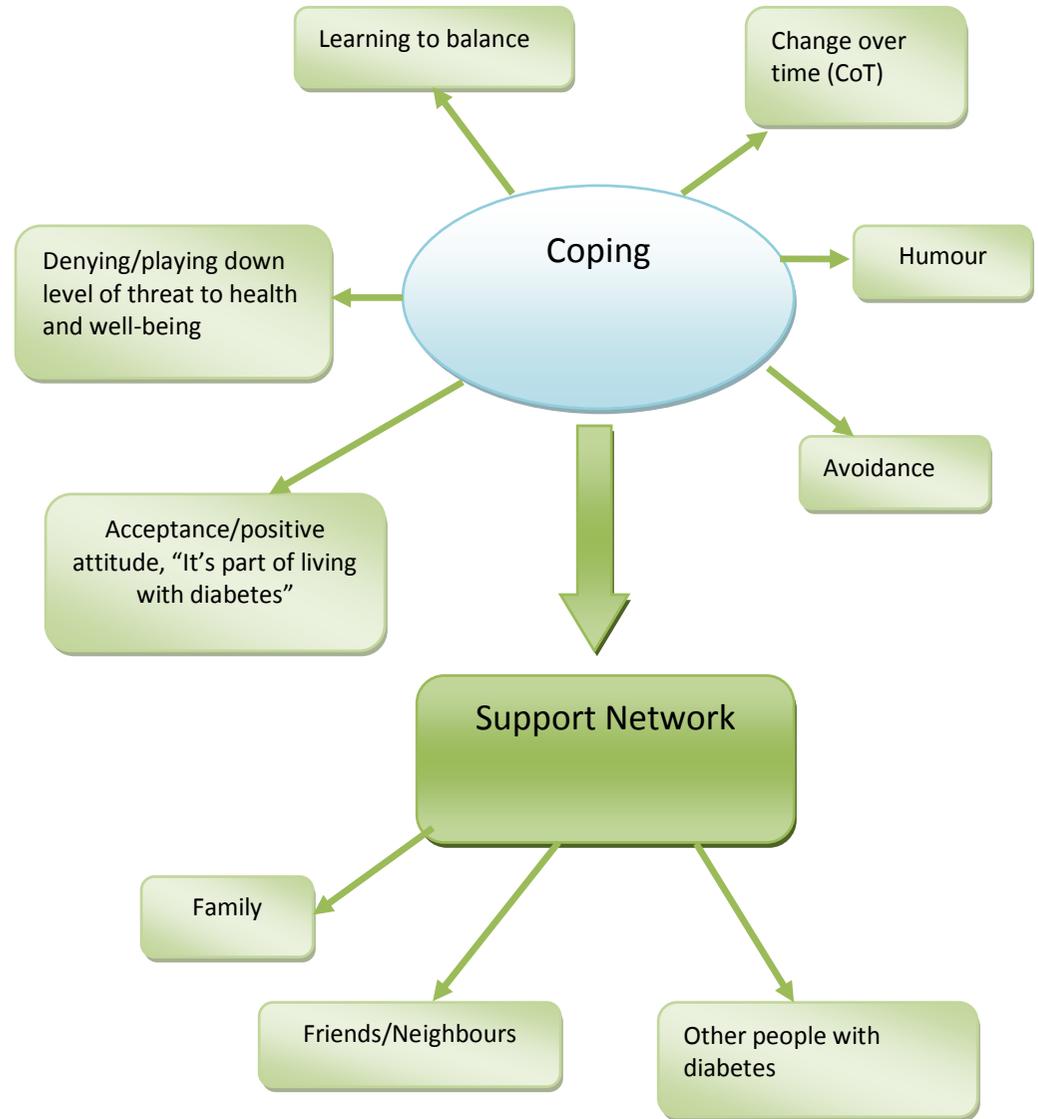
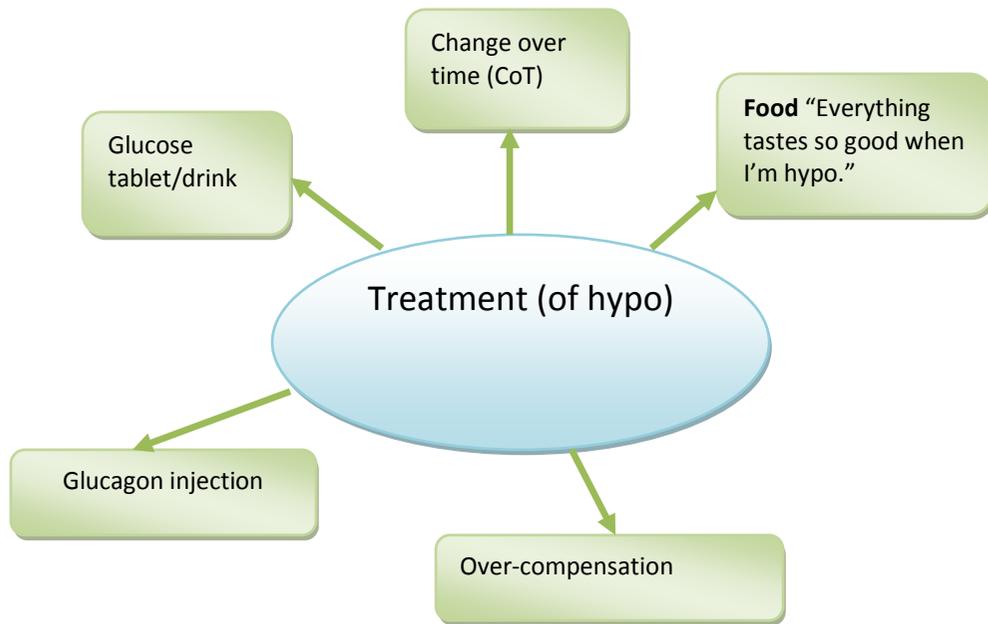
Is there anything else you wish to tell me (relating to your experience of hypoglycaemia)?

