

Hypoglycaemic emergencies attended by the
Scottish Ambulance Service: a multiple
methods investigation.

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ABSTRACT

Background

Changing service demands require United Kingdom ambulance services to redefine their role and response strategies, in order to reduce unnecessary Emergency Department attendances. Treat and Refer guidelines have been developed with this aim in mind. However, these guidelines have been developed in the absence of reliable evidence or guiding mid-range theory. This has resulted in inconsistencies in clinical practice. One condition frequently included in Treat and Refer guidelines is hypoglycaemia. Therefore this thesis aimed to investigate prehospital hypoglycaemic emergencies in order to develop an evidence base for future interventions and guideline development.

Research approach

A pragmatic and inductive applied health services research approach was employed. Multiple methods were used in a sequential explanatory design. Three linked studies were undertaken with the results of previous studies informing the development of the next.

Study one: A scoping review of prehospital treatment of hypoglycaemic events.

Aims: i) To describe the demographics of the patient population requiring ambulance service assistance for hypoglycaemic emergencies; ii) To determine the extent to which post-hypoglycaemic patients with diabetes, who are prescribed oral hypoglycaemic agents (OHA), experience repeat hypoglycaemic events (RHE) after being treated in the prehospital environment.

Methods: A scoping literature review was conducted using an overlapping retrieval strategy that included both published and unpublished literature.

Findings: Twenty-three papers and other relevant material were included. Hypoglycaemia related ambulance calls account for 1.3% to 5.2% of ambulance calls internationally. Transportation rates varied between studies (25%-73%). Repeat

hypoglycaemic emergencies are experienced by 2-7% of patients within 48 hours. There was insufficient detail to determine any relationship between repeat events and OHA. The low quality of included papers means that the results should be cautiously interpreted. The safety of leaving patients on OHA at home post hypoglycaemic emergency is unknown. Consequently patients taking OHAs who experience a hypoglycaemic emergency should be transported to hospital for observation. There was a lack of knowledge about the Scottish demographics of the patient population.

Study two: A retrospective cross-sectional observational study of diabetes related emergency calls.

Aims: To investigate i) the patient demographics and characteristics of hypoglycaemia related emergency calls; ii) the incidence of repeat hypoglycaemic events; and iii) the factors associated with emergency calls that result in individuals being left at home.

Methods: A retrospective observational cross-sectional study conducted using Medical Priority Dispatch System[®] call data from West of Scotland Ambulance Control Centre over a 12 month period. Data were extracted on age, gender, dispatch code, time of call, deprivation category, and immediate outcome (home or hospital). Multiple regression analysis was used to determine predictors of remaining at home.

Findings: 1319 calls for hypoglycaemia were received. Patient demographics were similar to the scoping review findings. Most patients remained at home (N = 916 vs N = 380; $p < .001$). RHE's were experience by 3.1% within 48 hours, and 10.6% within two weeks. The most significant independent predictor for patients remaining at home was a prior call to the ambulance service (OR of 2.4 [95%CI 1.5 to 3.7]). Patients' reasons for remaining at home and the causes of subsequent severe events are unknown. It is likely that non-clinical factors may explain some of this behaviour.

Study 3: Investigating patients' experiences of prehospital hypoglycaemic care.

Aim: To investigate the experiences of patients who are attended by ambulance clinicians for a hypoglycaemic emergency.

Methods: In-depth interviews with adults with diabetes who had recently experienced a hypoglycaemic emergency treated by ambulance clinicians. Participants were recruited from Greater Glasgow and Clyde and Lanarkshire Health Board areas. Data were analysed using Framework Analysis.

Findings: Twenty six patients were interviewed. Three key themes were developed. Firstly, an explanation for help seeking behaviour; patients' impaired awareness of hypoglycaemia as well as the inability of friends and relatives to cope can contribute to an ambulance call-out. Secondly, the perceptions of ambulance service care; patients felt the service provided was good; however ambulance clinicians' advice was inconsistent. Thirdly, the influences on uptake of follow-up care; patient preferences for follow-up care were influenced by previous experiences of home, hospital and primary care. Post-hoc analysis identified three psychological theories that may explain these findings and provide a useful basis for intervention development: Common Sense Model (Leventhal et al, 1998); Health Belief Model (Rosenstock, 1966); Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995; 1981).

Conclusion

Most people treated for severe hypoglycaemia by ambulance clinicians remain at home and do not follow-up their care. A few experience repeat hypoglycaemic emergencies. Key causal, but modifiable factors, contributing to this include:- impaired awareness of hypoglycaemia; inconsistent delivery of ambulance clinician referral advice; and patients' perceptions of the costs and benefits of follow-up care. Ambulance services cannot address all these factors in isolation. The studies in this thesis have generated an evidence base and identified plausible candidate theories. This will support the future development of novel interventions to improve severe hypoglycaemic emergency follow-up.

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DECLARATION

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

Signature: _____

Date: _____

PERSONAL STATEMENT

My career in the Scottish Ambulance Service (SAS) began 18 years ago with much of my clinical experience developed whilst based in Lanarkshire, one of the SAS's busiest Divisions. I spent my first year as an Ambulance Care Assistant before moving onto the Accident and Emergency (A&E) tier of the service. My first four years on A&E were undertaken as a relief ambulance technician¹, thereafter as a paramedic on A&E ambulances and then, more recently, on a Paramedic Response Unit (PRU).

The diverse population demographics of the West of Scotland provided a broad base on which to develop as an ambulance clinician. However the rural settings within Lanarkshire provided the greatest challenges in terms of their extended transportation times. Here, as a paramedic, application of the full range of assessment and treatment options were often necessary, particularly when dealing with the poly-trauma or critically ill medical patient.

My secondment on the PRU began at the end of 2000. It provided a very different experience to that on front line ambulances; the PRU involved responding solo, using a car rather than an ambulance. You relied entirely on your own experience and knowledge, a shift from the luxury of the 'shared' decision making and team work afforded whilst working on ambulances.

Frequent reflection on the broad spectrum of calls attended whilst working on the PRU often generated more questions than I had answers. Such experiences highlighted the

¹ The entry level qualification for A&E duties. You must successfully complete a one year probationary period before becoming qualified.

shortfalls of the ambulance service education and training at that time and served as a strong stimulus to improve both my breadth and depth of clinical knowledge. Consequently I undertook numerous certified courses on Advanced Life Support, Advanced Trauma Life Support and some undergraduate modules from a nursing degree course. My clinical studies culminated in achieving the Diploma in Immediate Medical Care of the Royal College of Surgeons, Edinburgh which is increasingly perceived as the 'Gold Standard' for immediate medical care (Le Clerc, 2005; Porter and Steggles, 2005).

Towards the end of my PRU secondment, a significant change occurred in the way paramedics in Scotland practiced. Compulsory transportation of all 999 patients to the Emergency Department (ED) ended. Paramedics were permitted to treat specific patient groups at home and refer on to other more appropriate services. This new practice was known as Treat and Refer (T&R) and was supported by clinical guidelines covering four conditions; asthma, hypoglycaemia, epistaxis, and seizure. T&R was introduced in response to Government policy aimed at reducing unnecessary hospital attendances and waiting times (Scottish Executive, 2005a). It permitted a greater degree of clinical autonomy for paramedics.

Non-transportation of patients however, heralded a significant change in clinical practice for ambulance clinicians. This was accompanied with a new type of responsibility, and risk, associated with the decision to leave somebody at home. Most ambulance clinicians in Scotland received no education or training on this new practice. However, a small number of paramedics were provided with an opportunity to attend 'pathfinder extended skills' courses which taught alternative T&R guidelines. These were developed and delivered by the British Association of Immediate Care

(BASICS) Education Scotland, in collaboration with the SAS. I was fortunate enough to attend one of these three day courses. The course, delivered by Doctors, provided bespoke education in the clinical assessment, treatment and risks associated with T&R and culminated in a written examination and objective structured clinical examinations (OSCE's). Regrettably, the follow-up mentorship to be organised at Divisional level did not transpire.

In October 2005, six months after completing the pathfinder training I, and a colleague (Keith Colver) secured a secondment to the Chief Scientists Offices' Nursing, Midwifery and Allied Health Professions Research Unit (NMHAP RU) at the University of Stirling. The purpose of the secondment was to develop the SAS's research capabilities and capacity. As a Unit that undertook applied health service research, training was undertaken through an apprenticeship approach and it wasn't long before we began our first research study.

During the pathfinder training course I had identified inconsistencies between the SAS and Pathfinder T&R guidelines. These differences had potential safety implications for patients, particularly in terms of repeat hypoglycaemic events. However, as a developing research paramedic, through the application of my newly acquired knowledge I felt that I could now investigate these differences through a review of the literature. It was this basic review that eventually led to the undertaking of the robust scoping review presented in chapter three and thereafter led on to the development of the further studies presented in this thesis.

CHAPTER 1: AN INTRODUCTION TO PREHOSPITAL EMERGENCY CARE

1.1 Overview

In order to understand the context within which ambulance services currently operate, it is useful to have a knowledge of how these services have developed. This chapter will provide a brief summary of the development of prehospital emergency care; from its military roots to the civilian run charity ambulances that eventually merged to form the National Health Service (NHS) ambulance services. The evolving role of prehospital emergency care will be described with a focus on the considerable changes it has undergone, predominantly over the past ten to fifteen years in the UK. Influencing factors, including government policy, will be discussed along with the service's response to these changes. The chapter concludes by discussing how best to develop an evidence base to support the future direction of prehospital emergency care.

1.2 A brief history of prehospital emergency care

The roots of prehospital emergency care can be traced back to the battlefields of Roman times during the reign of Emperor Augustus (63BC–14AD) (Efsthatis, 1999). Ancient transcripts describe doctors being summoned to the battlefield to tend to the injured and of *capsarii* (Doctors' assistants) applying bandages to wounded soldiers before removal to field hospitals. These *capsarii* were akin to the combat medic of modern times (Efsthatis, 1999). It has been proposed that the Romans, through their developments in military medicine, significantly enhanced the traditional Greek medicine on which their practices were based (Southern, 2007).

More recently, advances in prehospital military medicine were recorded during the Napoleonic war of 1792, where ambulance carts were introduced to remove injured soldiers from the battlefield; purportedly saving countless lives (Robertson, 2011; Ortiz, 1998). However, the developments in the French Military arrived over a century after the

first documented civilian ambulance in the UK. The use of ambulance carts was first charted in the mid 17th century (1665) by Samuel Pepys, a civil servant, Member of Parliament and Naval Officer of this era (Robertson, 2011; Liverpool Medical Institute, 2010). In Pepys' famous diary, recorded during the great plague, he wrote of the use of 'pest coaches'.

“and was forced to send people to take her, which he did; and they got one of the pest coaches and put her into it to carry her to a pest house.”

(Diary of Samuel Peypys, Volume 37, August 3rd 1665)

A century later (1775) Scotland witnessed its first formal ambulance service, consisting of a pair of sedan chairs procured by Doctors from the Royal Infirmary Edinburgh (Liverpool Medical Institution, n.d.). Little was documented thereafter, until the late 19th century when both the St Johns and St Andrews Ambulance Associations were formed (1877 and 1882 respectively) (St Andrews Ambulance Association, n.d.; Robertson, 2011). Both were created to provide volunteer ambulance services and first aid training to the public, a concept developed by the Royal Humane Society which had been established in 1774 (Robertson, 2011; Pearn, 1994). A building collapse at a Woolwich dockyard on March 13th 1887 which buried 160 men and subsequently an accident involving the Princess Alice steam boat on 3rd September 1887, which resulted in the loss of 600 lives, reinforced the need for civilian based first aid (Pearn, 1994). Education for the St Johns Ambulance Association was delivered through published lecture notes written by Dr James Cantle (Pearn, 1994). However, the prolific oncologist and surgeon, Sir George T Beatson authored one of the earliest ambulance text books (Beatson, 1891). This book became core material for first aid courses delivered by the St Andrews Ambulance Association (Beatson, 1891).

Over the next six decades there were a number of developments in ambulance care. The first was after the Great War, when motorised military ambulances (used to recover and move injured soldiers) were shipped over from Europe and redistributed across the UK for civilian use (The Home Ambulance Service, 1920; Liverpool Medical Institution, n.d.). The second, in 1925, made first aid training for ambulance drivers mandatory, further developing prehospital care provision (Development of the Home Ambulance Service, 1925). And the third, in 1937, was the introduction of a standardised emergency telephone number, giving members of the public access to the emergency services (Ambulance, Police and Fire) (British Telecom, 2012). This number remains the same today: '999'.

1.3 The creation of the NHS Ambulance Service

In 1946 the National Health Services Act for England and Wales was published (National Health Service Act, 1946) and set out a duty for the Health Minister to create a comprehensive Health Service for England and Wales. Similarly in Scotland, during 1947, the Secretary of State for Scotland created a Department of Health for Scotland, subsequently the National Health Service Act for Scotland (Department of Health for Scotland, 1947) was enacted. This was amended in 1949 by the National Health Services (Amendment) Act to include all three countries (Her Majesty's Stationery Office, 1949). Ambulance Services in Scotland were placed under the control of the regional Health Boards (Department of Health for Scotland, 1947) and in England they remained with local authorities (National Health Service Act, 1946). Section 27(I) of the National Health Service Act (1946) required local authorities to provide ambulance services (Health Service Act, 1946). The Act stated:

"It shall be the duty of every local authority to make provision for securing that ambulances and other means of transport are available, where necessary, for

the conveyance of persons suffering from illness or mental defectiveness or expectant or nursing mothers from places in their area to places in or outside their area”

(Health Service Act, 1946, pg. 24)

The principal role of ambulance services clearly was to provide only transport; there was no requirement for any form of clinical care. However, this was to change with the publication of the Millar report in 1964 (Ministry of Health, Scottish Home and Health Department, 1964).

1.4 Education, Guidelines and Professional registration

The Millar report revolutionised UK ambulance care with the recommendation that ambulance drivers should be required to treat as well as transport patients (Ministry of Health, Scottish Home and Health Department, 1966). This report can be considered as the catalyst for the development of modern day civilian prehospital emergency care within the UK. The report made recommendations on first aid training and equipment provision on ambulances (Ministry of Health, Scottish Home and Health Department, 1966). Further advances in UK ambulance education followed during the late 1970's and early 1980's where intubation, cannulation and defibrillation were introduced in small pilots across England (Lucus, 1979; Mackintosh *et al*, 1978). Despite the limited evidence base to support this movement, extended training programmes expanded throughout the UK (Wright, 1985). In 1994 the first Institute of Health Care Development (IHCD) Paramedic Training Manual was published (IHCD, 1994) which standardised paramedic training nationally. IHCD were the awarding body for the UK paramedic qualification at that time.

However to ensure safe, standardised and effective care, paramedics were required to practise within the confines of clinical guidelines. Until recently, ambulance services

developed their own clinical guidelines or protocols. But local guidelines resulted in inconsistencies in care provision between NHS Ambulance Trusts; a problem exposed by the BBC Panorama programme during January 2000 (British Broadcasting Corporation, 2000). These inconsistencies have since been minimised through the introduction of nationally applicable clinical practice guidelines developed by the Joint Royal College Ambulance Liaison Committee (JRCALC) (JRCALC, 2009a). These guidelines were first published in 2000. There have since been several iterations including the most recently published guidance in 2013 (JRCALC, 2013). JRCALC guidelines are developed in accordance with the latest evidence along with expert consensus and are updated regularly. They evolve along with advances in prehospital emergency care, evidence and changes in health care provision.

Since the introduction of the JRCALC Guidelines and standardisation of education, the paramedic role has progressed to becoming a state registered profession. Initially registration was with the Council of Professions Supplementary to Medicine (CPSM) in 2001, and then the Health Professions Council in 2002 (The Health Professions Order 2001) which subsequently became the Health Care Professions Council 2012 (The Health Professions Order, 2009). The professionalisation transferred the responsibility for professional standards from ambulance services to the professional body (Whitmore and Rolland, 2006) and was supported by legislation (The Health Professions Order, 2009, 2001). Since 2001, to practice and use the title 'paramedic' in the UK, an individual must be registered with the Health Professions Council (The Health Professions Order, 2001). UK paramedics are now considered autonomous practitioners, having the authority and freedom to make decisions based on their own professional knowledge base (Health Care Professions Council, 2012). In 2013 paramedics were officially recognised by the Scottish Government as an 'Allied Health Professional' (Scottish Government, 2013).

1.5 Changing demands

While the ambulance services and paramedic profession in the UK were evolving, the demographics of the population were changing. People were living longer and more people were being diagnosed with long-term conditions (Scottish Executive, 2005a; Scottish Executive, 2005b; Department of Health, 2005a; Scottish Executive, 2003a). Consequently greater numbers than ever were in need of health care. These changes placed considerable pressures on those who provide unscheduled and emergency care such as EDs and Ambulance Services (George, 2006; Department of Health, 2005a; Downing, 2004; Audit Commission, 2001; Department of Health, 2001). Concerns that such demands on the NHS were unsustainable had been reported since the early 2000's (Scottish Executive, 2003a; Welsh Government, 2003; Department of Health, 2001). Since then annual increases of around 1% in those attending EDs were recorded across the UK (Audit Scotland, 2010; Audit Commission, 2001). Similarly, over the past ten years the Scottish Ambulance Service experienced a 19% rise overall in the number of calls it responded to (SAS, 2009a; National Audit Office, 1999). This was further compounded by the change in General Medical Services (GMS) contracts that occurred during 2004 allowing General Practitioners to 'opt-out' of providing out-of-hours care (GMS 2, 2004). This meant that services were not provided by GP's between the hours of 18:30 and 09:00 hours, nor at weekends and required alternatives to be developed. These changes paved the way for a nurse led 24 hour telephone triage and advice service called NHS24 (Heaney *et al*, 2005). However this new service experienced a number of challenges with demand considerably higher than anticipated (Heaney *et al*, 2005).

As the demographic 'crisis' was unfolding, the Scottish Ambulance Service was setting out on their 'Beyond 2000' project (SAS, 2002). This focussed on the upgrading of the ambulance control rooms and the implementation of a new telephone triage system; the

USA developed Medical Priority Dispatch System (MPDS[®]). This was introduced to ensure people with the greatest need received care first. This upgrade was completed during 2003 (SAS Annual Report, 2004). In that same year the 'Partnership for Care': Scotland's Health White Paper (Scottish Executive, 2003a) was published which emphasised the need for NHS redesign and integration. The White Paper pushed for greater partnership at both local and national level, and emphasised treating patients at the "*right time and in the right place*" (Scottish Executive, 2003a, pg. 7). Simultaneously in England and Wales during 2003, a national review by the Commission for Health Improvement called for greater integration of ambulance services within the broader NHS healthcare systems (Ball, 2005). Soon afterwards Government policy mandated changes to reduce unnecessary ED attendances and admissions (Scottish Executive, 2005a; Scottish Executive, 2005b; Department of Health, 2005a).

Treating patients "*at the right time and in the right place*" (Scottish Executive, 2003a, pg. 7) had significant implications for the ambulance service. In Scotland the focus between 2000 and 2004 had been on delivering emergency care, getting to the patient as quickly as possible and transporting them expeditiously to the nearest ED. Treating patients at the right time and in the right place required a significant change in practice. In 2005 the Scottish Executive (2005b) provided a vision for how the reduction in unnecessary attendances could be achieved. The report emphasised the delivery of care in the community, redefining services and the up-skilling of health care professionals, including ambulance clinicians, to facilitate these changes. This message was reiterated within the Department of Health Document; Taking Health Care to the Patient: Transforming NHS Ambulance Services (Department of Health, 2005a).

UK ambulance services were required to redefine their role and reconfigure their traditional A&E response to reduce unnecessary ED attendances (Mason *et al*, 2006;

Ball, 2005; Department of Health, 2005a; Scottish Executive, 2005b; Snooks *et al*, 2004a). Whilst paramedic education and practice remained rooted in the provision of emergency care, the changing population demographics and demands meant changes to their clinical practices were inevitable. Such changes required the development of new roles for ambulance clinicians.

1.6 Changing role

Within the broader context of the development of prehospital care, world-wide there have been two predominant modes of Emergency Medical Service (EMS) care delivery evolving since the early 1970's (Al-Shaqsi, 2010). These models were known as the Anglo-American and Franco-German EMS models (Dick, 2003). The traditional mode of UK ambulance service fell within the Anglo-American model. This comprised of an immediate response to an emergency call, followed by treatment, assessment, and then transportation of the patient to the nearest ED.

The Anglo-American model of delivery was based on the 'scoop and run' philosophy whereby non-physicians such as Paramedics and Emergency Medical Technicians provided care and support before and during transportation to the nearest ED. Here the patient received advanced care within the ED from the physicians. Conversely the Franco-German model was based on the 'stay and stabilise' philosophy whereby Emergency Medical Services (EMS) transported the physician to the patient (Al-Shaqsi, 2010). Here the physician provided advanced clinical intervention at the location of the incident but could also make the often complex decisions around non-transportation. Few patients therefore were transported to the ED with most being taken directly to the most appropriate hospital unit.

Unlike the Franco-German model, within the UK based Anglo-American model, patients

would traditionally only be left at home if they refused transportation to the ED. However with the changes in government policy, there was now a need to develop ways in which the service could manage more patients at home or refer onwards to more appropriate care, similar to those services operating within the Franco-German systems.

A range of specialist paramedic roles were introduced such as the paramedic practitioner and critical care paramedic (Ball, 2005; Mason *et al*, 2003). Although the evidence demonstrating their impact continued to grow, a recent paper has suggested that even now, more research is required to establish their true effectiveness in terms of cost, care and safety (Hill *et al*, 2013). However, the development of a few specialist roles were unlikely to provide a solution to the substantial challenges faced. More was needed.

Subsequently in Scotland the SAS pioneered a new concept for use by all ambulance clinicians; 'Treat and Refer' (T&R) guidelines (Scottish Ambulance Service, 2005). It was anticipated that these T&R guidelines would reduce the number of unnecessary hospital attendances and therefore reduce hospital admissions. This, to an extent, represented the integration of the Anglo-American and Franco-German models of care delivery to provide greater flexibility in the provision of EMS care.

1.7 Treat and Refer

The introduction of T&R enabled ambulance clinicians to attend, treat, discharge or refer patients with a defined list of conditions as appropriate (SCOTTISH AMBULANCE SERVICE, 2005). The initial conditions included were hypoglycaemia, seizure, epistaxis and asthma. Consensus based guidelines were rolled out nationally for use by ambulance clinicians in Scotland. Initially, there was no training or education provided alongside these guidelines. Although a small cohort of paramedics attended the

BASICS Scotland Pathfinder Course: a three day course, delivered by Doctors, which focussed on the assessment, management and risk management for the included T&R conditions (Johnston, 2005; BASICS Education Scotland, 2004). Despite SAS and Pathfinder T&R sharing the same concept, the guidelines differed considerably in both format and content (see appendices 1 and 2).

Research established that most ambulance clinicians supported the concept of T&R but were dissatisfied with the lack of training, education and support provided by the service during their implementation (Dalglish, Colver and Fitzpatrick, 2008). Similar challenges were reported in other published studies on T&R (Snooks *et al*, 2005; Snooks *et al*, 2004b). The true effectiveness of these guidelines remained unknown, however data from these studies demonstrated the complexity of T&R and that their introduction did not necessarily guarantee patients remaining at home.

The study by Dalglish, Colver and Fitzpatrick (2008) exposed some of the challenges faced by ambulance clinicians during application of these guidelines. However, there was little supporting evidence for the four included conditions. Ambulance clinicians reported feeling most comfortable and confident in applying the hypoglycaemia guideline (Dalglish, Colver and Fitzpatrick, 2008). This particular guideline was reportedly used more often than any of the others. It was hypothesised that this may have been due to the objective electronic measurement device used to measure blood glucose and the usual rapid recovery of such patients.

By 2005/06 both the SAS T&R Guideline (SCOTTISH AMBULANCE SERVICE, 2005) and Pathfinder T&R guideline (BASICS Education Scotland, 2004) were in use by the SAS and the latest JRCALC Guidance (JRCALC, 2006) also made some recommendations on when to advise transportation. Examples can be found in

Appendix 1 (SAS T&R), Appendix 2 (Pathfinder T&R guidelines) and Appendix 3 (Welsh T&R Guideline). But inconsistencies were identified in post-hypoglycaemic care and JRCALC (2006) included a recommendation for transportation for patients with diabetes treated with oral hypoglycaemic agents regardless of post treatment response. This recommendation was not included in the existing SAS T&R guidance (SCOTTISH AMBULANCE SERVICE, 2005). Anecdotally, these differences led to confusion. Where SAS T&R guidance was used to assist in non-transportation decisions, patients treated with certain oral diabetes medications were being left at home and exposed to the possibility of subsequent events. The concerns about the quality and safety of post-hypoglycaemic care stimulated the series of research studies that form this thesis.

1.8 Developing the evidence base for the paramedic profession

In the past, prehospital and ambulance care research has been led and undertaken by physicians, with a tradition of higher level education. When compared to the in-hospital domain, proportionately fewer prehospital studies have been undertaken (and therefore published) (Peconi, Snooks and Edwards, 2008; Callaham, 1997). In 2005 a report undertaken by the World Health Organisation on prehospital trauma care stated:

“The lack of empirical data on the benefit of many prehospital care interventions is a serious problem...there is insufficient evidence to prove or disprove the benefit of many interventions in widespread use.”

(Sasser *et al*, 2005, pg. vi)

The historical nature of ambulance service education has undoubtedly contributed to the lack of research culture within ambulance services today. Indeed, up until recently, education for paramedics had been provided only at undergraduate diploma level (Gowens and Gray, 2011). But this changed after the publication of the Department of Health report ‘Transforming NHS Ambulance Services’ in 2005 (DOH, 2005a). Since

then the profession has progressed towards degree level education permitting the learning and development of basic research knowledge and skills (Cooper, 2005).

Along with the development of paramedic education, over the past seven years, UK funding has been allocated for emergency and unscheduled care research (Peconi, Snooks and Edwards, 2008). The dearth of evidence in this area was recognised by the Department of Health in 2005 and later they commissioned a national study to prioritise prehospital research (Snooks *et al*, 2009; DOH, 2005a). The commissioned work sought to identify current gaps in prehospital knowledge and to develop research priorities. The recommendations focused on the urgent need to develop “*alternative methods of patient management to reduce transports to ED*”, and “*for research evidence to underpin the delivery of clinical care in the prehospital setting*” (Snooks *et al*, 2009, pg. 549). T&R was identified as the third highest research priority by participants of this national study; a noteworthy finding.

Although ambulance clinician-led research is in its infancy, the studies presented in this thesis, within the context of hypoglycaemic emergencies, sought to address some of the research needs identified by Snooks *et al* (2009). But the limited available evidence base has made this process challenging. The widely accepted starting point for new research involves an exploration of the literature, but there were little secondary research sources on which to draw. Broad search strategies often concluded with few studies being recovered, particularly when search terms such as ‘ambulance’ or ‘paramedic’ were included. The limited nature of existing published knowledge, evident from the scoping review (presented in chapter 3), inevitably influenced the research approach in this thesis and resulted in the development and use of primary data, in a sequential manner, in order to provide answers to the research questions developed.

1.9 Approach to research in ambulance care

As a consequence of these past challenges, and perhaps a lack of appreciation of the benefits of research, ambulance services have historically introduced change without rigorous evaluation or by translating evidence from studies originally developed for informing practices in the in-hospital domain. But there were, and continue to be, consequences to this approach. This, arguably naïve, translation of evidence from other environments has led to a distinct lack of knowledge about what works in prehospital emergency care, and which theoretical approaches are most appropriate in informing this area of clinical practice.

But what is meant by ‘theory’ and ‘approach’? Theory can be viewed on two levels i) the philosophical underpinning of the research and as in ii) the ‘theoretical framework’ that may apply. And the approach could be ‘inductive’ or ‘deductive’. This next section will now discuss these in turn and consider the use of theory and type of approach within the context of its specific application to the programme of research presented in this thesis.

1.9.1 Ontological and epistemological foundations of research

There is considerable variation in the way the term ‘theory’ is applied, with numerous classifications or definitions (Parahoo, 2014; Bryman, 2004; McKenna, 1997). However, within the philosophical context of enquiry, there is described a relationship between the nature of knowledge (ontology), the approach to knowledge/what it means to know (epistemology), the theoretical perspective, and the research methods chosen (Gray, 2009; Denzin and Lincoln, 2005).

There are two key ontological perspectives on phenomena: the realist and the idealist. The realist views the world as existing in an external reality and as being empirically accessible (Giacomini, 2013; Snape and Spencer, 2008). This simply means that the

world is understood to exist independent of people's beliefs or understandings of it and therefore is pure and unbiased (Giacomini, 2013; Snape and Spencer, 2008). The idealist believes that we each have our independent realities and beliefs. This places focus on subjectivity, individuals' perceptions and a belief that reality only exists in the minds of the individual or through socially constructed meanings (Giacomini, 2013; Snape and Spencer, 2008).

These ontological perspectives underpin an individual's epistemological perspective. Epistemology is concerned with "*how phenomena come to be known*" (Giacomini, 2013, pg. 131). Indeed several epistemological perspectives may influence an approach and it is from past efforts to understand what it means 'to know' (epistemology) that a range of theoretical philosophical perspectives have evolved and developed.

These perspectives support researchers to define and provide a foundation or framework for their projects. The three most influential theoretical epistemological perspectives (or paradigms) to date are positivism, post-positivism and interpretivism (Gray, 2009). Although the positivist and post-positivist paradigms both derive from realist ontology and are aligned with the quantitative methods of data collection and analysis (Denzin and Lincoln, 2005), they do not take the same perspective on reality. Positivists argue that there is an absolute reality which is measurable and understandable, whereas the post-positivists contend that absolute reality can never be fully understood (Denzin and Lincoln, 2005). The post-positivist position became known as critical realism, which evolved from the belief that it is possible get very close to truth, an approximation (Parahoo, 2014). Critical realists argue that there is an independent reality but also, and critically, that observations are fallible, and that consequently we cannot know reality with absolute certainty (Parahoo, 2014).

Antipositivistic perspectives disagree with both of these paradigms, viewing them as restrictive (Gray, 2009). Antipositivistic theorists, influenced by the idealist ontological perspective, argue that multiple constructed realities exist as people experience the world in different ways (Gray, 2009). This perspective is associated with interpretivist research approaches which are more closely aligned with qualitative methods of enquiry (Denzin and Lincoln, 2005).

Critical realism is arguably most closely aligned to the pragmatic research approach, which selects the most appropriate method to adequately answer the research question (Snape and Spencer, 2008). Pragmatism originated in America and was introduced as a philosophy by Charles Sanders Peirce and William James over a century ago (Dansy and Sosa, 1994). Within the research context, pragmatism proposes that findings should be understood in relation to the practical consequences of their application. (Haack, 2003, pg. 774). Pragmatist researchers focus on the research questions and which methods are best used to answer these. They also permit the use of multiple perspectives to address research problems (Rossman and Wilson, 1985). The relationships of the aforementioned ontological, epistemological and methodological approaches to theory are outlined in Table 1.

Table 1: Relationship between ontological, epistemological and methodological approaches to theory.

Ontology	Realist	↔	Idealist
Epistemological perspectives	Objectivism/Positivism	Pragmatism/ Critical Realist	Constructivism/ Interpretivism
Methodological	Quantitative	Mixed/Multiple methods	Qualitative

The practical nature of the paramedic profession frequently requires the clinician to use what is necessary to achieve the desired outcome. This requires a flexible and pragmatic approach in the application of both knowledge and theory in practice. My

experiences and beliefs have therefore naturally, but not intentionally, developed within the pragmatist theoretical paradigm. The applied nature of this research, along with this natural paradigmatic positioning, has led this thesis to be positioned within the context of the pragmatist paradigm.

1.9.2 Theoretical frameworks

The preceding approaches to theory are regarded as a philosophical foundation, position, worldview or as a paradigm of enquiry (Creswell and Clark, 2011). However, theories may also be considered within the context of a particular health care discipline. Such theories are often described in a hierarchical manner: Grand theory, which represents the highest level, and middle-range theory which represents a lower, more applied approach (Parahoo, 2014).

High level, grand theories, are abstract and often based on a theorist's personal synthesis of their ideas. These are sometimes referred to as "*arm chair*" philosophies (Parahoo, 2014, pg. 137). Their abstract nature, broad conceptualisation and use of multiple concepts help explain phenomena, may result in them being too abstract from the realities of patient experience and clinical practice (Parahoo, 2014; Bryman, 2004). They are criticised for lacking utility in informing how best to gather any empirical evidence (Bryman, 2004). Consequently, in both social research and applied health service research, middle-range theories are more likely to be the focus of enquiry (Parahoo, 2014; Bryman, 2004). They are more grounded and relevant to practice than the abstract, high level 'arm chair' type philosophical theories (Bryman, 2004; Merton, 1967) as they use fewer concepts thus permitting more explicit measurement between variables at the empirical level (Parahoo, 2014). Bryman describes middle-range theories as:

“falling somewhere between the grand-theories and empirical findings. They represent attempts to understand and explain a limited aspect of social life”.

Bryman (2004, pg. 6)

Middle-range theories are frequently used in health services research to help explain or predict patient behaviour or outcome (Topping, 2010). They are constructed to help describe or predict specific phenomenon at a more practical, real world level rather than developing the more abstract grand theories that are more philosophically or fundamentally grounded (Parahoo, 2014; Topping, 2010; The Improved Clinical Effectiveness through Behavioural Research Group, 2006; Merton, 1967). Theories commonly applied and tested in health service research are constructed within the social or psychological sciences (see Table 2).

These middle-range theories have been described as bridging the gap between grand theory and empirical findings (Merton, 1967). Such theories, once developed, are tested deductively and then refined in order to help describe or explain a specific phenomenon (Bryman, 2004).

Table 2: Common middle-range theories used in health research

<i>Social theories</i>	<i>Psychological theories</i>
The Sick Role (Segall, 1976)	Health Belief Model (Rosenstock, 1966)
Model/Stages of Change (Prochaska & Velicer, 1997)	Theory of Planned Behaviour (Ajzen, 1991)
Social Cognitive Theory (Bandura, 1986)	Health Locus of Control (Wallston <i>et al</i> , 1978)
	Self-Affirmation Theory (Steele, 1988)

1.9.3 Application of theory in research

As has been described, theories may be applied in research in different ways. They may provide a high level, more abstract framework within which a study is undertaken, or be less abstract, middle-range and developed and subsequently tested to help explain or predict behaviours (Parahoo, 2014). However, despite their apparent popularity, there are conflicting views with regards to the benefits of theory. There are some who argue that, without theory, research is simply a collection of data, statistics and observations permitting little coherence or understanding (Giacomini, 2013; Moody, 1990), while others acknowledge that research may be theory-linked or theory-isolated (Chinn and Kramer, 1995). Both approaches can generate valuable new knowledge but theory-linked research arguably holds a greater authority in the development or generation of new knowledge as it permits the findings from separate studies to be compared within the context of the relevant theory (Chinn and Kramer, 1995). Others suggest that the use of theory (theoretical framework) should not be a prerequisite and that researchers may forgo any allegiance to any particular theoretical approach (Avis, 2003). However, the theory isolated view has been challenged by those who believe that all research undertaken originates within a theoretical framework whether the researcher recognises this or not (McKenna, 1997). There are then potential advantages and disadvantages to the use of theory in research (see Table 3).

Reflecting on these advantages and disadvantages, the use or application of theory is not a straightforward process. Any individual embarking on a research project must carefully consider its use and/or application in any study and acknowledge the importance of identifying theory rather than suggesting it is absent. In this thesis philosophical theory has been useful in providing a foundation, an argument and therefore guidance on the overall approach. The sequence of studies presented in this thesis being positioned within the context of the pragmatist paradigm. This has provided

a foundation for the overall approach. However, the use of middle-range theory to provide a framework for paramedic research may be problematic. Although there are many advantages of using an appropriate theory, as can be seen in Table 3, one of the more notable disadvantages would be choosing an unsuitable theory and the potential detrimental effects this may have on the development of any proposed intervention (McKenna, 1997; Davidoff *et al*, 2015). Any mid-range theory selected to help inform this thesis would therefore be required to have a firm rationale. But the choice of theory would be difficult where existing knowledge on prehospital care for hypoglycaemic events is so limited. While it is likely that any theory isolated approach will be underpinned by theory at some level (McKenna, 1997) the supporting theory is the more abstract higher level of epistemological theory and not at the level of mid-range theory.

Table 3: Advantages and disadvantages of theory in research

Advantages	Disadvantages
Provides a framework for describing, explaining or predicting events (McKenna, 1997; Giacomini, 2013)	Unsuitable choice of theory may have detrimental effects on patient care (McKenna, 1997)
Can be “ <i>borrowed</i> ” successfully from other disciplines (McKenna, 1997, pg. 131)	Dangers in a theory becoming an ideology whereby other, potentially useful theories are ignored entirely (McKenna, 1997).
Permits a positioning of the researcher so others may better understand philosophical foundations on which any argument is developed. (Giacomini, 2013)	Theories may be difficult for practitioners to understand, perhaps viewed as the ‘ivory tower’ (McKenna, 1997).
Can support development of clinical practice whereby theory can help make sense of practice (Parahoo, 2014)	Significant number of Grand theories (in nursing) may make it difficult to choose correct one.
Hypothesis drawn from established theory may be empirically tested (Parahoo, 2014)	Pragmatist argues that theory is of little value unless it is of use in practice (McKenna, 1997).
Can “ <i>suggest legitimate and illegitimate use for findings</i> ” (Giacomini, 2013, pg. 146)	Theory may be rejected or modified and so are only interpretations, not factual (Parahoo, 2014)

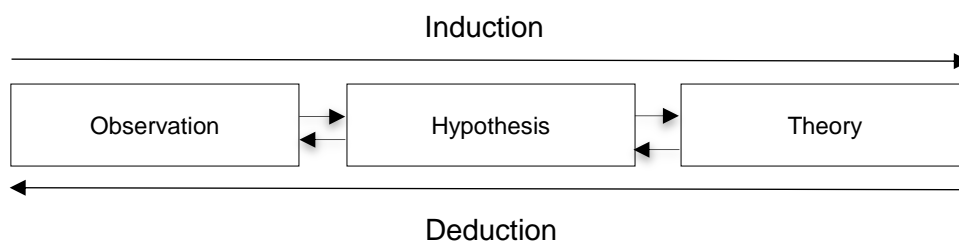
Whilst the epistemological approach of this thesis has been firmly situated within the pragmatist paradigm, there remains a dearth of prehospital evidence on which to base any mid-range theoretical approach or assumption. This raises the question - what non-

theoretical routes of enquiry, if any, exist to support this approach? To determine this however, this section will continue by exploring what is meant by the terms ‘inductive’ and ‘deductive’.

1.9.4 Deductive and Inductive approach

The deductive approach is used upfront (a priori) where hypotheses are set, or theory has already been developed and is then tested and subsequently verified or rejected (Parahoo, 2014; Snape and Spencer, 2008; McKenna, 1997). The inductive approach is used in the absence of existing theory, using observation and description to generate theory and explanations (Topping, 2010; Creswell, 2008). According to Glaser and Strauss (1967) the inductive approach, where theory is generated, is undertaken prior to the process of deduction, where theory is tested. This view describes one approach as complementing the other, not as two polarised and separate entities (see Figure 1).

Figure 1: Inductive and Deductive approach (Topping, 2010)



Within health services research there is a rich tradition of studies conducted using both approaches, with the approach being used in each study determined by the particular research problem identified (Topping, 2010).

1.9.5 Strengths and limitations of inductive and deductive approaches

The inductive approach is truly exploratory, the strengths of which lie within its ability to develop theories where there is little (or no) evidence to support their relevance to research enquiry (Mitchell and Cody, 1993). The inductive approach is undertaken in the absence of theory; a “*research-then-theory*” approach (McKenna, 1997, pg.199).

Inductive research is undertaken for “*the purpose of discovery and exploration of the phenomena as they occur*” (McKenna, 1997, pg. 199). This permits the researcher to approach the research setting with an open mind allowing for original themes to develop (Chinn and Kramer, 1995).

There are, however, risks associated with an inductive approach to research. The researcher must consider the influence of their own perspectives during the development and analysis process (Parahoo, 2014). This may be managed, and many of the risks mitigated, through a process known as reflexivity. The most commonly used and understood form of reflexivity is methodological reflexivity although there are said to be 6 overlapping forms and fourteen subcategories (Lynch, 2000). Reflexivity should be central to all inductive studies. It permits the researcher to position themselves by considering their own prejudices and assumptions, acknowledging these and seeking neutrality (Potvin, Bisset and Walz, 2013; Snape and Spencer, 2008).

Conversely, the deductive approach begins with existing theories and is undertaken explicitly to test ideas or hypotheses (Parahoo, 2014). The relationship between constructs (variables) is tested to determine whether a null hypothesis can be rejected (Kerlinger and Lee, 2000). The theory may be an argument, a discussion or a rationale, but whichever, will seek to provide an explanation of the phenomena under investigation (Creswell, 2008). From the positivist perspective, the use of sensory knowledge within this approach is widely accepted as providing a more ‘true’, objective and more difficult to challenge result (Creswell, 2008; Williams, 2007). It is therefore perceived as the foundation of the empirical or a priori knowledge approach (Snape and Spencer, 2008).

The deductive approach has a number of limitations. It advocates the application or testing of known or existing theory and as such introduces an early degree of control and

focus for the research design and interpretation (Topping, 2010). In doing so this approach may miss more relevant alternative theories. Additionally, no test can deduce with absolute certainty that any conclusion drawn is true (Giacomini, 2013). The uncertainty arises from the difficulties this particular approach faces in controlling for other factors that may have influenced results. And, when controls are introduced to minimise the effect of extraneous variables during testing, the artificial environment created for such testing may subsequently limit the usefulness of such findings in the 'real world'.

1.9.5.1 Examples from the diabetes literature

There are many examples of both inductive and deductive approaches, with and without theory, within the diabetes/hypoglycaemic research literature. Their use can be found in older and in more contemporary studies. Inductive approaches have been undertaken to explore the patient's experience of hypoglycaemia (Brod *et al*, 2013; Wu, Juang and Yeh, 2011; Rajaram, 1997). These studies appear to subscribe to the viewpoint of Avis (2003) in that none acknowledge the use of any particular theoretical approach or framework but focus on the application of qualitative methods to develop key themes aimed at informing practices.

Alternatively, within the context of theory-linked research, Rogers, De Zoysa and Amiel (2012) explored patient's perceptions and experiences of their condition. Once key themes were identified they then drew on a known psychological theory (Leventhal's Common Sense Model [Leventhal *et al*, 1998]) post hoc to help explain their findings.

Deductive approaches too have been used in order to test established theory within a diabetes specific context. For example, the study by Williams *et al* (2004) took a generic psychological model (Self-Determination Theory) and tested this within a specific

population with diabetes. They found that their results could be explained by the theory, thus confirming their hypothesis. This study explored the theory's ability to predict general control. At this stage in the research process it is unknown if general diabetes control is of concern or whether there are other underlying problems associated with emergency call-outs.

So whilst these mid-range theories have been successfully applied to help explain patients' actions or behaviours, similarly informative studies have been conducted without the explicit use of either grand or middle-range theoretical approaches. Such inductive approaches are most appropriately undertaken when there is little knowledge on which to base the selection of an appropriate theory a priori.

Understanding the use and limitations of approach and theory in research is essential when selecting a study design. Additionally, one must not naively presume that a particular research method aligns neatly with a particular research approach. Although often the inductive and deductive approach are described as being inextricably linked with either qualitative or quantitative methods respectively (Parahoo, 2014), such pigeonholing can be misleading. Snape and Spencer, describing the theoretical approach, state that the:

“distinction is not clear cut: some qualitative approaches have sought to emulate natural science models, and not all quantitative studies are based on hypothesis testing but can produce purely descriptive and inductive statistics”.

(Snape and Spencer, 2008, pg. 14)

Similarly, in this thesis, the retrospective cross-sectional observational study presented in chapter 5 could be considered more descriptive and therefore as inductive in approach, despite being quantitative.

1.10 The use of theory in this thesis

“to increase and enhance our understanding of phenomena, we must build upon our present knowledge. One cannot, however ‘build upon’ if one does not know what already exists.”

(Parahoo, 2014, pg. 142)

This statement exemplifies the current position of knowledge on prehospital hypoglycaemic care. Very little is known about the population who experience severe hypoglycaemic events requiring prehospital care from the ambulance service. The use of an a priori mid-level theoretical framework is not mandatory (Avis, 2003; Chinn and Kramer, 1995) and meaningful results can be produced in its absence. In the absence of existing knowledge, a priori selection of a psychological or sociological theory to test in a deductive manner would have no empirical basis and little justification. Instead it would rely upon personal preferences or professional biases or heuristics. As a paramedic researcher, it is arguable that this thesis already contains a number of professional and experiential theoretical biases. Through the process of reflexivity these will however be identified and discussed within the thesis.

There has been almost no previous research on patients’ experiences of prehospital emergency care (Togher, Davy and Siriwardena, 2012), and none regarding hypoglycaemic care. The approach adopted in this thesis is therefore induction. In keeping with Rogers, De Zoysa and Amiel (2012), the findings generated within the thesis will be discussed in relation to known psychological and social theories that data

indicates may be of relevance. Whilst it is acknowledged that an alternative, deductive use of theory could have been applied to the study questions, the rationale for selection of an appropriate theory would have been sparse. Consequently a priori selection of theory led methods have been discounted and are outwith the scope of this thesis. As a result this thesis will focus on a series of inductive studies with an overarching aim of exploration. The rationale for this sequential approach using multiple methods will be described later in chapter 5 (see section 5.2).

1.11 Methods

No approach can be exclusively inductive in applied health service research, as there are inevitably pre-determined aims (Pope, 2000). In this case these aims were informed by the clinical experiences and practice of the author. The direction of research was informed by the evidence developed from the preceding study/studies. This permitted a flexible and responsive approach whereby multiple methods were used to investigate prehospital hypoglycaemic emergency care. This sequential, explanatory design was described by Creswell *et al* (2003). The design involved the use of sequential triangulation where “*projects are conducted one after the other to inform enquiry, with the first project informing the nature of the second project*” (Creswell *et al*, 2003, pg. 223-227). This approach is clearly suitable to the development of the proposed research programme and will be discussed in greater detail in chapter 5 (see section 5.2).

1.11.1 Research location and population

The location and population within which the research was undertaken was an important consideration. There were a number of reasons why Scotland has been selected as the location for this research. Scotland’s population demographics, including ethnicity, are different from those in other countries; there are also variations in health profiles, particularly in the West of Scotland. NHS Scotland is increasingly divergent from the rest of the UK NHS not only with regards to policies and practices, but also in terms of

geography and the remote and rural challenges faced. Although there is consistency in terms of the concept of T&R across the UK, T&R clinical guidelines differ between ambulance services. These differences may influence patient outcome. There are also pragmatic reasons, for example the author was employed by, and undertook research, on behalf of the Scottish Ambulance Service. And the inconsistencies identified were identified within SAS T&R guidelines (other guidelines recommend transportation for those on OHA's). These reasons provide the rationale as to why research that is specifically applicable to Scotland is required and why the subsequent studies were undertaken in Scotland. In order to investigate this topic it is first necessary to understand the major condition that people who experience hypoglycaemic emergencies have: diabetes.

CHAPTER 2: DIABETES

2.1 Introduction

In order to achieve the overarching aim of the thesis to investigate patients who have required ambulance service assistance for severe hypoglycaemic events, an overview of the condition diabetes is required. This chapter aims to provide a reference for clinical explanation and discussion throughout the thesis including the aetiology and physical presentation of diabetes.²

Existing knowledge on the pathophysiology, presentation and causes of hypoglycaemia will demonstrate the complex nature of hypoglycaemia and the treatment challenges faced by ambulance clinicians functioning within the prehospital environment. This will aid understanding of how and why a patient acts or fails to act to restore normal blood glucose levels. These uncorrected reductions in blood sugar can lead to depression of consciousness and, on rare occasions, death. Although infrequent, this potentially life-threatening consequence of diabetes emphasises the need for the mandatory emergency response initiated through MPDS[®], and importantly, explains why ambulance services come into contact with this patient population. The recent evidence recognises the limitations of prehospital practices and illustrates that whilst hypoglycaemia may appear to be a relatively straightforward condition to treat, factors related to its causes and to ongoing treatment and support are complex issues that require further exploration.

2.2 Diabetes

Glucose, a simple sugar found in many foods, is a major source of energy and essential for human survival. The brain is the neediest of our organs in terms of glucose

² It will not be assumed that the reader has an existing level of knowledge on diabetes.

requirements, requiring around 1mg kg^{-1} of bodyweight every minute simply to function (Kumar and Clark, 2001; Owen *et al*, 1967). Without glucose, brain cells fail to function, manifest in impaired cognitive function, reduced level of consciousness, possible airway compromise and seizure (Frier, 2007; Hepburn, Steel and Frier, 1989). When blood glucose levels are low this is known as hypoglycaemia. Severe hypoglycaemia can lead to significant cardiac changes that may cause sudden death (Heller, 2009) and so is a considerable concern for ambulance clinicians.

In health, and where food intake is sufficient, there are many body mechanisms that act to ensure the brain receives a constant supply of glucose. Several organs and systems are involved in this process. The Endocrine system plays the greatest part of all in the regulation and control of blood glucose (Tortora and Derrickson, 2009). The endocrine system helps to maintain and control the many physiological mechanisms that are designed to preserve a constant biological balance known as haemostasis (Waugh and Grant, 2010).

A group of specialised cells within the pancreas, known as the 'islets of langerhans' produce and secrete the hormones insulin and glucagon, which through opposing actions, play a vital role in the regulation of blood glucose levels. Glucagon, increases the breakdown of glycogen into glucose raising blood glucose levels. Insulin, facilitates the movement of glucose from the blood across cell membranes, accelerates the conversion of glucose to glycogen, and reduces the rate of generation of glucose from non-carbohydrate carbon substrates such as protein and fat (Tortora & Derrickson, 2009).

A negative feedback mechanism controls the rate at which glucagon and insulin are released such that when blood glucose levels rise, glucagon release is inhibited, preventing the breakdown of glycogen into glucose. Concurrently, insulin secretion is

increased, enabling the uptake of glucose at the cellular level and reducing levels of glucose within the blood to within normal parameters. If either of these normal physiological processes fail, or changes occur that are significant enough to affect the normal process of glucose utilisation, the individual may experience persistently elevated blood glucose levels. If this occurs then the individual can be considered to have developed a condition known as Diabetes Mellitus (Tortora & Grabowski, 2004).

Diabetes Mellitus is one of the most frequently encountered endocrine disorders (Pierce, Keen and Bradley, 1995). The World Health Organisation (WHO) defines diabetes mellitus as:

“a metabolic disorder of multiple aetiology characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both.”

(WHO, 1999, pg. 2)

The body's failure to regulate blood glucose leads to persistently elevated levels of glucose in the blood that over time can adversely affect many of the major body systems (WHO, 2013a). Consequently diabetes mellitus becomes a complex, long-term condition. The pathophysiology of diabetes represents the functional changes that occur, that in turn determines the classification or type of diabetes an individual is diagnosed with. Currently the World Health Organisation defines three types of diabetes: Type I, Type II and Gestational (WHO, 2013a).

Type I diabetes: occurs when the insulin secreting cells in the pancreas (β -cells in the islets of langerhans) cease production, leading to elevated blood glucose levels. It accounts for approximately five to ten percent of all individuals with the condition

(Diabetes UK, 2013; Daneman, 2006). It has a bi-modal peak incidence at 12 years of age and then between 20 and 35 years and is caused by the autoimmune destruction of β -cells (Waugh and Grant, 2010; Tortorra and Derrikson, 2009). The catalyst to this autoimmune response is not yet fully understood though genetic predisposition and a number of environmental factors have been implicated (Daneman, 2006).

Type II diabetes: occurs when there is partial destruction of the pancreatic β -cells, or when the body is unable to use the insulin it produces, known as insulin resistance (Kumar and Clark, 2001). Type II diabetes accounts for ninety percent of all individuals diagnosed with the condition (Stumvoll, Goldstein and Van Haeften, 2005). Although it typically presents in individuals over the age of 40 years, increasingly the condition is being detected in younger people, where it has been linked to the rising prevalence of childhood obesity (Rosenbloom *et al* 1999). Contrary to Type I diabetes, in Type II diabetes the pancreas does secrete insulin, although in insufficient quantities or with a reduced effect on blood glucose regulation, the consequence of which is a more gradual increase in blood glucose level (Stumvoll, Goldstein and Van Haeften, 2005). As in Type I diabetes the cause of Type II remains uncertain. Possible causative factors include increased life expectancy, genetic factors and general lifestyle triggers such as over-eating, reduced exercise and obesity all of which are strongly linked to insulin resistance (Stumvoll, Goldstein and Van Haeften, 2005; Bloomgarden, 1997). Those with a positive family history of Type II diabetes have a two to four fold increase in risk for developing the condition (Pierce, Keen and Bradley, 1995).

Gestational diabetes: occurs during pregnancy and presents in a similar manner to Type II diabetes (Ben-Haroush, Yogev and Hod, 2004). Recent data from Diabetes UK suggests that one in twenty pregnant women will experience gestational diabetes (Diabetes UK, 2010; Ben-Haroush, Yogev and Hod, 2004). It is the result of hormonal changes occurring during the second and third trimester that affect insulin resistance. A

recent systematic review and meta-analysis concluded that women with gestational diabetes have an increased risk of developing Type II diabetes compared to those who did not (Bellamy *et al*, 2009).

2.2.1 Prevalence

The prevalence of a condition is an important consideration in the provision and delivery of health care. Where prevalence is identified as increasing, this permits a degree of forward planning to limit impact and improve care. Current estimates suggest that the world wide prevalence of diabetes in the 20-79 year old age group stands at 285 million (International Diabetes Federation, 2010). Projected figures published by the World Health Organisation (WHO) state that between the years 2000 and 2030 the world wide prevalence of diabetes for all age groups will grow from 2.8% (n=171,228,000) to an estimated 4.4% (n=366,212,000) (WHO, 2009).

Patterns between developing and developed countries vary, with developing countries experiencing a higher prevalence specifically within the 35 to 64 year old age group, when compared to developed countries, who experience a higher incidence in the over 64 years age group (World Health Organisation, 2013; Danaei *et al*, 2011; Stumvoll, Goldstein and Van Haeften, 2005). This is particularly important in terms of Type II diabetes that constitutes 90% of those diagnosed with the condition. And, as treatment regimens change, particularly for those with Type II diabetes where the introduction of insulin has become more commonplace (see section 2.3), the frequency of severe hypoglycaemic events are likely to increase (Leese *et al*, 2003). Consequently this will place additional pressure on ambulance services.

The increases in developing countries have been linked to the theories on industrialisation, westernisation and urbanisation all of which suggest that with changes

in diet, level of exercise, stress and obesity; are factors that contribute to the development of Type II diabetes (Stumvoll, Goldstein and Van Haeften, 2005; Neel, 1999; Bloomgarden, 1997). Within the developed countries there are a number of key contributors to the development of Type II diabetes. Some of these changes are in part due to the considerable demographic changes relating to population 'age', specifically in the over 60's age group, that is, people are living longer (Wild *et al*, 2004). But primarily these increases have been associated with the rising levels of obesity and a sedentary life-style (Harding, Griffin and Wareham, 2006). Recent data from the United Kingdom indicate prevalence of diabetes to be around 2.9 million (4.26% of the population) and estimates suggest this figure will rise to 5 million by 2025 (Diabetes UK, 2012a). These increases are therefore not solely due to improved reporting mechanisms and diagnostic tools (Scottish Diabetes Survey Monitoring Group, 2007).

The prevalence of Type I diabetes is also on the increase and, although the true cause remains uncertain, it has been attributed to factors such as viral infections (Van der Werf, 2007), cow's milk (Paronen *et al*, 2000; Hypponen *et al*, 1999; Vaarala, 1999) and food additives (Helgason and Jonasson, 1981). However, a number of review papers have stated that there has been no evidence to suggest any of these factors are responsible for the triggering of Type I diabetes (Devendra *et al*, 2004; Aitkinson and Eisenbarth, 2001). Only congenital rubella syndrome has been "*conclusively associated with the disease*" (Devendra *et al*, 2004, pg. 751). The debate on the true cause of increasing prevalence of Type I diabetes will continue.

In Scotland, a report from the Scottish Diabetes Survey Monitoring Group (2009) indicated that, in 2008, 219,963 (4.3% of the Scottish population) were diagnosed with the condition. At the beginning of 2010, almost 228,004 (4.4% of the Scottish population) were diagnosed with diabetes representing an increase of over 8,000 people

diagnosed over a twelve month period (Scottish Diabetes Survey Monitoring Group, 2009).

The absence of effective prevention and treatment strategies for diabetes nationally and internationally has permitted its prevalence, and therefore its associated complications, to escalate (Wild *et al*, 2004). As such, the burden of healthcare for this patient population will continue to rise. This growth will place considerable pressures on a wide range of health care resources, including ambulance services. Individuals with poorly controlled diabetes will continue to regularly require the assistance of ambulance clinicians. Acknowledging this, efforts are being made to improve health care systems to diagnose, treat and minimise the long-term effects of the condition (WHO, 2012a). Within the context of this existing evidence, the generation of new knowledge, particularly on the prehospital elements of emergency hypoglycaemia care, may have benefits for the international diabetes community.

2.2.2 Symptoms of diabetes mellitus

The symptoms experienced by an individual developing diabetes depend greatly on the underlying pathophysiology. In Type I diabetes, even though the pathophysiological changes develop slowly (Atkinson and Eisenbarth, 2001), symptoms generally only occur after ~ 80% β -cells have been destroyed (Fowler, 2010). The resultant physical symptoms often occur after ingestion of a large carbohydrate laden meal and can therefore be rapid in onset - from hours to days - and can be particularly severe. Individuals most commonly experience excessive thirst (polydypsia), excessive hunger (polyphagia) and excessive urination (polyurea), and weight loss is apparent in the longer term (Diabetes UK, 2012b; WHO, 2013a).

In Type II diabetes, although symptoms may be similar to those experienced in Type I, generally they are less obvious. This is primarily due to gradual β -cell dysfunction, with some studies suggesting 40% β -cell loss with glucose intolerance (a pre-diabetic state) and 60% of β -cell loss when clinical Type II diabetes develops (Butler *et al*, 2003; Fowler, 2010).

The variability in onset of the condition mean that individuals who first experience the symptoms of diabetes may not seek help immediately. Some will become acutely unwell requiring emergency management, possibly via the ambulance service. This is more often the case in Type I diabetes. In others, the condition will develop slowly, be less obvious, and may only be picked up during routine screening (Diabetes UK, 2006). It is therefore vital that health care professionals recognise the signs and symptoms early and undertake appropriate assessment to determine whether the individual has diabetes mellitus.

2.2.3 Diagnosing diabetes

Clinical diagnosis of diabetes relies on the detection of abnormal blood glucose levels. However, to define abnormal it is first necessary to define normal blood glucose levels (normoglycaemia). Considerable variation can be found in published normal blood glucose levels³ with lower thresholds ranging between 2.5 to 3.9 mmol/l (45 to 70 dL) and upper between 5.3 to 6.1mmol/l (95 to 110dL) (Waugh and Grant, 2010; Tortora and Grabowski, 2004; Longmore *et al*, 1999). The World Health Organisation confirmed that “*there is insufficient data to accurately define normal glucose levels*” and that “*the term normoglycaemia should be used for glucose levels which are associated with a low risk of developing diabetes or cardiovascular disease*” (WHO, 2006, pg. 1).

³ Measurement of blood glucose levels is generally in millimoles per litre (mmol/L), however in some regions of the world i.e. USA, decilitres (dL/L) is the preferred measurement.

This definition does not allow a clinical diagnosis to be established. The most recent WHO parameters for the clinical diagnosis of diabetes were derived from an extensive review of recent evidence (WHO, 2006). The review explicitly identified blood glucose levels associated with a greater likelihood of developing microvascular and macrovascular complications (WHO, 2006). The clinical definitions are as follows:

- *“fasting plasma glucose (FPG) : 7.0 mmol/l (126mg/dl); or,*
- *plasma glucose : 11.1 mmol/l (200mg/dl) at two hours after a 75g oral glucose load (oral glucose tolerance test).”*

(WHO, 2006, pg. 3)

Until recently glycated haemoglobin (HbA1C), a measure of average blood glucose levels over a two to three month period, was not used as a diagnostic tool for diabetes (although it remained an essential measure of blood glucose control after diagnosis). There were two reasons for its exclusion; firstly there were a number of conditions known to affect the readings, and secondly, because many countries could not afford the sophisticated equipment required. However in 2011 WHO published new guidance recommending an HbA1c of 6.5% (48mmol/mol) as being diagnostic of diabetes in the absence of those other conditions known to affect the readings (WHO, 2011). NICE adopted these guidelines in 2012 (NICE, 2012) but the most recent SIGN guidance have not (SIGN, 2010). Nevertheless, across the UK, HbA1c remains an important measurement of diabetes control and aids in the prevention of the known risk factors secondary to microvascular and macrovascular disease that reduce when HbA1c is controlled to <7% (53mmol/mol) (SIGN, 2010). Currently SIGN recommend maintaining HbA1c < 7% (SIGN, 2010) and NICE < 6.5% (48 mmol/mol) (NICE, 2012).

2.3 Treatment of diabetes

In chapter 1 the historical context of prehospital care was described. It should also be recognised that diabetes possesses a similarly ancient history (see Appendix 4). What is clear is the paucity of any advancement in either prehospital or diabetes care until the late 1800's and early 1900's. Diabetes care was transformed in 1922 when the first human, a young boy named Leonard Thomson, was successfully treated using insulin. The individuals involved, Professor James J. Macleod (a Scottish physiologist) and Dr. Frederick Banting both received the Nobel Laureate for Medicine award in 1923 for their work (Stylianou and Kelnar, 2009). Since then insulin has been used in various forms to regulate blood glucose levels in humans.

2.3.1 Type I treatment

In Type I diabetes, where the pancreas no longer secretes insulin, subcutaneous injections of insulin are required. These are often administered two to four times a day (SIGN, 2010; NICE, 2012). The type of insulin used will vary, but can be short or long acting (Daneman, 2006). Combined use of both long and short acting insulin ensures that cells receive an adequate and continuous supply of glucose enabling the individual to function normally throughout the day. Patients treated with insulin also need to distribute their carbohydrate intake evenly throughout the day to ensure the dose of insulin administered meets their anticipated energy expenditure, otherwise extremes may occur in the form of hypoglycaemia or hyperglycaemia. For patients whose control of HbA1c levels has been problematic, newer modes of therapy have been introduced such as insulin pumps or continuous subcutaneous insulin infusion (NICE, 2012; SIGN, 2010).

2.3.2 Type II treatment

Treatment of Type II diabetes, where the pancreas still has some residual function and secretes insulin, differs to that provided in Type I. Where HbA1c levels are in the pre-diabetic range (<6.5%) then lifestyle measures will be initiated such as exercise and diet (NICE, 2012; SIGN, 2010). However where levels continue to rise above this threshold, oral medication is prescribed, such as sulphonylureas, biguanides etc (see Appendix 5 for list of oral medications). Further treatments are initiated where HbA1c remains above the 6.5% threshold despite active treatment. This involves the use of both insulin and oral agents together. Insulin therapy is considered where HbA1c \geq 7.5 despite oral therapy (NICE, 2012; SIGN, 2010). Finally, individuals with Type II diabetes may be moved onto insulin alone. The aim of all treatments for diabetes is to prevent or minimise both the long and short term consequences of the condition

2.4 Complication of diabetes

Controlling blood glucose in diabetes can be challenging. In cases where control is problematic there can be significant short and long-term consequences. These complications are related to the extremes of blood glucose levels. The consequences of the presenting clinical complaint may be short-term and easily remedied, or significant with life-changing consequences. The acuity of the condition and its initial presentation will dictate the type and urgency of care required. From the perspective of ambulance clinicians, identification of the presenting condition will ensure appropriate management and on-going referral, whether the complication is directly or indirectly related to diabetes.

2.4.1 Long-term consequences of hyperglycaemia and hypoglycaemia

The long-term effects of diabetes are often described within the context of the hugely damaging effects of chronically elevated HbA1c levels (hyperglycaemia) and, in

particular, the microvascular and macrovascular changes (Young, 1993; Tchobroutsky, 1978). These microvascular changes can lead to foot ulceration, subsequent amputation (Margolis *et al*, 2005) and renal failure (Bohle *et al*, 1991). The macrovascular changes cause atheroma and calcification of the tunica media of larger arteries; the consequence of which can manifest as heart disease and/or stroke, both of which have significant associated morbidity and mortality (Vinik and Flemmer, 2002). Besides the physiological problems, many individuals with diabetes suffer from psychological or mental health problems and, in particular, depression. Indeed, it has been recognised that those with long-term conditions such as diabetes are two to three times more likely to suffer from depression than those who don't (NICE, 2009).

Whilst the link between hyperglycaemia and long-term complications are clearly evidenced, the long-term effects of hypoglycaemia are less well defined. Some have described the occurrence of acute brain injury after severe hypoglycaemic events (Auer, 2004), but such cases are often associated with prolonged and severe events. There are also some who believe that repeated severe hypoglycaemic events can lead to an accumulative effect on cognitive function. Several studies have been undertaken on both adults and children to establish whether a progressive deterioration in cognitive function occurs after repeated hypoglycaemic events (Matyka, 2007; Strudwick *et al*, 2005; Northam *et al*, 2001). However the evidence is conflicting. Some suggest there is a relationship between severe hypoglycaemia and neuropsychological deficits (Matyka, 2007; Northam *et al*, 2001), whereas others suggest no link (Strudwick *et al*, 2005; Austin and Dreary, 1999; Kramer *et al*, 1998). So it can be concluded that, at present, further high quality longitudinal research is required to determine whether repeated hypoglycaemic events impact on long-term cognitive function.

The long-term consequences of diabetes such as acute myocardial infarction or acute cerebro-vascular accident are unlikely to be considered by ambulance clinicians within

the context of their acute clinical presentation. These conditions would be managed by ambulance clinicians based on their presentation, not necessarily the underlying cause. However, the acute short-term complications of diabetes such as hypoglycaemia and hyperglycaemia would be more likely to be considered by ambulance clinicians within the context of their underlying condition; diabetes.

2.4.2 Short-term consequences of hyperglycaemia and hypoglycaemia

The two acute complications of diabetes pertain to hyperglycaemia and hypoglycaemia. When these changes occur rapidly they disrupt the body's normal homeostatic mechanisms and can lead to time critical emergencies. Hypoglycaemia is the most frequently encountered endocrine related medical emergency (Carroll *et al*, 2003), and as the focus of this thesis is on prehospital hypoglycaemic emergencies this will be discussed in greater detail than hyperglycaemia.

2.4.2.1 Acute hyperglycaemia

Acute hyperglycaemia will present as either Diabetic Ketoacidosis (DKA) or Hyperosmolar Hyperglycaemic State (HHS). Both can be found within the context of a first presentation prior to diagnosis of either Type I or II diabetes; both can take hours, days or even weeks to develop and are accompanied by significant morbidity and mortality (Tentolouris and Katsilambros, 2011). There are a number of causes of DKA and HHS in individuals with diabetes and most commonly include infection, inadequate insulin therapy or other acute illness such as myocardial infarction or cerebrovascular accident (Kitabchi *et al*, 2009).

Any individual with diabetes can develop ketoacidosis although it is more common in insulin treated individuals; HHS is more common in Type II diabetes where some residual pancreatic function is present (Kitabchi *et al*, 2009). In either case both should be considered as acute medical emergencies requiring immediate intervention (Fowler,

2009). The pathophysiology of both DKA and HSS is essentially the same. They occur where there is insufficient insulin to facilitate the transfer of glucose across the cell membrane for use (Fowler, 2009). Insulin deficiency or absence has two effects i) the cells do not receive the glucose they require for energy production and activate a process that uses stores of fat as an alternative, and ii) blood glucose levels rise. Individuals with ketoacidosis will present similarly to those with Type I diabetes on initial diagnosis, experiencing polydipsia, polyphagia, polyuria and nausea and vomiting. Due to the disturbance in acid base balance and electrolytes, little treatment is currently undertaken during the prehospital phase of care other than rapid transportation to the ED (JRCALC, 2013; 2006). In contrast, much can be achieved in the prehospital treatment of the other short-term complication of hypoglycaemia.

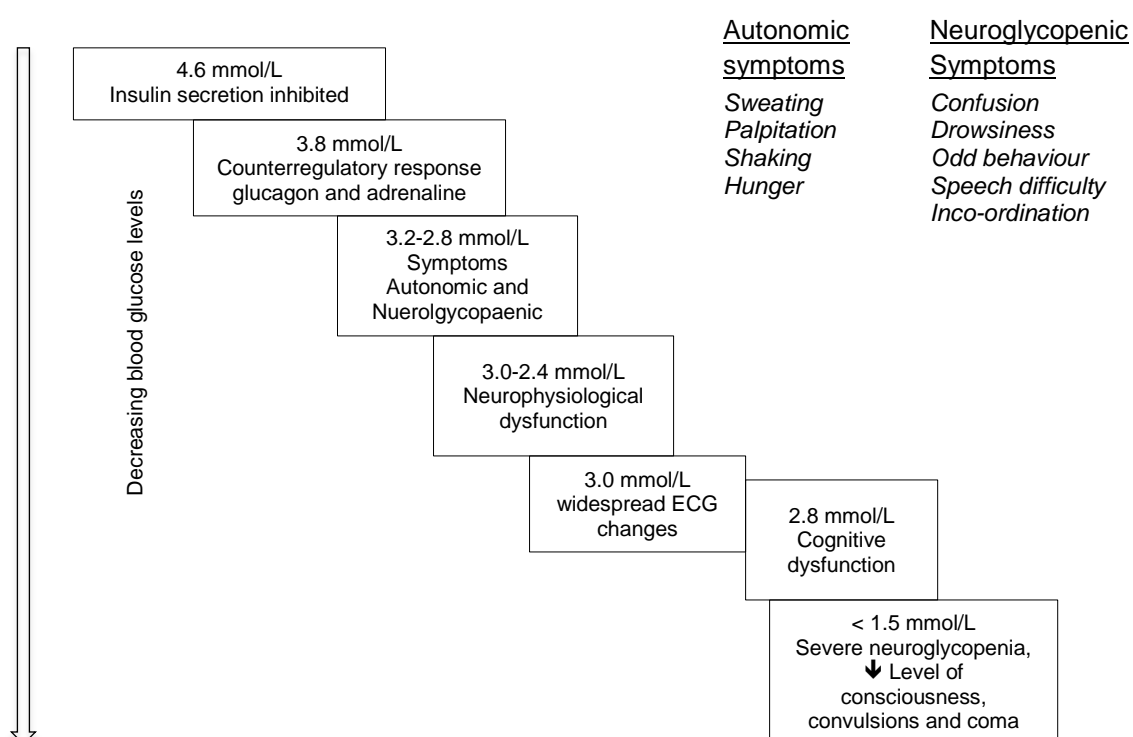
2.4.2.2 Acute hypoglycaemia

In diabetes, hypoglycaemia may be secondary to either excess insulin or insufficient glucose. Several factors can influence the delicate balance of these substances both of which may contribute to the development of hypoglycaemia. These factors are listed below (adapted from Frier, 2007):

- Inappropriate insulin injection – excessive dose, inappropriate time, inappropriate insulin infusion.
- Inadequate exogenous carbohydrate – missed meal or overnight fast.
- Increased carbohydrate utilisation – exercise, illness.
- Decreased endogenous glucose production – excessive alcohol intake.
- Increased insulin sensitivity – night time, exercise, weight loss.
- Decreased insulin clearance – renal failure.
- Oral hypoglycaemic agents – particularly the sulphonylurea group.

Knowledge of the counter-regulatory response to low blood glucose is necessary to understand the signs and symptoms associated with the hypoglycaemia. Many people who experience hypoglycaemia are sensitive to the associated biochemical changes because they manifest as symptoms or signs. Several studies have attempted to categorise these signs and symptoms as either autonomic or neuroglycopenic (Figure 2) (McAulay *et al*, 2001; Weinger *et al*, 1995; Deary *et al*, 1993; Towler *et al*, 1993; Mitrakou *et al*, 1991).

Figure 2: Signs and symptoms of hypoglycaemia. Hierarchy of endocrine, symptomatic and neurological responses to acute hypoglycaemia in non-diabetes subjects. Adapted with kind permission from: Hypoglycaemia in clinical diabetes, Frier and Fisher, copyright © John Wiley and Sons Ltd, 2007.



When blood glucose levels drop to 4.6mmol (83 mg/dL) the counterregulatory response reduces insulin secretion in an attempt to conserve glucose. At 3.8 mmol/L (68 mg/dL), the hormones adrenaline and glucagon are released to mobilise glucose stores and

convert stored glycogen into glucose, raising blood glucose levels where available. If glucose levels continue to fall (to between 3.2 - 2.8mmol/L (58 – 50 mg/dL) the patient will become symptomatic. The associated symptoms are likely to be sweating, palpitations, hunger and shaking (McAuley *et al*, 2001). Mitrakou *et al* (1991) suggests symptoms linked to the autonomic response occur at around 0.5.mmol/l greater than those associated with neuroglycopenia, thus alerting the patient prior to the ensuing cognitive impairment. It is the early recognition of these signs and symptoms, particularly from the sympathetic response, that may afford the patient time to initiate self-help measures and prevent further falls in blood glucose levels (Warren and Frier, 2005). Notably, the glucagon and epinephrine response may be slower in the older population, placing them at higher risk of severe hypoglycaemic events (Zammitt and Frier, 2005).

Below 2.8mmol/L (50 mg/dl) neuroglycopenic symptoms occur simultaneously with the onset of cognitive function deterioration (Warren and Frier, 2005; Mitrakou *et al*, 1991). This may be recognised as confusion, incoordination, odd behaviour or speech difficulties in those affected. Neuroglycopenia makes it difficult for the individual to perform complex tasks and, if blood glucose levels continue to fall, the ability to take corrective action will diminish, leading to a reduction in level of consciousness, possible airway compromise, seizure and in rare cases death (Frier, 2007; Hepburn, Steel and Frier, 1989).

Where present, both the autonomic and neuroglycopenic signs and symptoms have been shown to carry equal importance in detecting and preventing hypoglycaemia (Hepburn, 1990). Recognising either the neuroglycopenic or autonomic signs and symptoms are therefore essential if an individual is to avert a hypoglycaemic emergency (Frier, 2007; Cox *et al*, 1993).

Yet, recognition is not always straightforward, particularly in individuals who lack knowledge or are distracted. They can fail to assign their symptoms to hypoglycaemia (Cox *et al*, 2007; Cox *et al*, 1999). Additionally, in some who are treated with insulin a physiological hypoglycaemic unawareness develops, known as ‘impaired awareness’. This can contribute to severe hypoglycaemia (Graveling and Frier, 2010).

2.4.2.3 Impaired awareness

Impaired awareness arises in those where the “*perception of the onset of hypoglycaemia becomes diminished or absent*” (Graveling and Frier, 2010, pg. S65). It increases the possibility of severe hypoglycaemic events and is more commonly recognised in those with insulin controlled diabetes (Graveling and Frier, 2010). There is no clear or agreed definition of impaired awareness (Frier, 2007), however its prevalence is known to range between 8 to 25% of those treated with insulin (Pramming *et al*, 1991; Hepburn *et al*, 1990) and increases with the duration of insulin therapy (Hepburn *et al*, 1990). It is caused by recurrent hypoglycaemic episodes and strict glycaemic control and causes a dampening of the sympathetic response (Frier, 2007). This absence of sympathetic response results in an under-recognition of the onset of hypoglycaemia, progression to neuroglycopenia and subsequently an inability to self-treat. The condition can be objectively identified using a number of validated tools (Gold, MacLeod and Frier, 1994) and is reversible through strict avoidance of hypoglycaemia for a period of weeks or months (Cranston *et al*, 1994; Dagogo-Jack, Rattarasarn and Vryer, 1994; Fanelli *et al*, 1994).

2.4.2.4 Defining Hypoglycaemia

Various organisations and guideline development groups have defined a low blood glucose level or hypoglycaemia as being below 4mmol/l (~72 dL/L) (Canadian Diabetes Association, 2004; Diabetes UK, 2012b; JRCALC, 2013; American Diabetes Association,

2013). However some studies have used slightly lower thresholds, citing biochemical markers of 3.0 or 3.3mmol/l (54 – 59 dL) as indicative of hypoglycaemia (Dromgoole, 2004; Kagansky *et al*, 2003). The reason for such inconsistency may arise from the varying physiological and neurological thresholds for hypoglycaemia in non-diabetic individuals, and the unpredictable way in which the counter-regulatory hormones influence the body systems (Warren and Frier, 2005). Irrespective of precise biochemical markers, most definitions are used as recommended levels for the patient to instigate self-treatment or for the health care professionals to intervene. Given the prehospital context of this thesis, hypoglycaemia will be defined throughout within the context of current National Ambulance Service Guidelines as a blood glucose level of less than 4mmol/l (~72dL/L) (JRCALC, 2013).

2.4.2.5 Clinical Classifications of hypoglycaemia

Hypoglycaemia has been clinically classified in a number of ways and can include the categories mild, moderate and severe (Strachan, 2007). The Diabetes Control and Complications Trial, a landmark study that compared intensive versus standard diabetes therapy, defined severe hypoglycaemia as “*an episode of hypoglycaemia in which assistance from a third party was required to effect treatment and recovery*” (The Diabetes Control and Complications Trial, 1997, pg. 272). Although this is non-specific in terms of blood glucose concentrations, Strachan (2007) argues that its simplicity means it can be useful in a diverse range of clinical settings. The classifications of mild and moderate, however, appear to be a little more subjective. Both Leckie *et al* (2005) and Amiel *et al*, (2008) define a mild hypoglycaemic event as any symptomatic episode that was self-treated, and moderate as “*a self-treated episode involving significant disruption to life-style*” (Amiel *et al*, 2008, pg. 247). Amiel *et al* suggest that the moderate classification is not used often now “*because of its imprecision and subjective nature*” (Amiel *et al*, 2008, pg. 247). So as both mild and moderate may be self-treated,

with severe requiring third party assistance, it seems more appropriate to consider hypoglycaemic events within the two classifications of 'mild' and 'severe'.

2.4.3 Immediate consequences of hypoglycaemia

Severe hypoglycaemia is a dangerous, potentially life-threatening condition. The effects of hypoglycaemia on the cardiovascular system have been described by others (Frier, Schernthaner and Heller, 2011; Heller, 2009). Severe hypoglycaemia is known to affect the electrical conduction of myocardial cells and can lead to potentially life-threatening cardiac conditions; these include angina, acute coronary syndrome and the cardiac conduction abnormalities associated with sudden death in young people (Heller, 2009). The condition should not therefore be underestimated.

The progressive nature of hypoglycaemia can lead patients to become aggressive making management difficult for any carer. Physical injury has also been reported during severe events (Ben-Ami *et al*, 1999; Hepburn, Steel and Frier, 1989). For those who continue to deteriorate, unconsciousness and airway compromise ensue which pose the greatest risk in any patient (Nolana *et al*, 2010). When glucose levels become critically low, seizure can occur leading to hypoxia, cerebral oedema and in some cases death (MacLeod, Hepburn and Frier, 1993). Repeated hypoglycaemic events can also contribute to the development of impaired awareness as described previously (Graveling and Frier, 2010). This increases the risk of severe events. Fortunately, in many cases severe hypoglycaemia can be treated safely and effectively in the prehospital environment but recognition of the consequences of hypoglycaemia supports understanding of the need for rapid intervention to restore normoglycaemia.

2.5 Prehospital management of hypoglycaemia

Understanding the consequences of severe hypoglycaemia allows an appreciation of the necessity for an urgent or emergency response. Treatment for hypoglycaemia is initiated

to restore normoglycaemia. Diabetes UK (2012b) provides advice on self-management should blood glucose levels drop below 4mmol/L. The advice is clear, and suggests ingestion of sugary drinks or tablets, followed by longer acting carbohydrates such as cereal bars etc (Diabetes UK, 2012b). Examples of drinks and foods containing these carbohydrates are also provided. For severe hypoglycaemic events glucagon injections are advised. If these are not available then an ambulance should be called (Diabetes UK, 2012b).

Treatments available from ambulance clinicians have evolved considerably over the past three decades. The earliest published UK based study on ambulance clinician's treatment of hypoglycaemia was undertaken in Wales (Weston and Stevens, 1990). This prospective non-randomised intervention based study included thirty one patients who had experienced a total of 35 episodes of hypoglycaemia treated with intravenous dextrose by paramedics (then known as 'extended trained ambulance clinicians'). The authors concluded that ambulance clinicians could "*diagnose and treat most patients with severe hypoglycaemia*" (Weston and Stevens, 1990, pg. 909). They also drew attention to the fact that intravenous (i.v.) dextrose was not always the most appropriate treatment. This was supported by three cases. One, where intravenous access had not been possible, and in two others where patients had been aggressive and uncooperative. One patient was successfully treated after the arrival of a GP who administered intramuscular (i.m.) glucagon. This resulted in the recommendation that glucagon, in addition to i.v. dextrose, should be available for use by ambulance clinicians.

In subsequent years a number of comparable studies were undertaken with similar findings thus strengthening this earlier recommendation (Steel, *et al*, 1992; Vukmir, Paris and Yealy, 1991). Prehospital hypoglycaemic care continued to develop, and by the mid

90's the SAS introduced glucagon for use by ambulance clinicians, a practice reflected in 77% of all UK ambulance services at that time (Howell and Culy, 1997). During 2001 the SAS adopted the latest version of JRCALC guidelines in which the use of 10% intravenous glucose was introduced along with electronic blood glucose monitors to aid diagnosis. Ten percent glucose was recommended over the 50% more commonly used in hospitals as it had been demonstrated to be just as effective in raising blood glucose levels but carried less risk (Moore and Wollard, 2005). This finding was further reinforced in a review published more recently (Nehme and Cudini, 2009). However expertise in the provision of prehospital care varies. Ambulance Technicians are currently not authorised to cannulate⁴ or administer intravenous medications, precluding them from administering 10% glucose. They are, however, authorised to administer glucagon intramuscularly or oral glucose. Glucagon has similar efficacy to intravenous glucose, although its effects are slower in onset and it only works where there are sufficient glucose stores within the liver (Carstens and Sprehn, 1998; Howell and Guly, 1997; Hvidberg, Jorgensen and Hilsted, 1992; Vukmir, Paris and Yealy, 1991; Patrick *et al*, 1990).

The choice of intervention is dependent on the ambulance clinician's assessment of the severity of hypoglycaemia and the safety of each possible intervention. In mild hypoglycaemia, where individuals are cooperative, oral glucose can be administered. When significant neuroglycopenia has developed, patients can become uncooperative or aggressive. In such cases, it may be appropriate to administer intramuscular glucagon. In unresponsive/unconscious individuals either intramuscular glucagon or intravenous glucose should be used (Westons and Stephens, 1990). Several studies

⁴ Cannulation involves placing a tube into a patient's vein so that drugs may be administered intravenously directly into the patient's bloodstream.

have been conducted to compare the efficacy of intramuscular/subcutaneous glucagon and intravenous glucose (Carstens and Sprehn, 1998; Howell and Guly, 1997; Hvidberg, Jorgensen and Hilsted, 1992; Vukmir, Paris and Yealy, 1991; Patrick *et al*, 1990; Maccuish *et al*, 1970) (see Table 4).

Current JRCALC Guidelines suggest that if “*an improvement in level of consciousness is not observed within 20 minutes of drug administration*”, immediate transportation to hospital is advised (JRCALC, 2013, pg. 151). As can be seen from Table 4, the response is more predictable and rapid with the use of intravenous glucose and this supports the rationale of its initial use where intravenous access is possible. With the exception of prolonged hypoglycaemia, or deliberate overdose of insulin or oral agents, in most instances patients recover relatively quickly.

Table 4: Recovery response times: glucagon vs’ intravenous glucose

Author	Glucagon response (mins)	Glucose response (mins)
Patrick <i>et al</i> (1990)	Mean 9 (5-30)	Mean 3 (2-15)
Howell <i>et al</i> (1997)	Median 17.5 (15-34)	Mean 3.5 (2-15)
Vukmir <i>et al</i> (1991)	Mean 8.85 (\pm 4.37)	n/a
Hvidberg <i>et al</i> (1992)	Max values within 10 mins	10mmol after 2 mins
Carstens <i>et al</i> (1998)	8 to 21	1 to 3

Maccuish (1970) is not included as administration of glucagon was i.v., not i.m.

When patients recover from a hypoglycaemic emergency attended by the SAS, they have a number of options. The first is for immediate transportation to the ED, the second to refuse further care and the third to enter the Treat and Refer system (T&R) (see section 1.7). The latter was introduced by ambulance services in response to the Government Policy whereby Ambulance Clinicians may, where deemed safe and appropriate, leave patients at home with advice on self-referral.

2.5.1 Hypoglycaemia Treat and Refer Guidelines

There are a variety of T&R guidelines in use across the UK (Wales, 2006; SCOTTISH AMBULANCE SERVICE, 2005; BASICS Scotland, 2004). Hypoglycaemia is one condition commonly included and is reportedly the most frequently applied T&R guideline in Scotland (Dalglish, Colver and Fitzpatrick, 2008). The hypoglycaemia T&R guidelines will only be considered for those patients who have fully recovered. Where any of the risk factors listed in the guidelines are identified (see Appendix 1), transportation to the ED is advised (although patients may still refuse). For those with no identified risk factors, Treat and Refer will be discussed with the patient and, where agreed, the guideline applied. These patients will then remain at home with appropriate follow-up recommended. A Patient and Carer (PAC) form will then be left by the ambulance clinicians with the patient. This will contain clinical information on their event as well as referral advice for the patient. The patient will be advised to make an appointment with their GP at the earliest opportunity and to hand over the PAC during their consultation.

As was previously discussed (see section 1.7) the introduction of T&R had been in response to government policy (Scottish Executive, 2005a; Department of Health 2005b). Ambulance clinicians supported the concept but had concerns about the lack of training and support. There was also little evidence to support their effectiveness (Colver, 2013; Dalglish, Colver and Fitzpatrick, 2005; Snooks *et al* 2004b). The introduction of T&R guidelines for hypoglycaemia had occurred rapidly and without the development of any robust evidence. This area clearly required further research to establish its effectiveness (Snooks *et al*, 2009).

2.5.2 Inconsistencies in Treat and Refer guidelines

A consequence of the rapid introduction of T&R guidelines, without first developing the underpinning evidence, was that the existing guidelines were based on consensus opinion. This may have led to the identified inconsistencies pertaining to OHA's (see Appendix 1 and 2). The concern was that some OHA's exert their pharmacological effects for up to 48 hours, and when hypoglycaemia occurs, the effects can be prolonged or recurrent (BNF, 2007; Harrigan *et al*, 2001). It is for these reasons that some hypoglycaemic T&R guidelines recommended patients treated with such medication be transported to the ED. (JRCALC, 2006; Welsh Ambulance Service, 2006; BASICS Education Scotland, 2004). However these recommendations were not included within the SAS T&R Guidance (SCOTTISH AMBULANCE SERVICE, 2005).

These inconsistencies may have been compromising the safety of some patients treated for hypoglycaemia, however the frequency of repeat hypoglycaemic events associated with OHA's within the context of T&R were unknown. This clear gap in knowledge and the importance of ensuring the safety of patients who had experienced a severe hypoglycaemic event, led to the development of the scoping review presented in the next chapter.

CHAPTER 3: A SCOPING REVIEW TO DETERMINE THE SAFETY OF PREHOSPITAL TREATMENT OF HYPOGLYCAEMIC EVENTS

3.1 Introduction

The previous chapter described the prevalence, complications and prehospital treatment of diabetes. Describing the aetiology, pathophysiology, and associated risks of hypoglycaemia has illustrated that treatment of hypoglycaemia in people with diabetes is more complex than may initially be perceived. This also develops our understanding on the reasons ambulance clinicians become involved in hypoglycaemia care and the need for rapid, emergency responses to minimise associated risks (see section 2.4.3). However, the apparent ease of treatment and rapid recovery (see section 2.5) has meant that hypoglycaemia has become a common condition for which ambulance services in the UK have been able to develop T&R guidance (Welsh Ambulance Service, 2006; Scottish Ambulance Service, 2005; BASICS Education Scotland, 2004). The introduction and application of T&R guidelines permits individuals who have experienced a severe hypoglycaemic event to remain at home post-recovery.

Historically, patients who were not transported to the ED would be recorded as a transportation refusal and would not necessarily receive, or be advised to seek, follow-up care. Attempts to formalise and improve the follow-up care, and thus safety, of non-transportation have been made with the introduction of T&R. But, as previously identified (see section 1.7 and 2.5.2), there are inconsistencies between the SAS and broader hypoglycaemia guidelines, particularly around patients treated with Oral Hypoglycaemic Agents (OHA's) (Welsh Ambulance Service, 2006; Scottish Ambulance Service, 2005; BASICS Education Scotland, 2004). As was identified in the diabetes chapter (see section 2.4.3.2) OHA's can cause severe hypoglycaemic events. And, some guidelines suggest there is possibility of subsequent events due to their long-acting nature (Appendix 3). A significant concern therefore remains around the safety of

the non-transportation of patients treated with OHA to the ED post-hypoglycaemic event. However, the extent to which this occurs in practice and the demographics of this particular patient population are unknown. As discussed earlier (in section 1.8) the widely accepted starting point of any research process is the review of the literature. However, as prehospital care is an under-researched area the process and aims of any review requires careful consideration. This chapter will therefore begin by describing review typology, appraisal processes and methods before presenting the rationale for selecting an appropriate review type for this study.

3.2 Exploring the literature

The process of searching and synthesising literature is complex. Prior to the development of evidence-based medicine in the 1990's, literature review processes were largely unstructured and open to bias (Booth, Papaioannou and Sutton, 2012; Petticrew and Roberts, 2006; The Cochrane Collaboration, 2002). Since the 1990's there have been significant efforts to develop explicit and systematic methods which ensure that the search, synthesis and reporting elements of literature reviews are explicit, reproducible, and reliable (Booth, Papaioannou and Sutton, 2012).

3.2.1 Review types and terminology

Arksey and O'Malley contend that there is, "*no single 'ideal type' of literature review, but rather that all literature review methods offer a set of tools that researchers need to use appropriately*" (Arksey and O'Malley, 2005, pg. 4). There are now multiple review types each of which have been developed to address particular search, appraisal, and synthesis challenges. Whilst such methodological advancements are helpful, they may have led to typological confusion and methodological overlap (Booth, Papaioannou and Sutton, 2012). Consequently there have been calls for a greater degree of terminological clarity (Arksey and O'Malley, 2005).

The debate about literature review categorisation is dynamic, ongoing and polarised. Whilst the argument in favour of methodological classification in the social sciences has been made for many years (Bailey, 1994), some have opposed its development in relation to literature review methods, arguing that the pace of review method development is too fast for any classification to be helpful (Gough, Thomas and Oliver, 2012).

In order to improve clarity and utility, Booth, Papaioannou and Sutton advocate focussing “...on the techniques and ingredients of the review process in the hope that this will stimulate cross fertilisation of technique and act as a counter balance to methodological pigeon-holing” (Booth, Papaioannou and Sutton, 2012, pg. 21). Whilst this approach acknowledges the value of classification, it also enables a useful blending of review methods, where appropriate. One helpful attempt at focussing on the techniques and ingredients of literature reviews is the Search, Appraisal, Synthesis and Analysis (SALSA) framework (Grant and Booth, 2009) (Table 5). SALSA will be used here as it helps define different review types within a visual framework that facilitates simple comparisons. Each stage will now be briefly discussed.

Table 5: SALSA Framework (Grant and Booth, 2009)

Label	Description	Search	Appraisal	Synthesis	Analysis
<i>Systematic Search and Review</i>	Combines strengths of critical review with a comprehensive search process. Typically addresses broad questions to produce 'best evidence synthesis'	Exhaustive	May or may not include quality assessment	Minimal narrative, tabular summary of studies	What is known; recommendations for practice. Limitations
<i>Systematic Review</i>	Seeks to systematically search for, appraise and synthesis research evidence, often adhering to guidelines on the conduct of a review	Exhaustive	Quality assessment will determine inclusion/exclusion (Cochrane)	Typically narrative with tabular accompaniment	What is known; recommendations for practice. What remains unknown; uncertainty around findings, recommendations for future research
<i>State of the art review</i>	Tends to address more current matters in contrast to other combined retrospective and current approaches. May offer new perspectives on issue or point out area for further research	Current literature	No formal quality assessment	Typically narrative, may have tabular accompaniment	Current state of knowledge and priorities for future investigation and research
<i>Scoping review</i>	Preliminary assessment of potential size and scope of available research literature. Aims to identify nature and extent of research evidence (usually including ongoing research)	Comprehensive but determined by time/scope	No formal quality assessment	Typically tabular with some narrative commentary	Characterizes quantity and quality of literature, perhaps by study design and other key features. Attempts to specify a viable review
<i>Rapid Review</i>	Assessment of what is already known about a policy or practice issue, by using systematic review methods to search and critically appraise existing research	Comprehensive but determined by time/scope	Time limited formal quality assessment	Typically narrative and tabular	Quantities of literature and overall quality/direction of effect of literature
<i>Meta-Analysis</i>	Technique that statistically combines the results of quantitative studies to provide a more precise effect of the results	Exhaustive and funnel plot	Quality assessment may determine inclusion/exclusion and/or sensitivity analysis	Graphical and tabular with narrative commentary	Numerical analysis of measures of effect assuming absence of heterogeneity
<i>Critical Review</i>	Aims to demonstrate writer has extensively researched literature and critically evaluated its quality. Goes beyond mere description to include degree of analysis and conceptual innovation.	Includes most significant	No formal quality assessment	Typically narrative	Significant component: seeks to identify conceptual contribution to embody existing or derive new theory

Table 5: SALSA Framework (Grant and Booth, 2009)

Label	Description	Search	Appraisal	Synthesis	Analysis
	Typically results in hypothesis or model				
<i>Mapping Review</i>	Map out and categorize existing literature from which to commission further reviews and/or primary research by identifying gaps in research literature	Comprehensive but determined by time/scope	No formal quality assessment	May be graphical and tabular	Characterises quantity and quality of literature, perhaps by study design and other key features. May identify need for primary or secondary research
<i>Literature Review</i>	Generic term: published materials that provide examination of recent or current literature. Can cover wide range of subjects at various levels of completeness and comprehensiveness. May include research findings.	May or may not include all	May or may not include quality assessment	Typically narrative	Analysis may be chronological, conceptual, thematic, etc.
<i>Mixed studies review</i>	Refers to any combination of methods where one significant component is a literature review (usually systematic). Within a review context it refers to a combination of review approaches for example combining quantitative with qualitative research or outcome with process studies	Requires either very sensitive search to retrieve all studies or separately conceived quantitative and qualitative strategies	Requires either a generic appraisal instrument or separate appraisal processes with corresponding checklists	Typically both components will be presented as narrative and in tables. May also employ graphical means of integrating quantitative and qualitative studies	Analysis may characterise both literatures and look for correlations between characteristics or use gap analysis to identify aspects absent in one literature but missing in the other

3.2.1.1 Search process

Identifying the literature is central to any review and is often achieved through structured search processes using key search terms within selected/relevant electronic databases. Occasionally non-published, grey literature may be sought depending on the nature and scope of a review (Booth, Papaioannou and Sutton, 2012). Exhaustive search processes are mandated in systematic review, systematic search and review and meta-analysis methods. This requirement being linked to their primary aim to inform policy and practice (The Cochrane Collaboration, 2014). Importantly, any errors in search process or strategy can affect the sensitivity of the search and adversely impact on accuracy of findings (Yoshii *et al*, 2009). As the aims of the remaining review types, listed in Table 5, consist of mapping or scoping of available literature, generating hypothesis or identifying current knowledge, they do not require the same degree of exhaustive search process as systematic reviews, but rather focus on having a comprehensive or focussed search.