Anything you noticed by keeping the diary? Any new insights?

Do you have any questions?

## Appendix 16: Mind map of initial themes





## Appendix 17: Thematic Coding Framework

### COPING (COP)

- COP – Avoid hypo
- COP – CoT
- COP – Denial
- COP – humour
- COP – positive attitude
- COP – learning to balance

### EXPLANATIONS (EXPL)

- Expl- Activity
- Expl- Alcohol
- Expl- Hypo unaware
- Expl- injection sites
- Expl- natural drop in BG
- Expl- None
  - No- Evidence no match experience
  - No- lack understanding
- Expl- too much insulin
- Expl- Weather or temperature

### HYPO TREATMENT (HT)

- HT- CoT
- HT- Food
- HT- Glucagon Inject
- HT- Glucose
- HT- Over-Compensation

### IMPACT EVERYDAY LIFE (IEL)

- IEL- always prepared
- IEL- avoid social situations
- IEL- balance
- IEL- change job-career
- IEL- inconvenience
- IEL- monitor BG
- IEL- never off
- IEL- other people worry
- IEL- recovery time
- IEL- self-care
  - Self-care- pos
  - Self-care- neg

### HYPO EXPERIENCES (HE)

- HE- Acceptance
- HE- blame n guilt
  - Blame by others
  - Blame guilt self
- HE- Confusion
- HE- Control
- HE- CoT
  - CoT- frequency
  - CoT- severity
  - CoT- symptoms
- HE- Fear
- HE- hypos cluster
- HE- night
- HE- struggle
- HE- Symptoms
- HE- Variation of BG- sympt exp
  - Variat- feelings
  - Variat- trust BG

### SUPPORT NETWORK

## Appendix 18: Revised Thematic Coding Framework

### **COPING (COP)**

- COP - Avoid hypo
- COP – CoT
- COP – Denial
- COP – humour
- COP - positive attitude
- COP- learning to balance

### **EXPLANATIONS (EXPL)**

- Expl- Activity
- Expl- Alcohol
- Expl- Hypo unaware
- Expl- injection sites
- Expl- natural drop in BG
- Expl- None
  - No- Evidence no match experience
  - No- lack understanding
- Expl- too much insulin
- Expl- Weather or temperature

### **HEALTH EDUCATION/HEALTH LITERACY (new code)**

### **HYPO TREATMENT (HT)**

- HT- CoT
- HT- Food
- HT- Glucagon Inject
- HT- Glucose
- HT- Over-Compensation

### **IMPACT EVERYDAY LIFE (IEL)**

- IEL- always prepared
- IEL- avoid social situations
- IEL- balance
- IEL- change job-career
- IEL- inconvenience
- IEL- monitor BG
- IEL- never off
- IEL- other people worry
- IEL- recovery time
- IEL- self-care
  - Self-care- pos
  - Self-care- neg

### **HYPO EXPERIENCES (HE)**

- HE- Acceptance
- HE- blame n guilt
  - Blame by others
  - Blame guilt self
- HE- Confusion
- HE- Control
- HE- CoT
  - CoT- frequency
  - CoT- severity
  - CoT- symptoms
- HE- Depression (new code)
- HE- External Help (new code)
- HE- Fear
- HE- hypos cluster
- HE- injury (new code)
- HE- night
- HE- struggle
- HE- Symptoms
- HE- Variation of BG- sympt exp
  - Variat- feelings
  - Variat- trust BG