The distinction between the comprehensive, focussed or exhaustive search strategies is somewhat subjective, but are determined by the aims of the study and the reviewers' accepted risk of the search strategies trade-off between sensitivity and specificity. The more sensitive the initial strategy, the more exhaustive it will be. However, this is likely to result in the retrieval of studies that are not relevant to the review; that is, it will lack specificity (Zhang, Ajiferuke and Sampson, 2006). Where search criteria are exhaustive the reviewer aims to locate and consider all available literature on the subject, published and unpublished (Cooper, 1988). Such search strategies will be highly sensitive. Alternatively, a comprehensive search requires a less rigorous

approach, and can be more specific whilst acknowledging (and accepting) that some studies may be missed. Ultimately, the ideal search process will be a balance between sensitivity and specificity (Zhang, Ajiferuke and Sampson, 2006). Whilst it is understood that more exhaustive search strategies may reduce the number of missed studies, the current review will be comprehensive, but not exhaustive, so as to ensure time is not unduly spent on finding papers that may have little impact on outcome.

3.2.1.2 Appraisal process

The need for, and form of, appraisal is explicitly linked to the aims of the review. Numerous types of literature review demand an assessment of methodological quality. Those review types, frequently undertaken to impact on policy or practice, require rigorous quality appraisal (The Cochrane Collaboration, 2014; Grant and Booth, 2009). There are many quality appraisal tools available to aid this process (Katrak *et al*, 2004). Indeed a relatively recent systematic review discovered over 100 available appraisal tools, most of which were developed for application to experimental studies and studies of a specific design (Katrak *et al*, 2004).

However, despite the advancement and development of more sophisticated appraisal tools there is no defined gold standard (Katrak *et al*, 2004). Nevertheless, there is an acknowledged and widely accepted hierarchy of research studies where study design permits a rudimentary grading of the quality of the evidence (Guyatt *et al*, 1995). One example of a well-recognised and respected literature appraisal tool is the GRADE approach (The Cochrane Collaboration, 2014). The GRADE approach provides four levels of quality rating (see Table 6). However, the quality appraisal process can be time consuming and is not generally considered appropriate or required for reviews of

a scoping, mapping or hypothesis generating nature (Grant and Booth, 2009).

Table 6: The Grade Approach (The Cochrane Collaboration, 2014)

<i>Underlying methodology</i>	<i>Quality rating</i>
Randomized trials; or double-upgraded observational studies.	High
Downgraded randomized trials; or upgraded observational studies.	Moderate
Double-downgraded randomized trials; or observational studies.	Low
Triple-downgraded randomized trials; or downgraded observational studies; or case series/case reports.	Very low

3.2.1.3 Synthesis

Approaches to literature synthesis could be integrative or interpretive (Noblit and Hare, 1988). The integrative approach, bearing some resemblance to the positivist approach, involves the aggregation or pooling of data, such as undertaken in meta-analysis. The interpretive approach involves the synthesis of findings through induction and interpretation at a more conceptual level, and has been linked with the constructivist paradigm of enquiry (Noblit and Hare, 1988).

Others argue that the two approaches are not entirely distinct (Dixon-Woods *et al*, 2005). They suggest that a degree of interpretation around theories of causality or generalisability is required in the integrative approach, and similarly, some degree of aggregation of data is required within an interpretive approach. This results in an element of cross-over within either approach, with one being the more dominant (Dixon-Woods *et al*, 2005). Dixon-Woods *et al* (2005) position is endorsed by Pope, Mays and Popay (2007) who also discuss the mixing of approaches. Their proposed integration of both interpretive and integrative approaches is supported in turn, by Gough, Thomas and Oliver (2012) and Grant and Booth (2009) who argue that these

approaches are complementary. Ultimately, the aim of synthesis is to organise data in a meaningful way (sometimes using charts or graphs) in order for it to be collated (Pope, Mays and Popay, 2007). There are numerous ways in which this may be achieved. For example a narrative synthesis, typically used where studies are heterogeneous, will provide a descriptive summary of results. Alternatively, where studies are homogeneous, statistical meta-analysis may be conducted where studies included consist of randomised controlled trials (Booth, Papaioannou and Sutton, 2012). In qualitative research, meta-ethnography may be considered more appropriate, where themes or concepts are developed (Booth, Papaioannou and Sutton, 2012; Pope, Mays and Popay, 2007). Or the 'realist review' which has been developed in order to synthesise research using a realist approach (Pawson et al, 2005). It helps to develop an understanding of how an intervention works, its mechanisms and outcomes. Not necessarily whether the intervention is effective or not. The aims of a review therefore dictate the type of literature included, which then influences the heterogeneity/homogeneity of included data, and consequently the approach to synthesis. The aims of this review are described in section 3.2.2. The requirement to investigate the patient characteristics/demographics and determine frequency of repeat calls will undoubtedly involve a degree of quantification of results. But the anticipated heterogeneity of studies will prevent aggregation of data via meta-analysis. An approach via a narrative synthesis will permit a descriptive summary of results and therefore a more complementary representation and, as such, conforms more to the views of Gough, Thomas and Oliver (2012) and Grant and Booth (2009).

3.2.1.4 Analysis

Analysis is explicitly linked to the original aims of the reviews and the approach to synthesis. It should generally consist of the description of findings, what is known, the limitations and any recommendations (Booth, Papaioannou and Sutton, 2012). The process of analysis and its presentation should be consistent with, and reflect the data synthesised from the included studies. As Booth, Papaioannou and Sutton state “*The analysis stage focuses on telling you what the literature means*” (Booth, Papaioannou and Sutton, 2012, pg. 170). The core component as described by Noblit and Hare (1988) is the provision, or drawing together, of the core findings and these should be presented with due consideration to the within study and between study limitations. The quality or weight of evidence of each study should be considered, particularly for those review typologies aiming to inform policy and practice (systematic review and meta-analysis) (Booth, Papaioannou and Sutton, 2012). For the more theoretical or qualitative review, new or evolving theories or themes may be presented and discussed. It is essential that during analysis these discussions remain grounded within both the aims of the review and the evidence presented from the included literature.

The SALSA framework emphasises the importance of linking the aims of a literature review to its research questions and methods. However, despite this framework, and with the exception of a few distinct typologies (namely systematic review and meta-analysis), it is clear that there remains a degree of typological confusion with differing labels being allocated to reviews methods which are, in fact, very similar in aim and scope (Gough, Thomas and Oliver, 2012; Arksey and O’Malley, 2005).

3.2.2 Aims of Review

After conducting a preliminary scoping search, as recommended by Booth, Papaioannou and Sutton (2012), the aims of this review were determined as follows: i) to provide a summary of the demographics of the patient population requiring ambulance service assistance for hypoglycaemic emergencies; and, ii) to determine the extent to which post-hypoglycaemic diabetic patients who are prescribed OHA's experience repeat hypoglycaemic events (RHE) after being treated in the prehospital environment, and iii) whether they should be transported to hospital regardless of post treatment response.

3.2.2.1 Selecting an appropriate review method

To date, very little high quality research has been conducted with ambulance clinicians in prehospital emergency care settings (Institute of Medicine of the National Academies, 2006). There is a justifiable need to extrapolate knowledge from the existing evidence base in order to inform practice and develop guidelines for use by ambulance clinicians. Consequently, current JRCALC National Clinical Guidelines (2013) comprise evidence from multiple in-hospital based studies involving physicians and nurses, as well as consensus opinion from experts in the field of prehospital care.

Few relevant studies were identified in the scoping search. Only one randomised controlled trial was identified that had been published in relation to prehospital hypoglycaemic care (Moore and Woollard, 2005). A small number of population-based studies, clinical guidelines, case studies and review papers were also retrieved. Despite the desire to conduct a systematic review with meta-analysis, the heterogeneity of the studies identified in the scoping search suggested this approach

would not be possible. A narrative Cochrane style systematic review could have been conducted, but would likely have resulted in a nil-return review that would be of little clinical utility. This preview of available literature demonstrated the benefits of the preliminary scoping search and permitted the early exclusion of systematic review and meta-analysis, as review options. Nevertheless, there remained a desire to conduct a comprehensive and systematic search of the literature and to ensure the search processes were explicit and reproducible, together helping to minimise bias (Booth, Papaioannou and Sutton, 2012).

Furthermore, the inclusion of only 'current' or 'significant' literature as defined in the state-of-the-art or critical review process respectively, would have limited the type and quality of papers included (see Table 5). Such restrictive inclusion criteria could have skewed results and would have been unlikely to have adequately addressed either of the study aims. A deliberate approach using mixed-methods or qualitative studies would have been inappropriate, as answers to the questions in this review would be most likely found in population based studies and through quantitative results, not qualitative findings. As such, this process of study type exclusion leaves only mapping, scoping, and rapid review typologies as potentially appropriate.

The rapid review determines what is known about policy and practice. However, the aims of the current review extend beyond this, exploring specifically the demographics of the population concerned along with a focussed clinical question. According to the defined typology, mapping and scoping reviews bear remarkable similarities (Grant and Booth 2009). These similarities somewhat typify the current status of review typology in that a degree of crossover commonly exists (Booth, Papaioannou and

Sutton, 2012; Arksey and O'Malley, 2005). But, the core aim of each differs: mapping reviews seek to identify gaps in the evidence base whereas scoping reviews aim to identify the nature and potential size and scope of the available research (Levac, Colquhoun and O'Brien, 2010; Civil Service, no date). The aim of the current review does not seek to identify gaps in the literature but to investigate the nature and size of the hypoglycaemia challenge faced by ambulance services. A scoping review may therefore be the most appropriate process to undertake the retrieval, synthesis and analysis of studies included in the proposed review. The usefulness of the scoping review merits further exploration.

3.2.3 Scoping Review

Whilst there remains no universally agreed definition of scoping review (Davis, 2009; Anderson, 2008), it has been described as a particularly useful review method in health disciplines where the existing evidence base is lacking and where other review approaches are not feasible (Levac, Colquhoun and O'Brien, 2010). Scoping reviews generally consist of a clearly articulated research question, such as those described earlier (see section 3.2.2) (Civil Service, n.d.). Mays *et al* state that the purpose of a scoping review is to:

“map rapidly the key concepts underpinning a research area and the main sources and types of evidence available, and can be undertaken as stand-alone projects in their own right, especially where an area is complex or has not been reviewed comprehensively before”.

(Mays *et al*, 2001, pg. 194)

However, Arksey and O'Malley expand on this stating that there are “*at least four common reasons why a scoping study might be undertaken*” (Arksey and O'Malley,

2005, pg. 6): i) to examine the extent, range and nature of research activity, ii) to determine the value of undertaking a full systematic review, iii) to summarise and disseminate research findings and iv) to identify gaps in existing literature.

As so little is known about the literature on prehospital hypoglycaemic care, an examination of the extent of literature available will be part of the review process. It was anticipated that a comprehensive scope of the literature would capture many of the key studies that contain the demographic information, and perhaps enough detail within these to help answer the second research question. It has already been established through an initial search that few studies exist, and where they do, there was a significant degree of heterogeneity of article type and study design. A narrative synthesis will therefore be most appropriate in providing a summary of the evidence and perhaps identifying any gaps in the literature. Additionally, as there is little evidence-based guidance available on prehospital care, this review also aimed to inform practice, although, traditionally the Scoping Review is not considered an appropriate choice of method for this purpose. However, the dearth of prehospital evidence perhaps requires a novel or more pragmatic approach, and for a degree of flexibility whereby the most appropriate tools are used to answer the research question (Booth, Papaioannou and Sutton, 2012). And so, although not a precise typological fit, this scoping review provides a framework within which to search, analysis and synthesise the literature and will, through adopting a more flexible approach, aim to help inform future prehospital care practices.

3.2.3.1 Process

The original scoping review approach developed by Arksey and O'Malley (2005) has since been refined (Levac, Colquhoun and O'Brien, 2010) and will be used in this study. This includes the following stages (adapted from Levac, Colquhoun and O'Brien, 2010).

- Identifying the research question – a clear articulation of the question to include the target population, health outcome of interest and establish search strategy.
- Identifying relevant studies – the research question and purpose will be guided by the scope of the review.
- Study selection – This should be an iterative process involving searching the literature, refining search strategy and reviewing articles for inclusion. Two authors should undertake this to reduce potential for bias.
- Charting the data – Need to determine the variables to extract in order to answer the research question/s. Two authors undertake this to ensure consistent approach and that the data relates to the research question/s posed.
- Collating, summarising and reporting the results - this should take 3 distinct steps, Analysis including a descriptive numerical summary, reporting of results and producing the outcome that refers to the overall purpose of the research question, and a consideration of the meaning of the findings.
- Consultation – where appropriate consultation with stakeholders.

3.3 Identifying the research question

To reiterate, the aims of the scoping review were, to: i) provide a summary of the demographics of the patient population requiring ambulance service assistance for

hypoglycaemic emergencies; ii) to determine the extent to which post-hypoglycaemic diabetic patients who are prescribed OHA's experience repeat hypoglycaemic events (RHE) after being treated in the prehospital environment; and iii) whether they should be transported to hospital regardless of post treatment response.

3.4 Identifying relevant studies

A scoping literature review was conducted. The following comprehensive search strategy was used to retrieve relevant material:

(i) Medline (using Pubmed) was searched using the following search strategy:

('diabetes'[All Fields] OR 'diabetes mellitus'[All Fields] OR 'diabetic'[All Fields]) AND (('sulphonylurea'[All Fields] OR 'sulfonylurea'[All Fields]) OR 'rebound hypoglycaemia'[All Fields] OR 'diabetic emergency'[All Fields] OR 'oral agents'[All Fields] OR 'oral hypoglycaemic agent\$'[All Fields] OR ('hypoglycaemia'[All Fields] OR 'hypoglycemia'[All Fields] OR 'hypoglyc\$'[All Fields]) OR 'glucose'[All Fields] OR 'dextrose'[All Fields] OR 'glucagon'[All Fields]) AND ('prehospital'[All Fields] OR 'prehospital'[All Fields] OR 'ambulance'[All Fields] OR 'paramedic'[All Fields] OR ('therapy'[Subheading] OR 'therapy'[All Fields] OR 'treat'[All Fields]) AND refer[All Fields]) OR 'see and treat'[All Fields])

(ii) Electronic searching of The Cochrane Library and clinicaltrials.gov using adaptations of above search terms.

(iii) Hand searching of clinical text books and key journals:

- a) BNF pharmacology 2006.
- b) Emergency Medicine Journal (Jan 2000 – March 2007).
- c) Joint Royal College Ambulance Liaison Committee National Clinical Guidelines(JRCALC) (2006).

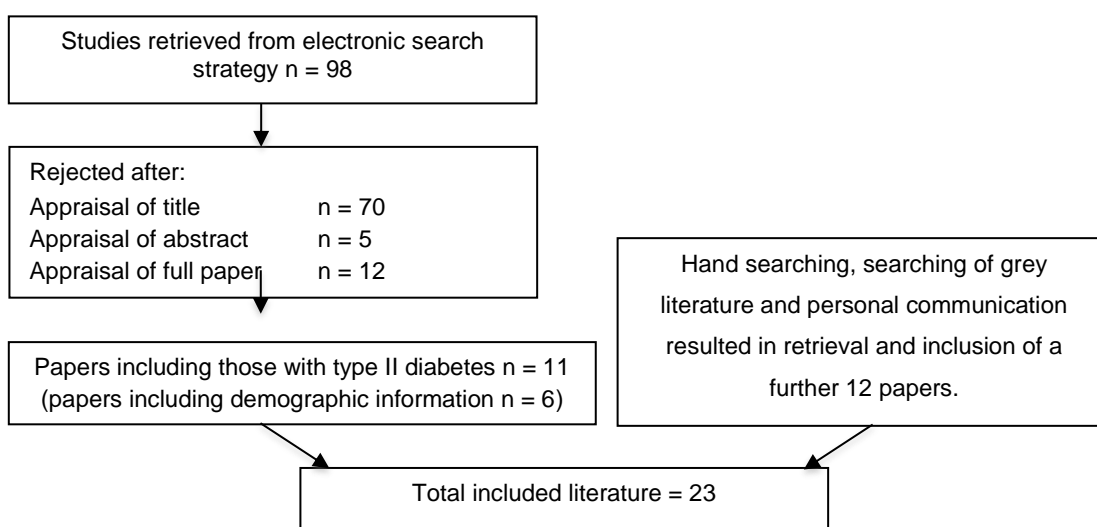
- (iv) Grey literature (unpublished material):-
 - a) 'Pathfinder' course material.
- (v) Personal communication with other ambulance services and Diabetologists.

3.5 Study selection

Peer reviewed papers, letters and unpublished documents were all included in the review. To address the first aim, all retrieved material that presented demographic information from ambulance call-outs based on all diabetes related or hypoglycaemic related calls were included. To address the second aim retrieved material was excluded if it did not include patients with Type II diabetes treated with OHA's, the topic was not of direct relevance, or the paper was not published in English.

Titles and abstracts were screened for inclusion (see Figure 3). All potentially relevant papers and material were retrieved and the full documents were then read by two researchers independently (the author and one supervisor) to check that each met the inclusion criteria (Levac, Colquhoun and O'Brien, 2010). Each paper was then categorised according to publication source and research method.

Figure 3: Flow chart of included literature



3.6 Charting the data

Twenty-three studies were retrieved. One control trial was included in this review with many other studies being of retrospective or prospective design. None of the cohort studies included control groups. A descriptive summary of the included paper's sources and research design was developed and a narrative synthesis of key themes from these papers is provided. Table 7 provides a summary of the papers including demographic information. Table 8 outlines the sources of literature and types of study design of the included papers.

Eighteen papers were retrieved from peer reviewed journals, one internet site and four publications from other sources were also included. Eight of the included papers were cohort studies (Socransky *et al*, 1998; Carter *et al*, 2002; Holstein *et al*, 2003; Leese *et al*, 2003; Cain *et al*, 2003; Walker *et al*, 2006; Steinmetz *et al*, 2006; Brackenridge *et al*, 2006). Six papers were literature reviews (Spiller, 1998; Murphy and Colwell, 2000; Harrigan *et al*, 2001; Roberts and Smith, 2003; Lheureux *et al*, 2005; Zammitt and Frier, 2005), one reported a retrospective case note analysis study (Anderson *et al*, 2002), one a descriptive/observational study (Langford *et al*, 2003) and one case study (Bussing and Grende, 2002). Only one controlled trial was found in this area (Mattila *et al*, 2004). Additionally, four guidelines (BASICS Education Scotland, 2004; Scottish Ambulance Service, 2005; Welsh Ambulance Service, 2006; JRCALC, 2006); and one well recognised reference book (BNF, 2007) were included.

Of the included studies from the retrieved literature (n = 18), thirteen included patients who had suffered hypoglycaemic events and were treated with OHA's (Steinmetz *et al*,

2006; Walker *et al*, 2006; Zammitt and Frier, 2005; Mattila *et al*, 2004; Langford *et al*, 2003; Roberts and Smith, 2003; Cain *et al*, 2003; Leese *et al*, 2003; Holstein *et al*, 2003; Bussing and Gande, 2002; Anderson *et al*, 2002; Murphy and Colwell, 2000; Socransky *et al*, 1998). Thirteen emphasised the inherent dangers of these drugs (Zammitt and Frier, 2005; Langford *et al*, 2003; Lheureux *et al*, 2005; Cain *et al*, 2003; Holstein *et al*, 2003; Leese *et al*, 2003; Roberts and Smith, 2003; Bussing and Gende, 2002; Carter *et al*, 2002; Harrigan *et al*, 2001; Murphy and Colwell, 2000; Socransky *et al*, 1998; Spiller *et al*, 1998), and eleven highlighted treatment in, or suggested a treatment only available within the hospital environment (Brackenridge *et al*, 2006; Lheureux *et al*, 2005; Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003; Langford *et al*, 2003; Roberts and Smith, 2003; Bussing and Gende, 2002; Harrigan *et al*, 2001; Murphy and Colwell, 2000; Spiller, 1998). Care was taken to ensure no double counting of individual studies occurred.

Table 7: Demographic data from included studies

Author (year)	Study Type/Duration	Geographical location	Population served (diabetes prev.%)	% of diabetes related emergency calls	% emergency calls relating to hypoglycaemia	Transportation rates	% Male	Average age
Sockransky 1998	Retrospective case note analysis (7 months)	Milwaukee USA	1.4 million	n/a	5.2% (n = 583 calls from 374 patients)	27.8% (n = 159)	52.7% (n= 197)	52.7 (mean)
Leese et al (2003)	Retrospective observational study (12 months)	Fife (Scotland, UK)	365,051 (4.4)	n/a	0.57% (n=223)	n/a	55.6%	53.8 (mean)
Cain et al (2003)	Prospective observational study (10 months)	Nova Scotia (Canada)	340,000 (8.9)	2.9% (n = 499)	1.3% (n=220) Only included > 15 years of age.	66% (n=145) not transported to ED	n/a	42 (mean)
Holstein et al (2003)	Prospective population based study (3 years)	Germany	18,000 (5.77%)	3.1%	2.73% (n=213)	25% (n=15) of Type I not transported to ED	48% (n=101)	n/a
Mattila (2004)	Prospective observational study (11 months)	Helsinki (Finland)	560,000 (8.3)	4.0%	4.0% (n=1333) ' <i>most</i> ' diabetes related emergencies were for hypoglycaemia	61% (n=812) not transported to ED	n/a	n/a
Brackenridge et al (2006)	Retrospective audit (12 months)	Surrey (England, UK)	1.1 million (5.8)	1.3% (n=1600)	0.6% (n=907) Estimated figures from 1 month period.	73% (n=883) not transported to ED	55% (n=52) from 1 month period	52.6 (mean)

Table 8: Summary of papers including patients with Type II diabetes and OHA's

Author, year and country	Patient Group/Study size	Study Design	Core findings and outcomes	Limitations/Weaknesses
Mattila <i>et al</i> , 2004, Finland	Investigation of the clinical epidemiology of severe out-of-hospital hypoglycaemia. 11 months (Feb-Dec 2001) 69 participants.	Control Trial	90% (n=62) of patients were left at scene. 55% (n=22) of questionnaire respondents suffered a RHE within 3 month follow-up period, none within 24 hours. The practice of leaving selected patients at scene after assessment and treatment was found to be effective, safe and economical. All Type II diabetics prescribed OHA's were transported to hospital.	Only 8.5% (n=69) of patients left at home were included in this study. Short study duration. Only Type I diabetics were left at home. Time between emergency contact and research contact was 3 months.
Steinmetz <i>et al</i> , 2006, Denmark	Assessment of patients preferences to locality of treatment i.e. hospital or home. 139 participants.	Prospective Cohort Study	6% (n=8) patients treated and discharged at the scene were admitted to hospital within 48 hours. Involvement of OHA's is unknown.	This intervention was limited to physicians. Did not provide sufficient detail to determine the cause of admission for the eight patients who were admitted within the 48 hour period. Limited information on study methods.
Walker <i>et al</i> , 2006, UK	Evaluation of ambulance crew referral pathway to a Diabetic Specialist Nurse. 3 months (Dec 2002 - March 2003) 38 participants.	Prospective Cohort Study	53% (n=20) of referred patients had medication altered, 37% (n=14) required ongoing review. From participants who returned questionnaire 73% (n=19) felt more able to treat a hypoglycaemic episode in the future. Recommends specialist pathways to Diabetic Specialists Nurse for patients who have suffered a hypoglycaemic event. Highlights the need for medication alteration and expert advice for patients.	Small sample size. Required shorter follow-up period i.e. <7 days required to ensure safety for patients.

<p>Brackenridge <i>et al</i> 2006, UK</p>	<p>Exploration of the use of emergency services by people with diabetes.</p> <p>12 month audit (Oct 2000 - Sept 2001)</p> <p>89 participants.</p>	<p>Prospective Cohort Study</p>	<p>Management of hypoglycaemia by the emergency services was varied and not always appropriate.</p> <p>11% (n=10) of sample were admitted to hospital.</p> <p>Many patients who attend A&E were discharged with no follow-up arrangements. Education is required for healthcare professionals. Highlights challenges of identifying people who need to be admitted to hospital.</p> <p>States that patients treated with OHA's should be treated as 'special cases'.</p>	<p>Patients were not followed up adequately to provide detail on, and determine if, a repeat hypoglycaemic event occurred.</p>
<p>Cain <i>et al</i>, 2003, Canada</p>	<p>Determined the outcomes of patient treated and not transported for hypoglycaemia and identified criteria for those who do not require to be transported.</p> <p>10 months (Aug - June, 2001)</p> <p>220 participants.</p>	<p>Prospective Cohort Study</p>	<p>Repeat hypoglycaemic events are reported to be common, however recurrences within 48 hours are not.</p> <p>From the 220 hypoglycaemic emergencies, 145 patients were left at home 27% (n=40) of whom made a repeat calls within study period; 2% (n=3) of these were within 48 hours.</p> <p>From the 75 patients transported to hospital 22.7% (n=17) reported a RHE, with 4% (n=3) occurring within a 48 hour period.</p> <p>Given the high incidence of repeat hypoglycaemic episodes paramedics and physicians need to emphasise the importance of follow-up.</p>	<p>Unable to determine OHA involvement in recurrence of hypoglycaemia.</p>

<p>Holstein <i>et al</i>, 2003, Germany</p>	<p>Obtained reliable data on the care of prehospital diabetic emergencies with a view to improving quality of care.</p> <p>3 years (Jan 1997- Dec 2000)</p> <p>213 patients.</p>	<p>Prospective Cohort Study</p>	<p>Training of emergency teams with a specific intervention improved quality of treatment and prognosis outcome for patients.</p> <p>Treatment of severe hypoglycaemia at scene was deemed safe in the Type I diabetic who had previously received structured patient education.</p> <p>Mortality rates for sulfonylurea induced hypoglycaemia dropped from 4.9% (n=2) to 0%</p>	<p>This intervention was limited to physicians.</p> <p>Limited number of Sulfonylurea induced hypoglycaemia, much larger trials including comorbidity, type of oral hypoglycaemic agent and dose would be required to substantiate the results of this study.</p>
<p>Leese <i>et al</i>, 2003, UK</p>	<p>Determined the incidence, predisposing factors, and costs of emergency treatment of severe hypoglycaemia in people with Type I and Type II diabetes.</p> <p>12 month period (June 1997- June 1998).</p> <p>160 patients.</p>	<p>Retrospective Cohort Study</p>	<p>Hypoglycaemia requiring emergency assistance is as common in patients with Type II diabetes as those in insulin dependent type I diabetes.</p>	<p>Episodes of hypoglycaemia that were treated in environments other than ambulance, primary care and hospitals were not recorded, this may have resulted in an underestimation of all severe hypoglycaemic events.</p>
<p>Carter <i>et al</i>, 2002, Canada</p>	<p>Determined if patients who had received prehospital i.v. dextrose seek additional medical care within a 72 hours period post-hypoglycaemic event.</p> <p>12 months (April 1999 to March 2000)</p> <p>100 patients.</p>	<p>Retrospective Cohort Study</p>	<p>68% refused transportation.</p> <p>The practice of treating patients with symptomatic hypoglycaemia and leaving them at scene appears to be safe. Further study required to confirm this.</p>	<p>Hawthorne effect: As paramedics were aware that this study was taking place the potential for such an effect cannot be excluded.</p>
<p>Socransky <i>et al</i>, 1998, USA</p>	<p>Aimed to identify RHE's in diabetic patients and compare outcomes of those who refused with those who were transported to hospital.</p> <p>7 months (Jan – July 1995)</p> <p>374 participants (made 571 emergency calls).</p>	<p>Prospective Cohort Study</p>	<p>Out-of-hospital treatment of hypoglycaemic diabetic patients appears to be effective and efficient independent of whether they were transported or not.</p> <p>Relapse rates did not differ significantly between the refusers and the transported patients.</p> <p>None of the 32 patients who suffered a relapse did so within the subsequent 48 hours.</p>	<p>Did not consider clinic visits as an indicator of relapse which may result in an underestimation of relapses.</p>

Langford <i>et al</i> , 2003, UK	Case report describing repeat hypoglycaemic events in a 62 year old female with impaired renal function, who is treated with Gliclazide.	Case report	Demonstrates the effects impaired renal function has on plasma insulin concentrations in a patient who is treated with OHA's. The patient suffered repeat hypoglycaemic events.	Single case.
Bussing & Grende, 2002, USA	Two case reports highlighting the interaction between clarithromycin and sulfonylurea's resulting in hypoglycaemia.	Case Report	Both patients received an initial bolus of iv glucose. The patient who did not receive a continuous glucose infusion suffered a repeat hypoglycaemic event.	Only two cases.
Anderson <i>et al</i> , 2002, Denmark	Aimed to validate the appropriateness of leaving the patient with prehospital hypoglycaemia after being safely treated at home in a physician based EMS system. 4 years (1995-1998) 1148 hypoglycaemic patients treated by a Mobile Intensive Care Unit were used. Possible predictors of transportation were identified.	Retrospective case note analysis	964 patients were released at home. RHE events between 0 and 72 hours post treatment were identified. 5% (n=46) of those treated and released at home experienced a RHE within the 72 hour period, 75% (n=31) occurring within 48 hours post treatment.	Generalisability i.e. physician based service.
Zammit & Frier, 2005, UK	Aimed to identify the frequency and pathophysiology of hypoglycaemia in Type II diabetes. Search via PubMed 1984-2005.	Systematic literature review	Results suggest that insufficient and misleading information may have contributed to the perception that hypoglycaemia is considered to be a mild and infrequent side effect of treatment in Type II diabetes. Identifies sulfonylurea-induced hypoglycaemia as a significant problem.	Variations in design, heterogeneity of study populations and varying classifications of hypoglycaemia. Looking at the elderly Type II diabetic patients suffering from hypoglycaemic events confounded attempts in this review to determine frequency of hypoglycaemia in Type II diabetes.
Roberts & Smith, 2003, UK	Identified outcomes for patients who were treated for hypoglycaemia out of hospital and included a set of recommendations for the safe follow-up of patients. Search strategy was defined using MeSH terms and conducted via Medline.	Systematic literature review	Advised transportation to hospital of all post-hypoglycaemic patients treated with OHA's - no rationale was provided.	Search terms do not include hypoglycaemia or other condition specific terms. Limited retrieval of papers.

Spiller, 1998, USA	Review on antidiabetic medications in overdose (deliberate and accidental).	Systematic literature review	Overdose with antidiabetic drugs produce major morbidity, require intensive care medicine and prolonged hospital stays. Monitored for at least 24 hours. When overdose does occur prompt recognition results in an improvement in successful outcome.	No search strategy defined, difficulty in reproducing review.
Harrigan <i>et al</i> , 2001, USA	Review of oral antidiabetic agents describing the treatment of Type II diabetes describing the pharmacology, toxicity and treatment.	Review	Pharmacology of OHA described, adverse effects i.e. hypoglycaemia, drug interactions, and toxicities. Patients with hypoglycaemia in the setting of therapeutic error, impaired renal function etc should be admitted for observation.	Search strategy is not defined, difficulty in reproducing review.
Murphy & Colwell , 2000, USA	An educational review which details the pathophysiology of the condition as well as treatments and emergencies relating to the condition.	Review	Describes the prehospital treatment for diabetic related emergencies. Prolonged hypoglycaemia in patients treated with OHA's is highlighted. Patients on OHA are at risk of prolonged hypoglycaemia.	Search strategy is not defined, difficulty in reproducing review. Some of the treatments are either specific to region or dated.
Lheureux <i>et al</i> , 2005, Belgium	Focused on the antidotal treatment of sulfonylurea-induced hypoglycaemia with octreotide.	Review	Hypoglycaemia is a major potential adverse effect of sulfonylurea agents. Causes and treatments are described, specifically the use of octreotide. Clearly describes pharmacological actions of sulfonylurea's.	Limited number of studies on the use of octreotide in sulfonylurea-induced hypoglycaemia. Search strategy not defined.
BASICS Pathfinder Guidelines, 2004, UK	n/a	Guideline	Advises transportation of all post-hypoglycaemic diabetic patients treated with OHA's to hospital.	n/a
Welsh Ambulance Service T&R Guidelines, 2006, Wales	n/a	Guideline	Advises transportation to hospital for patients treated with OHA's who have experienced a hypoglycaemic event.	n/a

Joint Royal College Ambulance Liaison Committee, 2006, UK	n/a	Guideline	Advises that all patients treated with OHA's who have experienced a hypoglycaemic event should be transported to hospital.	n/a
Scottish Ambulance Service Treat and Refer Guideline, 2004, Scotland	n/a	Guideline	Does not specifically advise transportation to hospital for patients treated with OHA's who have experienced a hypoglycaemic event.	n/a
BNF online, 2006, UK	n/a	n/a	The BNF provides specific detail on sulphonylurea induced hypoglycaemia and highlights the prolonged effects and the need for treatment in hospital.	n/a

3.7 Descriptive summary of results

3.7.1 Patient Demographics

Many of the retrieved studies reported demographic information on patients requiring emergency ambulance assistance for hypoglycaemia. However only six studies included data pertaining to all hypoglycaemia related calls received (Brackenridge *et al*, 2006; Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003; Leese *et al*, 2003; Sockransky *et al*, 1998). The remaining studies published data only related to their respective cohorts. Therefore to ensure accuracy only those studies reporting all hypoglycaemia related calls were included (n = 6).

The percentage of diabetes related emergency calls received by ambulance services varied between 1.3% and 5.2% of all calls (Brackenridge *et al*, 2006; Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003; Anderson *et al*, 2002; Sockransky *et al*, 1998) and those related to hypoglycaemia, between 0.57% to 5.2% (Brackenridge *et al*, 2006; Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003; Leese *et al*, 2003; Sockransky *et al*, 1998). Studies from outwith the UK reported higher percentages of hypoglycaemia related emergency calls i.e. 2.9% to 5.2% (Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003; Sockransky *et al*, 1998).

Four studies provided detail on gender (Brackenridge *et al*, 2006; Holstein *et al*, 2003; Leese *et al*, 2003; Sockransky *et al*, 1998). Although three studies reported a slightly higher percentage of males requiring emergency assistance (52.7% to 55%) (Brackenridge *et al*, 2006; Leese *et al*, 2003; Sockransky *et al*, 1998), one study found slightly less males (48%) required emergency assistance than females (Holstein *et al*, 2003). However, these differences were slight. In the three studies providing information on patients' age, the average age ranged between 42 to 54 years

(Brackenridge *et al*, 2006; Cain *et al*, 2003; Leese *et al*, 2003). Transportation rates differed greatly with 25%-73% of patients remaining at home after ambulance intervention. Anglo-American ambulance models had higher non-transportation rates than the Franco-German models.¹

3.7.2 Incidence of OHA induced hypoglycaemia

Of the included studies, which followed up patients between 6 months and 3 years, the incidence of OHA induced hypoglycaemia (in Type II diabetes) was predominantly reported as being between 0.8% and 12% (Walker *et al*, 2006; Lheureux *et al*, 2005; Leese *et al*, 2003; Socransky *et al*, 1998). However, one study reported an incidence of 23% over a 3 year period (Holstein *et al*, 2003).

3.7.3 Consequences and causes of OHA induced hypoglycaemia

The potential for hypoglycaemia was highlighted as the most significant complication associated with OHA use (BNF, 2007; Zammitt and Frier, 2005; Harrigan *et al*, 2001). The primary threat to any hypoglycaemic patient is reduced levels of consciousness. This may lead to airway compromise, seizure, cerebral oedema (potentially resulting in permanent neurological deficit) and in rare cases, death (Zammitt and Frier, 2005; Harrigan *et al*, 2001). Other complications, such as prolonged hypoglycaemia or RHE, are a consequence of the long acting nature of some OHA, particularly the sulphonylurea group (Zammitt and Frier, 2005; Holstein *et al*, 2003; Langford *et al*, 2003; Harrigan *et al*, 2001). Cases have been described where hypoglycaemic patients prescribed OHA have been treated appropriately with intravenous glucose only to experience RHE hours or even days after the initial event (Cain *et al*, 2003; Langford *et al*, 2003).

¹ A description of the Anglo-American and Franco-German models of care can be found in chapter 1, section 1.6.

Two reviews describe the general factors associated with hypoglycaemia in patients treated with OHA (Harrigan *et al*, 2001; Murphy and Colwell, 2000). These include the elderly, history of vascular disease, renal failure, reduced food intake, alcohol consumption and drug interactions. Specific examples of these factors in the included papers include medication interactions (Bussing and Gende, 2002; Harrigan *et al*, 2001), quiescent renal or hepatic disease (Langford *et al*, 2003) and accidental or deliberate ingestion (Harrigan *et al*, 2001; Spiller *et al*, 1998). Many of these arise from the clinician's failure to consider the contribution of these factors to either an initial or RHE and illustrate how overlooking these unnecessarily exposes the patient to the dangers associated with hypoglycaemia.

3.7.4 Repeat calls for hypoglycaemic events

Five of the papers included in the review directly discussed repeat emergency calls for hypoglycaemic events (Steinmetz *et al*, 2006; Cain *et al*, 2003; Anderson *et al*, 2002; Carter *et al*, 2002; Socransky *et al*, 1998). These papers were examined to identify rates of RHE and whether OHA were viewed as a contributory factor. There was no standard definition of the term 'recurrence' in the literature. Reported recurrence times ranged between 24 and 120 hours with the incidence of RHE within a 48 hour period varying between 2% and 7% (Steinmetz *et al*, 2006; Cain *et al*, 2003; Anderson *et al*, 2002; Carter *et al*, 2002; Socransky *et al*, 1998). No studies were detailed enough to determine how many of these RHE were directly related to OHA.

3.7.5 Transport to hospital

Roberts and Smith (2003) identified post-hypoglycaemic patients treated with OHA as high risk and recommended that they be transported to hospital; no rationale was provided. Brackenridge *et al* emphasise that patients on OHA are "*special cases*" and suggests the "*threshold for admission*" be low (Brackenridge *et al*, 2006, pg. 185) while Socransky *et al* (1998) state that patients taking OHA who have suffered a

hypoglycaemic event should be convinced to travel to hospital. The British National Formulary (BNF) (2007) recommends that such patients should always be treated in hospital. A recent review supports this stance and recommends that patients are observed for at least 24 hours (Spiller, 1998); whilst less conservatively, Harrigan *et al* (2001) suggest a minimal observation time of 8 hours. The length of time patients should be observed, therefore, remains unclear.

The reviews by Murphy and Colwell (2000) and Harrigan *et al* (2001) reveal the dangers of hypoglycaemia caused by OHA and highlight treatments such as continuous glucose infusions and constant blood glucose monitoring. A strong case for such treatments and transportation of patients with OHA induced hypoglycaemia is demonstrated in the study by Holstein *et al* (2003) where they specifically targeted sulphonylurea induced hypoglycaemic patients with a treatment protocol. This consisted of mandatory additional glucose infusions and hospital admission for further treatment and observation. The study's pre-intervention statistics on mortality rates associated with all sulphonylurea induced hypoglycaemia were 4.9%, and 1.7% for all other causes. Post intervention, mortality rates from severe hypoglycaemia caused by sulphonylureas were reduced to 0%.

3.8 Discussion

This scoping review has retrieved and analysed 23 documents in an attempt to answer the aims set out in section 3.2.2. The patient demographics of this population have been explored and detailed analysis undertaken to establish if post-hypoglycaemic patients, who are prescribed OHA, experience RHE after being treated in the prehospital environment and whether such patients should be transported to hospital regardless of treatment response.

Reporting on demographic characteristics it was found that 0.57% to 5.2% of all calls to ambulance services were for patients experiencing a hypoglycaemic emergency (Brackenridge *et al*, 2006; Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003; Leese *et al*, 2003; Sockransky *et al*, 1998). Although the frequency of calls varied between studies it was clear that ambulance clinicians come into contact with this patient group relatively often. Where data on gender was available, with the exception of one study (Holstein *et al*, 2003), it was found that more males required emergency care than females. There are likely to be numerous possible explanations for this finding but none were explored within the literature and so this element may warrant further exploration. However, one reasonable explanation may simply be the higher prevalence of diabetes in the male population (American Diabetes Association, 2013; Diabetes UK, 2012a; Canadian Diabetes Association, 2011; Heidemann *et al*, 2009; Niemi and Winell, 2006). People who required emergency ambulance care for hypoglycaemic events tended to be older (mean age reported between 42-54 years). Although it should be noted that the study by Socransky *et al* (1998) only included those over 18 years of age, this does not appear to have influenced these results as other studies have published similar results.

Earlier work suggested that non-transportation rates varied between 34% and 69% of all hypoglycaemia related emergency calls (Socransky *et al* 1998). In light of this new review these figures should be revised and broadened to between 25%-73%. Ambulance service models that focus on bringing physicians to the patient (the Franco-German Model), appear to have lower non-transportation rates than models such as the UK approach which are crewed chiefly by ambulance clinicians (paramedics and Emergency Medical Technicians). Such findings would benefit from further investigation to determine why this may be the case.

3.8.1 Hypoglycaemia associated with OHA use

Although a relatively rare occurrence, diabetic patients treated with OHA can and do experience hypoglycaemic episodes. This review clearly the possible dangers of RHE when leaving post-hypoglycaemic patients treated with OHA at home (BNF, 2007; Brackenridge *et al*, 2006; Langford *et al*, 2003; Roberts and Smith, 2003; Bussing and Gende, 2002; Harrigan *et al*, 2001). A decision not to transport these patients may result in repeat hypoglycaemia leading to seizure, cerebral oedema, permanent neurological deficit and rarely death (Harrigan *et al*, 2001; Spiller, 1998).

3.8.2 Repeat calls and OHA

It cannot be determined from the five papers documenting repeat call-outs if OHA were directly involved (Steinmetz *et al*, 2006; Cain *et al*, 2003; Anderson *et al*, 2002; Carter *et al*, 2002; Socransky *et al*, 1998). However, it is evident that unrecognised associated factors, such as those outlined in the study by Harrigan *et al* (2001), and failure to treat accordingly may lead to patients being vulnerable to repeat or recurrent hypoglycaemic events. Repeat calls also directly impact on ambulance resources reducing ambulance availability and consequently affecting response times. On the basis of the limited available evidence, the safest action to be taken by ambulance clinicians attending a post-hypoglycaemic diabetic patient treated with OHA is to transport them to hospital to be admitted for a period of observation, appropriate treatment and follow-up care. Potential benefits of admission may include extended monitoring, continuous glucose infusions, pharmacological interventions, exploration of underlying cause and medication alteration if required. In the UK the standard prehospital treatment for hypoglycaemia includes either i.m. glucagon or the i.v. administration of 10% glucose, in 100ml boluses to a maximum of 300ml (30g) (JRCALC, 2006). Similar guidelines to those used in the study by Holstein *et al* (2003) i.e. continuous infusion of 10% glucose after the initial bolus, could be considered for

UK ambulance clinicians. This may be particularly beneficial in the remote and rural areas, where transportation times can be prolonged and repeat intervention may be required.

Currently, Scottish Ambulance Service guidelines enable clinicians to refer or discharge patients with certain conditions, including hypoglycaemia. However, whilst basic ambulance service education includes recognition of and emergency treatments for patients suffering from hypoglycaemia, there is little specific education on the risks associated with OHA or provision of appropriate care plans. Lack of awareness of the possibility of a RHE may be resulting in patients being left at home inappropriately. Patients treated with OHA who have suffered a hypoglycaemic event requiring treatment from an ambulance clinician should be transported directly to hospital so they can be observed, treated and receive appropriate follow-up care. Ambulance clinicians should be educated to this effect.

Although it is not always necessary to transport the post-hypoglycaemic Type I insulin dependent patient with diabetes, this review has highlighted other issues that require to be addressed with this population. Some T&R guidelines place the responsibility of contacting the G.P. following a hypoglycaemic event on the patient (Scottish Ambulance Service, 2005): ambulance clinicians typically leaving a carbon copy of the T&R form containing details of the event and the patient is asked to pass this onto their GP. This system is ineffective. Patient's attendance for follow-up in primary care (which enables medication alteration and specialist education to be provided) is low (Cain *et al*, 2003); and when patients do make an appointment the time delay between the original referral and attendance can often be several days during which time a relapse may occur (Walker *et al*, 2006). The review demonstrated that 2-7% of patients will experience repeat severe hypoglycaemic within 48 hours of the initial

event. This may suggest that the care provided in the immediate aftermath of a severe hypoglycaemic event is lacking and that current ambulance care for this population is ineffective.

Irrespective of diabetes type efforts should be made to increase these patients attendance to primary or specialist care within as short a time frame as possible. This would enable more patients to receive expert advice, medication review and subsequent follow-up care. Evidence-based interventions to increase post-hypoglycaemic patient attendance in primary care should be developed.

3.9 Quality of papers

As this was a scoping review no formal quality appraisal was undertaken as this is not normally considered part of this process (Grant and Booth, 2009). The small number of studies included in this review reflect the dearth of evidence available on prehospital hypoglycaemia care. The heterogeneity of the studies resulted in a narrative synthesis to describe the results and also precluded meta-analysis. With respect to demographic information, the population characteristics were well described however only two studies had been conducted within the UK. This limited its generalisability with the context of current UK ambulance settings. Despite population data being available to answer the first research question, none of the included studies directly answered the second question around the relationship between OHA and repeat calls. Nevertheless, sufficient data was available to extract relevant information on repeat and recurrent calls, although these could not be linked to patient medication type. Study specific limitations are included in Table 8.

3.10 Limitations

Only English language publications were included in this review. Whilst the literature was comprehensively searched and appraised, little high quality research was retrieved. As stated previously, a narrative synthesis was undertaken due to the heterogeneity of the available studies. Consequently caution is required in interpreting these findings. Demographic data and repeat call data were identified however it was not possible to establish any direct relationship with OHA use.¹

3.11 Conclusion

The scoping review indicates that hypoglycaemia related emergency calls are responsible for between 0.57% and 5.2% of all ambulance service calls world-wide, with non-transportation rates ranging between 25% and 73%. At the time of review no study identified any predictors of non-transportation. This would have been useful with such a high proportion of patients remaining at home after the event. The findings of this study indicate that 2% to 7% of post-hypoglycaemic patients treated in the prehospital environment will experience a RHE within 48 hours. The potential for OHA to cause RHE is referred to in the reviewed literature. However the extent to which this occurs within the context of T&R practice remains unknown. Although scoping reviews are not undertaken specifically to inform clinical practice, it was imperative that the established association between OHA's and repeat events was recognised and considered within the context of prehospital non-transportation practices. Despite the apparent rarity of these occurrences, the absence of evidence suggesting non-transportation is safe for this sub-group has led to the recommendation that

¹ Despite these limitations dissemination of results occurred via various formats. Key stakeholders included the Scottish Government Long-term Conditions Unit, Diabetes UK Scotland and JRCALC Guideline Development Group. The results of the review informed the Diabetes Framework, Scottish Diabetes Round Table event and the 2013 JRCALC National Clinical Guidelines (JRCALC, 2013).

conservative management, through admission to hospital is appropriate. The identification of RHE beyond the 48 hour period was also alarming and suggests that follow-up care may be lacking for some people. These repeat or recurrent events emphasise that appropriate follow-up care of all post-hypoglycaemic patients is required.

The scoping review confirmed the dearth of high quality evidence in the included studies. But the differing models of ambulance care provision are likely to have influenced the results. Only three small UK studies were included in the review (Brackenridge *et al*, 2006; Walker *et al*, 2006; Leese *et al*, 2003), with only one of these undertaken in Scotland (Leese *et al*, 2003). Very little is therefore known about hypoglycaemia emergencies within the UK, and Scotland in particular. To further this programme of research, and to inform future developments on hypoglycaemia care in the Scottish Ambulance Service, it is essential to improve our understanding of this population within a Scottish context (section 1.8.2). This particular population therefore requires more detailed further investigation.

CHAPTER 4: A RETROSPECTIVE CROSS-SECTIONAL OBSERVATIONAL STUDY OF DIABETES RELATED EMERGENCY CALLS

4.1 Introduction

The scoping review identified that demographic information on individuals who require emergency care for severe hypoglycaemic events was lacking. This was particularly the case in Scotland where there had been only one previously published study (Leese *et al*, 2005). The scoping review also identified that a small proportion of individuals experience repeat hypoglycaemic events. However, these data were variable in terms of follow-up duration and quality. The finding that many people were not transported to hospital was of particular interest, but the predictors of non-transportation had not been investigated in any of the included studies.

In order to improve care it is first necessary to acquire a knowledge and understanding of the patient population concerned (Bowling, 2009). Grundy suggests “*The health and health-care needs of a population cannot be measured or met without a knowledge of its size and characteristics*” (Grundy, 2011, pg. 807). Despite the heterogeneity of the included studies, the results of the scoping review did provide an insight into the demographics of the prehospital hypoglycaemic patient population. But, there were limitations. First, only two of the included studies were from the UK (Brackenridge *et al*, 2006; Leese *et al* 2003) with the remaining three from Canada, Germany and Finland respectively (Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003). Second, data on non-transportation were sparse beyond the 48 hour period after an emergency call, little was therefore known about patients’ actions beyond this point.

The geographical differences between studies were important too. The prevalence of diabetes varies between countries (WHO, 2009). This may affect the demographics of the population investigated i.e. those who experience hypoglycaemia and subsequently

require ambulance service support. These differences are presented through the variability in the proportion of diabetes related calls, hypoglycaemia related calls and of patients transported to the ED (Table 7). Additionally, ambulance service provision and ambulance clinician educational backgrounds vary between country; the USA and UK being primarily paramedic/technician led (Anglo-American Model) and European Services tending to be physician led (Franco-German Model) (Al-Shaqsi, 2010) (see section 1.6). These differences may impact on the success of treatment and on non-transportation rates. Such geographical discrepancies and variation in service provision suggest that the use of primary data would be beneficial in order to investigate post-hypoglycaemic care on a more local level (Scotland). This chapter will therefore present a retrospective observational cross-sectional analysis of primary data on prehospital hypoglycaemic emergencies from the Scottish Ambulance Service. The study will be reported in line with the reporting guidelines for cross-sectional studies (STROBE Statement, 2007).

4.2 Aims

To investigate:

1. The patient characteristics of hypoglycaemia related emergency calls.
2. The incidence of repeat hypoglycaemia events.
3. The factors associated with emergency calls that result in individuals being left at home will be predicted.

4.3 Methods

4.3.1 Study Design

This was a retrospective observational cross-sectional study conducted using MPDS[®] call data from a 12 month period (1st June 2006 to 30th May 2007). The objective of

which was to investigate the patient demographics of those individuals who required emergency assistance from the Scottish Ambulance Service for hypoglycaemic events.

4.3.2 Data sources

At the time of study it was known that the SAS responded to approximately 6500 diabetes related emergency calls each year (Robin Lawrenson, personal communication, December 2008). Despite the availability of large quantities of demographic data, the SAS traditionally used these only for clinical benchmarking against defined treatment standards. At the time of study, the SAS held demographic/clinical data in two formats.

1. Paper Patient Report Form (pPRF): contained clinical information about the patient recorded by the ambulance clinician at the point of care (see Appendix 6).
2. Ambulance Control Centre (ACC) emergency call information: electronically recorded information within the MPDS[®] (see section 1.5).

Data recorded on pPRF's were dependant on ambulance clinicians entering clinically focussed data, by hand, on to paper. The recording of information would generally occur during or after assessment and intervention with pPRF's being completed for each patient attended. The pPRF contained sections for recording the MPDS[®] code and demographic information such as name, address, post code and clinical information by way of vital signs such as heart rate respiratory rate etc. Importantly, in the case of hypoglycaemia, blood glucose levels were recorded along with any interventions undertaken such as intravenous glucose, glucagon etc (see section 2.5). This report would be passed on to physicians on arrival at the ED with a carbon copy kept for SAS clinical records.

In contrast, the MPDS[®] used within the ACC, automatically and electronically recorded demographic information as the emergency call was received. MPDS[®] underpins the sequence of interrogation of 999 callers. The system determines the level of severity (acuity) of the presenting complaint and subsequently the appropriate level of ambulance response i.e. whether the call mandates a blue light Advanced Life Support response or not (Cady, 1999; Curka *et al*, 1993).¹ MPDS[®] originated from West Central USA (Utah) where it has been in use since 1981. It supports the dispatch systems of Emergency Medical Services in more than 23 countries worldwide (National Academies of Emergency Dispatch, 2011). The ability of MPDS[®] to improve the recording of key patient information was established in the mid 1990's in a UK ambulance based study (Nicholl *et al*, 1996) and more recently the system has also been shown to help accurately identify cardiac arrest over the phone (Heward *et al*, 2004).

MPDS[®] assists call takers, known as Emergency Medical Dispatchers, to determine the level of ambulance response necessary through a sequence of fixed, standardised questions. The responses to these questions form a pathway through the system concluding with the appropriate dispatch code that determines the level of response. Simplistically, this sophisticated system is a triage tool. The level of response can range from a category A call (Immediately Life Threatening), to category B call (Urgent), or finally a category C call (Routine). Diabetes related emergency calls are categorised under a 'code 13' with affixes pertaining to the level of response required:

- 13D01 – red response unconscious – (blue light response within 8 minutes).
- 13C01 – amber response not alert – (blue light response within 19 minutes).

¹ MPDS[®] also determines the level of response by provider: Advanced Life Support Provider (Paramedic) or Basic Life Support Provider (Technician).

- 13C02 – amber response abnormal behaviour – (blue light response within 19 minutes).
- 13C03 – amber response abnormal breathing – (blue light response within 19 minutes).
- 13A01 – alert behaving normal but requires third party verification – (non-blue light cold response).
- 13001 – alert behaving normal but with third party verification – (possible referral to alternative service).

The system enables the recording of all details of the emergency call, including the patient's perceived clinical condition. Additional clinical and non-clinical information can be recorded by the call-taker and subsequently forwarded to ambulance clinicians as they respond to the emergency. Within the context of the current study this additional information could be used to help determine whether the patient was experiencing a hypoglycaemic emergency. Occasionally this clinical information would include blood glucose levels that had been provided by the patient or carer during the call. Call takers were required to meet the training standards as outlined in the National Academy of Emergency Medical Dispatch quality assured guidelines and were routinely audited by external auditors to ensure compliance (Patrick O'Meara, National Head of Ambulance Control Services, personal communication, January 2011). The system records electronically all information from the emergency call and includes information such as age, gender, date and time of call, reason for call, dispatch code (in this case a diabetes emergency call pertaining to a code 13).

4.3.2.2 Validity and reliability of existing data sources

Anecdotal evidence suggested the quality of information recorded on paper pPRF's was variable and completion rates were poor. These inconsistencies raised concerns

over the accuracy of the pPRF data. Alternatively, the reliability of MPDS[®] in gathering data had previously been demonstrated (Nicholl *et al*, 1996). But, MPDS[®] recorded little clinical information, with the exception of an overall diagnostic code. Despite MPDS[®] guidance that stated a diagnosis of 'diabetes' had high face validity (see Appendix 7) there was no evidence to confirm its accuracy in determining hypoglycaemia.

A number of studies have been conducted to measure the accuracy of MPDS[®] in determining the severity or acuity of the condition that had led to an emergency call (Sporer *et al*, 2007; Hinchey *et al*, 2007; Fieldman *et al*, 2006; Flynn *et al*, 2006; Heward *et al*, 2004; Wilson *et al*, 2002; Bailey *et al*, 2000). Only one study included specific detail on diabetes. This was an observational study by Fieldman *et al* (2006), which included almost 200,000 ambulance calls, and measured the sensitivity (true positives) and specificity (true negatives) of MPDS[®] in determining the acuity of each of the respective conditions/emergency calls. True positives were calls that were correct in establishing the need for an Advanced Life Support (ALS) response (Charlie, Delta or Echo level calls) and true negatives were calls where ALS was correctly not required and where Basic Life-Support (BLS) response sufficed (Bravo and Alpha level calls). The clinical need for ALS or BLS response was determined through a comparison of MPDS[®] codes with the previously validated Canadian Triage and Acuity Scale (CTAS) recorded by ambulance clinicians after assessment but before patient transportation.

Fieldman *et al* (2006) found the best performing protocols for sensitivity (correctly requiring an ALS response) were Breathing Problems (sensitivity 100%; CI 99.9% to 100%; specificity; 0%; 95% CI = 0.0 to 0.2), Cardiac Arrest (sensitivity 99.1%; CI = 90.3% to 94.3%; specificity; 0%; 95% CI = 0 to 0.86) and Stroke (sensitivity 99.6%; 95% CI = 99.2% to 99.8%; specificity; 0.5%: 95% CI 0.1% to 2%). The best performing

protocol for specificity (correctly requiring a BLS response only) were 'psychiatric problems' (sensitivity 5.5%; 95% CI 4.3 to 7%; specificity 98.1%; 95% CI = 97.5% to 98.7), Animal Bite (sensitivity 10%, 95% CI 1.8 to 33.1; specificity 100%; 95% CI = 93.1% to 100%) and eye problems (sensitivity 0%; 95% CI = 0% to 7.4%; specificity 99.0% ; 95% CI 94.0% to 99.9%).

Diabetes related calls made up almost 1% of the total calls (n = 1,813) and the protocols were also found to be reasonably accurate in determining the requirement for an ALS response with a sensitivity of 82.7%; CI = 80.6% – 84.6% and a specificity of 46.1%; 95% CI 41.0% to 51.3%. As previously discussed in chapter 2 (see section 2.4.2) the immediate short-term complications of diabetes most likely to require immediate assistance are caused by extremes in blood glucose levels; hypoglycaemia and hyperglycaemia. The most common endocrine emergency is hypoglycaemia (Carroll *et al*, 2003) and this is often of rapid onset. Other prehospital studies have demonstrated that between 42% to 98% of ambulance calls for diabetes related emergencies were for hypoglycaemia (Brackenridge *et al*, 2006; Mattila *et al*, 2004; Cain *et al*, 2003). Although no study has established the sensitivity or specificity of MPDS[®] in identifying hypoglycaemia related calls, it is reasonable to assume that a significant majority of high acuity diabetes coded calls will be for this particular condition.

Using the existing MPDS[®] data set, it was not possible to determine sensitivity or specificity of MPDS[®] in identifying hypoglycaemia as objective outcome data were not available. Nevertheless, to assess and provide some measure of effectiveness of the call-taker/MPDS[®] data in accurately identifying hypoglycaemia during telephone triage, a random sample of 50 diabetes related emergency calls recorded as 'hypo' were cross-referenced with pPRF data (Robin Lawrenson, Clinical Performance Manager,

personal communication, June 2008). This determined that almost all randomly selected diabetes related calls had blood glucose measurements recorded of less than <4mmols; diagnostic of hypoglycaemia. MPDS[®] data, including recorded information, appeared able to identify hypoglycaemia. However, it is also acknowledged that MPDS[®] systems will miss some patients with diabetes experiencing severe hypoglycaemic events. They may receive an alternative code such as 'unconscious', or perhaps the behavioural changes associated with hypoglycaemia may be misinterpreted as a psychiatric related emergency. Within MPDS[®] it is not possible to identify these patients without cross-referencing with pPRF's. However ease of access and availability of data precluded this from taking place and as such, true sensitivity and specificity could not be measured.

4.3.2.3 Ease of access to data

pPRF's were stored locally, at each of the 5 geographical divisions within Scotland, but were not categorised according to condition. To use these data, identification of diabetes related calls would require a manual search of approximately 300,000 paper PRF's (the total number of calls received from the West of Scotland within the study period). To conduct analysis on these data, all diabetes related emergency calls (n ~ 3500) would then require to be entered into SPSS manually. Conversely, there were clear benefits to the use of data recorded via the MPDS[®]. Firstly, there were large quantities of demographic data electronically recorded and the diabetes specific data could be easily and reliably identified and extracted. Secondly, searching MPDS[®] could be undertaken using call codes and post codes and presents data using Microsoft Excel. This would considerably reduce the time taken to identify patients and ensured its compatibility with SPSS. For reasons of validity and reliability, and ease of access and practicalities of manual data-entry to Excel of such a large volume of data, MPDS[®] data were selected for use in this study.

4.3.3 Setting

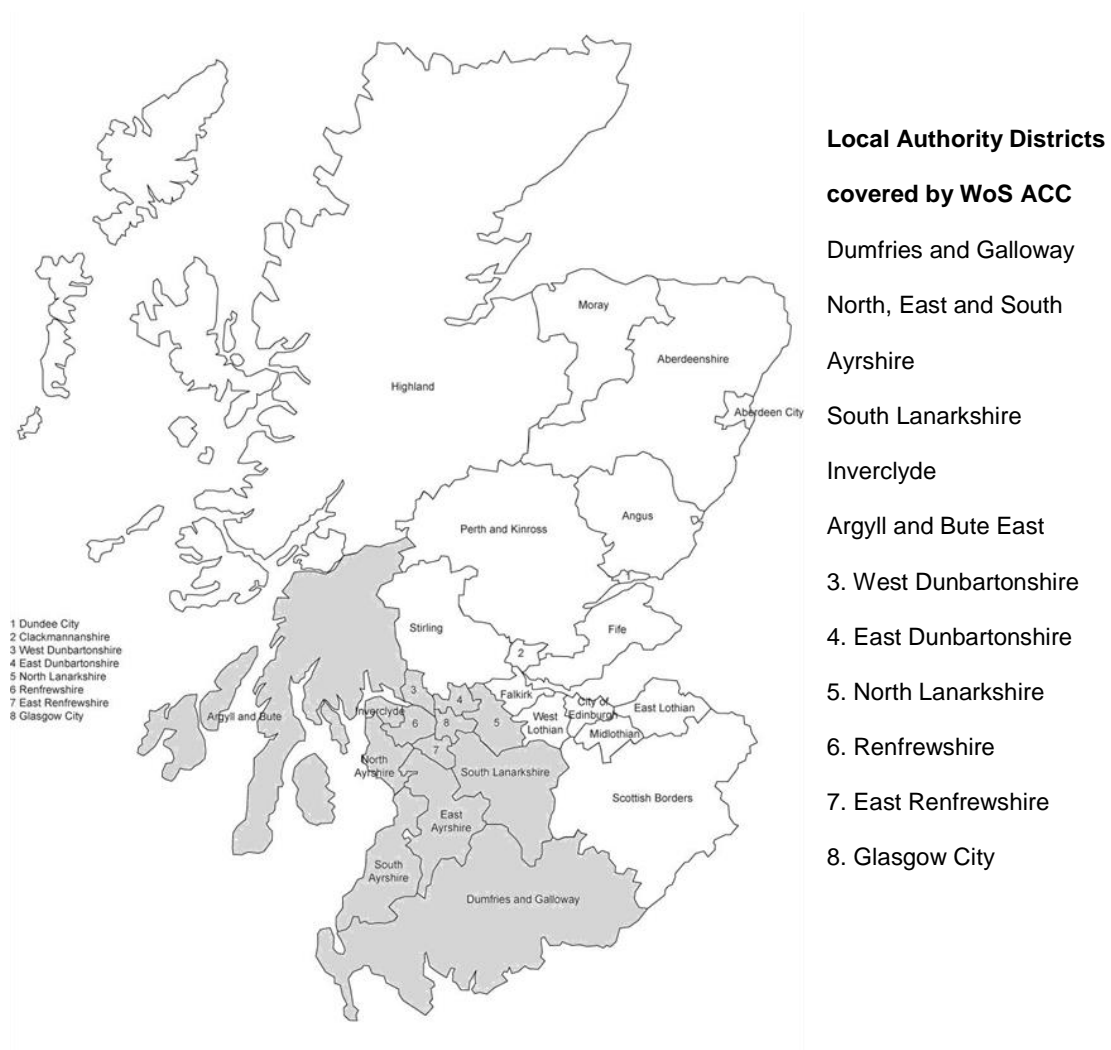
Three Ambulance Control Centres (ACC) receive 999 'emergency' calls in Scotland. These are based in Inverness, Edinburgh and Glasgow. Each ACC holds their own call data; Inverness receives approximately 10% of all calls, Edinburgh approximately 40% and Glasgow approximately 50% (Scottish Ambulance Service, 2009a). Figure 4 (shaded area) provides details on the geographical coverage of WoS ACC.

As it was possible to observe and identify a specific geographical population, the ACC that received the greatest number of calls was selected from which to extract data. This would provide an accurate description of the patient demographics and be less likely to be effected by regional variation. The West of Scotland (WoS) ACC serves over 2.4 million people (Office of National Statistics, 2011) and, at the time of this study, received around 50% of Scotland's emergency ambulance calls (David Hunter, Ambulance Control Centre Duty Manager, personal communication, 2009). It also covers some of the regions of Scotland that contain some of the highest prevalence of diabetes (Scottish Diabetes Survey Monitoring Group, 2007).

4.3.4 Participants

Data were retrieved from all diabetes related emergency calls recorded on the West of Scotland ACC MPDS[®] system in a 12 month period (1st June 2006 to 30th May 2007). All diabetes code 13's were identified with the post code area covered by WoS ACC (Figure 4).

Figure 4: West of Scotland Ambulance Control Centre coverage



4.3.5 Call data

The following variables on call data were extracted from WoS ACC MPDS[®] system:

- MPDS[®] dispatch code: the level or priority of call.
- What's the problem?: additional details recorded by the call-taker during the call.
- Age: recorded as a continuous variable.
- Gender: recorded as a categorical variable.
- Call number: allowed repeat calls to be identified.
- Post code: allowed deprivation category to be calculated.

- Address: allowed repeat call details to be identified.
- Time of call: established the time of call using a 24 hour clock.
- Date of call: provided the day, month and year of call.
- Call stopped reason: the outcome of the patient.

These data were transferred into SPSS v13 for cleaning and analysis.

4.3.5.1 Call categorisation – hypoglycaemia or hyperglycaemia

To identify and subsequently categorise the type of diabetes related emergency call all MPDS[®] clinical and non-clinical information were reviewed. From the ‘What’s the problem?’ variable, calls were categorised as hypoglycaemia related if the following terms were used:

- ‘hypo’.
- ‘diabetic coma’ (presumed rapid onset due to 999 call).
- Blood glucose ‘< 4mmol’.

Patients were categorised as hyperglycaemia if the following terms were used:

- ‘hyper’.
- ‘Ketones’.
- ‘sugar levels high’.

Patients were categorised as ‘other’ if they did not fall within either of the other two categories. Some examples of other call types were as follows:

- ‘passed out’.
- ‘sick and lightheaded’.
- ‘paralysed can’t move’.
- ‘Q diabetic problem’.
- ‘taken turn’.

Although some of the calls included in this final category may have been for hypoglycaemia, the detail included was insufficient to determine this. For this reason they were recorded as 'other'.

4.3.6 Data sources/analysis

The types of data analysis were selected based on the study's aims (see section 4.2). The unit of analysis for aim one was the emergency call i.e. each call was treated as an individual call, replicating the way in which they are treated by the ambulance service. The unit of analysis for aims two and three was the patient i.e. this could represent a number of calls for one patient but would permit the use and identification of repeat calls.

To investigate aim one, summary (descriptive) statistics were presented on age, gender, deprivation category, time of call and immediate outcome. Age was treated as a continuous variable, the remaining variables of interest were treated as categorical variables. Deprivation categories were calculated from postcodes using the Carstairs Score for Scottish postcode Sectors (McCloone, 2004). The Carstairs Score provides "*a method of quantifying levels of relative deprivation or affluence in different localities*" and ranges from DEPCAT 1 (the most affluent postcode sectors) to DEPCAT 7 (the most deprived) (McCloone, 2004, pg.1). The variable deprivation category (DEPCAT) was included for each call identified through the cross-referencing of postcodes with their respective DEPCAT. Deprivation categories were aggregated into three groups: Group 1: Depcat 1 and 2; Group 2: Depcat 3 to 5; and Group3: Depcat 6 and 7. Such grouping has previously been undertaken for analysis on long-term conditions in Scotland (Scottish Health on the Web, 2013). Data from the variable 'time of call' were categorised into one of three time periods corresponding to the traditional 8 hour shift period (07:00-14:59; 15:00-22:59; 23:00-06:59). This time categorisation was

specifically introduced to avoid any double counting between change-over time periods i.e. finishing and beginning at 15:00hrs.

Immediate patient outcome were derived from the call stopped variable. The four possible codes included: transportation to hospital, Treat and Refer, refused transportation and not required. These were aggregated into two key variables: 'Transportation' or 'Non-transportation' for the calculation of differences between age and gender on transportation or non-transportation.

To investigate aim two repeat calls were identified through patient's unique i.d. number. Repeat or recurrent calls were ordered by date and time using SPSS v13 and re-coded as 'call_1', 'call_2', 'call_3' and so on. Repeat call data were presented as frequencies and percentages over the 12 month period.

In aims one and two continuous measures such as age were reported as mean (*M*) and standard deviation (*SD*) and range as appropriate. Categorical variables were reported as frequencies and percentages. Parametric tests were used for normally distributed data and nonparametric tests for data that were not normally distributed. Significant differences were sought using T-tests and Chi-square analysis as appropriate. An alpha level of .05 was used for all statistical tests with the exception of post hoc analysis where bonferoni correction was applied. Missing data are reported within tables.

To investigate aim three, logistic regression modelling was estimated with the outcome variable of being 'non-transportation' or 'transportation'. Statistical support and advice for this analysis was provided by an NMAHP RU statistician (Nadine Dougall, NMAHP Research Unit). For the regression analysis, independent (explanatory) variables

tested were age, gender, deprivation category, number of previous calls, shift time. The coefficients associated with individual predictors were presented with odds ratios (OR) and their 95% confidence intervals.

Logistic regression analysis was conducted to assess the extent to which characteristics of patients or calls predicted their subsequent outcome of being left at home or being transported to hospital. The explanatory (independent) variables tested in the model were age as a continuous variable, gender as a categorical variable ('fem'), deprivation as an ordered categorical variable treated as continuous variable ('depcat'), number of previous calls treated as a continuous variable ('calls'), previous calls yes or no treated as a categorical binary variable ('priorcalls'), shift time as a categorical multinomial variable ('shift', reference category 0 – the night shift [2300-06:59]), and the interaction term of age with shift pattern ('ageshift'). The quadratic term for age ('age2') was added in as an explanatory variable as it improved model fit.

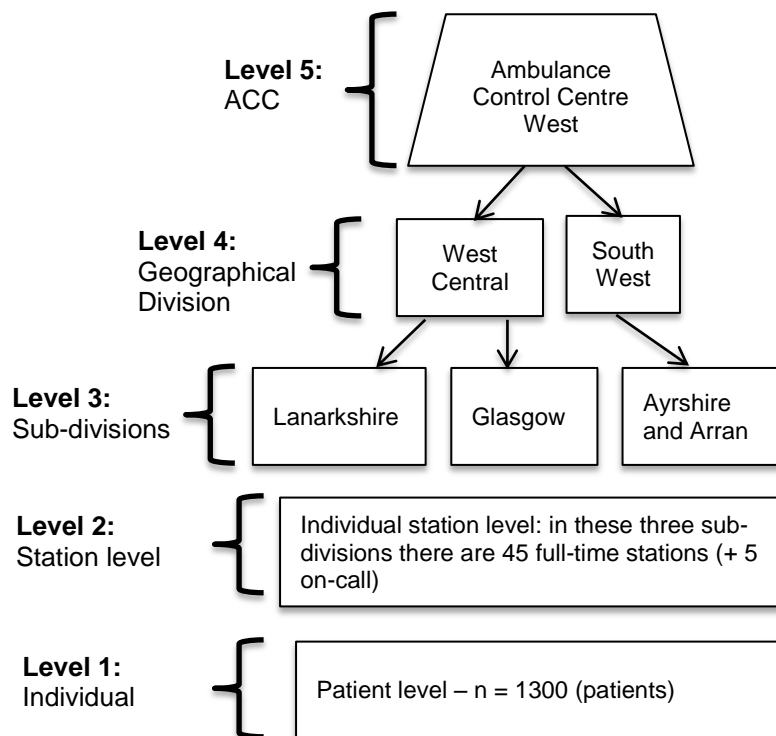
4.3.7 Multilevel modelling

The standard regression analysis model, as described above, has limitations as it makes certain assumptions about the independence of observations which may, if violated, lead to Type I or II error (false positive, false negative results) (Osborne and Waters, 2002). For immediate patient outcome and repeat calls it was recognised that measureable factors, beyond individual patient characteristics, may influence these. Possible influencers may have included, the Ambulance Control Centres, geographical divisions and sub-divisions, and individual stations as well as primary care providers and Health Board areas. The standard regression models fail to consider this hierarchical nature or structure of data, and consequently may result in an overestimation of statistical significance. To investigate the influence on outcome of

these other ambulance and non-ambulance service related factors further, more sophisticated analysis, would be required.

Multilevel analysis has been described as an “*extension to the standard statistical regression techniques*” (Twirsk, 2010, pg. 4). Multilevel modelling determines different levels of aggregation within a data set and is usually conceptualised in a hierarchical manner (Gill and Womack, 2014; Hox, 2010). An example of the multiple levels within the context of the existing SAS data is provided in Figure 5.

Figure 5: Multiple Levels within the Scottish Ambulance Service



Use of multilevel analysis using these data would permit a measure of relationship between individuals nested within the groups at these differing hierarchical levels (see Figure 5) and their immediate outcome. For example, it is possible to determine whether the immediate (dichotomised) outcome of patients treated for hypoglycaemic

emergencies (remain at home or transported to ED) differs in respect to each nested hierarchical level. Such multilevel analysis would permit estimates that would provide a statement about the magnitude of 'higher level' effects of either the ACC, or of a divisional/sub-divisional or station level. It may also improve estimates about the lower level model parameters such as correlation coefficients (the relationship between dependant and independent variables) (Taylor, 1990) and standard errors (measuring the size of error in each model).

Whilst this type of analysis would have been desirable in this study there were a number of reasons why it was not conducted. These will now be discussed within the context of each respective level.

Level 5 to 3 - Ambulance Control Centre, Divisions and Ambulance Stations

To limit operational impact and time demands on operational managers who extracted the data, only one ACC was selected for inclusion. Therefore, the ACC that received the greatest proportion of calls in Scotland (approximately 50%) was chosen (West of Scotland). It offered the largest data set providing results that would be more generalisable, being representative of approximately half of those patients experiencing severe hypoglycaemic events in Scotland. However, the inclusion of data from only one ACC prevented any comparisons between ACCs. Supposing the inclusion of all three ACCs (West, East and North), any effect at this level would still have remained unlikely due to the standardisation of MPDS[®] triage tools. The acuity of each patient's condition, and subsequently the speed/level of response to an emergency call, is determined through the application of the objective MPDS[®] triage tool. This tool is standardised across Scotland and routine training and audit is undertaken to ensure high compliance and concordance rates in its application by ACC staff. Both published and unpublished research has established that both within ACCs (Afolayan *et al*, 2013)

and between ACCs compliance with protocols, and concordance between Scottish Ambulance ACCs, is high (Jayne Scaiffe, Scottish Ambulance Service Head of Professional Standards, personal communication, 2014). Recent SAS data demonstrate overall compliance as 97% across the three ACCs with the final MPDS[®] code, with little variation between centres. This high level of compliance and national standardisation of MPDS[®] across ACCs suggests that it is unlikely that there would be any variation in determined acuity level and therefore speed of response between centres that would influence results. These 'across ACC' similarities also lend support to the prospect of being able to generalise the results.

Other features of these data, at lower divisional and station level, also indicated that multilevel analysis would be inappropriate. More than fifty units are required at each level to ensure non biased results during any multilevel analysis (Mass and Hox, 2004). Within the various hierarchies in the sample there were data from two geographical divisions and three sub-divisions on which to conduct analysis. According to Mass and Hox (2004; 2005), any analysis of such a small number of units (two or three), would introduce significant degrees of bias.

Consideration was also given to the measurement of effect at Health Board level. It is possible that different diabetes services exist within each area and these could influence overall care that may affect frequency of hypoglycaemic events. Health board area could have been calculated via call postcode data. However, again the existence of only three Health Board areas for hierarchical analysis is too small a unit of analysis, considerably less than the 50 required for multilevel analysis (Mass and Hox, 2004). Even if this particular limitation were disregarded, there were additional challenges with these data. Analysis would require an assumption that all patients experience a hypoglycaemic event at their home address or at least within their own

Health Board area. Previous Scottish research has demonstrated that approximately 38% of hypoglycaemic events occur outwith patients' homes (Leckie *et al*, 2005). And there is also a considerable proportion of the population who commute during the day into different geographical areas. For example, 33% (N = 195,471) of people who work in Glasgow come from other local authorities (Office for National Statistics, 2011c). Similar commuter effects occur in other areas of Scotland. These factors demonstrate that assumptions on relationships between ambulance control centre (incident) post code data and an individual's home post code or Health Board area cannot be reliably made.

Level 2 - Ambulance Station

Each hypoglycaemia related call is allocated an immediate ambulance response that has a recorded and traceable base station location (SAS, 2009b). The purpose of measuring dependency on outcome (transportation or non-transportation) at this level would be to determine any clinical practice influence at station level. There are a higher number of units (Ambulance Stations) at this level of analysis (45 full time stations and 5 on-call stations). Therefore, the unit number is almost sufficient for multi-level analysis (Mass and Hox 2004), however whilst this may be the case, there are embedded complex organisational and operational factors that contaminate the data to such an extent as to preclude their use.

The Scottish Ambulance Service is a national service, meaning there are no specific boundaries within which vehicles or ambulance clinicians operate. There is considerable Divisional and NHS board cross-boundary work. A gross measurement of this cross boundary work established that up to 10% of ambulances delivered patients to a hospital ED outwith their 'normal' geographical division (Richard Combe, Information Analyst, personal communication, 2014). Whilst base stations are

identifiable, ambulances and their crew move between stations and over geographical boundaries.

Almost one third of ambulance clinicians employed by the Scottish Ambulance Service are classified as divisional relief (Paul Forbes, Head of Management Accounts, personal communication 16th Sept 2014). These individuals are full time staff but are employed on the basis of the provision of cover for mandatory education and training, annual leave, paternity leave and sickness. Therefore, approximately one third of staff on shift at any one time are not allocated to a specific base station.

During 2006 the ratio of Ambulance to response car was 8:1, with response cars (operated by a single paramedic) targeted only to high acuity category A calls (The Scottish Ambulance Service Board, 2006). A significant proportion of hypoglycaemia related calls are likely to be category A, which means a high proportion of this patient population will receive a dual (two ambulance vehicle) service response. An ambulance response to a single patient can therefore be provided from two separate resources; a car (with a paramedic), or an ambulance (with a paramedic crew or a technician crew). Not only may the responding crew have different skill sets which could influence treatments (see section 2.5), but multiple responses could result in staff from different base stations arriving at the one patient. To complicate matters further, if the paramedic response unit shift is covered on overtime, then a third station level mix may be introduced. This mixing of staff from differing base stations would further contaminate any analysis aimed at identifying any station level effect.

The cumulative uncertainties about the available data relating to geographical cross-over prevent any assumptions from being made regarding a relationship between ambulance stations and patients' post-code. And, multiple ambulance responses,

along with staff variation, (ambulances and staff from different ambulance stations) would likely affect the validity of any analysis on outcome based on station level data. These limitations were discussed in-depth with three statisticians, experienced in multi-level analysis, to determine whether multilevel analysis could be conducted on these data in a way that would produce valid, reliable and therefore meaningful results. It was determined that, whilst multi-level analysis was physically possible using these data, the small number of hierarchical units at levels 3-5 and the likelihood for significant contamination at station level led to the conclusion that any results would be untrustworthy. Multilevel analysis was therefore not conducted.

4.3.8 Governance and ethics

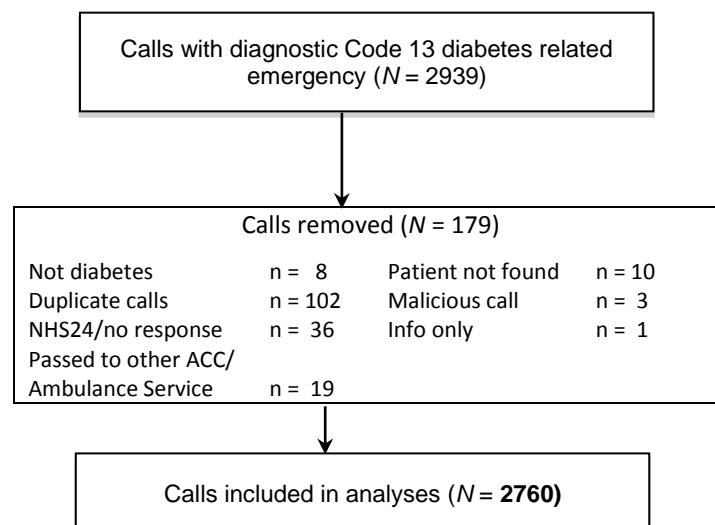
This study was deemed as audit under the Department of Health Research Governance Framework (Department of Health, 2005c). NHS Research Ethics approval was therefore not required. Study approval was granted by the Scottish Ambulance Service. Data were stored and managed in accordance with NHS data protection regulations (Scottish Executive, 2003b). Data were stored on an NHS password protected and encrypted laptop and deleted once data had been anonymised. Only the Clinical Research Paramedic and study supervisor (ED) had access to this.

4.4 Section 2: Results

4.4.1 Total calls

During the 12 month period (June 2006 to May 2007) 2939 calls were received and coded by WoS ACC as a diabetes related emergency (code 13). Stop codes for all calls were reviewed to ensure only diabetes related calls that were both responded to and treated were included. Six percent ($N = 179$) of all calls were removed from the data set¹ (Figure 6). To determine incidence of hypoglycaemia related calls the additional call information from call takers' detailed electronic records ($N = 2760$) were reviewed. Calls were then categorised into 'hypoglycaemia', 'hyperglycaemia' and 'other'.

Figure 6: Number of calls included in analyses



¹ Duplicate calls were marked as such by the call taker. Where not marked they were defined as calls that were made within the first 1 hour after the original call.

4.4.2 Incidence and type of diabetes related emergency call

Significantly more calls were received for hypoglycaemia related emergencies ($N = 1319$) than for hyperglycaemia related emergencies ($N = 75$), $\chi^2(1, N = 1366) = 1110.41, p < .001$ (Table 9). A large number of calls were assigned to code 13 that were neither hypoglycaemia nor hyperglycaemia related ($N = 1366$; 49.5%). It was not possible to determine clear causes for these calls from the call takers notes. Consequently they were classified as 'other' (Table 9). These calls were not explored any further.

Table 9: Type and frequency of diabetes emergency call

Chief complaint	Frequency (%)
Other	1366 (49)
Hypoglycaemia	1319 (48)
Hyperglycaemic	75 (3)
Total	2760 (100)

4.4.3 Patient characteristics for diabetes related calls

4.4.3.1 Age and gender for all diabetes related calls

There was a considerable variation in age among individuals requiring assistance for all diabetes related emergencies (Table 10). Age specific data were recorded as missing in 5% ($N = 139$) of cases. The mean age for all patients was 48 years ($SD = 19.39$). Differences in age by gender for all diabetes related emergency calls determined that females ($M = 50.07$) were significantly older than males ($M = 46.91$), $t(2606) = -4.16, p < .001$. More males ($N = 1548$) than females ($N = 1193$) required emergency assistance $\chi^2(1, N = 2741) = 45.97, p < .001$ (Table 11). Age and Gender data were not recorded in 5% ($N = 139$) and 0.7% ($N = 19$) of calls respectively.

Table 10: Patient age for all diabetes related emergencies

Condition	N (% total)	Age		
		Mean (SD)	Min	Max
Hypoglycaemia	1277 (47.8)	48.01 (18.56)	3	94
Hyperglycaemia	74 (2.7)	39.50 (18.46)	15	74
Non-specific	1270 (49.5)	48.74 (21.13)	2	99

Table 11: Patient gender for all diabetes related emergencies

Gender	N (% total)	Sub-group <i>n</i> and within group percentage		
		Hypo (%)	Hyper (%)	Other (%)
Female	1193 (42.7)	576 (48.3)	43 (3.6)	574 (48.1)
Male	1548 (56.1)	734 (47.4)	31 (2.0)	783 (50.6)

4.4.4 Aim 1: Patient characteristics for hypoglycaemia related calls

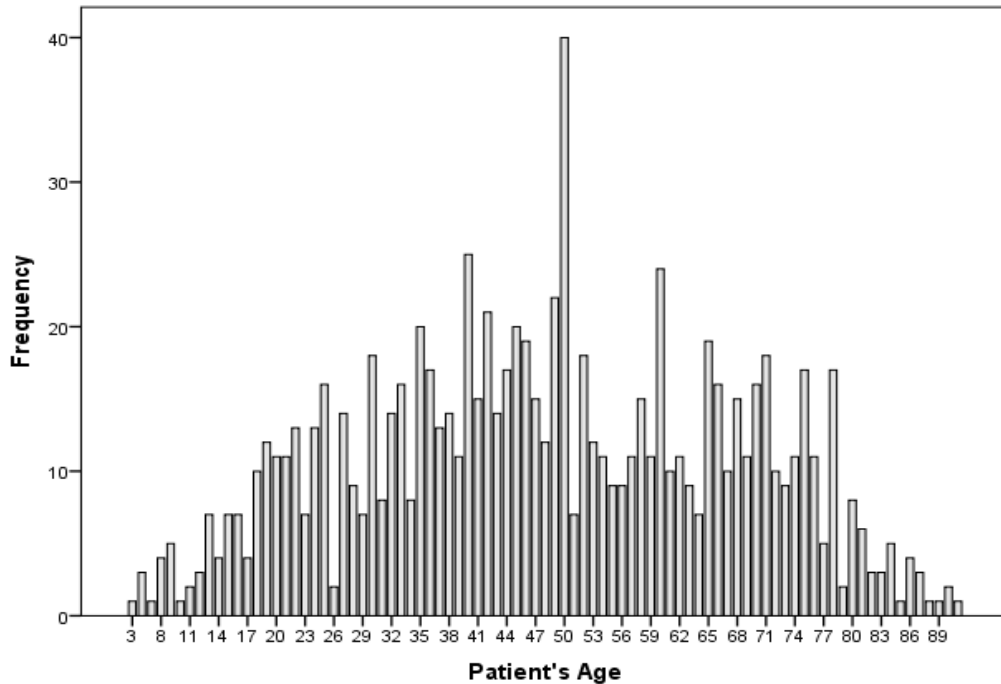
4.4.4.1 Age and gender of hypoglycaemia related emergency calls

The mean age for all hypoglycaemia related calls was 48.01 years (*SD* 18.56) (Table 12). Males requiring emergency assistance were slightly younger ($M = 46.73$, $SD = 18.19$) than females ($M = 49.90$, $SD = 18.67$). This difference was significant, $t(1270) = -3.06$, $p = .002$. Significantly more males ($N = 734$) than females ($N = 576$) required emergency assistance for a hypoglycaemic related emergency call $\chi^2(1, N = 1310) = 19.06$, $p < .001$. The age distribution is presented in Figure 7. Age data was missing in 42 calls and gender data in 9 calls.

Table 12: Age and gender of hypoglycaemia related emergency calls

Gender	N (% total)	Age		
		Mean (SD)	Minimum	Maximum
Male	734 (55.6)	46.73 (18.19)	6	86
Female	576 (43.7)	49.90 (18.67)	6	94
Total	1319 (99.3)	48.01 (18.56)	3	94

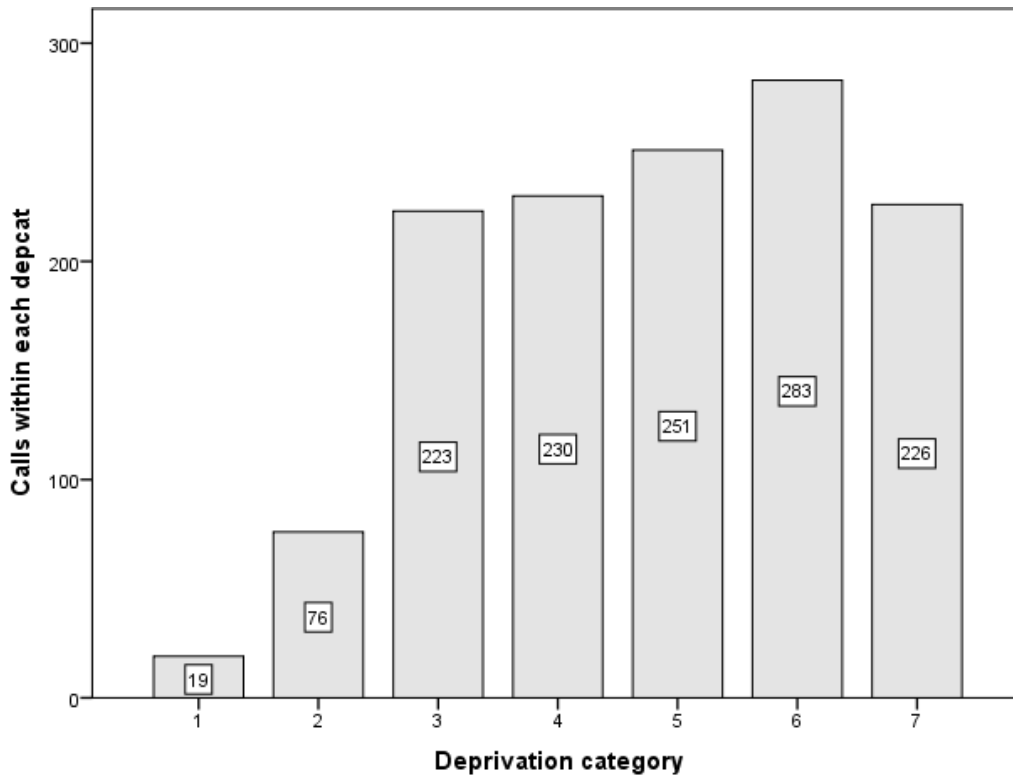
Figure 7: Frequency of hypoglycaemia calls by age



4.4.4.2 Deprivation category of hypoglycaemia related calls

The highest frequency of calls were found in areas with a DEPCAT of 6 and the lowest in areas with a DEPCAT of 1 (Figure 8). Within the aggregated DEPCAT groups (see section 4.3.6) the differences between groups were significant, $\chi^2 (2, N = 1308) = 443.65, p < .001$). To determine where these differences lay, post hoc analysis with bonferroni correction applied was carried out, resulting in a significance level set at $p < .02$. There were statistically significant differences between DEPCAT group 1 and DEPCAT Group 2 ($\chi^2 (1, N = 799) = 464.18, p < .001$), DEPCAT group 1 and DEPCAT Group 3 ($\chi^2 (1, N = 1213) = 302.0, p < .001$), and DEPCAT group 2 and DEPCAT Group 3 ($\chi^2 (1, N = 1213) = 31.34, p < .001$). The frequency of hypoglycaemic related emergency calls were greater in those areas within the DEPCAT group 2.

Figure 8: Frequency of calls by deprivation category using Carstairs Scores



4.4.4.3 Immediate patient outcome (Transported to hospital or Treat and Refer)

Of the 1319 hypoglycaemic patients, 1310 had their immediate outcome recorded; gender was missing in 9 cases. Twenty nine percent ($N = 380$) of patients with hypoglycaemia were transported to hospital, 71% ($N = 916$) remained at home (or at the incident location). These data were aggregated to those who were transported to hospital and those who remain at home. The observed frequencies were significantly different with more people remaining at home post event than were transported to hospital $\chi^2 (1, N = 1310) = 221.67, p < .001$. The breakdown of the immediate outcome can be found in Table 13.

Table 13: Immediate patient outcome (hospital vs. home)

Gender	Total (%)	Transport to hospital (%)	T&R (%)	Refused transport (%)	Not required (%)
Male	734 (100.0)	193 (26.3)	199 (27.1)	226 (30.8)	116 (15.8)
Female	576 (100.0)	182 (31.6)	150 (26.0)	156 (27.1)	88 (15.3)
All	1310 (100.0)	375 (28.0)	349 (26.5)	382 (29.0)	204 (16.5)

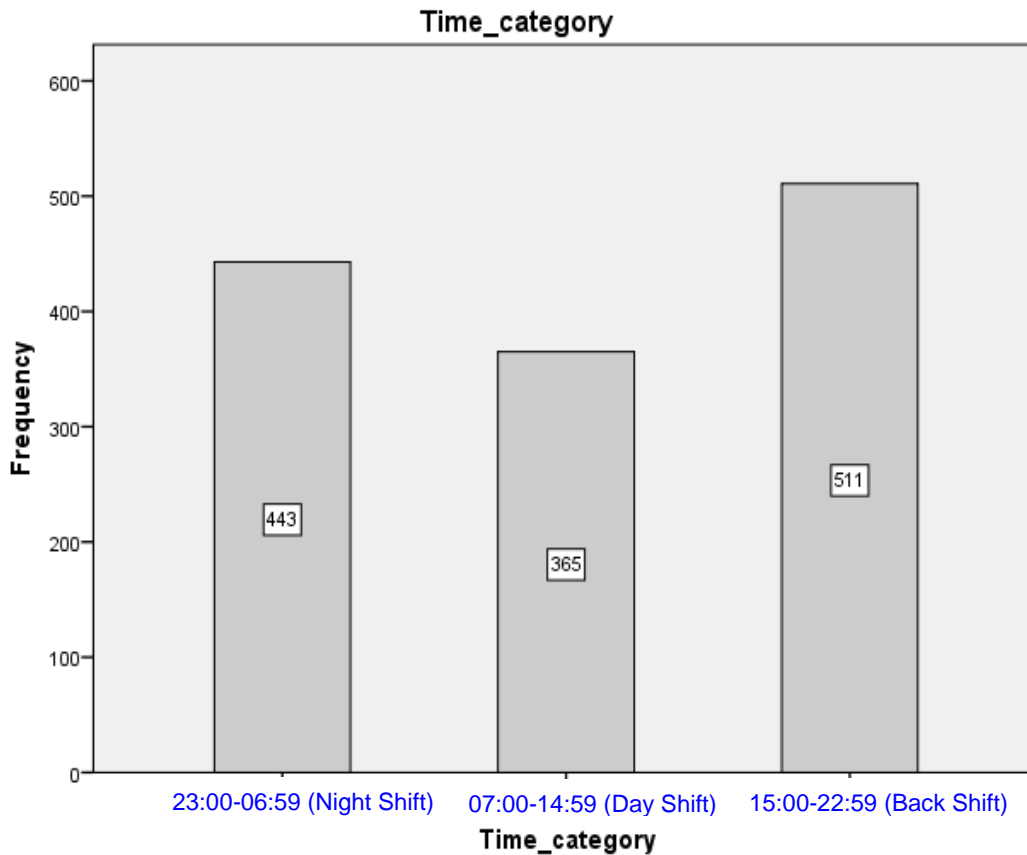
Within group analysis of those transported to hospital determined that there was no difference in mean age between gender $t(366) = -1.12, p = .26$. There was no significant difference in the number of males ($N = 193$) transported to hospital compared to females ($N = 182$), $\chi^2(1, N = 375) = .32, p = .570$. For those who remained at home males were significantly younger ($M = 46.15, SD = 17.37$) than females ($M = 49.47, SD = 17.27$), $t(908) = -2.85, p = .004$. Significantly less females ($N = 394$) remained at home than males ($N = 541$), $\chi^2(1, N = 935) = 23.11, p < .001$.

4.4.4.4 Time of day of Calls

The time of day of emergency calls for hypoglycaemia made during the 12 month period were reviewed. Each call was rounded up or down to the nearest hour. Calls were then categorised into three time periods corresponding to a traditional 8 hour shift period (Figure 9). The observed frequencies were significantly different $\chi^2(2, N = 1319) = 24.27, p < .001$.

Post hoc analysis was conducted to determine where these differences lay with bonferroni correction applied, resulting in a significance level set at $p < .016$. There were statistically significant differences between Night shift and Day shift $\chi^2(1, N = 808) = 7.53, p = .006$, Day shift and Back shift $\chi^2(1, N = 876) = 24.33, p < .001$ but not Back shift and Night shift $\chi^2(1, N = 954) = 4.87, p = .028$. This demonstrates that significantly less calls occur during Day shift hours than during other times.

Figure 9: Frequency of calls within time category



4.4.5 Aim 2: Incidence of repeat hypoglycaemia events

There were a high number of repeat calls in a small proportion of patients. Over the 12 month period the mean number of calls was 1.4 ($SD = 3.12$) (range 1 - 28 calls). Nine hundred and sixty patients accounted for 1319 emergency calls. Table 14 demonstrates the immediate outcomes of those who made only one call and those who made more than one call over the 12 month period. Three hundred and fifty nine (27.2%) of these calls were made by 157 (16.4%) of patients. Overall, 3.1% ($N = 41$) of patients experiencing a severe hypoglycaemic event experienced a repeat hypoglycaemia event within 2 days, 6.7% ($N = 88$) within the first seven days, and 10.6% ($N = 140$) within two weeks.