### **SUPPORT NETWORK**

## Appendix 19: Extract of summary chart for themes used to develop the HEBC

Extract of summary chart for themes used to develop the Hypoglycaemic Episode Balancing Continuum (HEBC)		
Participant	Theme: Fear of hypoglycaemia	Theme: Perception of long-term complications
NS1_M07	"I always tend to err on the side of having a hypo and bulk up with sweets rather than taking less insulin and running high on my glucose." (p.10) – does not express any fearful attitude towards hypoglycaemic episodes	"I would rather have a hypo than go blind." (p.10) – he is very concerned about long-term complications
AS1_F09	"It's scary; hypos are scary in the fact that you feel vulnerable." (p.1)	"You do worry about the long-term effects but then the short-term effects will affect you right now. It's just always a balancing act." (p.13)
NS2_F02	"I've never collapsed or anything but I know that that can happen and that's a hugely worrying thing to live with." (p.1)	"You feel split between two things: you want to get your blood glucose, your HbA1C, you want to get that down [to avoid long-term complications], but you don't want to get it so down that it's giving you more hypos [...] it's just that balancing act you've got to do." (p.2)
NS3_F10	"If I was constantly just going below the five and feeling a hypo coming on, I couldn't live like that day in/day out, I wouldn't want to. That is just not a good life experience." (p.13)	"I do worry about the complications that you can have with diabetes [...] but it is always way into the future rather than something immediate [...] each time you get a bad report or some complication that seems to be starting, [...] you do worry about it." (p.12)
NS3_M17	"I get very impatient if I can't have something to eat [when experiencing a hypoglycaemic episode], because I'm scared stiff that I'm going to go too low and I'm out." (p.5)	"I don't think GPs and medics realise the worry that patients have of getting the [long-term] side effects, you know, like your retinopathy or neuropathy or anything like that, I really don't think they realise that." (p.2)
AS3_F29	"I wouldn't like to take another hypo. That was terrible." (p.2)	Did not express any concern about long-term complications.

# Appendix 20: University of Stirling/School of Nursing Midwifery and Health Research Ethics Committee Approval

JE/SG

04 March 2011

Theresa Ikegwuonu



**UNIVERSITY OF  
STIRLING**

SCHOOL OF  
NURSING, MIDWIFERY  
AND HEALTH

Email: [nursingmidwifery@stir.ac.uk](mailto:nursingmidwifery@stir.ac.uk)  
Web: [www.nm.stir.ac.uk](http://www.nm.stir.ac.uk)

Josie Evans  
Chair (Acting on behalf of Fiona Harris)  
School Research Ethics Committee

School of Nursing, Midwifery and Health  
University of Stirling  
Stirling FK9 4LA

Tel: +44 (0) 1786 466352  
Fax: +44 (0) 1786 466333  
Email: [josie.evans@stir.ac.uk](mailto:josie.evans@stir.ac.uk)

Dear Theresa

## **Participants' Experiences of Hypoglycaemia and Diabetes**

Thank you for your detailed responses to the points picked up at the recent Ethics Committee meeting.

You now have approval from the School Ethics Committee to continue with your study and to seek approval from IRAS.

We wish you well with your research.

Yours sincerely

Josie Evans  
Chair (Acting on behalf of Fiona Harris)  
School of Nursing, Midwifery and Health Research Ethics Committee

**Highland Campus:**  
Centre for Health Science  
Old Perth Road  
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## Appendix 21: NHS Research Ethics Committee Approval



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### East of Scotland Research Ethics Service

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#### Fife & Forth Valley Research Ethics Committee

Research Ethics Office  
TAHSC, Residency Block, Level 3  
Ninewells Hospital & Medical School  
George Pirie Way  
DUNDEE  
DD1 9SY

Mrs Theresa Ikegwuonu  
PhD Research Student  
NMAHP Research Unit  
Iris Murdoch Building  
University of Stirling  
STIRLING FK9 4LA

Date: 05 August 2011  
Your Ref:  
Our Ref: FB/11/AL/0330  
Enquiries to: Miss Fiona Bain  
Extension: Ninewells extension 32701  
Direct Line: 01382 632701  
Email: [fionabain@nhs.net](mailto:fionabain@nhs.net)

Dear Mrs Ikegwuonu

**Study title:** Diabetes and Pre-hospital emergency care: Participants' Experiences of Hypoglycaemia and Diabetes  
**REC reference:** 11/AL/0330  
**Protocol number:** N/A

Thank you for your letter of 14 July 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 02 August 2011. A list of the members who were present at the meeting is attached.