Differences in age were investigated between those with one call and those with recurrent calls. Participants who made more than one call to the ambulance service

during the twelve month period were slightly younger ($M = 47.51$, $SD = 17.96$) than those who made only one call ($M = 48.74$, $SD = 21.58$) but the difference was not significant, $t(1, N = 920) = 0.91$, $p = .361$. A chi square analysis was conducted to examine difference by gender between those who made more than one call. There was no significant difference in gender between those who made only one call compared to those who made more than one call $\chi^2(1, N = 157) = 0.16$, $p = .690$.

Table 14: Immediate outcome: 1 call vs. > 1 call during the 12 month study period

Call out	Transport to hospital (%)	T&R (%)	Refused transport (%)	Not required (%)	Total (%)	Missing (%)	Total (%)	Gender	
								Male	Female
1 call out	86 (18.8)	135 (29.5)	143 (31.2)	57 (12.4)	421 (91.9)	37 (8.1)	458 (100.0)	244 (53.3)	214 (46.7)
>1 call out	293 (30.5)	198 (20.6)	236 (24.5)	136 (14.1)	863 (89.7)	99 (10.3)	962 (100.0)	551 (57.3)	401 (41.7)

4.4.6 Aim 3: Factors associated with staying at home

Of the included variables 'Deprivation' was not significant in any model, did not improve model fit (parsimony) and was therefore removed. 'Previous calls' was tested as both a continuous 'calls' and categorical variable; the latter was selected in preference because there was a better fit to the model (parsimonious). It also resolved the problem of the skewed distribution of the continuous variable.

Other interaction variables were tested: age and gender; age and prior calls; age and calls; shift and prior calls; shift and calls; however, none of these additional interaction terms improved the model parsimony and were therefore left out. NB age*gender*shift was also tested in preference to age*shift, and although significant resulted in a poorer model fit.

An odds ratio of 1 means an event (predictor variable) is equally likely to occur in both groups (remaining at home or going to hospital); an OR > 1 means that the event is more likely to occur in the group remaining at home; an OR < 1 indicates the event is less likely to occur in the home group.

For n = 913 events (calls made to Scottish Ambulance Service), the model significantly predicted that people who were left at home were: less likely to be female callers (OR = 0.7); to be slightly older age overall (OR = 1.1); and to have made at least one previous call to SAS during the data collection period (OR = 2.4). Therefore, the variable with the most substantial impact on whether people remained at home was whether callers had made prior calls to SAS – OR 2.4 (95%CI 1.5 to 3.7) (Table 15).

Table 15: Logistic regression analysis: predictors of remaining at home

Logistic regression				Number of obs	LR =	960.00
				chi2(7)	=	68.99
Log likelihood = -545.71				Prob > chi2	=	0.00
				Pseudo R2	=	0.06
home	Odds Ratio	Std. Err.	z	P> z	[95% Conf. Interval]	
Fem	.74	.11	-2.07	0.04	.55	.98
age	1.08	.02	4.40	0.00	1.04	1.12
age2	1.00	.00	-4.14	0.00	.99	1.00
shift						
0700-1500	.80	.23	-0.77	0.4	.46	1.40
1500-2300	1.65	.79	1.05	0.30	.67	4.20
ageshift	.99	.00	-2.43	0.02	.98	1.00
priorcalls	2.36	.53	3.84	0.00	1.52	3.65

The model was mediated by the interaction term of age*shift¹ which was significantly inversely associated with remaining at home; this suggests that although shift pattern was important in whether people remained at home or not, we know from the bi-variate analysis that calls from people who phoned during the backshift who were older were more likely to be transported to hospital (and less likely to remain at home).

4.5 Section 3: Discussion

This retrospective analysis was one of the largest undertaken on prehospital diabetes related emergency calls using MPDS[®] data. Comparing the results with other countries provides a benchmark by which the extent of the challenge within Scotland can be determined. The scoping review (chapter 3) identified several papers that contained population demographics and call characteristics on hypoglycaemia related emergencies. To ensure the most recent literature was considered in relation to the retrospective analysis, the search strategy developed for the scoping review was repeated from 2009 onwards (see section 3.4). This reflected the sequential nature of the research reported in this thesis. An additional three studies (Khunti *et al*, 2013; Farmer *et al*, 2012; Parsaik *et al*, 2012) were identified for inclusion within this discussion section (see Table 16).

¹ The 3-way interaction age*shift*gender instead of age*shift was significant in a model but the model fit was a poorer fit, therefore age*shift was selected as the interaction term instead.

Table 16: Table of all population based studies including demographic data on hypoglycaemia emergency calls

Author (year)	Study Type/Duration	Geographical location	Population served (diabetes prev.%)	% diabetes related emergency calls of total number of calls	% hypoglycaemic related calls of total number of calls	Transportation rates	% Male	Average age
Fitzpatrick and Duncan (2007)	Retrospective case note analysis (12 months)	West of Scotland Greater Glasgow, Lanarkshire, Ayr etc. (Scotland, UK)	2.1 million (4.4)	1.3% (n = 3021)	0.5% (n = 1319)	71% (n = 916) not transported to ED		48 (mean)
Brackenridge <i>et al</i> (2006)	Retrospective audit (12 months)	Surrey (England, UK)	1.1 million (5.8)	1.3% (n = 1600)	0.6% (n = 907) Estimated figures from 1 month period.	73% (n = 883) not transported to ED	55% (n = 52) from 1 month period	52.6 (mean)
Leese <i>et al</i> (2003)	Retrospective observational study (12 months)	Fife (Scotland, UK)	365,051 (4.4)	n/a	0.57% (n = 223)	n/a	55.6%	53.8 (mean)
Khunti <i>et al</i> (2013)	Retrospective population study (4 months)	Derbyshire (England, UK)	1,530,000	N/A	0.6% (n = 523)	68% (n = 356) not transported to ED	54.3 (n = 284)	66 (median)
Farmer <i>et al</i> (2012)	Retrospective observational study (12 months)	South East Coast (England, UK)	5,121,100 (5.8)	N/A	1.02% (n = 4081)	64.7% (n = 2640) not transported to ED	53.8% (n = 2108)	69.3 (median)
Cain <i>et al</i> (2003)	Prospective observational study (10 months)	Nova Scotia (Canada)	340,000 (8.9)	2.9% (n = 499)	1.3% (n = 220) Only included > 15 years of age.	66% (n = 145) not transported to ED	n/a	42 (mean)
Holstein <i>et al</i> (2003)	Prospective population based study (3 years)	Germany	18,000 (8.9%)	3.1%	2.73% (n = 213)	25% (n = 15) not transported to ED	48% (n = 101)	n/a
Mattila (2004)	Prospective observational study (11 months)	Helsinki (Finland)	560,000 (8.3)	4.0% (36,000 calls per annum)	4.0% (n = 1333) 'most' of diabetes related emergencies were for hypoglycaemia	61% (n = 812) not transported to ED	n/a	n/a
Parsaik <i>et al</i> (2012)	Retrospective observational study (7 years)	Minnesota (USA)	141,360 (7.3)	N/A	4.7% (n=914)	40% (n = 546) not transported to ED	51% (n = 464)	60 (mean)

4.5.1 Patient Characteristics of hypoglycaemic related emergency calls

During the 12 month period (1st June 2006 to 30th May 2007) the WoS ACC received 2760 diabetes related emergency calls, 47.8% ($n = 1319$) of which were for hypoglycaemia; an average of 4 hypoglycaemia related calls per day. At the time of data extraction, WoS ACC received approximately 50% ($n = 281,766$) of all emergency calls made to the SAS (SAS 2007) and served a population of around 2.1 million (General Register Office for Scotland, 2009). Therefore diabetes related emergency calls ($n = 3021$) and hypoglycaemia related emergency calls ($n = 1319$) make up 1.1% and 0.5% of all calls received by WoS ACC respectively. Similar proportions have been found in other UK based studies where hypoglycaemia related calls ranged between 0.57 to 1.02% of all calls received (see Table 16). Outside the UK, reports on percentages of hypoglycaemic related emergencies were higher, ranging between 1.3% and 4.7% of all emergency calls (Parsaik *et al*, 2012; Mattila *et al*, 2004; Cain *et al*, 2003). The disparity between countries can be explained by the varying worldwide prevalence of diabetes (International Diabetes Federation, 2013) within each country, there is some consistency between the proportion of emergency calls and prevalence of the condition.

4.5.2 Age and emergency hypoglycaemic calls

Hypoglycaemia affected all age groups from 3 – 99 years of age ($M = 48$ years, $SD = 18.56$). The average age was lower than in other UK based studies which ranged between 52.6 to 69.3 years (Khunti *et al*, 2013; Farmer *et al*, 2012; Brackenridge, 2006; Leese *et al*, 2003). Beyond the UK, data on average age for hypoglycaemic events requiring ambulance service assistance were similarly diverse; from 43.5 to 60 years of age (Parsaik *et al*, 2012; Mattilla *et al*, 2004; Holstein *et al*, 2003). There are a number of possible explanations for such variation. These include the possibility of sampling error in the studies of shorter duration (Khunti *et al*, 2013; Brackenridge *et al*,

2006); variation in measures of central tendency (Khunti *et al*, 2013; Farmer *et al*, 2012); international prevalence of diabetes (Diabetes UK, 2012a; International Diabetes Federation, 2013) and health inequality and life expectancy (Office for National Statistics, 2011b; 2013). Changing treatment regimens (see section 2.3) may also impact on the frequency and severity of hypoglycaemic events in those with Type II diabetes (Leese *et al*, 2003; The Diabetes Control and Complications Trial Research Group, 1997). These associated factors suggest an explanation for these geographical differences is complex and unlikely to be explained through the existing available data.

4.5.3 Gender and emergency hypoglycaemic calls

This study found a similar gender profile to other studies (Khunti *et al*, 2013; Farmer *et al*, 2012; Parsaik *et al*, 2012; Brackenridge *et al*, 2006; Mattilla *et al*, 2004; Leese *et al*, 2003). In all but one study (Holstein *et al*, 2003) more males were reported requiring assistance than females (see Table 16). These data may reflect the slightly higher proportion of males diagnosed with both Type I and II diabetes in the UK, Europe and America (Centers for Disease Control and Prevention, 2011; Scottish Diabetes Survey Monitoring Group, 2010; Soltesz *et al*, 2007). No reason could be found as to why the results from the study by Holstein *et al* (2003) differed as Germany too has a slightly higher prevalence of diabetes in males than females (Heidemann *et al*, 2009). However, these slight variations in gender are unlikely to have any impact on the care ambulance services deliver.

4.5.4 Time of call

Little data were available on time of call from the included prehospital studies. The current study however presented data on call frequency by time of day. Frequency of calls were measured over three 'shifts'; Night shift (2300hrs - 06:59hrs), Day shift (0700hrs - 14:59hrs) and Back shift (1500hrs - 22:59hrs) (see 4.4.4.4). Significantly

more calls were received during back shift (n = 511, 39%) and night shift hours (n = 443, 33.6%) than were received during day shift hours (n = 365, 27.6%). However the difference between number of calls received during back shift and night shift was not significant.

The frequency of calls received during night shift hours were similar to the 27.6% reported in the study by Khunti *et al* (2013). However, Khunti *et al* (2013) did not report on the spread of the remaining calls, precluding further comparison. Nevertheless, these results were noteworthy. Previous research has found that almost 50% of all severe hypoglycaemic events occur at night or during sleep (Allen and Frier, 2003). These events, due to their asymptomatic nature, often go unrecognised by both patients and relatives (Yale, 2004). This may help explain some of the variation found between back shift/night shift and day shift. Furthermore, another small scale study (n = 60) (Gold *et al*, 1994) compared frequency of hypoglycaemia in those with impaired and normal awareness in Type I diabetes. They demonstrated that those with impaired awareness experienced more severe hypoglycaemic events between 1300hrs - 00:00hrs and those with normal awareness experienced more severe events during 00:00hrs - 12:00hrs. Whilst impaired awareness could not be directly measured in the retrospective analysis, the known correlation between this condition and severe hypoglycaemic events (Pedersen-Bjergaard *et al*, 2004) suggests that this could be a factor in the higher frequency of calls during the back-shift time period. This is an important consideration within the context of T&R and these individuals would benefit from further specialist support (Allen and Frier, 2003).

4.5.5 Hospital or home – immediate outcome

Significantly more people who experienced a hypoglycaemic event treated by ambulance clinicians remained at home than were transported to the ED (see section 4.4.4.3). This replicates other UK based studies that have established non-

transportation rates of between 63%-73% (Khunti *et al*, 2013; Farmer *et al*, 2012; Brackenridge *et al*, 2006).

In contrast, non-transportation rates presented in studies outwith the UK had greater variation; 25% to 89.9% (Parsaik *et al*, 2012; Mattila *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003). Parsaik *et al* (2012) noted an increase in transportation rates over the course of their study, from 59% to 79%. They offered several explanations for these such as the severity of the hypoglycaemic event, variation in local clinical practice, level of EMS personnel, reimbursement structure and ambulance clinicians' fear of litigation. Such fears have also been reported in other recent qualitative research (Dalgleish, Colver and Fitzpatrick, 2008; Snooks *et al* 2005). Dalgleish, Colver and Fitzpatrick (2008) found that ambulance clinicians believed that by obtaining a refusal they were protected from litigation should there be a subsequent adverse incident. Consequently, an ambulance clinician's preferences may have an influence on patient's transportation decisions and the immediate outcome that is recorded.

4.5.6 Repeat and recurrent calls for hypoglycaemic events

The scoping review (chapter three) defined a repeat call as any subsequent call within a 48 hour period, and recurrent calls beyond 48 hours. The review found that 2-7% of patients experienced a repeat hypoglycaemic event requiring ambulance care within 48 hours of this first call. In the current study 3.1% ($N = 30$) of patients experienced a repeat event requiring ambulance support within two days of the initial call. These repeat call figures were reassuring as they were located at the lower end of the 2-7% range extrapolated from the other studies (Khunti *et al*, 2013; Farmer *et al*, 2012; Parsaik *et al*, 2012; Brackenridge *et al*, 2006; Mattilla *et al*, 2004; Cain *et al*, 2003; Holstein *et al*, 2003).

This study presents more detailed information and analysis about recurrent hypoglycaemic events than any paper included within the scoping review. Other studies provided no data (Farmer *et al*, 2012; Holstein *et al*, 2003), present data over a shorter time period (Khunti *et al*, 2013) or present limited detail on long-term data preventing direct comparisons beyond the 48 hour period (Parsaik *et al*, 2012; Mattila *et al*, 2004; Cain *et al*, 2003; Leese *et al*, 2003). The current study determined that 6.7% (n = 88) of patients experienced a repeat call in the first week and 10.6% (n = 140) within two weeks. Seventy nine patients were responsible for 3 or more calls. Over the 12 month period, 16% (n = 157) of patients were responsible for 27.2% (n = 359) of all calls. One other study (Brackenridge *et al*, 2006) also reported over a 12 month period but found slightly less repeat calls; twenty two patients responsible for three or more calls. Remarkably Khunti *et al* (2013) reported only two patients experiencing a repeat call within the four month study period. This was very unusual when compared with the other studies. After contacting the author via e-mail to explore this in greater detail (Appendix 8), it was reported that no additional data were available to determine why the frequency of repeat calls were so low.

Nevertheless, it was clear from these data that a small proportion of individuals treated for an out-of-hospital severe hypoglycaemia event will go on to experience further severe events, requiring ambulance support, within the days, weeks and months thereafter. This suggests that long-term care and self-management was sub-optimal in these individuals.

4.5.7 Predictors of immediate outcome (ED or Home)

With the exception of the studies by Khunti *et al* (2013) and Farmer *et al* (2012) none of the included studies predicted immediate patient outcome from demographic data or clinical characteristics. Both Khunti *et al* (2013) and Farmer *et al* (2012) focussed attention on determining predictors for transportation to the ED. Contrary to the current

study findings, and those presented by Khunti *et al* (2013), Farmer *et al* (2012) reported that those at the extremes of age i.e. <19 and >60 years were more likely to be transported to the ED than in other age groups. Khunti *et al* (2013) undertook multivariable logistic regression modelling and found age was not a predictor for transportation to the ED. Their study presented both positive and negative predictors of transportation to the ED. The only positive clinical predictor of transportation to the ED was reported to be a higher respiratory rate and negative clinical predictors were found to be higher post-treatment blood glucose level and those receiving insulin therapy. Other independent variables such as age, gender, heart rate, blood pressure, GCS and nocturnal events were not associated with transportation to the ED.

Whilst these results were useful, it was clear that proportionately more patients remained at home after receiving ambulance care for a severe hypoglycaemic event, than were transported to hospital. Although Khunti *et al* (2013) had measured the demographic and clinical predictors of transportation to hospital, their study sample differed. There were very few repeat/recurrent calls, detail on call times were not provided over the 24 hour period and deprivation category was not included. It was important therefore to determine predictors for remaining at home with these additional variables from within the present study. At the time of analysis (2009/10), this was the first study that investigated the predictors of remaining at home using the aforementioned demographic variables.

Unlike the study by Khunti *et al* (2013) the analysis did not include clinical variables, using only the demographic information available from ACC call data. Nevertheless the model was able to significantly predict the patient characteristics of those remaining at home and also included the repeat call variable. Those who remained at home were less likely to be female, to be slightly older age overall, and to have made

at least one previous call to the SAS during the 12 month data collection period. The greatest impact on non-transportation was found to be previous ambulance call-outs. Although Khunti *et al* (2013) found no effect of age or gender on transportation to the ED, their sample size was considerably smaller (n = 523) than that of the current study (n = 960) and the short study duration may have influenced their results.

This final result could be considered as counter-intuitive. Firstly, within the context of current SAS T&R guidelines, repeat or recurrent severe hypoglycaemic events were considered as clinical red flags for ambulance clinicians (see Appendix 1). These are considerably higher risk patients who should be advised to travel to the ED for follow-up care (JRCALC, 2013). Secondly, from the patient's perspective it could also be suggested that follow-up is advisable secondary to repeat or recurrent events. Patients who experience repeated severe hypoglycaemic events are more likely to develop impaired awareness and would benefit greatly from expert follow-up care and support (Allen and Frier, 2003).

4.5.8 Strengths and Limitations

There are a number of limitations to be considered. The analysis was retrospective and therefore had access only to the recorded data available through MPDS[®]. A prospective design would have permitted the collection of more specific data. However, altering the MPDS[®] system for recording of additional data would have required education, training and possible software changes within the Ambulance Control Centres to ensure adequate data were collected. Alternatively, pPRF data could have been used but for the same reasons as previously given (see section 4.3.2) this would not have been reliable or practical.

Despite its benefits, the validity of the MPDS[®] data could be questioned in terms of its ability to accurately identify hypoglycaemic related calls. The ambiguity surrounding

the coding of hypoglycaemia related calls suggests that a degree of caution is required in the interpretation of these results. Hypoglycaemia can be mistaken for other conditions such as cerebro-vascular accident (CVA) and psychiatric emergencies, as both can present similarly (Carter and Taylor 2002; Holstein and Egberts, 1999). There are many medical conditions that may co-exist in individuals with diabetes, some of which can present as unconsciousness or altered level of consciousness. It is possible too that some other conditions may have been incorrectly coded as hypoglycaemia. Where identification was possible these calls were removed from the data set.

However, the ambiguity apportioned to the sensitivity and specificity of MPDS[®] data was moderated through the cross-referencing of hypoglycaemia related pPRF's (n = 50) with MPDS[®] code 13 calls. This process determined that almost all calls were hypoglycaemia related. The inclusion of the term 'hypo' was subsequently determined to be a reasonably accurate identifier of true hypoglycaemia. Furthermore, the literature suggests that a high proportion of diabetes related emergency calls are for hypoglycaemia (Brackenridge *et al*, 2006; Mattila *et al*, 2004; Cain *et al*, 2003). Diabetes related emergency calls that are of rapid onset are therefore more likely to be related to hypoglycaemia than hyperglycaemia. But despite these measures, the coding system was not infallible, and it is probable that a small proportion of hypoglycaemia related calls were missed or incorrectly coded as such. However the coding system would be more inclined to result in an underestimation, rather than an overestimation, of hypoglycaemic related calls. The process of identification of hypoglycaemia related calls was as accurate as the existing data set would permit.

As previously identified (see section 2.4.2.1) although recovery from hypoglycaemia is common, death can occur. Data on mortality associated with non-transportation would

have been useful in this study particularly in relation to determining safety of non-transportation. However, identifying this patient group was not possible using the existing data set. Such calls would be recorded within MPDS[®] under an alternative code: code 9 Cardiac Arrest. Furthermore, ambulance clinicians would record these calls on pPRF's as 'cardiac arrest'. No information on cause of death would be available (or trustworthy) through existing ambulance service data. It was therefore not possible to identify cause of death/cardiac arrest through ambulance service records. This meant that these other data were not included for analysis. However, using ICD 10 codes it was possible to determine that 73 hypoglycaemia related deaths did occur within the study area during the study period (National Records for Scotland, 2014). But, there were insufficient data to establish links with prehospital care/treatment. This also highlights the limitations of the existing data set in that deaths secondary to hypoglycaemia will have been missed. Nevertheless, this knowledge reinforces the view that although the serious consequences of hypoglycaemia are rare, their occurrence highlights the need to ensure appropriate follow-up care for these individuals.

In relation to the predictors of non-transportation, the inclusion of additional data, particularly clinical data, may have influenced these results. However, research that did include clinical variables, determined that few of these predicted transportation to the ED (Khunti *et al*, 2013; Farmer *et al*, 2012). This does not necessarily mean that the clinical data would similarly have had no influence on predictors for non-transportation. Other factors such as diabetes type, treatment, duration of hypoglycaemia may all influence immediate outcome. Ambulance clinicians too may have an impact on this in terms of advice provided or systems of care within which they operate (Parsaik *et al*, 2012). However, these factors could not be measured.

4.5.9 Reflexivity in quantitative enquiry

As was described in chapter one (see section 1.9.1) the positivist paradigm of enquiry seeks an objective and unbiased truth. But this view, and the views of those undertaking research who assume that an objective and neutral reality is reinforced by the use of complex statistical software, requires further examination (Mauthner and Doucet, 2003). There are elements that can influence this seemingly objective, unbiased approach to enquiry. From a reflexive position (see section 1.9.5), some decisions made during the study development and analysis phase may have influenced the findings presented within this cross-sectional study and, furthermore, the programme of research to follow. For example the decision to analyse specific variables from within the MPDS[®] data set may have introduced a degree of bias. In addition, the way in which time data were aggregated using the standard 8 hour shift pattern time excluded the 10 or 12 hour shift patterns also in place within the Scottish Ambulance Service. These factors could impact on the study's external validity and generalisability (Pannucci and Wilkins, 2010). Similarly, although significant measures were taken to demonstrate the accuracy of the coding of hypoglycaemia and hyperglycaemia related calls, it is possible that personal bias (via both personal and professional experience) influenced the final coding. These factors too may have influenced the results.

Lastly, there may have been a number of patients who experienced a call in the days prior to or immediately after the period data were extracted. Individuals falling into this category will have been missed. The decision to exclude these calls may have resulted an underestimation of the number of repeat calls.

So whilst reflexivity is often described and undertaken within the context of qualitative research, its application and importance extend beyond this. The influence of the

researcher on both quantitative and qualitative enquiry, questions whether any approach can be truly objective.

4.5.10 Conclusion

There have been few analyses undertaken on large data sets on hypoglycaemia related emergency calls to ambulance services. The results presented in this chapter positively contribute to the current, limited evidence on prehospital hypoglycaemic care. The three key aims of the study were achieved and the results embedded within the context of the broader literature. This proved challenging when investigating some of the subtle details, particularly those on repeat calls. But despite the heterogeneity of the studies it remained possible to determine that the patient demographics were broadly similar across all studies.

Internationally, the frequency of emergency calls for hypoglycaemia increased with the proportion of population diagnosed with diabetes. Similarly, the higher proportion of males requiring emergency assistance was likely to be a determinant of the higher incidence of diabetes in males within the included countries. Generally, those requiring care were of the middle aged and older populations. More locally however, people from the West of Scotland requiring ambulance care for severe hypoglycaemic events, were found to be younger than those in the other studies. These differences may be related to Scottish health and care issues such as geographical differences, life expectancy, diabetes incidence and ethnicity. Non-transportation rates were similar across the UK but greater variability was reported from the international literature.

Although most patients do not appear to require further emergency ambulance care for hypoglycaemic events, a small proportion do. The recognition that patients experience repeat events that lead to subsequent ambulance call-outs may indicate a problem with immediate follow-up care and the individual's personal management of their

condition. Equally, both repeat and recurrent calls may be a consequence of inadequate follow-up care independently. The identification of repeat calls in all studies suggests that this is an international and not just a local problem. Each subsequent emergency call represents a significant and immediate health risk to the patient and so amplifies the importance of expert follow-up care as advised in current clinical guidance (see Appendix 1 and 3).

The available data were not able to describe why such a large proportion of patients remained at home after a severe event or why some patients went on to experience subsequent severe events. Other studies have identified few clinical predictors for transportation to the ED (Khunti *et al*, 2013) and this suggests other factors may be implicated. Ambulance clinicians have also been involved both negatively and positively in the patient's transportation decisions (Dalglish, Colver and Fitzpatrick, 2008; Snooks *et al*, 2005). The current study used non clinical characteristics to determine that people not transported post-hypoglycaemic event were less likely to be female, more likely to be older and were more likely to have made at least one previous call to the ambulance service. The last and most significant predictor of 'previous call' was counterintuitive. From a health behaviour perspective one would presume that the more often an ambulance was required, then the more likely an individual would feel the need for further care and support (Rosenstock, 1966). According to current T&R guidance, recurrent, frequent and severe hypoglycaemic events require urgent follow-up care and support (Basics Education Scotland, 2004; Scottish Ambulance Service, 2005; Welsh Ambulance Service, 2006). Yet, many patients in the current study were recorded as declining ED follow-up. Similarly low follow-up rates with DCP's have been reported (Leiter *et al*, 2005).

Overall, these results suggest that, in terms of government and SAS policy on reducing unnecessary ED attendances, non-transportation of patients who have recovered from a severe hypoglycaemic event (via refusal or T&R) has been successful and safe. These results must, however, be tempered by the knowledge that subsequent cardiac arrests, deaths or associated repeat or recurrent calls not categorised as diabetes related calls have not been included in this analysis. Seventy three deaths were attributed to hypoglycaemia in the study area during the time of study, and so the risks associated with the condition must not be underestimated. The cost of remaining at home without follow-up may therefore be more significant than these data suggest. Nevertheless, the majority of patients who have recovered from a severe hypoglycaemic event remain at home and most without need for further ambulance care.

Of considerable importance and concern however, is the small proportion of individuals who are experiencing repeat calls within a relatively short time period. A bias in past studies towards investigating system centred problems or the ambulance clinician's perspective have meant that little has been undertaken to explore the patients' perspective on care. The findings of this, and previous studies, suggest that predictors of non-transportation or repeat calls are less likely to be exclusively clinically or demographically orientated. These affirm the need for an exploration of patients' perspectives of ambulance care and reasons for call-out and non-transportation.

CHAPTER 5: INVESTIGATING PATIENTS' EXPERIENCES OF PREHOSPITAL HYPOGLYCAEMIC CARE

5.1 Introduction

The evidence evolving from both the scoping review and retrospective analysis (chapter 3 and chapter 4) demonstrated objectively that ambulance services leave many individuals at home, avoiding transportation of patients to the ED. Additionally, it was reported that a considerable proportion of patients who remained at home after a hypoglycaemic event did not receive, or failed to seek, follow-up care. This was contrary to the philosophy of Scottish Ambulance Service Treat and Refer policy (Scottish Ambulance Service, 2009a). Lack of follow-up care had been evidenced in another prehospital hypoglycaemic care study that found a considerable proportion of patients who remained at home did not receive, or failed to seek, follow-up care (Leiter et al, 2005). The importance of patients receiving follow-up care was demonstrated in the recent small scale study by Walker et al (2006). In this study Walker et al. determined that approximately half all post-hypoglycaemic patients (n = 20) required (and received) medication changes, and all (n = 38) were given specific advice on managing their condition. This study suggests that patients who fail to seek or receive follow-up care may miss vital medication adjustments and advice. Without such interventions, some patients will be exposed to the risks of repeat hypoglycaemic events; a problem identified in both the scoping review (chapter 3) and retrospective analysis (chapter 4).

Neither the scoping review (chapter 4) nor the subsequent retrospective cross-sectional study (chapter 5) illuminated the patients' perspectives of care. The methods used in these studies were unsuitable for establishing why so many patients developed severe hypoglycaemia, required ambulance support, and then apparently chose not to seek immediate follow-up care. The scoping review on prehospital hypoglycaemic

care (see chapter 3) demonstrated that there were few, if any, studies published on patient's experiences and perspectives of emergency ambulance care of hypoglycaemic events. Important questions remain to be answered, such as why a particular decision was made by the patient, or how an individual feels about care received or their preferences for follow-up. These research questions are more appropriately investigated through qualitative methods of enquiry, justifying a shift in the research approach and the use of an alternative method of data collection and analysis (Creswell and Clark, 2011).

5.2 Considerations on research methods

The overall aim of the thesis is to investigate hypoglycaemic emergencies attended by the Scottish Ambulance Service. From the outset it was anticipated that more than one single method would be required to provide answers to such a general but complex area of care (see section 1.11). But the precise focus of investigation for each study could not be pre-planned due to the exploratory and inductive approach taken, and the emerging nature of the data. The development of new data fostered new learning on which subsequent questions were founded. Consequently, this thesis has now reached the previously anticipated point where a change in method is required to investigate more fully the population concerned.

5.2.1 The need for change

Quantitative methods are designed to determine facts and traditionally lie within the positivist paradigm (Gray, 2009). Positivism argues that properties can only be measured through direct observation and that reality exists independently of the researcher (Gray, 2009; Parahoo, 2006). The strengths of quantitative design are based firmly on its objective and deductive approach, and in its strict adherence to scientific measures. Such studies usually require large numbers of participants in order to be adequately powered for reliable hypothesis testing. This approach was

appropriate and usefully applied in the retrospective cross-sectional analysis. However, the pragmatic approach taken in this thesis permits different methods to be used within a programme of research without being constrained by either a positivist or constructivist underpinning philosophy. But these cannot be ignored completely. As previously mentioned (see section 1.9.1), qualitative research methods lie within the constructivist paradigm that argues against the existence of an independent reality and states that individuals construct their own meanings of reality (Gray, 2009; Denzin and Lincoln, 2005). The strengths of qualitative enquiry therefore lie in its ability to investigate people's perceptions, experiences or behaviours (Parahoo, 2006; Denzin and Lincoln, 2005). This is the converse of the quantitative approach, but will allow the experience of hypoglycaemic events to be viewed from the patients' perspective, or through their 'lens'. Patients' perspectives are essential in order to provide a balanced view of emergency hypoglycaemic care, the reasons for contacting the SAS and underpinning follow-up care practices.

5.2.2 Mixing approaches and methods.

The use of different methods in a scientific enquiry is known as mixing methods. Although the mixing of methods has been undertaken since the early part of the 1900's (Hesse-Biber, 2010; Roethlisberger and Dickson, 1939), it is recognised as an underdeveloped approach (Morse, 2009; Teddlie and Tashakkori, 2003). During the early and mid-part of the last century different epistemological approaches were fiercely debated in what were known as the "*paradigm wars*" but the mixed methods approach received little attention (Teddlie and Tashakkori, 2003, pg. 5). However, the past 30 years has seen an increased focus on mixed methods research (Greene, 2007). Theorists have sought for it to be recognised and approved as the "*Third Methodological Movement*" alongside postpositivism and interpretivism (Teddlie and Tashakkori, 2003, pg. 45). Explicit attempts have been made to refine and develop mixed method's processes and typologies and some consensus exists (Morse and

Neihaus, 2009). However, considerable disagreement remains about its philosophical underpinnings (Morse, 2009; Bryman, 2006; Teddlie and Tashakkori, 2003). Although, it should be noted that at least 13 authors have embraced pragmatism as the epistemological paradigm of enquiry underpinning mixed methods (Teddlie and Tashakkori, 2003); supporting again the choice of paradigmatic approach to this research programme.

There are several advantages to taking a mixed methods research approach. Mixed methods can provide more evidence than that produced through a single method alone (Creswell and Clark, 2011; Morse, 2003) and are also useful when alternative aspects of a phenomenon require to be examined (Morse and Niehaus, 2009). Mixed or multiple studies may be undertaken in sequence, where the findings of one informs the next, or concurrently, where studies are conducted simultaneously. There has been an acknowledged benefit of this concurrent approach in increasing the chances of developing unexpected, but valuable, outcomes (Bryman, 2006). Morse states “*by using more than one method within a research program we are able to obtain a more complete picture of human behaviours and experience*” (Morse, 2003, pg. 189). Changing method at this stage in the thesis will help explain patients’ behaviours that were identified in the earlier studies, and further inform the development of any future interventions.

5.2.3 Evolving typology of mixed methods

Two broad approaches have been used to describe the use of mixed methods and understanding these help clarify the sometimes confused terminology used i.e. mixed or multiple methods. The first, where both qualitative and quantitative methods are used within a single study is termed ‘mixed methods’. And the second, where different methods are used in separate studies but remain under the umbrella of a programme of research is termed ‘multiple methods’ (Morse, 2003). The movement by Morse

(2003) to develop a standardised and agreed typology (and terminology) that formalised the way alternative approaches were combined, was helpful in providing structure and validity to both mixed and multiple methods (Bryman, 2006). These typologies were described in a manner that suggested one strand (qualitative [qual] or quantitative [quant]) exerted greater priority or influence over the other (Morse, 2003). This is depicted for example as QUANT → qual or QUAL + quant (Morse, 2004), the dominant method being capitalised. In mixed methods the subsequent study has been called the 'supplementary study' undertaken to enhance earlier findings (Morse and Niehaus, 2009). The capitalised element retaining the theoretical 'drive' of the study. Table 17 provides an example of these typologies.

In contrast, multiple methods studies consider an individual study in its own right and can therefore also be of equal weight (Creswell *et al*, 2003, Tashakkori and Teddlie 1998; Creswell and Clark, 2011; Morse and Niehaus, 2009). Where neither study dominates it would be depicted typologically as QUANT = QUAL. In programmatic terms (referring to a sequence of individual studies using multiple methods aligned to an overarching aim) where no study dominates, the theoretical 'thrust' would be considered as 'inductive' (Morse and Niehaus, 2009; Morse, 2003). The theoretical 'thrust' therefore pertains to the more abstract overall aim of a programme of research and will be described as either inductive or deductive (Morse, 2003; Morse and Niehaus, 2009). The theoretical 'drive' is therefore less abstract and associated more with the individual methods used i.e. quantitative or qualitative. These are still described in inductive or deductive terms, but the overall theoretical 'thrust' overrides any study level methodological drive (Morse and Niehaus, 2009). Acknowledgment of this overall theoretical thrust is important as this enables a programme to retain its methodological integrity (Morse, 2003).

Table 17: Multiple method typology

Inductive thrust	Deductive thrust
QUAL + qual: two qualitative studies used simultaneously, one dominant.	QAUN + quan: two quantitative studies used simultaneously, one dominant.
QUAL → qual: two qualitative studies used sequentially, one dominant.	QUAN → quan: two quantitative studies used sequentially, one dominant.
QUAL + quan: for a multiple method study used simultaneously with inductive drive.	QUAN + qual: for a multiple method study used simultaneously with deductive drive.
QUAL → quan: for a multiple method study used sequentially with an inductive drive.	QUAN → qual: : for a multiple method study used sequentially with an deductive drive

Debate continues over these typologies as they are advanced and refined (Creswell and Clark, 2011; Bryman, 2006). It was suggested that past definitions were too precise for what was an evolutionary phase of mixed method development (Bryman, 2006). Indeed in a review published in 2006, Bryman exposes the reality of mixed methods studies, demonstrating that few researchers remain loyal to these typologies, giving weight to his argument that they have become too narrow and prescriptive (Bryman, 2006). Additionally, Bryman suggests that there remains no agreed language for mixed/multiple methods research and that those attempting to develop a distinct language for the mixed or multiple methods approach are “*trying to run before we can walk*” (Bryman, 2008, pg. 88). Later, Morse and Neihaus (2009) identified some exceptions to the generally agreed typologies in an attempt to address the concerns of Bryman (2008). Indeed it is here that the earlier work by Morse (2003) was advanced. Morse and Nieshaus now define a multiple methods research programme as “*a series of complete related qualitative or quantitative research projects, driven by the theoretical thrust*” (Morse and Nieshaus, 2009, pg. 13).

Setting this thesis within this context is helpful. This thesis consists of a number of studies with an overarching aim. The theoretical thrust is inductive, one of discovery, but this thesis begins with a quantitative drive (considered deductive). This is contrary

to the agreed multiple method typologies where all inductive approaches begin with a qualitative drive, depicted as 'QUAL' (see first column in Table 17). However, Parahoo (2014) and Snape and Spencer (2004) both highlight that quantitative methods are not always about hypothesis testing and can be more descriptive and inductive in approach. Furthermore, Morse and Niehasu (2009) state that in a programme of studies, it is the overall perspective (its aim) that overrides any theoretical drive. Whether the included research studies are QUAL or QUANT appears to be somewhat irrelevant. Despite stating this, they fail to provide any typological examples. Perhaps past arguments by Bryman (2006) and Maxwell and Loomis (2003) remain, in that existing typologies are too tight and prescriptive for the diversity that exists in mixed methods studies and that more flexible approaches to multiple methods are required.

Given the typological tensions that exist, and the fact that this thesis is not necessarily a precise fit with any of the existing typologies, this section will focus on the fundamental principles on which multiple methods research were based (Morse, 2003; Morse and Niehasuu, 2009).

5.2.4 Fundamental principles of multiple methods

There are three principles on which multiple method's design is based (Morse, 2003). These are i) identifying the theoretical drive; ii) developing an overt awareness of the theoretical dominance of each project; and iii) respecting methodological integrity. Each of these principles will be considered within the context of this thesis.

Principle 1: Identify the theoretical drive for the research project

Two levels of abstraction exist within the overall research approach to this thesis. At the most abstract level, the entire thesis is being undertaken within a theoretical drive that is inductive, the focus being on exploration. There is no specific mid-range theory

informing the process (see section 1.9.6). The research question led the specific theoretical drive of each study and therefore the methods used. The presence of different approaches within a programme of study is considered acceptable, even where the overall project design remains inductive, as the drive is still said to remain as one of “*discovery*” (Morse, 2004, pg. 196).

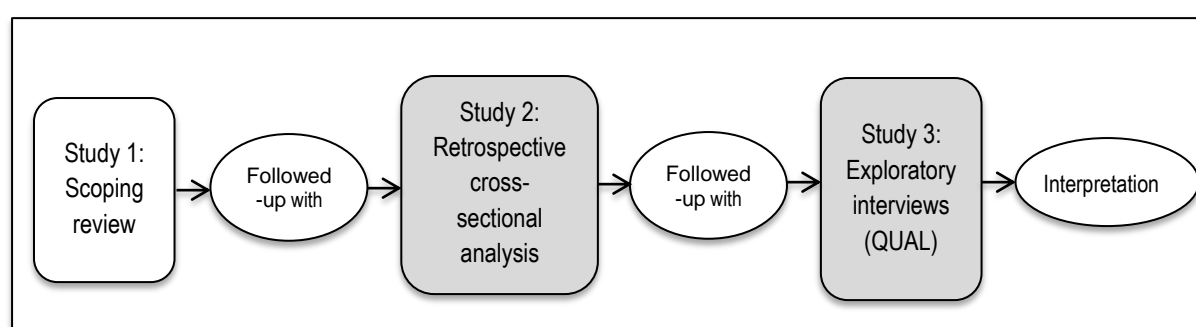
Principle 2: Develop overt awareness of the dominance of each project.

Morse (2003) suggested that the researcher must develop awareness throughout the project as to the theoretical drive of each stage. The development of this thesis is more akin to the multiphase design described by Creswell and Clark (2011). The multiphase design is said to “*examine a topic through an iteration of connected quantitative and qualitative studies that are sequentially aligned, with each new approach building on what was learned previously to address a central program objective*” (Creswell and Clark, 2011, pg. 100). The thesis has been developed inductively through a process that has involved both explanation and exploration through a dynamic process undertaken sequentially. It thus extends beyond the basic design typologies outlined previously (Morse, 2003).

The significance of the researcher’s awareness of the theoretical drive is essential in ensuring they remained grounded within their particular methodological approach, thus limiting any infringement of the underpinning theoretical principles of either method (Morse, 2003). This element is recognised as the primary difference between the mixed method and multiple method design. The fact that data are not merged within one project also plays to the key strengths of the multiple methods design and further lessens the likelihood of methodological confusion (Morse, 2003).

An inductive approach best depicts the overall drive of this thesis. While the qualitative study will aim to provide answers to some of the key questions developed from the retrospective analysis, the study will be broader in its exploratory aims. As such, there is no perceived dominance of either primary research study; QUANT = QUAL. Figure 10 portrays the two primary research studies in this thesis (undertaken after the initial scoping literature review presented in chapter 3) within an adapted version of the multiple method prototype as depicted by Creswell and Clark (2011).

Figure 10: Multiple method sequential design



Principle 3: Respecting methodological integrity

Morse describes this principle as “*keeping each method intact*” (Morse, 2003, pg. 199). The multiphase design is less problematic than that of the mixed methods design as each study is a stand-alone study in its own right (Morse, 2003). Nevertheless particular attention must be directed towards the sampling framework of each design, ensuring that each method is appropriate in answering the research question/s. For example in the quantitative study presented in chapter four, all individuals who required ambulance service assistance for a hypoglycaemic emergency were included. This ensured the results were representative of that particular population but also, and importantly with a method aligned to the positivist approach to enquiry, likely to be generalisable to the remaining Scottish population. In contrast this next study, the qualitative study, will interview patients to explore their experience of hypoglycaemic emergencies and care. The shift in method to qualitative enquiry will require

considerably fewer participants, and an in-depth approach to analysis focussing on subjectivity and individual perceptions; this approach is aligned more with the constructivist paradigm of enquiry.

The studies within the thesis are being conducted sequentially, with the findings from one informing the questions leading to the subsequent study. Although the change in approach was anticipated from the outset of this programme of research, the focus of the questions was not. The integration of studies will take place sequentially and in the overall discussion section of the thesis.

In summary the studies in this thesis are undertaken using an inductive, sequential approach within a pragmatic paradigm. Although this approach does not necessarily neatly fit within any of the agreed typological approaches on multiple methods research, this is not unusual within the context of existing literature where the need to introduce greater flexibility to existing typologies has been recognised (Bryman, 2006). This approach permits the focus to remain on the research questions that evolve from each study. Including qualitative methods of enquiry within the overall context of the multiple methods design approach provides a richer representation of this patient population, and will aim to address the questions that have been raised through the results of the previous study (see section 4.5.10).

5.2.5 Selecting the research method

The following qualitative study will investigate the experiences of individuals living with diabetes, examining specific elements of their hypoglycaemic event and post-hypoglycaemic experience and care. As this study is exploratory in nature and focused on the subjective experiences of participants, the qualitative approach is more appropriate (Parahoo, 2006; Denzin and Lincoln, 2005; Crombie and Davies, 1997).

5.2.5.1 Qualitative research

Qualitative research is well known for its ability to bring understanding to social research and for its focus on subjectivity (Lo-Biondo-Wood and Haber, 2006; Luborsky and Lysack, 2006; Polit and Hungler, 1989). Ritchie and Lewis (2008) distinguish between the 'types' of data available for use in qualitative research. They state that a decision is needed about the type of data required for the study before an appropriate method can be selected. This refers to whether or not the data sought will be naturally occurring or generated. They describe naturally occurring data as being derived from one of the following sources: observation, documentary analysis, conversation and discourse analysis, and generated data from in-depth interviews or focus groups (Ritchie and Lewis, 2008).

The strengths and limitations of each type of data were considered briefly to ensure an informed decision was made about the most suitable method for the proposed study. Through consideration of the research aim some methods can be excluded relatively quickly.

Naturally occurring data

Methods drawing on naturally occurring data such as observational methods used in ethnography and anthropology (Ritchie and Lewis, 2008; Pope and Mays, 2001) involve the observation of the patient in their natural environment. Here the researcher immerses themselves fully in the daily lives of the research participants (Parahoo, 2006). If such data were required for this study then data gathering would involve the researcher waiting for, and observing, a hypoglycaemic event. Whilst this may indeed provide an in-depth insight into the individual's social behaviour in a relevant setting (Parahoo, 2006), it is not suitable for use in the current study. Firstly, much time would be spent with only one participant, waiting for an event to occur; this would be time

consuming. Secondly, this method would only provide experiences of one or two incidents; many experiences with numerous individuals are required for this study. And, lastly, observing a hypoglycaemic event could be perceived as being unethical as the researcher would be precluded from acting. This method would therefore be uninformative, impractical and perhaps, unethical.

Documentary analysis (Bowling, 2009) involves the investigation of existing documents. Currently, the only available ambulance service data for this patient population is clinically or demographically orientated and would therefore not capture the patient's perspective of the event. The use of such data would only provide information on a single aspect of the participant's care, and this would be from the paramedic's perspective rather than the patient's. Finally, both discourse and conversation analysis methods require real time observation, and so for the same reasons as outlined previously would not be practical or appropriate for this study.

Interviews

There are four broad categories of research interview discussed in the literature: structured, unstructured, in-depth and semi-structured (Parahoo, 2006; Holloway and Wheeler, 1996; Lysack *et al*, 2006; Polit and Hungler, 1989). Each of these categories have different attributes. These will be discussed briefly and their relevance to the study considered.

Structured interviews have a number of strengths. These include being relatively quick to undertake and having the ability to include a large sample size (Fontana and Fray, 2005). It has even been suggested that these characteristics make structured interviews more suitable for quantitative research rather than for qualitative (Parahoo, 2006). However structured interviews are generally limited in permitting a detailed investigation of participants' views because questions tend to require fixed responses (Lysack *et al*, 2006; Holloway and Wheeler, 2002). To fully investigate a patient's

experience of hypoglycaemic events, flexibility will be required, to allow the pursuit of specific issues that may arise. The use of structured interviews will therefore not be explored any further.

The use of the word 'unstructured' is a little misleading as there is always some degree of structure to an interview (Ritchie and Lewis, 2008). Unstructured interviews may provide in-depth information but will to an extent be led by the participant rather than the interviewer (Lysack *et al*, 2006). In this study a greater degree of control will be required during interviews as participants are prompted to talk about specific aspects of their care. This means that an unstructured approach is not suitable for the purposes of this study.

With in-depth interviews, the interviewer attempts to explore in great detail a particular event or issue (Lysack *et al*, 2006). The focus is on the extraction of extensive relevant information about one or two issues, generally through the use of open-ended questions (Lysack *et al*, 2006; Pope *et al*, 2001). This technique is of interest as there are some aspects of this study that require a greater degree of probing to obtain the necessary detail needed to develop understanding. On some occasions fixed response questions may be required which will then lead into an open ended question to elicit detail on an event. With regards to its suitability for use in this study, the in-depth interview is the converse of the structured interview; the latter being too prescriptive and lacking depth, but the former providing too much depth and not enough breadth. So again, this study requires the investigation of a number of both broad and specific topic areas. Ultimately these requirements preclude the in-depth interview as the preferred method.

Having identified the limitations of other interview types this leaves the semi-structured interview. This method facilitates the use of both closed and open ended questions,

which are controlled by the interviewer and supported by a topic guide (Ritchie and Lewis, 2008). It affords a degree of flexibility to probe for more in-depth information when necessary (Pope *et al*, 2000). The use of the term topic 'guide' is a little ambiguous. Some literature suggest an interview 'schedule' is the more appropriate tool for use in semi-structured interviews (Parahoo, 2006) whilst others advocate the use of a 'guide' (Holloway and Wheeler, 1996). The difference between a 'guide' and 'schedule' is clarified by Parahoo (2006) who suggests that a topic guide affords the interviewer a greater degree of freedom to probe deeper should this be necessary, as opposed to a 'schedule' which is simply a questionnaire, which by its nature, provides little freedom for the interviewer to deviate.

The semi-structured interview creates, almost by default, a level of uniformity or standardisation of questions to be posed across participants, thus ensuring each is asked similar questions on the relevant topic area (Parahoo, 2006). This is attractive for the purposes of this study as a number of topic areas require to be included. Additionally, the flexibility of the semi-structured interview enables the wording of questions to be modified as they are posed without altering their meaning. This ensures the questions can be asked in the most appropriate way according to individual circumstances. Parahoo (2006) suggests that semi structured interviews are useful in addressing sensitive topics as they individualised, in contrast to focus groups, which involve a group of participants that are known to prevent individuals from talking about sensitive or uncomfortable topics. The ability of semi-structured interviews to provide structure, but also flexibility, and the personal/individualised manner in which they can be undertaken, all contribute to the rationale for this particular method of data generation to be used in this study.

Having chosen to use semi-structured interviews, there are important considerations in terms of how this qualitative research will be carried out. These concern the factors that may influence the decisions, assumptions and bias that will shape the questions, interview processes and interpretation of the generated data. These will be considered within the context of reflexivity.

5.2.6 The role of the researcher and reflexivity in qualitative research

“As qualitative researchers, we understand that the researcher is a central figure who influences the collection, selection, and interpretation of data. Our behaviour will always affect participants’ responses, thereby influencing the direction of findings. Meanings are seen to be negotiated between researcher and researched within a particular social context so that another researcher in a different relationship will unfold a different story. Research is thus regarded as a joint product of the participants, the researcher, and their relationship: It is co-constituted.”

Finlay (2002, pg. 531)

Reflexivity has already been briefly discussed in earlier chapters (see sections 1.9.5 and 4.5.9). This section discusses the role of reflexivity within the context of this qualitative study and aims to ensure that the approach to data collection and analysis is transparent. The qualitative approach aims to remain as neutral and objective as is possible during the collection, interpretation and presentation of data. In reality this can never be achieved (Snape and Spencer, 2008). Instead of denying the potential for researcher bias, some qualitative researchers openly acknowledge this. This permits the researcher to acknowledge upfront, any bias that may have influenced each stage in the study development process. This transparent approach permits an external

review of the processes applied and aims to increase the trustworthiness of the study (Snape and Spencer, 2008).

5.2.6.1 Reflexivity continuum

Reflexivity is an essential component of qualitative research and has been usefully described on a 'reflexivity continuum' (Woolgars, 1988). At one end of the continuum is 'benign introspection', in other words simple reflection focussed on what the participants say. This position is often aligned with an objective, positivist paradigm of enquiry. At the opposite end, where objective reality is denied, lies 'radical constitutive'. This describes a form of reflexivity, in which reality is constructed "*contemporaneously*" with equal value being placed on accounts of both the researcher and the participant (Shaw, 2010, pg. 243). Radical constitutive reflexivity is aligned more with the interpretivist/constructivist approach to reflexivity and thus requires much more than a simple description of what the participants have said. Researchers, according to Shaw, must "*turn your gaze to the self*" and focus on your involvement in the process of co-construction of evidence in a world that is viewed as inter-related (Shaw, 2010, pg. 236).

As an applied researcher, approaching this study through a pragmatic lens, but with limited experience in qualitative approaches, I was more naturally influenced by the positivist methodological approach, being more comfortable with objective enquiry. Perhaps this was as a result of my long exposure to the physician-led approach to prehospital scientific enquiry, undertaken through the positivist lens (Tavakol and Zeinaloo, 2004). However, the reflexive process inherent within the current qualitative study, required a fundamental shift towards a more interpretivist perspective (Woolgars, 1988). I had therefore to shift my natural and somewhat comfortable position, to a more unfamiliar interpretive approach. In doing so however, I tried to

avoid the “*naval gazing*” in this approach described by some (Clifford, 1999, pg. 644). I did not wish to be so subjective or superficial as to detract from the practical/clinical meaning of the findings within the context of the research questions.

5.2.6.2 Methodological reflexivity

The world of reflexivity can be confusing (Lynch, 2000). There are at least six ‘types’ of reflexivity described; mechanical, substantive, methodological, meta-theoretical, interpretative and ethnomethodological. The pragmatic lens through which this research is undertaken places importance on the practical meaning of the results. As such it is appropriate to concentrate on the methodological aspects of this study; methodological reflexivity. As I alluded to earlier (see section 1.9.5) methodological reflexivity is the most common form of reflexivity and the most understood of the reflexive typologies (Lynch, 2000). It is through this ‘reflexive lens’ that I will be developing and operationalising the various elements of this study. There are numerous benefits of reflexivity within social research (Shaw, 2010; Finlay, 2002). Perhaps the most important is its ability to permit the world to be viewed within the context of where things happen. And, by being reflexive, the researcher opens up any biases and influences to the reader as was previously mentioned. Lynch suggests that through methodological self-consciousness students become “*conscious of their own assumptions and prejudices, and to focus upon uncertainties, possible sources of bias, and problems of access and reactivity*” (Lynch, 2000, pg. 29). Adopting this approach it is hoped that I will, as Lynch stated, be in a position to “*attempt to correct biases that distort or confound access to the object of study*” (Lynch, 2000, pg. 29). If this is achieved, then readers will be able to understand my perspectives in approaching this study, and ultimately, the validity of my claims (Potvin, Bisset and Walz, 2008).

Although there is some agreement on the reflexive typology discussed above, qualitative researchers disagree in respect of how reflexivity should be undertaken

(Finlay, 2002). Finlay (2002, pg. 536) usefully recommends that reflexivity should begin from “*the moment the research is conceived*” and suggests reflexive analysis may be applied during different stages; the pre-research stage; the data collection stage; and the data analysis stage. This staged approach to reflexivity will be used to present a discussion on some of the key reflexive accounts of this study. These processes were undertaken simultaneously throughout the study, allowing the reflexive approach to become truly embedded.

5.2.6.3 Pre-research stage

When this programme of research began I had been employed by the Scottish Ambulance Service for 11 years, the latter two of which I had been attached to the NMAHP Research Unit. This relatively unique dual role has been described by others as a clinical-academic role and is said to bring with it both benefits and challenges (Yanos and Ziedonis, 2006). The benefits relate to the ability of those working within the clinical environment to identify key research problems, and the challenges, the confusion and difficulties of the ‘internal role’, that is, the problems experienced in shifting between researcher and clinician role (Yanos and Ziedonis, 2006).

As if exemplifying these points, I position myself precisely there, in that I had considerable expertise in my paramedic role, but remained a novice, and early career researcher. My research focus, on hypoglycaemic emergencies, had evolved from personal experiences, anecdotal reports and existing non condition specific evidence relating to the safety of non-transportation (Snooks *et al*, 2005; Snooks *et al*, 2004b). However, the data from the scoping review (chapter 3) and the retrospective analysis (chapter 4) two previous studies presented in this thesis, contradicted and challenged some of these early assumptions, particularly around the safety of leaving patients at home (see pg. xiii [personal statement] and section 1.7). It appeared that, for most patients, repeat severe hypoglycaemic events requiring further ambulance service

assistance were not a regular occurrence. However, for a small cohort, who had experienced repeat or recurrent events, my original concerns around lack of follow-up care and non-transportation remained.

I therefore continued to empathise with the patient and acknowledged the significant difficulties they faced in managing their condition. However, I also believed that referral to health care providers would offer them considerable benefit, and through professional support enable better control of their condition. This would, I assumed, reduce the frequency of severe hypoglycaemic events. I felt that the Scottish Ambulance Service was failing these individuals and this provided the drive to further investigate this patient population. There remained an urgent need to ensure follow-up care to help this sub-group of patients manage their condition and prevent further events. This desire to support and do more for the patient and to act in their best interest, created a tension between my clinical and research needs, biases and assumptions (Yanos and Ziedonis, 2006). Reflecting on these beliefs whilst undertaking my research, helped me to lessen many of these tensions.

Support from clinical and research colleagues

In acknowledging these assumptions and the potential for the introduction of bias, experienced researchers (my supervisors) from alternative health care backgrounds were involved in all stages of the study. Both supervisors had considerable experience in qualitative and quantitative research. The qualitative research questions were developed using an iterative process with all three researchers ensuring that a range of experiences contributed to the design, analysis and synthesis. Their inclusion also contributed to the development of trustworthiness in the research process (see section 5.8.4.1).

Although methodologically this approach minimised bias, neither supervisor was able to contribute clinical experiential knowledge. My clinical assumptions therefore remained unchallenged. To ensure a reflexive approach, during each stage, I turned to respected and experienced paramedic colleagues, to gauge my clinical thought processes and challenge my own assumptions. For example, during discussion and development of the qualitative questions I was keen to retain a focus on the original concerns on Oral Hypoglycaemic Agents (as described in chapter 3). After discussion with clinical colleagues (and subsequently again with supervisors) it became apparent that I had become somewhat fixated on this particular element of care. The association between OHA's and repeat hypoglycaemic events had already been identified through the scoping review, the results of which had been published in a respected international peer-reviewed journal (Fitzpatrick and Duncan, 2009). These results were already changing clinical guidelines in Scotland and thus mitigating the associated problems between hypoglycaemia and repeat calls in people treated with these medications.

Recognising this, in what I now view as a blinkered approach, enabled me to look at the bigger clinical picture. Subsequently the study refocused on the more significant problems identified in chapter 4 around non-transportation, repeat calls and the lack of immediate follow-up care. An approach that encapsulated and explored the patient's experience, rather than one concentrating on the pharmacological aspects of care was required. This reflexive process, therefore, strongly, and positively influenced the change in direction of this programme of research.

Developing a coherent aim is central to the success of any research project (Parahoo, 2014; Lewis, 2008). The change in direction from a pharmacological to a patient experience perspective required me to refine the study's research aims and ensure that

the research questions were closely aligned to these. The questions were therefore developed and refined through an iterative process, in consultation with my supervisors. This helped minimise any bias introduced through my personal experiences and assumptions, capitalised on the considerable expertise of others and ensured that the research aims remained central to the process of enquiry.

5.2.6.4 Data collection stage

There is some evidence that where participants know their interviewer is a health care professional they are likely to provide more positive reviews of the health care they receive (Smithson, Hukins and Jones, 2006). Therefore, to ensure participants were as open as possible about their experience of care, the following steps were taken:

Firstly, to mitigate against any personal confusion about my 'internal role' (Yanos and Ziedonis, 2006), I chose to present myself as a researcher rather than a paramedic. I was therefore able to mentally separate being a clinician from a researcher. This helped me to focus on conducting interviews rather than being distracted by any clinical elements.

Secondly, all participant documentation were labelled from the University of Stirling and I introduced myself as a researcher from the University. I chose to neutralise my dress-code (Manderson, Bennett, and Andajani-Sutjahjo, 2006) and conduct interviews, in smart casual clothing. I did not disclose my affiliation to the Scottish Ambulance Service unless asked. It was anticipated that presenting as a researcher from the University of Stirling would limit any potential biases from the participant's perspective and permit greater reliability in the findings (Shenton, 2004). Disclosure of professional status (paramedic) occurred only on a small number of occasions, and only when interviews had been completed.

Thirdly, during the interview set-up, I remained as relaxed as possible attempting to portray a friendly and genuine interest in the participant's story. My general experience of working with the general public from all social backgrounds, particularly with those living in the more deprived areas in the West of Scotland, assisted this process greatly. Having been clinically based in the area where interviews were being conducted, I understood the local dialect. To ensure their understanding of questions, I altered the terminology used in the topic guide accordingly. This strategy was also used for those interviewed with a greater understanding of the technical aspects of their condition. I appropriately reinforced my interest in their experiences through both verbal and non-verbal communication (nods of head, smiling and acknowledgments during conversation).

As interviews progressed and I grew in confidence and experience in this process, the process became more natural. The interviewer and interviewee, thus, became more active conversational partners with equal voices (Rubin and Rubin, 2012). The freedom to operate purely in this research role, with minimal clinical distractions, greatly assisted this process and should not be underestimated.

The researcher-clinician challenge

Whilst I had made every effort to detach myself from the clinical aspects of care, somewhat inevitably, a number of distinct clinician/researcher conflicts developed during interviews that required sensitive handling. The potential for the identification of concerns around poor emergency treatment practices from either the participant, relatives or ambulance clinicians had been considered during the ethics application process. These instances were fortunately uncommon. However, on one occasion the relative of one participant described their attempts to force chocolate bars into the mouth of their unconscious hypoglycaemic husband; a potentially hazardous activity.

Rather than interject immediately, this was recorded in notes during interviews. At the end of the interview the dangers of this practice were discussed and more appropriate techniques recommended. On another occasion the participant had received advice on insulin therapy from the attending ambulance clinicians. This type of advice is currently beyond the scope of paramedic practice in Scotland. Again, on closure of the interview, I discussed the limitations of the education paramedics receive on diabetes, and advised the participant to seek advice from their diabetes care provider about insulin dosage. On both occasions I disclosed my professional status to ensure credibility regarding the advice provided. Had I been more reactive during these interviews and diverted discussion onto appropriate personal management of hypoglycaemia, the early disclosure of my professional status may have influenced the participant's subsequent responses.

5.2.6.5 Data analysis stage

Qualitative research analysis is a laborious process and the analysis of data for this study was no different. This analysis time permitted considerable reflection and consideration of the meaning of the data. Themes emerged and were then subsequently redefined through an iterative analytical process led by myself but assisted by my supervisors. One clear theme that emerged was that of the overwhelmingly positive experience of care provided by ambulance clinicians. Had such care not been taken to ensure a neutral approach i.e. through disclosing links to the ambulance service or professional background etc then this finding may have been open to criticism. As such, more trust may be placed in the finding that participants report this positive experience.

Shifting analytical approach

The manner in which qualitative research is analysed and presented can influence the interpretation of the findings. In my more positivist comfort zone, there was initially a

tendency to quantify the qualitative findings to convince myself, and any reader, of validity and reliability. However, it was essential to ensure the focus was retained on the meaning of participants' responses and to avoid the numerical counts in an attempt to illustrate representativeness (for example; 19 said this, and 5 said that). Indeed, during earlier attempts at analysis I struggled to shift from my more natural quantitative position. One of the most fundamental changes in my PhD experience came during a supervisory meeting. One supervisor highlighted that the manner in which I was reporting the findings was reflecting what *I* thought and not what the *participants* thought. Thereafter, throughout the analysis, I held onto this assertion and shifted my approach to view the findings through each participant's lens rather than my own. Participants' responses were also presented as direct quotations to help establish transparency, and therefore trustworthiness, of the qualitative research approach (Elo *et al*, 2014). This shift in analytical approach remains as one of the most significant challenges I experienced during my PhD journey.

Challenging assumptions

During the analysis of transcripts I had to further acknowledge and challenge my assumptions and biases. For example, at the outset I had generated both professional and personal assumptions about the known social deprivation in many of the areas in which interviews took place. I presumed alcohol would play a significant part in many severe hypoglycaemic events. However, my assumptions appear to be wrong; very few participants identified this as a problem or cause of hypoglycaemia. On the contrary, impaired awareness of hypoglycaemia (a condition I had no knowledge of before undertaking this thesis), and the challenges faced by relatives in treating the condition, appeared to be two of the key influences on the need for ambulance assistance.

The benefits of the reflexive process therefore enabled the initial identification of these biases and, in doing so, permitted a more open interpretation and approach to analysis. This allowed the findings to focus on the meaning of the participant's accounts rather than on one or two areas that confirmed my assumptions, thus limiting any confirmation bias.

Reflexive diary

Keeping a reflexive diary throughout the research process is recommended by several authors (Tufford and Newman, 2010; Hancock, Ockleford and Windridge, 2009). Keeping a reflexive diary can provide transparency in study developments and also support personal growth during the research process. I did not keep a reflexive diary. I did however make notes and meet to reflect with both supervisors on a weekly basis, particularly during the data collection and analysis stage.

I had not made a conscious decision to omit this useful 'tool'. However, the focus at the time, as a part-time research student, was on undertaking the research and improving my research interview technique while concurrently working on other research and clinical projects. Notes were made during interviews and weekly meetings held with supervisors to ensure a reflexive approach. But, having been through this process I can now see the tremendous benefits of keeping (and maintaining) a dedicated reflexive diary of thought processes and events as they develop. Appreciating now the importance of the reflexive diary will ensure that it becomes firmly embedded in any further qualitative enquiry I undertake.

In summary, the reflexive process has allowed me to consider my personal and professional biases. This has enabled this study to be approached and undertaken with an open-mind, thus allowing participants' voices to be heard. This transparency

will help readers to understand the decisions made during the research process and subsequently permit a level of trustworthiness in the findings.

5.2.7 Study aims

The aims of this study were to describe people with diabetes:

1. experiences of hypoglycaemia,
2. reasons for requiring the SAS, and;
3. why patients do or do not subsequently attend for follow-up care in either the Emergency Department or with their Diabetes Care Provider following SAS treatment for a hypoglycaemic event.

5.2.8 Methods

5.2.8.1 Recruitment area

The sample was drawn from the catchment area of the West of Scotland Ambulance Control Centre (WoS ACC). WoS ACC covers approximately 7724 square miles in NHS Greater Glasgow and Clyde and NHS Lanarkshire. It receives approximately 50% of ambulance service emergency calls from within Scotland (David Hunter, personal communication 2008). These regions have a combined population of 1,229,922 (General Register Office for Scotland, 2010) with 81,920 people diagnosed with diabetes (Scottish Diabetes Survey, 2010).

5.2.8.2 Sample/participants

The objective was to conduct semi-structured interviews with 30 adults with diabetes who had experienced a hypoglycaemic emergency and had been attended by SAS ambulance clinicians. The sample was purposively selected. Previous work (Fitzpatrick and Duncan, 2009) established that the Scottish Ambulance Service responds to approximately 6500 diabetic emergency calls (code '13's) each year of which around fifty percent are known to be for hypoglycaemia. Data from the retrospective analysis

highlighted that over a twelve month period, between June 2006 and May 2007, WoS ACC received around 2,760 diabetic related emergency calls. After analysis it was determined that 48% (n = 1319) of these calls were for hypoglycaemia. Over a 12 month period it was estimated that WoS ACC would receive approximately 770 hypoglycaemia related emergency calls from the proposed catchment area of Greater Glasgow and Clyde and Lanarkshire. To recruit approximately 30 people (a 10% response rate) it was estimated this would take around six months to achieve.

A sample size of 30 was chosen as it was anticipated that this would allow a sufficient number of participants to generate a broad range of information about their experiences. Achieving data saturation is a contentious methodological aim. There are currently no available guidelines on how to achieve this (Guest *et al*, 2006). Some have suggested that despite its hypothetical usefulness, in a practical sense, true saturation can never be achieved (Dey, 1999). A recent review and study to determine the point at where data saturation occurs demonstrated that between 88% and 92% of codes were identified after 12 interviews (Guest *et al*, 2006). Based on this evidence a sample size of 30 should be more than sufficient to reach saturation.

Various types of non-probability sampling methods were considered: accidental, volunteer and snowball sampling methods. All have their inherent strengths and limitations (Parahoo, 2006). However the results from chapter four found that the target population had an age range of between 3 and 99 years and their genders were equally represented (see Table 12). The sampling frame included all patients who had experienced a severe hypoglycaemic event within the Greater Glasgow and Lanarkshire post code areas. A purposive stratified sample was therefore selected to ensure the full range of salient issues were identified within this particular patient group. The sample aimed to include people who belonged to the following groups that

were likely to have different experiences and attitudes relating to diabetes care: men/women; people with both Type I and Type II diabetes; those treated at home and/or taken to hospital; people aged under 65, people aged 65 and older (see study protocol: Appendix 9). It was not possible to purposively include people from a variety of ethnic cultural backgrounds as this information is not routinely gathered.

5.2.8.3 Participant identification

Potential participants were identified through a weekly review of the electronic Patient Report Form (ePRF) database for all calls received by WoS ACC with a Greater Glasgow and Lanarkshire postcode (Appendix 9). The ePRF was chosen as a source of data as its national introduction had been completed by the time of this study. The forms contained a detailed clinical record of each patient, recorded at the time of the event by the ambulance clinician. Despite the accuracy of ACC data in identifying hypoglycaemia events, the use of clinical data, would ensure only those with a definitive diagnosis of hypoglycaemia (via blood glucose <4mmol) for each event would be included. Potential participants were contacted where they had a final coding of a diabetes related emergency (Code 13), were hypoglycaemic (capillary blood glucose <4mmols) and were aged 16 years and over. Contact with potential participants was made by the author who is a staff member and employed by the SAS. A flow chart of the recruitment process can be found in Figure 11. The recruitment process was undertaken over a six month period between February and August 2010.

5.2.8.4 Inclusion / Exclusion Criteria

Once identified an inclusion/exclusion criteria was applied to all potential participants:

Inclusion Criteria:

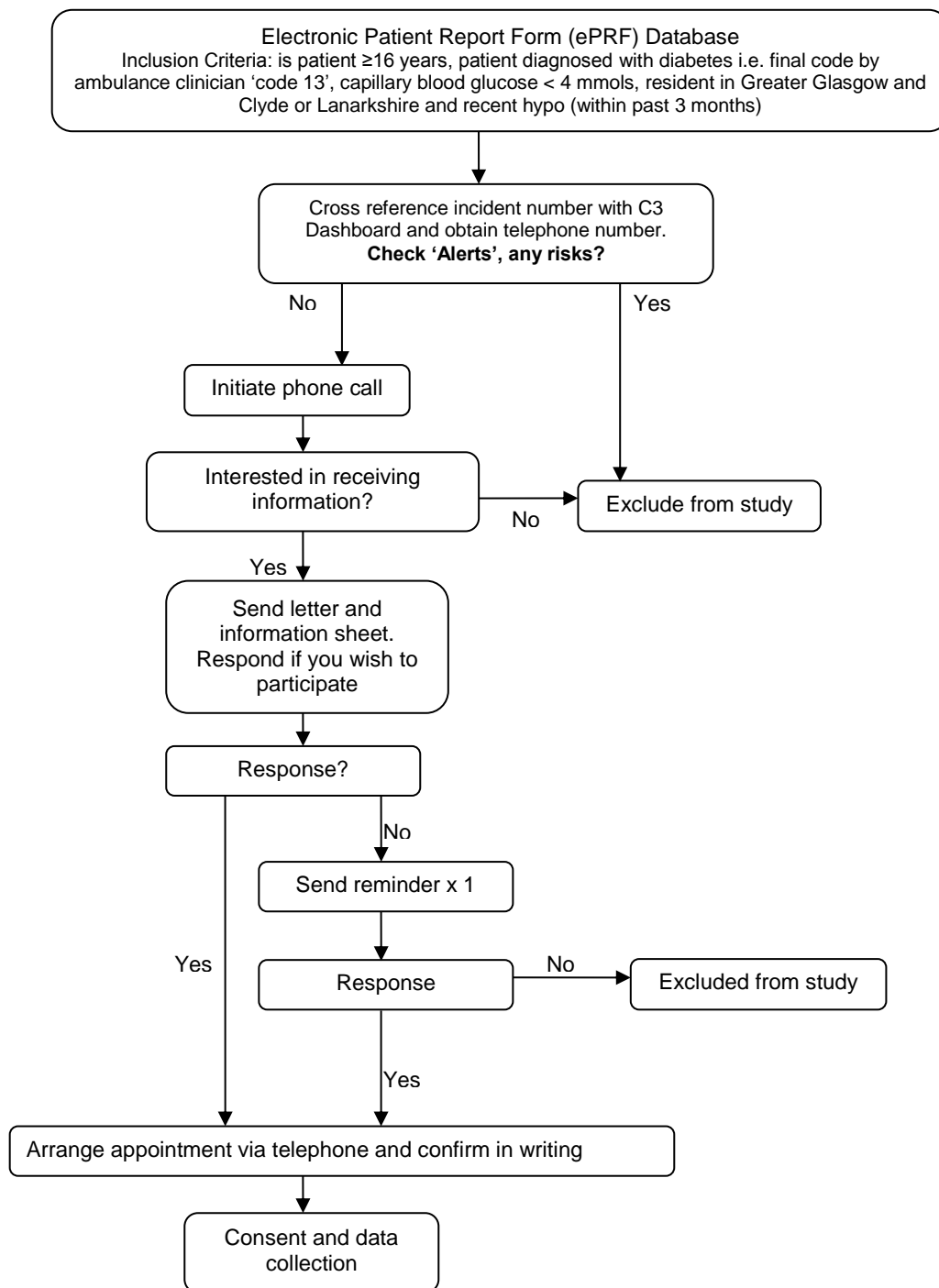
- Patients with Type I or II diabetes.
- Have required assistance from the Scottish Ambulance Service for hypoglycaemia defined as blood glucose , <4mmol/l.

- ≥ 16 years of age.
- Resident in NHS Lanarkshire or NHS Great Glasgow and Clyde

Exclusion criteria:

- All individuals aged below 16 years of age (current Scottish Ambulance Service Policy/Guidelines do not authorise ambulance clinicians to Treat and Refer this age group, meaning no individual in this age group will be left at home)
- Where patients cannot communicate.
- Where patients lack capacity to consent.
- Where patients were identified as violent or aggressive via MPDS[®] system.

Figure 11: Flow chart of recruitment process



5.2.9 Ethics

As the study involved the interviewing of NHS patients, NHS Research ethics approval was required. An ethics application was submitted electronically via the Integrated

Research Ethics Application system (IRAS, 2009). The main ethical challenges were detailed during this process and due consideration given to how participants could be affected as a result of participation in the research study. The key ethical consideration was the initial contacting of patients via a telephone call to confirm correct address details. However, similar calls to patients identified using this database had been made in this manner before and was normal practice for both the SAS and NHS24 via their call-back systems. There was also a small potential for patients to become upset during interviews as they recalled an unpleasant event. This may have caused embarrassment or emotional distress. The author's clinical skills provided appropriate expertise to deal with this sensitively. Furthermore, Diabetes UK (Scotland) offer counselling services and agreed to be a contact point for participants in the study for any support required. The contact number, e-mail address was provided to all participants in the Participant Information Leaflet.¹

5.2.10 Caldicott approval

Caldicott Guardian approval was sought and granted from the SAS to access the patient database to identify potential participants. Permission to review the ACC database for this purpose was granted by the SAS Caldicott Guardian and Medical Director (Dr George Crooks).

5.2.11 Data protection

The author, was employed by the SAS and authorised to access and identify all potential participants from the SAS ePRF database. Approval was granted for this purpose from the SAS Caldicott Guardian. Weekly research team meetings reviewed this process and ensured that no breaches of confidentiality occurred. As a state registered paramedic, the author adhered to regulations laid down by the Health Care

¹ To my knowledge this number was used on one occasion after interview to provide support to one participant who had questions about her diabetes medication.

Professions Council with respect to patient confidentiality (Health Care Professions Council, 2012). The Scottish Ambulance Service complies with NHS and Data Protection Laws (Data Protection Act, 1998).

All electronic data were stored on a password protected and encrypted Scottish Ambulance Service laptop. Thereafter data were transferred using secure NHS e-mail to a secure password protected hard drive based at the Nursing Midwifery and Allied Health Professions Research Unit (NMAHP RU), University of Stirling. All paper based data and personal information were stored in a locked, metal cabinet in the NMAHP RU. Personal details were only made available to the author (and employee of the SAS). These were held separately in another locked metal cabinet.

5.2.12 Obtaining contact information of potential participants

Over a 6 month period the author received a weekly summary report of data on hypoglycaemia related emergency calls within the recruitment area (see section 5.2.8.1). These included the incident number¹ for each potential participant. This information was delivered by SAS Management Information Services by secure e-mail. The information was obtained through a weekly review of ePRF data. Using the SAS C3 Dashboard for West Service² each incident number was individually entered to extract the electronically recorded details of the original emergency call; including the telephone number used to make each 999 call. To ensure accuracy, the name and address recorded on the ePRF was cross-referenced with those on the C3 Dashboard.

¹ An individual incident number is assigned to each patient during an emergency call. This number is unique to that patient and incident and enables patients to be traced back to the original event.

² A software package for retrieving and viewing call data.

5.2.13 Interviewer Safety

The current MPDS[®] call taking system contains an alert box within which any additional clinical or safety information relating to either the patient or location is recorded. This is undertaken by the call-taker by way of text input at the time of call. As a safety measure, the input text within the 'alert box' was checked for each incident and any recorded or known risks to that address or patient, such as violent or abusive behaviour, was noted and resulted in the participant's exclusion from the study. In cases of dubiety the author discussed the information with the on-shift call-takers and a decision was made to exclude or not. The interview location was identified as a possible risk to the researcher. To minimise these risks interviews were organised in a mutually agreed location. When interviews were conducted in participants' homes, or other isolated locations, systems were put in place to ensure a telephone call was made to the supervisor immediately prior to and after interview. This ensured the author was 'clocked' in and out and his location was known at all times. In the unlikely event that contact was not made with the author at the agreed time, the Police would be notified of the supervisors concerns and followed up until the author's safety had been established.

5.2.14 Contacting potential participants

The author contacted potential participants using an agreed telephone protocol (Appendix 10) within 7 days of their hypoglycaemic emergency and informed them of the study.

To those who expressed interest, permission was obtained to send the study information pack to their home address. The information pack included a study information sheet (Appendix 11), participation consent form (Appendix 12) and prepaid envelope. Potential participants were invited to return confirmation that they were

willing to be contacted to arrange an interview to discuss their hypoglycaemic emergency, the care they received, and the ways in which follow-up care might be improved in the future. Where answering machines were activated no message was left so as to avoid worry or confusion.

5.2.15 Consent

If no response was received within two weeks, a reminder pack was sent. Where consent was provided, the participant was contacted by telephone to arrange interviews at a mutually agreeable location. During this telephone call potential participants were given the opportunity to ask any questions about the study. A confirmation letter was sent with the date, time and location. Information on age and gender was recorded, from those who consented, on a central database. This ensured the broad representation and stratified sample as outlined earlier was being achieved.

At the start of the interviews the interview process was described and opportunities for questions provided. Some participants had not completed the participation consent form were asked to do this before the start of the interview. Consent was also sought to inform their GP of their participation in the study (Appendix 13). For those who agreed, a letter was sent to their GP outlining the study and their patients' participation (Appendix 14).

5.2.16 Interviews

A topic guide was developed by the author along with his supervisors using an iterative approach. The topic guide provided an 'aide-memioire' for the interviewer, ensuring questions were not lost or forgotten during the interview process (Burgess, 1984). The topic guide allowed a degree of flexibility during interviews so that questions were not so fixed or unchangeable that it restricted both the interviewed and the interviewer (Ritchie, Spencer and O'Conner, 2008). The topic guide was altered, for example, by

rewording questions for individual participants to help them understand what was being asked, or to simply enable the re-ordering of questions to facilitate the natural flow of the interview. Such flexibility helped interviews develop into a conversation rather than an interrogation which may have occurred using a more restrictive format.

Careful consideration was given to deciding which questions were to be included in the topic guide to ensure the salient issues were covered. There were a number of principle areas to be covered during each interview. The questions were informed and shaped by the results of the studies presented in chapter 3 and 4. In particular, the questions around the quality of care from the patient's perspective and around non-transportation and follow-up care. Questions were aimed at exploring the events leading up to the hypoglycaemic emergency, what the ambulance clinicians did once they arrived and what they did after the ambulance clinicians had left. The semi-structured format was designed to help patient recall by taking them through the sequence of the events.

As Ritchie, Spencer and O'Conner (2008) suggest it is always wise to test the topic guide early in the research process. This testing was undertaken in two stages. Once the topic guide questions had been developed, and interview training completed, two individuals with diabetes, accessed through Diabetes UK, were interviewed. These interviews were observed by one PhD supervisor (ED) who provided feedback along with the two individuals from Diabetes UK. A number of small changes were made to the wording of a number of the questions. After the first five interviews the data collected were reviewed together with both supervisors. No significant changes were made to the questions on the topic guide, however some points were raised around interview technique. The key questions can be viewed in the topic guide (Appendix 15). The interviews were conducted in a conversational style and aimed to last no

more than an hour.¹ At the end of interviews participants were presented with a £10 gift token in thanks for their time.

5.2.16.1 Interview Transcripts

Interviews were recorded on a digital recorder (Olympus DS-2200 Digital Voice Recorder). Completed interviews were uploaded to the NMAHP Research Unit secure, password protected server. They were then sent securely to a professional transcription service where they were transcribed verbatim. These transcripts provided the raw textual data for this study (Pope *et al*, 2000).

Only the author had access to personal details of potential participants. Transcriptions were anonymised using a unique reference code. A coding sheet linking anonymised transcript data with participant information was held separately in a locked metal cabinet.

5.2.17 Analysis – applied qualitative research

As this study was undertaken within the context of applied health service research, it therefore seemed appropriate to use a method recognised as being specifically designed for this purpose. Framework analysis is one of these methods (Pope *et al*, 2000). A pragmatic approach using framework analysis was taken in order to identify key themes (see section 5.2.16).

Framework analysis was introduced in the 1980's "*for the conduct of qualitative studies within social policy enquiry*" (Ritchie, Spencer and O'Conner, 2008, pg. 220). It was developed primarily to help manage and organise data but was also found to be useful

¹ Three of the initial interviews were conducted in collaboration with an experienced qualitative healthcare researcher to develop my research interviewing skills.

during the stages of data analysis. Ritchie and Spencer outline a number of advantages to using framework analysis:

- “Grounded or generative: it is heavily based in, and driven by, the original accounts and observations of the people it is about.
- Dynamic: it is open to change, addition and amendment throughout the analytic process.
- Comprehensive: it allows a full, and not partial or selective, review of the material collected.
- Enables easy retrieval: it allows access to, and retrieval of, the original textual material.
- Allows between and within-case analysis: it enables comparisons between, and associations within, cases to be made.
- Accessible to others: the analytic process, and the interpretations derived from it, can be viewed and judged by people other than the primary analyst.”

(Ritchie and Spencer, 1994, pg. 176)

Although framework analysis is inductive and enables themes to emerge from within the recorded data (Ritchie and Spencer, 1994), it often begins deductively, with areas of investigation developed from specific research questions (Pope, 2000). The main advantages of the framework approach are the shortened timescales in which it permits analysis. There are a number of stages involved in using framework analysis (Ritchie et al, 2008; Ritchie and Spencer, 1994):

Stage 1: Involves becoming familiar with the data. Reading through the transcripts to get a ‘feel’ for what is being said and considering this in respect to the studies original aims: all transcripts were read to enable familiarisation.

Stage 2: Identifying recurring themes or ideas such as relevant experiences, beliefs, attitudes, behaviours etc. expressed by each individual. This enables the development of an 'index' list of the emerging themes (see Appendix 16): After familiarisation with five interview transcripts, a preliminary coding scheme was developed to organise the data according to domains of interest. This coding scheme was then applied to two interviews, checked with supervisors and refined before being systematically applied to the other interview transcripts.

Stage 3: Labelling the data using the 'index' category. Coloured pencils were used to manually highlight recurring themes. The data labelling was further checked by one supervisor (ED) for consistency (Pope *et al*, 2001).

Stage 4: Generating the chart enabled each main theme to be allocated a chart and then sub themes designated a column. Participants were identified via rows with the participant i.d. number occupying the first column followed by the sub-themes (Appendix 16): For each domain of interest, summary charts were used to record the relevant experiences, beliefs, attitudes, behaviours etc. of each participant. These facilitated both within case and across case analysis.

Stage 5: Summarising the data. This involves summarising the original data using key phrases or quotes, to ensure accuracy and context are not lost (Appendix 16).

Themes were developed within each topic area. This process was undertaken through an iterative approach together with the PhD supervisors. A thematic framework was developed using these key themes. Following Ritchie, Spencer and O'Conner's methods each main theme was "*charted*" in its own "*matrix*" (Ritchie, Spencer and O'Conner, 2004, pg. 231). Sub themes were contained in columns and participants in each row.

5.3 Findings

5.3.1 Introduction

The previous section described the research approach, methods used and rationale for the use of semi-structured interviews to investigate the patients' experiences of prehospital emergency hypoglycaemic care. The findings of these interviews will now be presented.

5.3.2 Summary of themes

Theme 1 focusses on explanations of help seeking behaviour, particularly use of the emergency ambulance service. Impaired awareness affected many participants ability to self-manage, but relatives or friends often recognised the signs of hypoglycaemia and acted on their behalf. However their relative's knowledge, confidence and ability to provide treatment varied, often leading to an ambulance call-out. Theme 2 centres on participants' experiences of prehospital emergency care. Participants reflected positively on their experiences of the SAS, perceiving the SAS to be appropriately equipped to respond to hypoglycaemic emergencies. However inconsistent and limited advice and information provided by ambulance clinicians may have led to confusion around the need for follow-up care. The third and final theme (Theme 3) confirms that participants prefer to remain at home after treatment and described why participants chose not to follow-up their care. Previous hospital and primary care experiences for immediate and short-term follow-up were generally negative and therefore reinforced their preference to remain at home and carry on as they were.

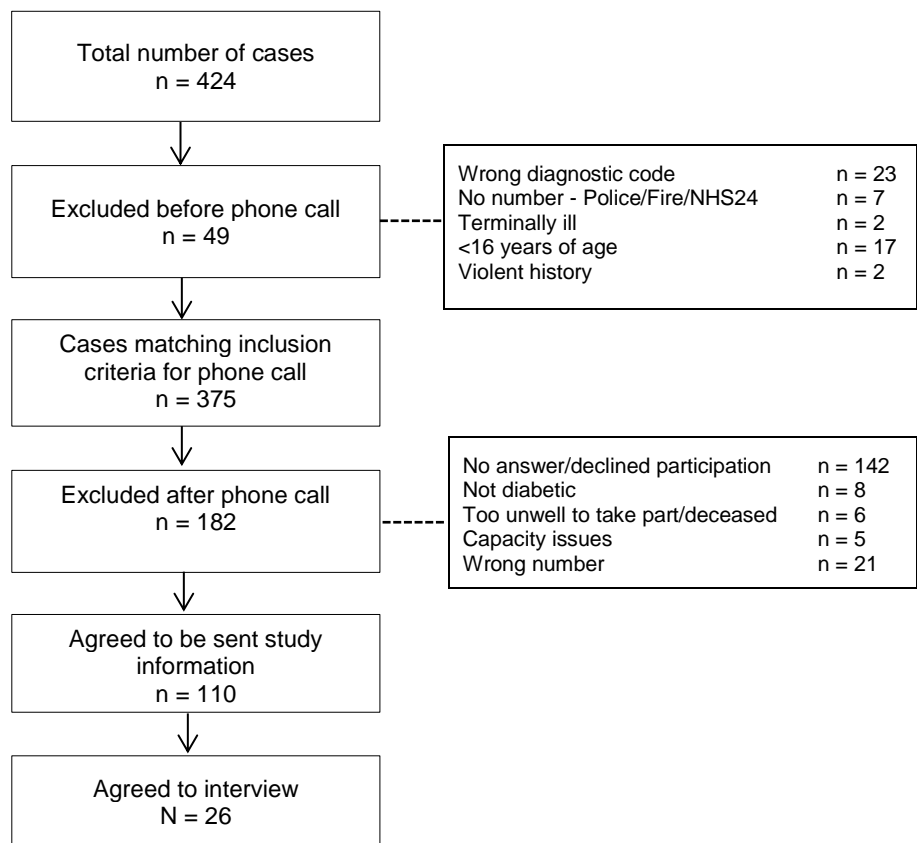
5.3.3 Participant demographics

During the recruitment period (February to August, 2010) the details of 424 calls were received from SAS Management Information Services. This was slightly higher than estimated (see section 5.2.8.2). Each call was checked against the inclusion and

exclusion criteria before attempts were made to contact the individual. Figure 12 provides details of the recruitment process.

From the 424 cases, the average age of individuals (where age was known) was 55 years (SD 8.00). Age data were missing in 45 cases. There were slightly more calls for males (n = 226, 53.2%) than females (n = 194, 45.6%). One hundred and ten (25%) participants agreed to be sent the study information pack. Twenty six individuals (25%) consented to participate.

Figure 12: Recruitment process for interviews



Of the 26 participants who took part in this study, the average age was 54 years (range 22-85 years). Slightly more males (n = 15, 58%) than females (n = 11, 42%) took part (Table 18). This was broadly similar to the overall demographics of the hypoglycaemic

population requiring emergency ambulance assistance in the West of Scotland (see section 4.4.4.1).

Table 18: Overview of participants recruited

Gender	Age in years (by stratification criteria)					
	16-25	26-35	36-45	46-55	56-65	>66
Male	1	2	1	4	3	4
Female	1	1	2	2	1	4

Most participants provided information on employment status (n = 23). A small number were employed (n = 5), with the majority being either unemployed (n = 10) or retired (n = 8). Employment status of the remaining participants (n = 3) was not known (see Table 19). Most of the participants (n = 21) lived with a partner or relative with a few living alone (n = 5). Table 19 provides a detailed summary of the participant demographics and summarises participants' characterisations of their emergency and standard diabetes care.¹

¹ To ensure anonymity participants have been provided with a pseudonym. Throughout this chapter, where quotations are included to provide the evidence to the theme, the participant's pseudonym and page number are included. This will allow the themes to be clearly linked back to the categories or 'topics' generated through the framework analysis process.

Table 19: Participant demographics and support characteristics

I.D.	Age, Gender, Treatment Age diagnosed	DEP CAT	Employment status	Lives alone/Lives with other people	Participants comments about support networks at home	Contact with health professionals and general care
I.D. 33 Susan	42 year of age Female Diagnosed at age 7 Insulin	6	Unemployed	Lives with two children – son (aged 10).	Husband lives nearby – involved when children need help e.g. picked up from school. Partner and sons try to help and usually call the ambulance if in coma.	Requires ambulance service 2-3 times a week for hypos Diabetes clinic 2x year does not get on with them.
I.D. 52 Marion	42 years of age Female Diagnosed at age 19 Insulin	7	Unemployed	Lives with partner (present during interview) Husband lives nearby – involved when children need help e.g. picked up from school if in coma	Lives with partner – works – can help with hypos particularly if caught early. Partner supportive with general care and encourages good diet. Husband also involved when children need help eg picked up from school and if pt in coma	Has required ambulance service numerous times over the years. GP and Diabetes Nurse provide care.
I.D. 60 Rory	41 years of age Male Diagnosed at age 27 Insulin	6	Employed	Lives with wife (present during interview) and two children (aged 11 & 6).	Wife sometimes panics when Rory has hypos and calls brother who then calls ambulance. Sometimes try to treat hypo but scared to use 'jab'.	Has required ambulance service numerous times over the years. GP and Diabetes Nurse provides care. Gets on well with them.
I.D. 71 Karen	68 years of age Female Diagnosed at age 40 Tablet	6	Unemployed	Lives with daughter (present during interview)	2nd daughter lives down road (pg. 3) Daughters help significantly with control the diabetes (pg. 2) Daughters also try to treat hypo themselves.	Only had to call ambulance once for a hypo. Has GP and Diabetes Nurse to help manage condition. Feels they are supportive.
I.D. 74 Margaret	44 Female Diagnosed at age 13 Insulin	6	n/a	Lives alone (partner present during interview)	Partner lives nearby – visits every couple of days. Partner stays here – he has keys since hypo (pg. 2)(pg. 25) Partner has heart condition & asthma (25)	Required ambulance once for a severe hypo. Sees both GP and Diabetes Nurse – gets on fine with them.

I.D.	Age, Gender, Treatment Age diagnosed	DEP CAT	Employment status	Lives alone/Lives with other people	Participants comments about support networks at home	Contact with health professionals and general care
I.D. 75 Ron	64 years of age Male Diagnosed at age 21 Insulin	4	Retired	Lives with wife (present during interview)	Wife supports with general management and often helps when having a minor hypo. Couldn't help when hypo was severe.	Sees Diabetes Nurse and finds her supportive. Only one severe hypo requiring ambulance.
I.D. 114 Dave	60 years of age Male Diagnosed at age 50 Insulin (initially tablets)	3	n/a	Lives with sister (present during interview)	Sister provides general diabetes support and tries to intervene during hypos.	Used ambulance service for 3 severe hypos in a 6 month period Gets on well with Diabetes Nurse.
I.D. 119 Ronan	35 years of age Male Diagnosed at age 15 Insulin	3	Employed	Lives with wife	Wife is generally supportive but not good in a 'crisis'.	See's Diabetes Nurse who is 'tremendous'. Consultants unhelpful
I.D. 120 Peter	55 years of age Male Diagnosed at age 49 Insulin	5	Unemployed	Lives with wife (present during interview)	Lives with wife – supportive in general diabetes care. Tries to help treat hypos when they occur but not always successful.	6 severe hypos requiring ambulance service in a 12 month period. See Diabetes Nurse and suggests 'she's no bad'.
I.D. 124 Edward	85 years of age Male Diagnosed at age 55 Insulin	7	Retired	Lives with wife	Lives with wife who is very supportive – very dependent on her (pg. 4) Wife is the only one who can look after him – would like some help (wife) (pg. 16)	Usage of ambulance service varies (as much as 4 times in a week) Sees 'Sisters' at clinic who are 'very good'.
I.D. 133 Tony	36 years of age Male Diagnosed at age 11 Insulin	5	Unemployed	Lives with partner	Partner very supportive with condition but panics during hypo.	Experienced 3 severe hypos in past month all requiring ambulance call-out. Sees both GP and Diabetes Nurse at 'drop in clinic'. Diabetes Nurse is 'amazing'.
I.D. 146 Stephen	65 years of age Male Diagnosed at age 21 Insulin (initially on tablets)	4	Employed	Lives with wife (present during interview)	Lives with wife – supportive and tries to treat hypos when they occur but will not use glucagon.	Has used the ambulance on numerous occasions for hypoglycaemic events. Sees Diabetes Nurse and GP. Very happy with general care.

I.D.	Age, Gender, Treatment Age diagnosed	DEP CAT	Employment status	Lives alone/Lives with other people	Participants comments about support networks at home	Contact with health professionals and general care
I.D. 162 Ian	55 years of age Male Diagnosed at age 20 Treated with insulin	6	n/a	Lives with wife (present during interview)	Wife is on constant night shift . If present she will attempt to treat hypo. Recently been prescribed glucagon but no education on use. Also daughter (aged17) – not present	Frequently requires ambulance assistance for hypoglycaemic event (recently once a week) Sees Diabetes Nurse frequently and also visits consultant.
I.D. 165 Andrew	53 years of age Male Diagnosed at age 26 Treated with insulin	3	Employed	Lives with wife (present during interview)	Wife is very supportive with general management and attempts to treat hypos herself.	May require ambulance service 1x month for hypo. Sees DNS every 3-4 months and also visits GP. Participant feels they are not interested in hypo's.
I.D. 179 Calum	41 years of age Male Diagnosed at age 10 Treated with insulin	6	Unemployed	Lives with two sons (aged 17- not working and 10- at school)	Sons (17- not working &10- at school) – both will check BS & give him something to eat after hypo. Sometimes son will call Calum's sister who then contacts ambulance.	Has required ambulance service on numerous occasions to treat a hypo. See DNS and GP and Councillor.
I.D. 187 John	57 years of age Male Diagnosed at age 36 Treated with insulin	6	Unemployed	Lives with sons (1 travels a lot for work)	Separated from wife but she still comes up to help with medicines – on days off (she is a nurse)	Has required ambulance for hypos on numerous occasions. Sees DNS and GP and psychiatrist
I.D. 221 James	73 years of age Male Diagnosed at age 40 Treated with insulin	6	Retired	Lives alone	Nephew, niece and brother appear to be main helpers . 'sees me some nights and brings shopping in for us', 'my brother comes down with the morning paper'. All provide support when in hypo.	Has 2 or 3 severe hypos a month requiring ambulance care. Has Diabetes Nurse and GP who help manage condition. James is not happy with care provided.
I.D. 222 Elaine	? years of age Female Diagnosed at age? Treated with insulin	5	Retired	Widow, lives on own	No family support	

I.D.	Age, Gender, Treatment Age diagnosed	DEP CAT	Employment status	Lives alone/Lives with other people	Participants comments about support networks at home	Contact with health professionals and general care
I.D. 237 Lesley	60 years of age Female Diagnosed at age 7 Treated with insulin	7	Retired	Lives with husband	Husband helps but is frightened and panics when Lesley has a hypo. Automatically calls an ambulance despite having glucagon available. Scared to use it.	Ambulance has been called 5 times due to hypo. Does not see a specialised Nurse, GP manages condition.
I.D. 242 Lisa	43 years of age Female Diagnosed at age 27 Treated with insulin	2/	Employed	Lives with husband and small son	Husband supportive but sometimes works away Husband does attempt to treat hypos.	Has had two sever hypos recently requiring ambulance call-out (none in past 10-15 years) GP provide diabetes care. Gets along well with them but doesn't see the point in seeing them.
I.D. 249 Kerry	55 years of age Female Diagnosed at age 35 Treated with insulin	4	unemployed	Lives alone	Excellent support from family and neighbours. Daughter lives two minutes away. Friend comes in every day . Complex conditions: CVA, diabetes/seizures, Anaphylaxis, dyslexic .	Only required ambulance on one occasion for a severe hypo. Sees Diabetes Consultant but very unhappy with care. Diabetes Nurse doesn't understand why her control is so poor.
I.D. 270 Randolph	70 years of age Male Diagnosed at age 15 Treated with insulin	3	Retired	Lives with wife	Wife provides general support and tries to treat when in a hypo. Will attempt to use glucagon which is available.	Has required the ambulance more than once for a hypo but it is infrequent. Is a little confused about who provides his health care although has a Diabetes Liaison nurse who he gets on well with.
I.D. 274 Natalie	77 years of age Female Diagnosed at age 47 Treated with insulin (initially on tablets)	5	Retired	Live with husband (present during interview)	Live in house with husband who has had stroke – patient cares for him but he can call for help if patient tells him. Three daughters live nearby and provide good general support.	Only required an ambulance once for a hypo. Receives care from a Diabetes Consultant and attend a diabetes clinic.