#### 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).

#### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*



Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

**Other conditions specified by the REC**

- Please submit a copy of the Caldicott Guardian approval letter.
- The GP letter should make reference to the fact that you are a PhD student. Please submit a revised version for our records
- The statistician member suggested that there was now no requirement to undertake a power calculation because you are not doing a comparison, but he recommends you undertake some confidence limits, as this would tell you how the limited sample size would affect the precision of your results.
- With regard to registration of the research on a Public database, you should try the following link: [www.clintrials.gov](http://www.clintrials.gov)

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.**

**Approved documents**

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

Document	Version	Date
Covering Letter		19 May 2011
Covering Letter	Email	20 July 2011
Evidence of insurance or indemnity		07 April 2011
GP/Consultant Information Sheets	Letter - 1.0	06 July 2011
Interview Schedules/Topic Guides	2	18 May 2011
Interview Schedules/Topic Guides	Telephone Version 1.0	18 May 2011
Investigator CV		19 May 2011
Letter from Sponsor		07 April 2011
Other: CV - Dr Edward Duncan		18 May 2011
Other: Blood Glucose Diary	1.0	18 May 2011
Other: Telephone protocol	1.1	06 July 2011
Participant Consent Form	1.1	06 July 2011
Participant Consent Form: For Participants	1.1	06 July 2011
Participant Consent Form: For Carers/Family Members	1.1	06 July 2011



Participant Information Sheet	1.8	06 July 2011
Protocol	1.1	07 July 2011
REC application	74567/215865/1/184	19 May 2011
Response to Request for Further Information		14 July 2011

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

<b>11/AL/0330</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely




**Mr Gavin Costa**  
Chair

Email: fionabain@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments  
"After ethical review – guidance for researchers"

Copy to: Carol Johnstone, University of Stirling  
Mr Andrew Wemyss, Scottish Ambulance Service



## Appendix 22: Scottish Ambulance Service R&D Approval



Scottish Ambulance Service



National Headquarters, Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB

Tel: 0131 314 0105

E-mail: [a.wemyss@nhs.net](mailto:a.wemyss@nhs.net)

PA E-mail: [imacleod2@nhs.net](mailto:imacleod2@nhs.net)

Chairman: DAVID GARBUTT  
Chief Executive: PAULINE HOWIE

From: Andrew Wemyss, Head of Strategy Implementation & Quality Improvement

16<sup>th</sup> December 2011

**PRIVATE & CONFIDENTIAL**

Theresa Ikegwuonu  
University of Stirling  
Iris Murdoch Building  
Stirling,  
FK9 4LA

**Re: R&D Approval for study "Participants' Experiences of Hypoglycaemia and Diabetes", Theresa Ikegwuonu**

Dear Theresa,

1. I understand that you have Ethics Committee approval, Caldicott Guardian Approval, and have been issued a Research Passport for your project.
2. In accordance with arrangements entered into between the NMAHP Research Unit, Stirling University and the Scottish Ambulance Service (hereafter 'SAS'), I confirm R&D approval and your entitlement to access the SAS's facilities. Access which may include contact with patients is approved to enable you to fulfil your responsibilities with your PhD research.
3. The tenure of this agreement is conditional on your continuing to hold your current PhD role within the NMAHP Research Unit, Stirling University. You are required as a condition of this agreement to advise the SAS of any changes in your status.
4. The confidentiality of information with regard to patients and their treatment must, at all times, be respected. Any other information identified as confidential to which you have access in the course of carrying out your duties must also be respected.
5. You are required to comply with the terms and conditions of all SAS Policies and Procedures.
6. You are requested to comply with SAS guidance on Research Governance issues.
7. The SAS does not accept responsibility in the event of theft, loss or damage to your personal property. You are therefore recommended to take out an insurance policy to cover your personal property.



A Special Health Board of the NHS in Scotland



8. The study is included in the University of Stirling indemnity arrangements with Aon Ltd. These policies are reviewed annually and the current period of insurance in 1 February 2011- 31 January 2012.
9. You have a duty to comply with the SAS Health and Safety Policy.
10. The SAS operates a no smoking policy and you will not be permitted to smoke in any of the SAS premises.
11. If you agree to the terms specified herewith, please sign the form of acceptance at the end of this letter and return the entire letter to Andrew Wemyss, SAS at the address at the top of this letter. Please retain a copy as this maybe requested during Audit.

Yours sincerely



Andrew Wemyss  
**Head of Strategy Implementation & Quality Improvement**