I.D.	Age, Gender, Treatment Age diagnosed	DEP CAT	Employment status	Lives alone/Lives with other people	Participants comments about support networks at home	Contact with health professionals and general care
I.D. 303 Mary	81 years of age Female Diagnosed at age 51 Treated with OHA's	7	Retired	Lives alone	Lived with husband who had dementia ('24/7 with him') had dementia for 7 years. Died recently (pg. 6) Husbands condition resulted in patient feeling couldn't go to doctors as she couldn't leave her husband alone. 'he would just go out the door and wander'. Doesn't have alert button in house. Son provides not much support.	Only required ambulance once for a severe hypo. Confused about treatment advice between GP and hospital. Doesn't know if practice nurse is a Diabetes Nurse specialist.
I.D. 323 Alan	27 years of age Male Treated with insulin	5	Unemployed	Lives both at home with mother and at girlfriends.		
I.D. 328 Janet	22 years of age Female Diagnosed at age 7 Treated with insulin	4	Unemployed	Lives with partner (present during interview) Mother lives nearby as does boyfriends father.	Partner in full time employment. All have been trained to administer glucagon.	Frequently requires ambulance service assistance for severe hypos. Diabetes Nurse Specialist provides care along with GP 'brilliant'

5.4 General overview

During interviews participants were encouraged to describe all aspects of care, including the emergency event, the period leading up to and including the ambulance call-out, and their actions afterwards. Almost all participants had experienced previous severe hypoglycaemic events. Some had experienced hospital care for hypoglycaemia and other diabetes and non-diabetes related conditions. Many described receiving good support from relatives with managing their diabetes at home and some appeared to have developed good family/friend support networks to help cope with their hypoglycaemic events.

All of the participants freely discussed their hypoglycaemic event, the routine and emergency care received. But as hypoglycaemia invariably affects cerebral function (Frier and Fisher, 2007) some aspects of care had been forgotten or were simply unknown. During several interviews (12 of 26), the participants' relatives and/or friends volunteered information about the hypoglycaemic event, aspects of care and the ambulance call-out. These accounts enriched the data and helped to enhance an understanding of the overall experience. Some participants recounted elements of the event through secondary information received from relatives or friends. All of these descriptions enabled the rich and unique perspectives of each individual to be experienced and understood.

The three key themes, and sub-themes, developed from analysis of the interviews were as follows:

Theme 1: Explanations of help seeking behaviour:

- Recognising hypoglycaemia
 - *“there are times when you get mixed signals”*
 - Hypoglycaemia unawareness

- Recognition and self-care still failed
- Influences of carer's perspectives
 - *"you're away with the fairies"*
 - Threshold for dealing with an event
 - *"we couldn't do anything"*
 - *"aggressive hypo's"*
 - Capacity and capability of first responder
 - *"my partner just flies into a mad panic"*
 - Lack of alternative's
 - *"if I'm not happy I phone up the 24 hour service"*
 - *"no glucagon"*
 - *"if I didn't have this fear of jaggging him"*
 - *"told to call back"*

Theme 2: Perceptions of prehospital emergency care and advice.

- Perceptions of the Ambulance Service
 - Ambulance Control Centre
 - Ambulance Clinicians – in safe hands
 - *"They are a bit of a crutch"*
- Perceptions of follow-up advice
 - *"no, they never left us any information"*
 - Trivialisation of immediate follow-up care
 - Patronising and patient scaremongering
- Perceptions of information transfer between services

Theme 3: Influences on uptake of follow-up care

- Experience of home recovery and care
 - Recovery: a normal and predictable process
 - *"Knackered", "dead beat" and "I want to sleep"*
 - *"I just lie in my bed" and "toast and jam"*
 - *"I'm as right as rain after it"*
 - Availability of home support
 - *"Get the quilt down and just relax"*

- Contextual factors influencing home recovery
 - Social circumstances
 - A burden on the system
- Experience of hospital recovery and care
 - Preference for home recovery
 - *“it’s a waste of time sitting there”*
 - *“I’ll be damned if I want other people administering my insulin”*
 - *“[the food] is pretty grim”*
 - Feel safer with ED care
 - Relative preferences *“I prefer he went up”*
- Primary Care experience
 - *“they do generally vary in quality”*
 - *“the [GP] didn’t waste a lot of time on it”*
 - *“I haven’t told any other medical staff about it”*
 - *“the damage is done, we’ll never prevent any more”*
 - Conflicting preferences – GP not always the preferred option
 - Confusion around information sharing

5.5 Theme 1: Explanations for help seeking behaviour

5.5.1 Recognising hypoglycaemia

Collectively, participants described the full range of the classic neuroglycopenic and sympathetic symptoms as described in the literature (see sections 2.4.2.2 to 2.4.2.5). Many spoke of their ability to recognise and self-treat mild hypoglycaemic events, thus preventing further deterioration. However some participants reported that recognising hypoglycaemia could occasionally be challenging; and, when the symptoms of hypoglycaemia were not recognised, they couldn't be treated.

5.5.1.1 *"There are times when you get mixed signals"*

Misinterpretation of symptoms, for some, leads to severe hypoglycaemia. Ronan, for example, described how the effects of caffeine and stress produced the same physiological symptoms of early hypoglycaemia (and on occasion hyperglycaemia). This caused confusion and appeared to add to the complexities of managing his diabetes. He felt that in these circumstances, what were in fact the early symptoms of hypoglycaemia could easily be mistaken for another, lesser, condition or cause.

Marion described getting few, if any, warning symptoms, but occasionally experienced a prodromal headache. However, as she also suffered from migraines, this particular symptom could be perceived as being due to a migraine rather than the ensuing hypoglycaemic event. Similarly, Tony, who more commonly experienced nocturnal hypoglycaemic events, confused the early signs of daytime hypoglycaemia with tiredness. He made no connection between the abnormal feelings of tiredness during the day with the possibility of hypoglycaemia. Therefore no checks were considered or preventative actions taken.

And finally there was Rory, who had required ambulance service assistance for numerous severe hypoglycaemic events over the years, and attributed some of these to his excessive alcohol consumption. He felt there was a clear link between his drinking habits and the hypoglycaemic events. But despite reducing his insulin dose after consuming alcohol, he continued to experience severe and unpredictable hypoglycaemic events.

"[Ronan]: ...there are times where you get contradictory symptoms, if for example, you've drunk a lot of coffee and to pee a lot it normally isn't if you have high blood sugars, you normally get that with, caffeine tends to give you a kind of mixed signal anyway which is entirely artificial and too much caffeine feels simultaneous like low blood sugars and high bloods sugars and none of the symptoms you are getting are related to... there are times if you get stressed you can get external things that feel like either high or low blood sugars..."

(Ronan: id. 119, pg. 27)

"[Marion]: I used to get warnings but I don't really get them now. The only sort of a warning I get, which I can't say is a warning because it isn't always hypo related, is I suffer migraines. And sometimes I can be sitting here and say to him oh, I need to go and lie down, my head's...and then go into a hypo."

(Marion: id. 52, pg. 3)

"[Tony]: I, it usually happens at night or when I'm sleeping. I think I mentioned on the phone that tiredness seems to be a major symptom of hypoglycaemia now, for me anyway. And sometimes I don't notice that it is a little out of the ordinary to feel tired at four o'clock in the afternoon and I think I'm tired, go for a little nap, and bam. And, because of that I've got no, no way of remedying the situation myself."

(Tony: id. 133, pg. 8)

"[Rory]: Honestly, drink as well, I maybe drink a bit too much more, but I know for a fact that definitely does affect my diabetes. To be perfectly honest maybe eight times out of ten I've been drinking the night before and then I go into a coma, so I definitely know that's a big, big problem that goes along with it..... [pertaining to night time insulin] I could no take it and it could be down and I could be near ready to go into a hypo, it's just a...[Rory's Partner]: The other night there you were going to go into a kind of hypo you were two point two. [Rory]: Aye it was right down aye and I've seen me have quite a high tolerance,

sometimes my blood will be at one point eight before I really actually know that I'm ready go into one."

(Rory: id. 60, pg. 4&5)

5.5.1.2 Hypoglycaemia unawareness

It was notable that over half of the participants reported the loss of warning symptoms during the onset of hypoglycaemia at some point in time since their diagnosis of diabetes. Rory (id. 60, pg. 3) spoke of hypo's "*sneaking up*" on him, inferring there was little warning, so he was unable to prevent deterioration. The inability to recognise and self-treat during the onset of hypoglycaemia always resulted in third party assistance being required. Lesley experienced no warning symptoms at all and Janet, since having her first child, had lost hypoglycaemia awareness altogether, only recognising low blood glucose levels during routine blood glucose testing.

"[Rory] To be perfectly honest no, no really, no really, it's just a bit, see the likes of when I have one of those hypo coma things, they just seem to sneak up on me, it's not that I don't get any type of warning, it's just one minute I feel okay and then the next minute I'm waking up and there's ambulance men there, if you know that I mean, to be perfectly honest with you, but I don't get any kind of pre warning."

(Rory: id. 60, pg. 3)

"[Lesley]: No, when I have a hypo, I don't have any feelings. I feel nothing. I could be sitting here and then the next minute an ambulance is there. [Interviewer]: So is there anything you notice as you're going into a hypo? [Lesley]: No. [Interviewer]: And that's across the board, then? You don't get any...? [Lesley]: I don't get anything. Absolutely nothing."

(Lesley: id. 237, pg. 13)

"[Janet] I could tell when a low blood sugar was coming."

(Janet: id. 328, pg. 3)

5.5.1.3 Recognition and self-care still failed

Whilst in many cases it was a friend or relative who contacted the ambulance service for help, in two instances where participants contacted the ambulance service themselves. This predominantly occurred where self-treatment had been ineffective and where there was no one available to help.

John lived alone much of the time as his son often worked away, however he did receive some support from his ex-wife who was a nurse. He suffered from recurrent pancreatitis and a condition that prevented adequate food absorption from the digestive system. This made blood sugar regulation a challenge and led to frequent ambulance call-outs. His brother had also been diagnosed with diabetes, at around the same time as he had, but had died as a direct result of a severe hypoglycaemic event. John described how, during the onset of hypoglycaemia, he had called for an ambulance when he believed his hypoglycaemia was not responding to self-treatment. During her pregnancy Janet described a similar experience where she called for an ambulance after personal treatment for a hypoglycaemic event failed. She recalled that, due to the neuroglycopenic effects of the hypoglycaemia, she struggled to clearly articulate to the call-taker why she was calling for help.

"[Interviewer]: A bad one to you is that when you become unconscious or is that when you can't control, you can't get it back up as such? [John]: I can't get it back up because if I can't get it back up I'm going to go unconscious anyway so I know that and once I'm unconscious I'm mostly here myself, but if I'm unconscious the same as my young brother, there's nothing there. So that's how I take all these thingmy lucozade, what I do is I take, they tell me no to take any more than two hypostops if I'm bad, one should help they say but it doesn't, so I don't care I just take them and take them. The reason being I know if I do go down, it will still maybe go through before it's too late and bring me back out. I've got my wee jag in there emergency jag, they know the one you...[Interviewer]: Glucagon? [John]: Aye I've got that, I had to use that once in all my time, once or twice at the most and I've actually done that myself before, it's always a through the night time, I keep checking myself, but there's time when I can't get myself up, I've maybe had one point seven, said no, just use that and I don't know if it's just everybody is different but I

thought that was to shoot you right up, but it doesn't, it brings you up, but it doesn't shoot you up high or anything like that it doesn't do that."

(John: id. 187, pg. 16)

"[Janet]... I tried to phone an ambulance when I was pregnant and the ambulance woman on the phone said I can't understand you, and it was so frustrating because I was trying to tell her and speak slower, so to try and make a bit more sense and she didn't get it, so I'm thinking it's time to try another insulin to see if it's maybe that."

(Janet: id. 328, pg. 14)

5.5.2 Influences of the carer's perspective

5.5.2.1 "you're away with the fairies"

The inability to recognise the onset of hypoglycaemia inevitably led to further, uncorrected, reductions in blood sugar and the subsequent severe hypoglycaemic event. Often, when hypoglycaemia awareness was impaired or lost, signs of low blood sugar were noticed by friends or relatives. Their ability to recognise and associate the unique signs with hypoglycaemia were essential. Recognising these prompted immediate assistance and the provision of immediate care, treatment or a call for help. Some relatives described a unique behavioural change, such as aggressive behaviour or being woken during sleep, for example, by their partner's profuse perspiration; all of which were typical symptoms of those described in the literature (see Figure 2, section 2.4.2.2). Tony, Lesley and Edward's partner all provided good examples of how hypoglycaemia was recognised by others.

"[Tony]: But, like I say, the day where I was skewing off into the middle of the road. I didn't know anything odd was going on until I felt his hand on my shoulder and that kind of snapped me back a little. It is always better having him around.....I've had two major incidents during the night now and he has become very conscious of those because I do start sweating profusely and he actually told me, it's like having a shower in bed whenever I'm having a hypo. There's just water everywhere. And that's how he

knows there's a problem when he's there with me."

(Tony: id. 133, pg. 13)

"[Lesley]: Uh-huh, he can recognise ...[Interviewer]: Do you know what sort of things he would..?"

[Lesley]: Just the way I look at him. I threw an apple at him. Just threw it! I don't know what made me do it. It was so funny!...But he knows right enough, the way I look at him and the way I speak. I think it's just the look, the dazed look."

(Lesley: id. 237, pg. 11)

"[Edwards Partner]: It was a Friday afternoon the last time, Friday afternoon. And he said, 'I think I'll go for my bath.'..... I thought, I'll wait another minute. I thought, oh, I'll need to go and hurry him up. I said, 'Are you not out?' And there he was standing, he was just kind of going back and forward like this and cleaning away at the sink and...and I said, 'Oh, you're away with the fairies, come on, sit down.' Oh, he wouldn't sit down for me. I said, 'I'd better go and get something."

(Edward: id. 124, pg. 5)

5.5.2.2 Threshold for dealing with hypoglycaemic event

In situations where participants' personal thresholds for self-care were exceeded the responsibility for care was, by default, delegated to a relative or friend. Mild hypoglycaemic events were frequently treated by the participant themselves or with help from a relative or friend via the provision of some form of oral carbohydrate. In many cases these simple actions prevented further deterioration. However, when treatment from a relative or friend was ineffective, assistance would be sought from the ambulance service. Indeed, in this study, the index emergency call (the call that triggered the invitation to take part in the study) was most often made by a friend or relative, less frequently by a third party caller (someone not known to the participant) or by the patient themselves.

5.5.2.3 “we couldn’t do anything”

Thresholds for seeking help varied from individual to individual and depended on the circumstances of the event. The interviews exposed many of the challenges faced in managing people with hypoglycaemia. For instance, where treatment had failed or been impossible to administer, or where the relative or friend encountered physical difficulties in moving the ‘patient’ into a manageable position. Or, for a few, it was simply being confronted with an unresponsive or unconscious relative and feeling or believing that they were powerless to help. One element was common however, whenever the perceived personal threshold for management of a participant’s hypoglycaemic event was exceeded, an ambulance was called. The experiences of Ian’s, Edward’s and Susan’s relatives provide a useful insight into these difficulties.

“[Ian’s relative]: That was just there when I got him round that was just the other week. The one on the Thursday was when I went to dentist and I found him slumped in the cupboard, he was out, couldn’t do anything. I had to get an ambulance and then the Saturday was the toilet, as I said, I tried to get him round, we couldn’t do anything so had to get the ambulance.....Aye noises kind of grunting noises and I think, oh God, he’s away again. I came in here, he was actually on the ground fitting and just as I phoned, I phoned the ambulance right away.....That was at night time, that was the worst to me I would say, I thought the one in the toilet last week was quite bad but the one when he was fitting, he’s fitted before but not like that. He bounces about and then he would open his eyes and his eyes were just staring. Glazed, but he has had fitting on the chair before haven’t you?”

(Ian: id. 162, pg. 10)

“[Edwards relative]: So I gave him a bit of banana and he wasn’t going to eat the banana. I gave him...no, I didn’t give you that time, the banana, he wasn’t coming out of it quick enough, and I thought, he’s going to fall. And I was frightened he would fall and hit his head on the... that’s why I called the paramedics out. And I’ve never any problem with them, touch wood, never had any problem, they’re there in minutes.”

(Edward: id. 124, pg. 5)

“[Interviewer] So, if you’re on your own during the day what happens then? [Susan]: I’m left till

somebody comes in. [Interviewer]: Till somebody comes in. And when they come in what do they do? [Susan]: Normally they phone right away. [Interviewer]: Phone right away. Do they try and help you at all? [Susan]: Normally they can't because I'm too far out of it, so they can't do nothing. So that's why they just phone the paramedics then and then they come and sometimes they're here for two hours at a time."

(Susan: id. 33, pg. 4)

5.5.2.4 "Aggressive hypo's"

In Rory's case, aggressive behaviour, a well-known manifestation of neuroglycopenia, physically prevented or made treatment by others very difficult. Whilst Rory's partner was confident to help during the recovery period with carbohydrate loading via tea and biscuits, she lacked confidence in providing initial care via an injection and become frightened by his behaviour. This precluded any form of assistance from them.

"[Rory's Partner]:but the last couple of hypos you've taken have been aggressive ones..... Well the aggressive ones I've kind of panicked more because he's like, started taking them. [Rory]: Aye, well honestly you're phoning my brother don't you, you know what I mean. [Rory's Partner]: Aye going, brother! [Rory]: And most times he comes up? [Rory's Partner]: Yes the last few times, you had ones where you're sweating and I can cope better with, I'll get up, get you a cup of tea a biscuit and things. [Rory]: Come round a bit easier. [Rory's Partner]: But the aggressive it's you just, not a pleasant person, but he doesn't know what he's doing, he's unaware of what he's going. [Interviewer]: And do you manage to get him to eat something at this point? [Rory's Partner]: Aye I try and get him to have a biscuit or a cup of tea. See maybe if I didn't have this fear of jag him with a hypo jag. I've never jag you yet have I?"

(Rory: id. 60, pg. 5)

5.5.2.5 Capacity and capability of the relative or friend

There were some instances where the ambulance call-out appeared inevitable. For example, Susan's young son had returned from school and found her collapsed on the kitchen floor. He immediately called his dad and then the ambulance service for help. It would be incredibly challenging for a child to manage an unconscious adult in a severely hypoglycaemic state.

“[Interviewer]: So, and, and do you have to call out the emergency services at...[Susan]: Normally quite often. [Interviewer]: About how often would you say that was? [Susan]: I normally get them about three times in a week. [Interviewer]: Right. [Susan]: Last week I had them twice in the one day. [Interviewer]: Right. And, who is it that calls them out? [Susan]: Normally my wee laddie, or my partner. [Interviewer]: Right. So, if you're on your own during the day what happens then? [Susan]: I'm left till somebody comes in. [Interviewer]: Till somebody comes in. And when they come in what do they do? [Susan]: Normally they phone right away. [Interviewer]: Phone right away. Do they try and help you at all? [Susan]: Normally they can't because I'm too far out of it, so they can't do nothing. So that's why they just phone the paramedics then and then they come and sometimes they're here for two hours at a time.”

“[Susan]: My wee laddie had come in from school. He found me on the floor. [Interviewer]: The floor. And what did he do? [Susan]: He phoned his dad. Cause my wee lassie hadn't been picked up. He phoned his dad, the school was on the phone to me, but because I was on the floor...[Interviewer]: You didn't hear... [Susan]: I couldn't hear it anyway and they phoned my partner and his son went up to get my wee lassie from school and my wee laddie had phoned the ambulance. [Interviewer]: He had phoned? [Susan]: He had phoned them. [Interviewer]: Right then. [Susan]: Because my partner was trying to get his laddie to go and pick up my wee lassie and they couldn't leave me here on my own with my wee laddie, cause he was kind of getting spaced.”

(Susan: id. 33, pg. 4)

5.5.2.6 “my partner just flies into a mad panic”

Severe hypoglycaemic events can also have a significant and immediate psychological impact on relatives or friends who are present. The inability to treat, or the fear induced through an emergency situation, can cause some to react in a manner that precludes any assistance to the patient. Their threshold for home/personal management is immediately exceeded. This panic or fear can lead immediately to an ambulance call-out. There are numerous examples of this in the transcripts.

“[Tony]: They not only took care of me but I think as they arrived [Partner] was hyperventilating so they were trying to look out for both of us.”

“[Tony]: And my partner just flies into a mad panic and that's usually when the paramedics end up on my door step.”

(Tony: id. 133, pg. 24 & 9)

"[John]: My oldest daughter she'll thingmy, she gets all going, but she'll sit with me, stand with me. She gets all upset and all going she gets all high and so does my other daughter. [Interviewer]: But they'll stay. [John]: I wouldn't need to say I'm all right away up the stair or away home or whatever where my boys, my boys seem to, I mean they've seen me taking bad ones, real bad ones and it's frightening to watch I suppose when they were younger."

(John: id. 187, pg. 16)

"[Lesley]: ...but the minute I take ill, he panics. [Interviewer].....And he's ... we have explained to the ambulance men, I've got the injections in the house... [Interviewer]: Glucagon, yes? [Lesley]: I've got that in the house, I have learned him how to use it, showed him it ... [Interviewer]: And still not, no? [Lesley]: No. [Interviewer]: And do you know why he doesn't? [Lesley]: Panics. [Interviewer]: Panics, sure, yes. [Lesley]: Just panics. He's explained it to the hospital. He explained it to the ambulance-men. [Interviewer]: Explained what, sorry? [Lesley]: That he just cannot do it. I think it's because I'm out of it. [Interviewer]: Is it the physical process of having to inject you that's an issue or ... [Lesley]: He's frightened in case he does me any harm."

(Lesley: id. 237, pg. 9)

"[Ian's partner]: Aye noises kind of grunting noises and I think, oh God, he's away again. I came in here, he was actually on the ground fitting and just as I phoned, I phoned the ambulance right away and I just seen my nephew he was coming up for his car. I said go and come in here, he got the fright of his life, he never came back. He ran away out then said I can't watch him."

(Ian: id. 162, pg. 10)

5.5.2.7 Lack of alternative services

During a severe hypoglycaemia event, some participants' friends or relatives sought care or help from alternative services, rather than make an immediate call to the ambulance service. Both Dave's partner and Susan described what happened when they contacted NHS24 for advice. For some, there appears to be a lack of clarity, or possibly a confusion, as to which service provided the most appropriate care in given situation.

5.5.2.8 *“if I’m not happy then I phone up the twenty four hour service”*

There were two occasions described where initial help was sought from services other than the ambulance service. However, both resulted in the respective alternative service quickly referring on to the ambulance service. In instances where Dave’s response to treatment was not as expected, his partner contacted NHS24 for advice. On the occasion described, NHS24 had provided some instruction around repeating a blood glucose measurement. But due to a protracted response to treatment the call was passed onto the Ambulance Service. They immediately dispatched an emergency ambulance.

Susan had been issued with a local authority ‘alert’ device. This consisted of a small electronic tag to be worn as a necklace at all times. When the button is pressed on this electronic tag the alert team is contacted and can communicate via speakerphone built into a telephone. During a recent hypoglycaemic event her husband activated the alert device. He was instructed by the ‘alert’ staff to call for an ambulance. He now questions the value of the alert system if all they will do is advise them to make an emergency call to the ambulance service.

“[Dave’s partner]: But then when I see him he looks awful drawn looking and he doesn’t seem to understand what I’m saying. He seems to be away in a trance, his eyes are just sort of staring into...the air. Then I realise there’s something wrong, when he doesn’t answer me or I say talk to me and he can’t talk to me.....Then just go and get a sugar drink for him...[(Dave) Aye, that’s me fine] It normally gets him round that way but if I’m not happy then I phone up the twenty four hour service, what I had to do and the lassies on the phone asking me to take his blood again and it was still, it wasn’t going up quick enough for them and that’s when they sent the ambulance out to us.”

(Dave: id. 114, pg. 9)

“[Susan]: I’ve got an alert. And I thought the whole point of an alert system was you pressed that and they sent you the help. My partner seems to press it and it says put it down and dial 999. So I think the alert system is a waste of time. Especially when they tell you to put it down

and dial 999. So when my partner phones 999 they just ask him how I'm lying and what to do until they get somebody out. But I would say you get more help off the 999 crew than you did with the alert people. Cause he keeps saying to me why have an alert."

(Susan: id. 33, pg. 23)

5.5.2.9 "I hadn't any glucagon"

A few participants discussed being prescribed glucagon, but most made no mention of it. In Kerry's case family members frequently administered glucagon for hypos. This action usually negated any requirement for ambulance assistance. On one occasion however, the index call, a pharmacy stock error had resulted in no replacement glucagon being delivered to her home. This meant that this treatment option was unavailable and an ambulance had to be called. Randolph also described occasions where his wife had used glucagon successfully, although he does not say whether an ambulance was still required.

"[Kerry]: Well my daughter came in She says mum, I came in, she said, you were out. She said and I couldn't get you to take anything. She was going sorry, but I had to phone the paramedics. I went aye, alright. [Interviewer]: Sure. This is before the ambulance arrived then. [Kerry]: Yeah. [Interviewer]: So you'd come round. [Kerry]: No, no, that's after I started to come round. She was telling me though what she had done. [Interviewer]: And she given you the glucagon...[Kerry]: No, because I hadn't any glucagon. I had waited over a week on the chemist delivering my glucagon. And then I phoned my doctors and they said they would phone them down, and it was the day after I had the hypo my glucagon got delivered. And I says aye, well you're lucky I'm here. And she goes what? I says well I had a hypo, I says, and my daughter had to get the paramedics, I said, because she couldn't give me an injection. I hadn't any."

(Kerry: id. 249, pg. 32)

"[Interviewer]:... when I started and I always call it glucagon as such, so you have the kit then?[Randolph]: Yes always take it with me any overnight places I'm going away, so she has used that even successfully to thingmy round if I'm, or just if I'm not, shall we say, just know that I'm low and she just feels I'm not responding properly, gabbling a bit, saying I'm fine."

(Randolph: id. 60, pg. 8)

5.5.2.10 “if I didn’t have this fear of jaggging him”

Conversely, where glucagon was available, some relatives were too frightened to administer it. For example in Rory’s case, his wife was too afraid to inject him with glucagon. In a bid to dispel these fears, Rory suggested that there may have been an opportunity during the emergency event for the ambulance clinicians to demonstrate the administration of glucagon. However Rory’s wife challenged this suggestion. She had been overwhelmed during the incident and had not taken notice of the ambulance clinician’s actions. Perhaps during the emergency is not be the most practical time to educate relatives or friends. Lesley discussed her husband’s fear of injecting earlier in this chapter (see section 5.5.2.6.) but importantly suggested that ambulance service assistance would be unlikely had her husband been able to administer the glucagon injection.

“[Rory’s Partner]: See maybe if I didn’t have this fear of jaggging him with a hypo jag. I’ve never jag you yet have I?..... I mean I know I’ve no had the braveness of one of these [inaudible 0.31.40] with the hypo kit and bring him round, but so far I’ve just called the paramedics out and they’ve been brilliant, they come out responding and do what they have to do. [Interviewer]: So sometimes do they have to inject him? [Rory’s Partner]: Yes they do aye, oh aye they’ve had to aye. [Interviewer]: Obviously it worries you having to give an injection, you wouldn’t feel you could talk to them about that and you might have been able to do it while they were there? [Rory’s Partner]: They do, they have done, but I’m still fait [frightened]. Aye they gave me the support.”

“[Interviewer]: I was just asking Rory if the emergency services actually told you what they had given him when they came, do they tell you that? [Rory’s Partner]: No just a hypo jag. [Rory]: But do they no go through it with you and sit and say we’re giving [Patient] this jag and we’re giving him this and it is to try, do they no explain? [Rory’s Partner]: No my brains everywhere else at the time. [Interviewer]: Yes how you’re feeling such that even if they told you you’re not really taking it in? [Rory’s Partner]: I’m taking some of it in aye, but obviously the one that I said earlier on about him put the saline stuff in it whatever it is that’s in the hypo kit. Had to put that in him, but not really no, just general. [Rory]: Just get on with their business.”

(Rory: id. 60, pg. 5 &15)

"[Lesley] Well, they're there when they're needed, which is great. But I don't want to send for an ambulance. If I can do it myself, I would. If my husband will use this injection, I wouldn't bother the ambulance service, and I keep apologising, telling them and so does my husband and ... it's terrible."

(Lesley: id. 237, pg. 20)

5.5.2.11 "Now, if you need us again, don't hesitate to call."

Several participants had also been advised to call the ambulance service back if there were further problems during recovery or in the event of recurrence. As most study participants had previously experienced severe hypoglycaemic events requiring assistance from the ambulance service it is possible that this repeated message from ambulance clinicians had led to subsequent call-outs.

"[Marion]: Aye, and he says if you feel ill.....just phone them straight back, know what I mean, she says they'll be one [an ambulance], know what I mean, if you don't feel you're getting any better."

(Marion: id. 52, pg.34)

"[Ron]: They stayed a long time. They made sure we were all right and they did say to me when they left, they were very good and they said, just phone right away if you're not happy with his condition, just phone and let us know."

(Ron: id. 75, pg. 6)

"[Edward]: The past two or three times that they've been in, they've always said, 'Now, if you need us again, don't hesitate to call.'"

(Edward: id. 124, pg. 20)

"[Stephen]:...but if they don't take him they always say, 'Now, if there's any relapse just phone immediately.' You know, they're really so good."

(Stephen: id. 146, pg. 14)

"[Ian]: Just know they have always said don't hesitate to call us back out they've always said that I must admit."

(Ian: id. 162, pg. 34)

"[Calum]: And, like, kind of, if there was any more problems just phone."

(Calum: id. 170, pg. 13)

"[Randolph]: Well, certainly to have no hesitation in calling them out again if it took minutes after they were out the door. They convinced me you mustn't feel any reluctance to do so, and that was it"

(Randolph: id. 270, pg. 15)

5.5.3 Summary

Prior to this study, very little was known about why individuals sought ambulance service assistance for hypoglycaemic events. These interviews have helped identify some of the factors that contribute to a call for help. The contributory factors are complex and individualised. Misinterpretation of symptoms and the development of hypoglycaemia unawareness can prevent individuals from self-treating. Even when individuals self-treat, this can be ineffective, ultimately leading to third party assistance being required. When relatives or friends recognise the signs of hypoglycaemia, it can be difficult, and sometimes terrifying to deal with. When their knowledge, comfort and ability are exceeded, the call to the ambulance service is the simple option for many. Past advice from ambulance clinicians to relatives and friends may also reinforce this behaviour. Theme 2 will now move on to explore the next stage of the event, that is, what happened once the ambulance was called.

5.6 Theme 2: Perceptions of prehospital emergency care and advice

This section presents participants' perceptions of the ambulance service and in particular their experiences of the care received. The themes developed will be presented within the sequence of the emergency response beginning with the initial call to the ambulance control centre, moving onto the care received from ambulance

clinicians, followed by the immediate post-recovery period where follow-up advice was provided.

5.6.1 Ambulance Control Centre (ACC)

The experience of the professional emergency response began before the ambulance clinicians arrived at the door. The first point of contact for professional help was the ambulance control centre, where call takers receive the emergency call and can offer, in certain circumstances, simple life-saving advice.

"[Ian partner]: I've given him the hypostop and it just won't come out. Normally when you phone they say don't give him any more, don't give him any more of those things or drinks or anything like that, that's what they normally tell you, the operator, because he was sick and that."

(lan: id. 162, pg. 10)

Participants said little about this important link in the chain. Perhaps this was because the interview questions were more focussed on the care provided by the ambulance clinicians. However, on the two occasions when mentioned, ACC call takers received a mixed critique. Stephen's partner describes a positive experience on the whole but feels they may have been losing patience with her. And Janet, during the onset of hypoglycaemia, was left feeling frustrated with the call taker when they appeared to become irritated as she struggled to articulate during the phone call.

"I asked the lady, and I was...I think she must have thought...she was telling me to do things, and I said that I'd done it all already. And I said, 'But he's choking', you know, he was losing his consciousness. And she was really very, very good. And that's the first time in all the years...we haven't called the ambulance that often, but she said to me, 'Put him into the recovery position.' And he's slippery and he's heavy, and I couldn't get him in. And I was...I had the phone...she said, 'Don't...you know, keep the phone on.' The phone's like this. And she said to me, 'Get him into the recovery position.' And I said, 'I can't get him in.' And she said, 'Why can't you get him in?' I said, 'Well, he's about sixteen stone, and he's slippery.....you know, when it's dead weight though, he wasn't able to help me at all. And she was, 'Oh, for goodness sake, surely you can get him into the...' and just at that the ambulance arrived. And

they were just unbelievably good.”

(Stephen: id. 146, pg. 12)

“... I tried to phone an ambulance when I was pregnant and the ambulance woman on the phone said I can't understand you, and it was so frustrating because I was trying to tell her and speak slower, so to try and make a bit more sense and she didn't get it, so I'm thinking it's time to try another insulin to see if it's maybe that.”

(Janet: id. 328 pg. 14)

5.6.1.1 “they were absolutely wonderful”

When the ambulance clinicians arrived however, participants' experiences of the ambulance clinicians were largely positive, portraying a picture of a consistent and dependable service. Many commented on the demeanour of ambulance clinicians with descriptors such as “*good*” (Tony, i.d. 133, pg. 6) and “*fantastic*” (Stephen, i.d. 146, pg. 24) used frequently. A few participants made positive remarks about the ambulance clinician's knowledge-base, with one or two implying that they were well educated, and suggesting that their knowledge had improved significantly over recent years. In some cases (Marion, Dave and Tony) participants' repeated experiences of the SAS had led them to feel supported by ambulance clinicians, describing feeling relieved, calmed or safe when the ambulance clinicians arrive. This created a sense that the ambulance service would always be there when needed.

“Well obviously they don't know you, the ambulance people and all that. But I would say most of the time, eighty percent of the time, they make you feel great..... they will sit with you.....they'll talk to you, they'll..... is there any other issues and that, like maybe something else that's maybe brought it on and that...”

(Marion: id. 52, pg. 33)

“[Dave's Partner]: They took the pressure off me because I knew that somebody knew what they were doing. Oh, they were a good help. No, it was...they come first and then an ambulance was there and cars were waiting to get out the street but nothing you could do, everybody was just considerate and was

waiting. They took their time, they were considerate with him, it weren't a case of, oh well, come on lets go, you know, we have to get you up there, they just let Dave go at his own pace. They said, 'oh we'll go and get the chair for you'. [Dave] says, 'no I can walk down stairs', and one went in front and the other went behind and they always said, 'are you sure you're okay now?' I mean, they were really keeping an eye on him."

(Dave: id. 114, pg. 40)

"[Tony]: I have not got a bad word to say about the paramedics that came up, they were absolutely wonderful.....they not only took care of me but I think as they arrived [Partner] was hyperventilating so they were trying to look out for both of us."

(Tony: id. 133, pg. 24)

This positive perception was underpinned by some participants' descriptions and experiences. For example both Mary and John spoke positively of the ambulance clinician's knowledge and advice. Marion felt that the ambulance clinician's knowledge on diabetes had improved over the years. John (id.187, pg. 22) valued the ambulance clinician's advice, stating that they "*never leave anything to chance*" and, when he compares them to doctors, suggested he had learned more from the ambulance clinicians.

"[Marion]: I would say, through the years, I would say they are a lot more knowledgeable now from when they were when I first became diabetic, know what I mean. Like when I first became diabetic."

(Marion: id. 52, pg. 33)

"[John]: They are good, just good, aye, they come out of the ambulance, they know what they're doing anyway and they've never left any chance..... a few of them and they write all things and my sister in the hospital, as I say they are actually, I've gained more things off them than I have off any doctors."

(John: id. 187, pg. 22)

One participant (Lisa) provided a different perspective. Although generally positive about her care, Lisa implied the ambulance clinicians fell short of her expectations as

she felt they lacked a generic or holistic knowledge. This was revealed through her anxiety about the ambulance clinicians perhaps not being aware of her cannula during blood pressure checks. She was concerned that they would damage it. The apparent focus of the ambulance clinicians was, she felt, entirely on her blood glucose meter readings with little consideration, if any, given to her other conditions.

"[Lisa]: I was concerned because they were talking about doing my blood pressure and thinking oh my God, they have to do it in my right arm, will they know that, and getting really quite fixated on...[were they going to notice the cannula for renal dialysis?] and stuff, you know. And I'm thinking, will they notice it, will they know? And thinking...and wanting to do my bloods and thinking... Oh no, what he was getting obsessed about was my meter reading [blood glucose reading] right."

"[Lisa]: They don't always... feels as if sometimes they don't always get the connections from other things. Like it's the diabetic... this is why you've been called but that I think the bit about [paramedic] that was annoying me that's all that [paramedic] could think about was the diabetes. But all the things going on my life the other conditions you have are not... that was [inaudible 0:13:33]. They don't exist so therefore we just don't treat them and we don't acknowledge they happen. So the stuff about my dialysis was, I [pertaining to the ambulance clinicians] don't do the dialysis type stuff so you don't come across that [inaudible 0:14:00]. That's the kind of the impression that you get which is a bit scary. I think I sometimes have a higher expectation of what they'd be able to do and then when they come it doesn't necessarily..."

(Lisa: id. 242b, pg. 6)

5.6.2 "they are a bit of a crutch"

Participants were asked about their understanding of the role of the ambulance service and links with other NHS services such as the ED and Primary Care. However any question aimed at exploring the participant's understanding of the role of the ambulance service may have seemed a little bewildering. Many perceived it to be simply an emergency service, they were only there for the immediate/emergency response. This fairly predictable, and traditional, perception of an ambulance service meant that the vast majority of participants struggled to directly answer the question.

Stephen described the service as a 'crutch', to be used when things went wrong. And Rory felt that the ambulance clinicians were there when you needed them, just to treat and enable recovery. These perceptions may have also been developed through past experiences of the advice received from ambulance clinicians, particularly about not hesitating to call them out again (see 5.5.2.11.)

"[Stephen]: The boys usually say, 'You'd be better to call your doctor or let the doctor know', in general. But they'll not sort of say to you, 'You should do this.'...If they weren't there...they are a bit of a crutch. Because I depend on [wife] giving me sugar. If I'm in America playing golf or something like that and she's not there I just make sure I don't end up with a problem. But with the ten [tenth hole] in the background, I can afford to be less careful that I'll get to the stage where [wife] can't do anything about it and I go over the edge. Because they're there as a backstop. So that to some extent is a comfort that makes things different. If that backstop wasn't there I would have to allow the sugars just to go higher because of the way I can't predict how much is still left of the insulin. [Stephen's partner]: It's certainly a lot easier for me knowing that there's going to be nice people coming who can do the job and won't be critical or anything. They're just fantastic."

(Stephen: id. 146, pg. 24)

"[Rory]: But the paramedics they are the front line with people they are the ones that come out to the emergency at the end of the day and that's it, that's them done their job basically."

(Rory: id. 60, pg. 29)

"[Lisa]: I would say they're for emergencies. And actually to do that extra bit of just checking that you actually are... because I think you become quite complacent and you're so... you think you're dealing with it and sometimes you need another person, another eye to be around to say actually this isn't quite right. And I see them as a back up, as the extra eye."

(Lisa: id. 242b, pg. 6)

"[Andrew]: Well they seem to have a pattern that they know, they seem to all say the same things because they have all been told the same things.....I dare say they attend hundreds of diabetics, they must because there must be thousands of diabetics don't look after themselves and just, you know, so

they go and say, no another diabetic and say these guys are driving me mental. We'll just go in and fill them with sugar and back out again and back the next night, oh not his guy again, they must, it's a natural thing they must."

(Andrew: id. 165, pg. 5)

5.6.3 Unsuccessful ambulance service treatment

Not all patients regained consciousness after treatment by ambulance clinicians. There were occasions where ambulance clinicians' treatment was ineffective and when this occurred the hypoglycaemic event would remain as a threat to life. In these instances, individuals were transported directly to the ED. In such circumstance individuals would have had no say in their care (lacking capacity) and by default were transported, most likely under blue lights, to the nearest ED.

Ronan experienced a particularly severe hypoglycaemic event from which he made no recovery during the prehospital phase of care. There was no option but to transport him to the ED for emergency treatment and prolonged infusions of glucose. Margaret simply states that she recovered in hospital.

"[Ronan]: Absolutely, a hypo is a hypo, is a hypo, in general terms as far as I'm concerned it's not a hospitalisable thing or there are cases I'm sure it can be, but I only have experience of one of those, I'm not quite sure how it happened that time.....I had a huge hypo, took about, I think it was about twelve hours until I responded, they had three glucose bags and I didn't respond..... I don't necessarily think that was entirely hypo, I think that was probably part hypo, but more significant emotional and psychological event."

(Ronan: id. 119, pg. 22)

"[Margaret]: I don't even remember going away in the ambulance. And then I woke up in the ambulance and I was on, my eyes, she said I was coming round..."

(Margaret: id. 74, pg. 18)

For these individuals there was no choice about immediate follow-up care, their condition necessitated transportation to the ED. This serves as a reminder of the seriousness of the condition and that care may not be as straightforward as some perceive it to be. This loss of autonomy had negative connotations for some participants and will be discussed later in this chapter in relation to experiences of hospital care (see section 5.7.4.2 and 5.7.4.3).

5.6.4 Perceptions of advice provided by ambulance clinicians

When asked about the information or advice provided by ambulance clinicians, participants' accounts revealed that there was no consistent format of either verbal or written information provided. Several topics were developed from these responses. They included the lack of written information provided, the ambulance clinicians' attitudes to follow-up care, participants' perceptions of advice provided, advice on insulin administration and the participants' inabilities to recall verbal information.

5.6.4.1 “no, they've never left us any information”

Following treatment and recovery many participants spoke of being advised, or given the option, to be transported immediately to hospital. Most however refused. A little under half of the participants reported receiving some form of information/advice from ambulance clinicians. Few recall being left any written information, and where written information was left the format and content varied (some received a patient report form and others a hypoglycaemia advice leaflet). Receiving both formats was very much the exception rather than the rule. On the rare occasion when written information did reach the participant, a small number reported they didn't take the time to read it.

Almost half of all participants recall receiving advice on self-referral for short-term follow-up care, most of them being advised to contact their General Practitioner, only a few suggested the Diabetic Nurse Specialist. John compared the discharge

experience between ambulance clinicians and the ED. He suggested hospital discharge letters were always provided and that he took them directly to the GP; Margaret spoke of handing the discharge letter received from the hospital to her GP, but she didn't seem to attend any form of consultation. In contrast, the form left by the ambulance clinicians was kept somewhere in her house and there was little concern about handing this onto her GP.

"[Interviewer]: and did they leave you any information or was it just verbally? Did they just tell you...?"

[Kerry]: No, he told me, he says is this the first, and I went no, I said, this has happened quite regularly, and he went like that, well go to that (GP's name) tomorrow morning and just tell her...well, the receptionist, and just tell them you need to see (GP's name) tomorrow morning. [Interviewer]: Right. Sure. And so nothing was left then, no information? [Kerry]: No. [Interviewer]: Have you seen anything like that before? I'm handing...it's a patient care information form. [Kerry]: No."

(Kerry: id. 249, pg. 29)

"[Interviewer]: But I'm thinking when you're in hospital for the hypos, when you go out, do they advise you, for you to go for follow-up appointment with your healthcare provider? [John]: What they do is they give me a letter or else they send the letter to my own GP, you know. That is to let me know, well what happened to [Patient] is telling me to go and see, back to the clinic to get checked, probably within two to three weeks of being released, that's the normal way it works."

(John: id. 187, pg. 21)

"[Interviewer]: Yeah. So when you've had, when you come out of hospital like that do you, do you normally go and see your GP, or do you, what to you do? [Margaret]: No I just, I just hand the letter in, I don't go and see the doctor...I don't see the doctor, then when I hand the letter in if the doctor needs to speak to me then they just say no you have to go back to see him."..... "[Margaret's partner]: Aye they leave that paper. [Interviewer]: Do they give you a bit of paper usually? [Margaret's partner]: Aye. [Interviewer]: And is that, is that to, what sort of things are on that? [Margaret's partner]: No idea. When the ambulance has been I just stick it by somewhere. [Interviewer]: Yes. [Margaret's partner]: There again I have no idea where it is. [Interviewer]: Yeah. And would you look at it again at some point? [Margaret]: Uh-huh. I've got one somewhere like. I've got a discharge slip, see when I was getting out of hospital..."

(Margaret: id. 74, pg. 21)

For those who received advice from ambulance clinicians, the content and quality of information varied considerably, but generally, most participants were either offered transportation or advised to travel to hospital for follow-up care. No rationale was provided by ambulance clinicians for this advice. This may explain why no participant spoke of understanding the need to receive immediate follow-up care. Susan spoke of receiving some advice from the ambulance clinicians on carbohydrate loading and how to expect blood sugars to rise after treatment. Ian, initially suggested he couldn't remember, but subsequently spoke of being advised to follow-up with his GP.

"[Susan]: Normally they do tell me you've had and your blood will go up but have something to eat."

(Susan: id. 33, pg. 21)

"[Interviewer]: What sort of advice did they give you after, for when they've gone away what would they say? [Ian's Partner]: I can't remember to be honest. Just go to the GP and pay attention to his insulin..."

(Ian: id. 162, pg. 32)

5.6.4.2 Trivialising immediate follow-up care

Edward's partner spoke of him being offered transportation to the ED, which he refused. The ambulance clinician's response appeared to validate this refusal, reinforcing negative views of secondary care experiences and trivialising follow-up advice by suggesting their advice was simply standard care. Alternatively, in Rory's case, although there was a recollection of verbal advice provided, there was no recollection of any written information being handed over.

"[Edward's Partner]: No, they just...last time they just said, 'Now, do you want to come down to the hospital?' He said no. He says 'what do you think?' I said, 'Well, I think he's coming out of it, he'll be all right now.' He said, 'I don't blame you right enough, the length of time you've to wait there. But we must...we've got to ask you that. Wait and I'll go down and get the...' I thought he said the form or something, but it's a big...it's a computer thing now, they don't sign forms, they just press the buttons or

something, your name comes up. And by this time he went down...there was a girl and a man, they went down to the ambulance and I'd got his pyjamas and that. I felt he was right as rain really after that. He got his dinner and that was it. [Interviewer]: and do they advise any follow-up or anything? [Edward's Partner]: No."

(Edward: id. 124, pg. 12)

"[Interviewer]: So after the emergency services have been do they actually leave you any information? [Ian]: No. [Interviewer]: Not at all, nothing? [Rory]: Nothing, no not a thing, they've never, they've never to be perfectly honest, no they've never left us any information or anything like that. [Interviewer]: Do they tell [Partner] or is she aware of what they've done, what they've given you? [Rory]: Oh aye I think whatever they're doing to me, as I say I don't really know, they do go through it with [Partner] and tell her where to inject it, in certain parts of your backside to inject it and no inject it somewhere else there is nerves and I think they do explain what they're doing and why they're doing it, but they definitely don't leave any information or advice or anything like that."

(Rory: id. 60, pg. 22)

5.6.4.3 Patronising and scaremongering patients

There were occasions where simple or basic advice was not welcome. Ronan, who appeared well educated and very well informed about his diabetes, often felt patronised by the type of advice provided. And on one occasion (Marion's) the information provided by an ambulance clinician could have been perceived as being insensitive or scaremongering.

"[Ronan]: No people saying the bleeding obvious to me, they can do it in the most empathic way and I get bloody irritated when I have low blood sugar again, I find that really quiet annoying, it's not a problem, I would far rather if they did so in a relatively objective and calm detached state...but it is actually irritating at the same time, so not for any bad reason, just for me and whatever and then they generally tootle off."

(Ronan: id. 119, pg. 21)

"[Marion]: But when it happened about four or five weeks ago they wanted to take her into the hospital for the night, you know, the ambulance man. He wasn't being bad or nothing, he just sat there and he said what I always say, 'If you keep carrying on like this, you're going to end up dead.' That's what he said. You're maybe not meant to say or whatever, but he's just saying what's really meant to be true,

because basically he said what I say; there's no point in you taking your insulin if you're not eating with it. This is what I always say, and I don't mean it bad or nothing."

(Marion: id. 52, pg. 37)

Lisa tells a similar story. She had extensive knowledge and experience in managing her diabetes and had excellent control of her blood glucose levels since diagnosis. Despite such exceptional self-care her kidneys had failed and she had recently started renal dialysis. This, she felt, had been affecting her glucose control. Lisa spoke of a mixed experience of care with one very good ambulance clinician and one not so good. She provided a different perspective that perhaps demonstrated a tension between the experiential, expert knowledge of the patient and the knowledge of the ambulance clinician. She appeared to have felt undermined, and that a male ambulance clinician had been condescending towards her. Lisa felt that she knew more about her condition than they, the ambulance clinicians, did. There was also an acceptance that her perceptions of the ambulance clinician may have been influenced by her post-hypoglycaemic state.

"[Lisa]: She was lovely. She was really really, really nice. The guy was pissing me off! [Interviewer]: Right, in what way? [Lisa]: Because as I was beginning to come to it was the...the impression was teach Granny to suck eggs. It was the daft wee lassie, and he was doing my head in. And if he told my husband once to make a cup of real sweet tea he must have told him about six times, and he was really quite obsessive about this. And I'm thinking...! (laugh) And you're that bit about being quite vulnerable at that point and thinking just shut up. I hate sweet tea. I don't drink it, it'll make me vomit. She (the female paramedic) was lovely, she was really, really nice. The guy was [paramedic's name]. Can't remember her name, but she was lovely. She was the one who was giving me the Glucagel...or the stuff, and she kept saying to me, stop biting. And I was trying to say to her I'm not aware that I'm biting. I didn't...and it was okay. I mean...and I couldn't stop myself biting it. It was happening and I was thinking, I know I shouldn't be doing this..... I don't know, maybe he was just grumpy. Might just have been grumpy. But it was patronising, that's how I would describe it, patronising. Uh-huh, that's the best way to describe it. Come here son, do you want to compare certificates, you know. (laugh)"

(Lisa: id. 242, pg. 2)

Both John and Marion spoke of ambulance clinicians providing pharmacological advice in relation to insulin. In Marion's case the ambulance clinicians had inferred that it would be beneficial to avoid taking insulin if she continued to feel sick. In John's case, although no direct advice was provided to change insulin dosage, he appeared to be reassured by his presumption that the ambulance clinicians knew about his personal insulin control. Similarly, there seemed to be an assumption made by the ambulance clinicians that John was competent in managing his insulin and blood glucose regulation.

"I can take in what they are saying [inaudible 1:05:25] know what I mean. But the way they'll say to me like well, if you're still feeling like for a lot of time, if I've been sick and that, if you're still feeling sick, you know, like hold off, know what I mean, obviously don't take anymore insulin because [inaudible 1:05:40] know what I mean like..."

(Marion: id 52, pg. 39)

"[John]: It's always the same, just make sure you check yourself, make sure you know the amount of insulin you're using for how high or how low you are, because I've been changing my insulin myself, so they know what I'm talking about."

(John: id. 187, pg. 20)

5.6.5 Perception of information transfer between services.

Participants' awareness of communication between the ambulance service and other parts of the NHS were explored. However this question may have been too abstract for some. Alan (i.d. 323, pg. 20), for example, had *never "entered my mind"* what happened to the information recorded by ambulance clinicians. The few who did respond seemed confused about what happened with the information recorded by ambulance clinicians once they had left. Susan presumed that ambulance clinicians passed this onto their diabetes care provider. Contrary to this, Ronan, who knew that information was not shared, expressed his concerns that vital information had been

'lost'. He felt that on several occasions this information would have helped inform his consultant during follow-up.

"[Susan]: It was him because it was too many times, he (the GP) gets the report, when the paramedics come he gets the report and he said cut it down. [pertaining to insulin]."

(Susan: id. 33, pg. 7)

"[Interviewer]: Yes how do you see the role of the ambulance staff and the other health care professionals that you are involved with, with diabetes how do you see them relating, interrelating? R: There appears to be absolutely no connection at all, which is I think quite disappointing. I know from perspective my sister's girlfriend who is a technician down south, she has got an awful lot of insight into the care of some of the people. We have conversations about it obviously the calls, she has got quite a lot of insight and I kind of get the impression, I don't know for a fact, but I kind of get the impression the reports from the front line aren't really picked up at a consultant level and again in terms of holistic care, [inaudible 1.25.48] us from the nineties, that should really be integrated and again the whole issue of paramedic would imply that there is possibly something that could be passed along the line and I would guess that's a structural issue more than anything else, but there is information that gets missed. Down south the kind of weird funny one, the thing that my wife keeps repeating that the ambulance men said is this is not a normal hypo, and yet when I came out of hospital when I was discharged, the discharge said it was just a normal hypo, so evidence gets dropped. I wouldn't be remotely surprised if that's simply because paramedics aren't well enough qualified to speak to doctors and doctors don't listen or aren't interested."

(Ronan: id. 119, pg. 28)

In the closing stages of each interview, participants were informed of the current SAS Treat and Refer system. They were advised that, currently, there were no direct links between the Ambulance and other NHS services. On learning this, Lisa (i.d. 242, pg. 7b) exclaimed "*that is really scary*", and Calum (i.d. 179, pg. 14) stated "*[I] could go to my doctors and he wouldn't have known [about the hypoglycaemic event]*". Whether the responsibility to inform is the patients, or the diabetes care providers, there was a recognised danger that crucial information may not be shared between health care providers.

Some participants (Dave, Margaret and Lesley) discussed the transfer of information between the hospital, general practitioners and their diabetes nurse specialists. They spoke of the GP or nurse accessing electronic appointment diaries or receiving the more traditional 'letter' from the hospital. This didn't necessarily always result in them receiving appropriate follow-up care however, particularly in Lesley's case.

"[Interviewer]: So you...so the role of the emergency services and the role of the diabetic nurse, do you feel they mesh at all or are they...? [Dave]: Well, at Hairmyres, yes, if I go to [hospital name], yes. If I was bad enough I would go straight there to the diabetic clinic. [Interviewer]: Right and then you'd see them up there, right. But for your actual care...so it was [hospital] that took you up there that time. [Dave]: And they get all the notes back on the computers telling them where I've been and everything else, kind of thing. [Interviewer]: Oh right, your diabetic nurse gets that as well? [Dave]: Yeah."

(Dave: id. 114, pg. 38)

"[Margaret]: I check it like, I check it every couple of days. Just suddenly it's been, because, because of my insulin going back down recently it's been high and they told me that at the, well, my neighbour that used to stay next door she was at the hospital for an appointment at the Southern and I went down, and I went into the diabetic with her and I told them that I'd been in hospital and that...they'd changed my insulin and she says well the nurse hasn't told me but I'll put it up on the computer. So they know I was in the Vicky and... they know all that. [Interviewer]: So you've got your history, yes. [Margaret]: So they, they've got my history anyway..."

(Margaret: id. 74, pg. 19)

"[Interviewer]: And did they arrange any follow-up for you? [Lesley]: No. No. [Interviewer]: Nothing at all, no? [Lesley]: But when I went back to my diabetic clinic, the doctor had already known that I was in. [Interviewer]: Right, so they contacted your GP, obviously on records or whatever. And did your GP make contact with you to see how you were? [Lesley]: No. [Interviewer]: Was it just a follow-up, just routine? [Lesley]: Uh-huh. [Interviewer]: It was an appointment you had with him? [Lesley]: Uh-huh."

(Lesley: id. 237, pg. 9)

The process of information transfer between GPs, hospitals and DNS appeared to be better understood than that between ambulance clinicians and other healthcare

providers. It is likely that an understanding of information sharing between hospital and diabetes care provider is enhanced because the patient is made aware of the information transfer retrospectively during follow-up consultations.

5.6.6 Summary

Participants reported that the initial stage of emergency care is good. They feel that they are in safe hands and that the ambulance service response is dependable. Despite some having required additional treatment in hospital, recovery from a severe hypoglycaemic event was relatively predictable, with all participants in this study reporting making a full recovery. With one participant, there was evidence that repeat (within 48 hours) hypoglycaemic events had occurred. For this reason, they stated they preferred being transported to the ED for further care. Some relatives also expressed concern about the possibility of a repeat hypoglycaemic event and as a result had actively encouraged transportation to hospital.

Participants' recollections of advice and information provided by ambulance clinicians demonstrated that there were inconsistencies in both its content and format. But, in areas where advice was consistent, where ambulance clinicians advised both transportation and follow-up care, most patients ignored or refused it. There may be occasions where the ambulance clinician had inadvertently reinforced the participant's decision on follow-up care, by perhaps trivialising its need. A few participants believed there were direct communication systems in place between ambulance and other NHS services. They were concerned to discover there were none and suggested vital treatment information would have been lost. The assumption that information about emergency events was shared led some participants to falsely believe they would be contacted by their diabetes care provider if their care providers thought they required attention. This may prevent some from actively seeking follow-up care.

5.7 Theme 3: Influences on uptake of follow-up care

Many patients do not attend the ED for immediate follow-up care after recovery, but little was known about the participants' decisions and actions after treatment by ambulance clinicians and why they chose to remain at home (see section 4.4.4.3).

This third theme will therefore focus on describing participants' behaviours once the ambulance clinicians left and on explaining the reasons why follow-up care is seldom sought. This theme will be presented in three sections, each of which will portray the experiences of participants within the context of the respective areas of care; these being:- Home; ED/Hospital and diabetes care provider. Responses will help to establish why so few participants accepted either immediate or short-term follow-up care in the ED or at their DCP.

5.7.1 Experiences of home recovery and care

5.7.1.1 Recovery: a normal and predictable process

Analysis of the data exposed three subtle phases of recovery. These imposed a specific course of action on the patient. Although not apparent in all cases, when discussed, a pattern emerged. The first stage was of feeling slightly unwell or tired; the second, a period of rest with carbohydrate loading and finally, the third, a general feeling of normality, 'okay' or 'recovered'. This, generally uneventful, recovery process seemed to suppress any thoughts about the need for follow-up care.

5.7.1.2 “knackered, dead beat and I want to sleep”

Many participants spoke of feeling drained during the initial stage of recovery. This was most likely as a result of the effects of the hypoglycaemic event and subsequent depletion of the energy resources. Rory (i.d. 60, pg. 25) reported “*any time I usually come out of a coma I'm knackered, dead beat and I want to sleep*”. Similarly Edward (i.d. 60, pg. 27) stated “*It makes you very tired like*”. A small number of individuals

described additional symptoms on recovery. For example Edward (i.d. 124, pg. 27) suggested “*there’s a post hypo set of feelings that I can’t...I recognise them. It’s more...I usually have a hot shower and that kind of gets rid of the [feelings]...*”. James (i.d. 221 pg. 18), told of feeling a “*little nauseated*” but attributed this symptom to the treatment provided by the ambulance clinicians, hypostop, an oral glucose gel.

“*[Interviewer]: And is that normal for you, to feel really fine after a hypo, a severe hypo? [James]: Aye, just a **wee bit sick**, maybe... under my tongue that day...aye, I said, ‘Oh don’t give me that son, the last time I was sick,’ and ‘Friend R’ told them the same, ‘Don’t give him that, I’ll have to clean the mess up!’*”

(James: id. 221, pg. 18)

“*[Rory]: **Exhausted, I always feel exhausted, I feel absolutely exhausted. See once I come out of it and I’ve got my senses, or back to myself, I feel absolutely exhausted. Really I’ve never felt so exhausted in all my life....Usually I just lie in my bed, I just stay in my bed and sleep it off.....Sleep uh huh. Obviously [Partner] will come up right you need to check your blood and I check my blood and then I **just go back to sleep**, but I feel absolutely, physically exhausted. I still feel a **bit confused**, when I wake up, did this really happen here and was there ambulance men in, just as if, no a dream, I don’t know the best way to describe it, I just feel that it’s hard to explain, it happened but maybe it didn’t really happen, I just feel really confused, it takes a wee while, then after a wee while I realise, right that’s it you’ve had a hypo and that’s it.***”

(Rory: id. 60, pg. 20)

“*[Edwards’ partner]: Well, that’s really the first time he went to his bed, yesterday. I said maybe you should go and lie down. He said ‘yes I **feel kind of rugged**’. I said, ‘Go and lie down.’ That’s the first time he’s ever done that. [Edward]: It makes you **very tired** like.*”

(Edward: id. 124, pg. 12)

Lisa spoke of a “*headache*” and of feeling “*hungover*” afterwards. Her experience illustrated the fairly typical recovery period from a severe hypoglycaemic event. In this instance, Lisa had contacted her husband via telephone to advise him that she had

been feeling unwell. However her husband received an incoherent message and so sensing something was wrong made his way home. There he discovered Lisa unconscious in a severe hypoglycaemic state. He immediately called the ambulance.

*“[Lisa]: It feels as though what I must imagine if you’ve been **drunk**.....I can remember being so **sleepy, incredibly sleepy** on Thursday night and because [husband] was in the house, he was looking after him [son] dealt with him. He let me nap for a wee while, but did that bit about coming through and making sure she’s fine and you look at her she’s fine, she’s not gone off somewhere. And was fine. Had my tea and was okay. The first one I... oh god the first one I had a stinking headache, so bad which is hardly surprising. I can remember taking some pain relief. It was like how do you describe the headache you get when you take TNT that kind of headache, but not having taken it, but that kind of a...(kind of throbbing - Interviewer) Ah just... oh, went to my bed for about an hour and woke up and was relatively okay in that I just felt a bit fuzzy, hung-over.”*

(Lisa: id. 242, pg. 4b)

5.7.1.3 “I just lie in my bed’ and ‘toast and jam”

The post-hypo exhaustion led many to rest or sleep once the ambulance clinicians left. Others chose to relax and watch the television as part of a recovery strategy. Understandably, for individuals experiencing nocturnal hypoglycaemia, returning to bed would be the ‘norm’ after recovery. The need and desire for rest afterwards is somewhat predictable as participants would be required to replenish their glucose stores. To promote and assist with recovery a number of participants spoke about carbohydrate loading to replenish glucose stores. Indeed this was a common part of the recovery process and was often undertaken either when ambulance clinicians were still present or immediately before or during their rest period after the ambulance clinicians had left.

“[Janet’s partner]: Make her something to eat toast or a crisp sandwich”

(Janet: id. 28, pg. 21)

“[Mary]: After ambulance crew left ‘just sat and watched tele....had another cup of tea with sugar in it”

(Mary: id. 303, pg. 21)

[Alan]: Well I was just actually coming out of the hypo with the gluco gel. Aye, and then I got...[Son] made me a cup of tea and a couple of slices of toast and jam and that...well they [ambulance clinicians] stayed until I'd finished that, checked my...done my sugars and that again. So they were, kind of, on the way up, sort of thing. And then they asked me if I felt better and I was like that, aye, and they were like 'we need to ask you this, are you wanting us to take you into hospital?' And I was like, that, no, I says, I'll be fine now."

(Alan: id. 179, pg. 12)

5.7.1.4 "I'm as right as rain after it"

The duration of rest period varied, with many participants suggesting they took an hour or so to recover during the day, and although some took longer or slept longer, all did recover, with some reporting feeling "fine" (Alan i.d. 323, pg. 19) or "right as rain" afterwards (James i.d. 221, pg. 24).

*[Interviewer]: So after you've come round and the paramedics will stay for a wee while you said then what's the pattern of things then? [Edward]: **Just go back to normal.**"*

(Edward: id. 124, pg. 12)

*[Lisa]: I can remember being so sleepy, incredibly sleepy on Thursday night and because [husband] was in the house, he was looking after him (son) dealt with him. He let me nap for a wee while, but did that bit about coming through and making sure she's fine and you look at her she's fine, she's not gone off somewhere. And was fine. Had my tea and was okay. The first one I... oh god the first one I had a stinking headache, so bad which is hardly surprising. I can remember taking some pain relief.....It was like how do you describe the headache you get when you take TNT that kind of headache, but not having taken it, but that kind of a...oh, went to my bed for about an hour and woke up and was **relatively okay in that I just felt a bit fuzzy, hung-over.**"*

(Lisa: id. 242b, pg. 4)

*[Interviewer]: What did you do after they (the ambulance) went away? [James]: What do you think?....I felt good, what did I do?...[Interviewer]: Started cleaning and tidying?...Aye.....I'm terrible. I get a row..... I go to bed for maybe an hour, an hour and a half, do you know what I mean, go to my bed for an hour, an hour and half...**and I'm as right as rain after it.**"*

(James: id. 221, pg. 21)

*"[Peter]: But having taken a few hypos. I know the consequences of what could happen. But by the time a couple of hours maybe say about two hours, I'm definitely **back to normal**, you know?"*

(Peter: id. 120, pg. 3)

5.7.1.5 Availability of support

Most participants were comfortable with treatment and recovery at home. A number of participants described self-care, but there were many examples of care and support being received from friends or relatives during the recovery period. This ranged from being brought tea and toast and receiving reminders about blood glucose testing to the subtle nudges after falling asleep to ensure no relapse had occurred.

"[Susan]: so my partner went and made me toast and beans and coffee and I don't drink his coffee cause it's disgusting.....and he made me that and then I sat and ate it and then I tested my blood."

(Susan: id. 33, pg. 19)

"[Marion's partner]: But within... because I had gave her the chocolate bar and I put, like, five/six sugars in milk and just stir it, or maybe kind of lukewarm tea to melt it.....And then I made her toast with jam and that. But they said it could go down again, so they waited nearly an hour and done it again, and it was fine, so... But that's...it must drop really quickly..."

(Marion: id. 52, pg. 3)

"[Janet's partner]: then once they've left [the paramedics] I'll do a BM to make sure it's still up and then I'll make her something to eat, even if it's just like a bit of toast or a piece on crisps or a piece or anything like that, just to get in her stomach, and I always do a BM after they've left just to make sure it's staying up, even if it's up at eleven, I just leave it at that for a wee while and then do one a wee while later to see.....Half an hour to an hour normally."

(Janet: id. 328, pg. 21)

"[Ian's wife]: I've seen a couple of times when you've been really bad and come out one he's went to bed and I say, no I don't want you to go to bed. Want to keep him up. He said I'm exhausted. [Wife], I said but you can't Ian, you need to. [Ian]: If you sit on the chair you get a nudge, because you want just to."

[Ian's wife]: So maybe if somebody is no used to that and you've gone back to bed because you're exhausted they might be thinking has he gone away back into [a hypo]..."

(Ian: id. 162, pg. 35)

"[Interviewer]: ...so how did you feel mentally and physically at that point? [Rory]: Usually I just lie in my bed, I just stay in my bed and sleep it off. [Interviewer]: You actually do sleep? [Rory]: Sleep uh huh. Obviously [Partner] will come up right you need to check your blood and I check my blood and then I just go back to sleep, but I feel absolutely, physically exhausted."

(Rory: id. 60, pg. 20)

5.7.1.6 "get the quilt down, the spare quilt and just and relax"

Participants seemed to value home recovery and the care received, being able to relax on their sofa and watch television or go to sleep in their own bed. They also spoke positively of the fact that they were independent and could make decisions for themselves with regards to meals, snacking and taking medications, quite different from some experiences of hospital care which will be discussed in the next section.

"[Mary]: I just sat and watched tele, had a cup of tea, another cup of tea with sugar in it....went mad....the Im bru and everything in..."

(Mary: id. 303, pg. 21)

"[Marions partner]: Well, when they go away, I just tell Marion to sit and rest, don't do anything. Just don't do nothing, just sit there and relax, get the quilt down, the spare quilt and just and relax, watch telly, don't do nothing, till you get a wee bit feeling better. That's it, you know."

(Marion: id. 52, pg. 32)

5.7.2 Contextual factors influencing home recovery

There were two other factors discussed, beyond those previously described, that influenced an individual's preference to remain at home. The first concerned the participant's social circumstances, meaning that it may not always be practical or possible to receive immediate ED follow-up care. The second, expressed by some,

was a perceived moral obligation not to use NHS resources unnecessarily. Examples of both are now provided.

5.7.2.1 Social circumstances

Mary, an 81 year old widow, who controlled her diabetes with oral medication, preferred to remain at home for a reason not previously discussed. Mary lived on her own and spoke of her recent husband who had suffered from severe dementia requiring 24/7 care. When Mary had experienced a hypoglycaemic event the ambulance clinicians had tried to persuade her to travel to hospital, but there had been no one available to look after her husband. As her husband's key carer Mary had no other option but decline transportation to the ED.

"[Interviewer]: So, so you were left at home after, were you quite happy being left at home? [Mary]: Aye, sure.[Interviewer] Or would you rather have gone into hospital? [Mary] Oh no, no, no, for a, I would go into hospital if I ever get that again...but I didn't want to go in for a hypo, or the blood pressure, it was shot up in the air...they brought it down. [Interviewer]: Why is it you feel that way? Why is it you don't want to go to hospital then? [Mary]: Well I had my husband here at the time and I couldn't leave him, there was nobody to look after him. [Interviewer]: Right, right I see. [Mary]: He had dementia. [Interviewer]: Is that when you had the hypo your husband was here? [Mary]: Aye, so I had to say no I'm no going. [Interviewer]: Right, right cause you felt as though you had to look after your husband. [Mary]: I had to look after him."

(Mary: id. 303, pg. 31)

This was particularly important in Mary's case as around a week after her first ever hypoglycaemic event (the trigger call-out) she required a second ambulance. This time she had required emergency care for a systemic infection, sepsis. It is possible that the first event of hypoglycaemia was caused by the early stages of the infectious process. Had she been transported to the ED in the first instance, the requirement for the second call-out may have been averted.

5.7.2.2 A burden on the system

Several participants suggested that they had a moral obligation not to waste NHS time, particularly where they felt care was not required. Randolph talked about not wishing to occupy a bed when, in his opinion, hospital attendance isn't necessary. James suggested there were others who require NHS resources more than he does. For some there may well be a deep rooted perception that their severe hypoglycaemic events were not serious enough to warrant ambulance and/or hospital care. Several participants expressed concern that they may in some way be pestering their GP or DSN. This occurred when they discussed both the immediate and follow-up phases of care. Some felt a moral obligation not to use services when they perceived that they had recovered sufficiently.

"[Rory]: Just I wouldn't want to bother them basically to tell you the truth, all right I feel okay now, right I had my wee thing last night, but I feel right so what's the point in bothering them."

(Rory: id. 60, pg. 31)

"[Edwards Partner]: Well, I didn't think he needed a follow-up then. I mean, any time that he has been down to the clinic, he'll say, 'You can't go and disturb...' I say, 'Yes, you can. You want to find out why you're as high as that. Go down. Or maybe that machine's not working or something like that.' We'd go down to the hospital and see them. And they've been really quite good. But you see, it's him, if he says, 'I'm not going', you can't make him go."

(Edward: id. 124, pg. 11)

"[Natalie]: Well, what prevented me [from going to GP], I felt that what the nurse told me I have to give it time.....I'm quite like that, I mean, I would never dream of calling the doctor."

(Natalie: id. 274, pg. 4b)

"[James]: I'd rather say at home, son, there's always somebody worse than me, be honest, come on."

(James: id. 221, pg. 21)

"[Randolph]: I would also feel I was occupying a bed that I didn't need to, and I'd just feel that a real waste of time and money."

(Randolph: i.d. 270, pg. 19)

5.7.3 Summary

For those who remained at home after a severe hypoglycaemic event, recovery was generally predictable and uneventful. Life returned to normal relatively soon after the ambulance clinicians left. Many of those who participated in this study had experienced previous severe hypoglycaemic events. As a consequence the participants were familiar, and appeared relatively comfortable, with the recovery process. However the psychological impact of the hypoglycaemic event may be underestimated and certainly appeared to bear heavily on those affected. Nevertheless, the predictable recovery, absence of severe side-effects or recurrent events, and comfortable home care, may reinforce or validate their idea that follow-up care in the ED is not necessary.

5.7.4 Hospital recovery and care

Despite almost all being advised or encouraged by ambulance clinicians (or relatives) to be transported by ambulance for care in hospital, almost all participants refused. As identified in section 5.7.1, the home recovery experience was perceived as a positive experience. This may have influenced the follow-up preferences of participants to remain at home. However, little was known about experiences of ED care post-hypoglycaemic emergency and whether this too had any impact on the decisions made. This next section presents some examples of participants' recovery preferences, before highlighting some accounts that provide explanations as to why participants were reluctant to travel to the ED.

5.7.4.1 Preference for home

As previously mentioned, many participants had prior experience of care at home and several had experience of care received in the ED. When questioned about recovery preferences most participants expressed a strong desire to remain at home immediately after the event.

“[Alex]: I’ve only be transported to hospital once and I mean in general terms, I honestly can’t answer your question with a definitive answer, I can generally say, oh no, the last time I was actually asked [to go to hospital] and I said no very forcefully, kind of in general terms my wife would prefer that I was staying at home and I would prefer that I was staying at home.”

(Alex: id. 119, pg. 22)

“[Rory]: A lot of the times, actually once I come out [of the hypo] they give me the option, do I want to stay here or go to hospital, but I always just stay here to be perfectly honest with you, but they do give me the option...I prefer just to stay here.”

(Rory: id. 60, pg. 19)

“[Peter]: Well the paramedics will wait, but there’s not a limited amount of time to handle that. There’s only a limited amount of time that they can wait and they’ll say to me once again, ‘Do you want to go up to the hospital?’ and I’ll keep on saying, ‘No, I don’t want to go’.”

(Peter: id. 120, pg. 22)

“[Margaret]: But sure they really do take me to the hospital they keep saying I need to take you to hospital, I need to, I don’t want to go, I don’t want to go, I keep saying I don’t want to go, but they say listen you’re going to make yourself better if you go in.”

(Margaret: id. 74, pg. 26)

“[Stephen]: And by the time I was in the ambulance my sugar level would have been up to six or something like that, and I was as normal as they were. I still had to go to hospital and get checked over and that took another two hours and then you were back out again. But there was no need for you to be there in the first place.”

(Stephen: id. 162, pg. 13)

However, some participants did prefer to be transported to the hospital post recovery.

John had good reason to prefer this. For example, as described earlier (5.5.1.3.), John

had a complicated medical and personal history that had significantly impacted on his self-management and awareness of hypoglycaemia. John had also experienced repeat hypoglycaemic events, requiring secondary ambulance responses within hours of the initial event. He understandably described feeling safer when transported to the ED after an event and, occasionally called out ambulances when self-treatment was perceived to be failing. Lesley, whose husband often panicked during an event, also preferred to be transported to hospital. She felt secure in the knowledge that she was being supported and treated in the most appropriate place. Both individuals who preferred immediate ED care appeared to lack reliable home support.

"[John]: when the ambulance came I was always taken into hospital. If the ambulance never came, it's never come actually, or a paramedic motor, you know the single one that comes out in the paramedic, they've never come, if he comes he checks me over and that, he will phone the ambulance, if anybody comes they have always took me into hospital." [Interviewer]: And would that be your choice to go?

[John]: They all ask me, but I know myself, I've found out that usually I'm all right, I'll sit here with whoever is in and before I know it I've got to get them back out again, so I always just go just to be safe, it's as simple as that. I've never liked the hospital anyway, now I just go just to make sure I'm going to be all right, that's it."

(John: id. 187, pg. 13)

"[Lesley]: I know this sounds terrible but I always feel safe when I go into hospital, see I've never been in for anything, sort of, mild, I don't think! But see the minute that I get to the hospital and I get into the bed and I know that the hospital's getting a right bad press and everything but I can't give it...I really say to myself, here I am and I've got everybody around about me that can...sort it, and therefore, I really feel quite good about it."

(Lesley: id. 237, pg. 19)

5.7.4.2 "it was a waste of time sitting there"

For those participants who spoke of ED care, and where the experience had fallen short of expectations, this dissatisfaction had clearly impacted on their willingness to be transported to ED after any subsequent hypoglycaemic event. Ian, Susan and

James all provided powerful examples of how the care received in hospital had impacted on their subsequent referral preferences.

Ian, frequently required ambulance service assistance for hypoglycaemic events. He had only experienced immediate follow-up care in the ED on one occasion. The story he told was one of negligible clinical intervention, little professional advice, and of being discharged approximately two hours after admission in a less than acceptable condition. This experience, combined with the short length of stay, had led Ian to question the need for, and benefit of, immediate follow-up care.

Susan (i.d. 33, pg. 20), who previously described being “*feared for days*” after recovering from a severe hypoglycaemic event, was losing hypoglycaemia awareness. The absence of hypoglycaemia symptoms was leading to frequent and severe hypoglycaemic events requiring ambulance service assistance. During her one and only post-hypoglycaemic ED experience she received conflicting advice. Following treatment from ambulance clinicians, Susan had been transported to the ED for further care. After waiting for two hours in the ED, the attending nurse informed her there had been no need for her to be there. This appeared to conflict with the actions of the ambulance clinicians and seemed to have directly impacted on her future decisions around immediate follow-up care.

When questioned about any differences between recovery at home or recovery at hospital, James (i.d. 221. pg. 19) suggested that he felt “*better*” treating himself at home. He provided an example of a non-hypoglycaemia related experience at his local hospital, where he had attended for a urinary catheter change, a relatively straightforward procedure, but that had resulted in a stay of over nine hours. This experience influenced his feelings around ED attendance post-hypoglycaemic event.

"[Ian]: Well I've been diabetic for thirty odd years and taking hypos, but surprisingly never took many hypos in the first ten years, but I took them, you go up there, somebody took the blood sugar straight away maybe it was four, maybe three point five something like that, it's okay, check your blood pressure and saying just contact your diabetic consultant or something like that or your diabetic nurse that was it, send you home. So even then it was you're dripping with sweat, frozen, so you've to make your own way home, so I said I'm not doing that again."

(Ian: id. 162, pg. 12)

"[Susan]: I was only there two hours and I was back home again. [Was that your choice?] No that was theirs.... yes.....they said to me the ambulance crew brought me round, and it was a waste of time sitting there.....I just decide not to go."

(Susan: id. 33, pg. 21)

"[James]: I'm better at home, I can treat myself. In the [hospital name] you just lie there and you'll do what they tell you, and as I say, that's nothing. Mind I got that thing put in me, that...what do you call it? [catheter?] Catheter, aye...I was nine and a half hours down there. That's ridiculous...they're all walking about doing nothing! I mean...seven times I watched a doctor, and he was doing nothing...he wasn't treating people or nothing."

(James: id. 221, pg. 19)

5.7.4.3 'I'm dammed if I want other people administrating my insulin'

When transported to hospital some participants described lengthy observation periods or of a requirement to be admitted for further care. When admitted to hospital an aspect of care that had upset some participants was the removal of their personal diabetes control; nurses took over their insulin administration. This was in stark contrast to the previously described personal and self-care provided and preserved during home recovery (see section 5.7.1.5). Preserving (or perhaps regaining) personal control was extremely important for some. These past experiences of care had impacted on subsequent decisions about immediate follow-up care. Alex's and Elaine's less than positive experiences of past admissions to hospital illustrate this well.

Alex, who had been slightly dismissive of hypoglycaemic events by declaring that “a hypo is a hypo, is a hypo”, subsequently described an occasion where he required considerable clinical support in the ED for a hypo that took many hours to stabilise. Despite acknowledging that the occasional hypoglycaemic event required hospitalisation for treatment, he suggested that, on the occasions when he had recovered enough to make a decision for himself he would feel ‘better off’ at home. His explanation for preferring home recovery was communicated through his concerns over the loss of personal management of his diabetes in hospital. He spoke about the patronising way he had been managed in hospital in the past. Elaine had similar experiences, but added, that her concerns were about nurses lacking the specialist knowledge required to manage her condition.

“[Alex]: Absolutely, a hypo is a hypo, is a hypo, in general terms as far as I’m concerned it’s not a hospitalisable thing or there are cases I’m sure it can be, but I only have experience of one of those, I’m not quite sure how it happened that time.....I had a huge hypo, took about, I think it was about twelve hours until I responded, they had three glucose bags and I didn’t respond.... I don’t necessarily think that was entirely hypo, I think that was probably part hypo, but more significant emotional and psychological event.”

“Basically if I’m conscious enough to be involved in the decision generally they send me home and in general terms I’m going to be better off at home. There are all sorts of issues when you’re diabetic in hospital with who administers insulin and all sorts of weirdness, because it’s a drug you’re not really supposed to be administering it yourself if you’re in hospital. I’m dammed if I want other people administering my insulin, thank you very much, it’s this weird funny thing, how much do you want, are you able to do it yourself, are we allowed to let, bloody hell, it’s kind of like asking whether this person can breathe unassisted.”

(Alex: id. 119, pg. 22)

“[Interviewer]: And do you feel there’d be any benefits of going into hospital, after you’ve had a really severe hypo, like the one you had last time? [Elaine]: Well the way the nurses treat you now, no.....Well the nurses think they know better than you, and the way they treat you, it’s all wrong...They’re not being taught properly...[Interviewer]: what would you like to see improve then there?[Elaine]: Well I think like me, they should realise that I know what I’m doing and if I’ve got to have insulin before I eat, I should

have it. Not for them to say I've not to get it. I'm very much against that....[Interviewer]: And did you find that, even before this recent event, that your experience with the nursing staff on the wards wasn't that positive? [Elaine]: Well my pancreas troubled me three years ago. The sister that I was in, on the ward, she refused to give me my insulin. And I told her I wanted to see Sister S or Sister C. So I saw them...I saw one of them, and she come up, and I told her what was happening. She says no, you must have your insulin. And the sister wasn't happy at all. She was angry at me for getting the diabetic sister. And that's what started off with me with the nursing staff. That's when I realised they weren't being taught properly."

(Elaine: id. 222, pg. 19)

"[Elaine]: They give me advice to do this and do that, but I find myself, I've actually been in the hospital through my diabetes in a ward and some of the nurses, I'm no talking about diabetic nurses in the centre, I'm talking about ordinary nurses or sisters or whatever, they can really annoy me, because they try to tell me this and that, I'm the one that has lived through this for twenty odd years and I try to tell them that and they get quite annoyed about it, I can see their point, I'm a sister and I'm this and I'm that, but you're no the diabetic missus, that's all I can say, try no to be cheeky, but they get you going..... All they are getting is a three or four page leaflet, they can read books and like that, but actually get a three or four page leaflet this is what you do, with your diabetic patient, because I looked at them myself."

(Elaine: id. 222, pg. 28)

5.7.4.4 "[the food] is pretty grim"

Non-clinical elements of care also influenced participants hospital experiences and decisions around immediate follow-up care. A nutritious diet, for example, is essential for individuals with diabetes if they are to maintain good health and regulate blood glucose levels. Food type is even more important for those who have specific dietary requirements. Home recovery (see section 5.7.1.1) already alluded to the fact that participants required carbohydrates post event. Whilst at home, participants are likely to have access to a range of personally selected food types. They therefore have more choice and can eat at times that suits their needs rather than others. Randolph found the opposite with hospital care and clearly described his feelings about the lack

of dietary choice, particularly for vegetarians like himself. This impacted on his willingness to attend for immediate follow-up care.

"[Interviewer]: Why is it you prefer to remain at home? [Randolph]: I suppose it's the, a lot of, one factor being I'm a vegetarian, I find they accommodate you in hospitals, but the stuff is pretty grim, the food. So if I stay at home I know I'm getting better, more suitable food and not dismissing stuff and saying I can't have that and can't have that. Narrowing my options, other than that..."

(Randolph: id. 270, pg. 19)

5.7.4.5 Feel safer with ED care

In contrast, there were some individuals who suggested they felt safer being transported to the ED for recovery and follow-up care. Both John and Natalie, although neither experiencing outstanding care, suggested they preferred to be transported to the ED. John spoke of being admitted for around ten to fourteen days for a particular 'type' of severe hypo about once every month. He didn't appear to know why he had been kept in for so long, and decided to discharge himself from hospital three days after admission. He felt that staying in hospital had been a 'waste of time'. Unlike most others however, John, did suggest that he felt safer when transported to the ED immediately after a hypoglycaemic event. This feeling of 'safety' again may be linked to his brother's death from hypoglycaemia and of experiencing repeat hypoglycaemic events. Natalie, who cared for her husband who was recovering from a stroke, preferred to be transported to hospital. Perhaps in both cases the preference for hospital recovery was due to the lack of immediate home support available, particularly should either experience a protracted recovery or a repeat event.

"[John]: They put me on a drip in the ambulance until I got to the hospital and then they put me on the thingmy, you know, the long...[the insulin pump]...Aye I got on to that and on to glucose drip whatever. I said I can't, anytime this happens to me it seem to be always ten to fourteen days they keep me in for some reason, but I just got home on the Sunday myself, that was the Friday, a couple of days, I said no I'm going home, because I knew, well I know anyway the way it works now, because even once they get me squared up, of course they want to keep an eye on you just to be sure, but after the amount of times

it happened to me I know it's going to be all right, it seems a waste of time keeping me in there, I'll just go home. I let them know where I'm going right enough.'..... 'I've never liked the hospital anyway, now I just go just to make sure I'm going to be all right, that's it."

(John: id. 187, pg. 10 & 13)

"[Interviewer]: What would you rather...if you had a choice of remaining home or being taken in to hospital? [Natalie]: I know this sounds terrible but I always feel safe when I go into hospital, see I've never been in for anything, sort of, mild, I don't think!.....but see the minute that I get to the hospital and I get into the bed and I know that the hospital's getting a right bad press and everything but I can't give it...I really say to myself, here I am and I've got everybody around about me that can.....sort it, and therefore, I really feel quite good about it."

(Natalie: id. 274, pg. 35)

5.7.4.6 Relative's preferences "*I prefer he went up*"

Occasionally participants' relatives spoke of trying to encourage transportation to the ED for follow-up care. Dave's wife persuaded him to travel in the ambulance to hospital despite his preference to remain at home. She was frightened that he may experience a repeat event or that his loss of consciousness was not related to his hypoglycaemic event. Dave's wife also suggested that if the ambulance clinicians had advised him that he was 'doing fine' then she would have been happy for him to remain at home. Peter's wife also acknowledged the possibility of a repeat event. She expressed her frustration in Peter's refusal for transportation to the ED.

"[Interviewer]: so when the emergency services come out you've always gone up to the hospital, yes? [Dave]: Yes. [Interviewer]: And is that what you would want? [Dave]: No really, I'm quite happy to sit in the house kind of thing. [Interviewer]: Yes, but would you prefer he went up to the hospital? [Dave's' partner]: I prefer he went up to see everything was okay.....I mean if it is a hypo and that if they, if there's going to be sugar and that for me to watch out for... but if he's going to take another one there again, what do I do? [Interviewer]: Do... [Dave's partner]: If I'm going to have to call the emergency out"

(Dave: id. 114, pg. 18)

"[Peter's relative]: That's it. The only thing that gets me is when he does take a hypo and the

paramedics come, they want to take him to the hospital to get checked out, but he'll not go. He keeps refusing to go. [Interviewer]: To go? Yes. [Peter's relative]: And, I think, sometimes they would rather just take him up and get him because as soon as they go away, he could fall back into one again.[Interviewer]: Uh-huh. [Peter's relative]: I don't think you understand that very well."

(Peter: id. 120, pg. 3)

5.7.5 Summary

The majority of participants perceived there to be several 'benefits' to remaining at home and several 'costs' associated with immediate follow-up care in hospital. It is clearer now to see why so many individuals would rather remain in their own home to receive a bespoke, self-managed, service in a comfortable and familiar environment. Although several participants described negative experiences in hospital, a small number reported positive experiences and were happier to be transported to the ED for recovery as they felt safer.

Having explored the hospital and home recovery experience in detail the next section will focus on the experiences of participants during follow-up at primary care or their diabetes care provider.

5.7.6 Experiences of diabetes care providers

Most participants recalled being advised by ambulance clinicians to follow-up with their diabetes care provider. But, as with immediate follow-up care, few did. This was despite many reporting a positive relationship with their diabetes care providers. Although all participants were asked about post-hypoglycaemic follow-up care, few discussed or elaborated on this. In fact many did not discuss it at all. Perhaps, as so few appear to have attended for post-hypoglycaemic follow-up care, they found that they had little to discuss. Factors that contributed or affected the participants' decisions for dismissing advice on seeking follow-up care were explored. As with follow-up care in the ED, for some, there was little perceived value in follow-up care with DCP's. DCP's generally consist of a multidisciplinary team led by General Practitioners with differing responsibilities. This next section will describe the participants' experiences of routine and short-term post-hypoglycaemic follow-up care in the context of post-hypoglycaemic care.

5.7.6.1 "they do generally vary in quality"

Where discussed, analysis of participants' experiences of general diabetes care could be described as 'variable'. Some participants inferred that care had been useful and access uncomplicated, while others described inadequate care or difficulties in obtaining access. Regardless, most did not attend for follow-up. Ronan emphasised this point during his interview as he talks of his variable experience of diabetes services across the UK.

"[Ronan]: I think I'm on my sixteenth address and I'm thirty-five, so since I left home, it doesn't count the two I had with my parents. I think I've experienced a lot of different diabetic services and they do generally vary in quality, so you find the good ones and you take advantage."

(Ronan: id. 119, pg. 10)

5.7.6.2 "he didn't waste a lot of time on it"

The disposition of the diabetes carer during consultation seemed to impact on some participants' future perceptions about need and desire for follow-up. Ambulance clinicians

had recommended that Randolph sought follow-up care. Coincidentally, he had an appointment already made with his GP for the following day. During this consultation he passed information about the hypoglycaemic event on to his GP, however his GP gave the impression that he wasn't that interested in discussing it. Randolph also questioned the authority of an ambulance clinician to refer and advise, inferring that he would be more likely to have followed advice if it was offered by a senior medic (Doctor) rather than a paramedic.

"[Randolph]: I told him [GP about the hypo], but he said och I, I got a feeling he said, oh God not another one, he's got to almost go through what they've [the paramedics] gone through and explain, perhaps explain stuff I can't remember, but he didn't waste a lot of time on it. [Interviewer]: Well if we're suggesting it's a good idea to speak to somebody after you've had a hypo, how does that make you feel if you're hearing it from a paramedic as such? [Randolph]: I suppose he doesn't, a paramedic I feel doesn't have the authority or knowledge of a doctor, so I'm afraid I would tend to want to hear it, how could I work this from someone in higher authority medical wise, if there is such a phrase, you know what I mean..... I'm afraid too I'm still slightly dismissing the, although the hypo of that severity is something I can't personally cope with, no way, then I feel that how would I put it, I can't deal with it myself..."

(Randolph: id. 270, pg. 17-18)

5.7.6.3 *"I haven't told any other medical staff about it"*

When the question was posed about need for post-recovery follow-up care some believed there was little need for follow-up, either with the ED or their diabetes care provider. Rory reflected on his past post-hypoglycaemia actions. He could not recall being advised to seek follow-up care and suggested that he was fine afterwards and therefore saw no need for follow-up. Tony too did not appear to value follow-up care.

"[Interviewer]: When you come round do you think of calling you health care provider?[Rory]: To be perfectly honest no really, I'm usually, as I say, I'm in a daze and then after that I just want to sleep and to be perfectly honest, I wake up the next day and I feel okay and I'm all right, so there's no point and I feel okay."

(Rory: id. 60, pg. 30)

"[Tony]: Because I don't think nothing to follow-up on, you know, what's happened, how it's happened."

(Tony: id. 133, pg. 37)

Tony reflected on his past feelings about follow-up care. He seemed to have accepted the fact that hypoglycaemic events were simply a part of his life.

“[Tony]: because previously I would have just, well I have just gone okay it’s one of those things.....I’ll get on with it, you know. I mean I told you last, last year I had a few other hypos, not...[Interviewer]: not major. [Tony]:... tightly spaced together...but I did just brush them off, I haven’t told any other medical staff about it... well except the specialist nurse. But that was just a kind of in passing, you know, I had a couple, dah, dah, dah”

(Tony: id. 133, pg. 37)

The relatively rapid recovery and normalisation after a hypoglycaemic event appears to lead some to believe that there is no need for follow-up care.

5.7.6.4 “the damage is done, we’ll never prevent any more”

Similarly, Susan provided examples of experiences of care from both her diabetes specialists and GP. Susan had been offered psychiatric support as her diabetes carers felt that she had not accepted her condition. Despite being advised to reduce her insulin doses, to eat more and undertake regular blood glucose testing at home (similar to reports of the advice given by ambulance clinicians), the frequency of events continued to impact significantly on her life. Her GP also informed her that she had already caused irreparable damage to her organs. A succession of these perceived failures in care had led Susan to believe that routine follow-up care was *pointless*. She conveyed a feeling of frustration and of utter helplessness.

“[Interviewer]: How do you get on with her, or him? [Susan]: I don’t really get on well with them (hospital diabetes carers}. Because I feel as if when I am going over there it’s a waste of time...and that’s just how I’ve got because they know I suffer from this, and they know I take a lot of these, quite often, but yet they just want to sit there and do nothing, know what I mean, and yet it’s only, yet I’m supposed to get insulin changed last year, at Christmas time, and I still haven’t seen one now...And I’m due to go back on the 16th of June this year and there is a lot happened. And that’s when I made up my mind, if they’re no going to do it, I’m no going back.And I’ll say...there a couple of weeks ago, they took me away, took a hypo right, they took me away, and, all he told me was come to (specialist diabetes centre name) in the morning and I went away over and, yes just carry on the way you’re going. Now that to me was a waste of time.”

"[Susan]: They don't advise me...all they, they told me, that was my own GP that told me to cut the insulin down. It was him because it was too many times, he gets the report, when the paramedics come he gets the report and he said cut it down. And I said but I'm going to end with nothing here, he says well that'll just have to happen. He says but we can't leave you with nothing. I says but you're telling me I, and I've ended up with nothing. He said but the damage is all done now and we'll never prevent any more. But they have told me, the paramedics have told my partner they are getting too severe now and it's only a matter of time, because I won't survive them all. And my wee laddie over heard them one of the times and he took a wee bit of a fright to it. And even my partner was like that to me, I didn't really think these were so bad until they've told me."

(Susan: id. 33, pg. 6)

Kerry was one of the few participants in this study who reported acting on the advice of ambulance clinicians to seek follow-up care. She had a complex medical history, and experienced frequent severe hypoglycaemic events treated by her family and friends without ambulance service assistance. She described her first experience of follow-up care post-hypoglycaemic event. Her consultation involved both a GP and a DSN. Despite being prescribed more glucagon and receiving a new insulin pen to allow for greater control over administration, she was told that there is little else they can do to help.

"[Kerry]: No, she says phone diabetic nurse. I said I've to go and see diabetic nurse on Friday. [Interviewer]: The diabetic nurse this is? [Kerry]: Uh-huh. And she went well that's fine. She said the only thing I can tell you, she says, is what everybody else has told you, just carry on. She says there's nothing we can do. She says we've been trying how many years, and I went 20."

(Kerry: id. 249, pg. 34)

"[Interviewer]: So what happened when you saw your diabetic nurse then on Friday? [Kerry]: She just says well, we'll see what diabetic nurse says when you go to her on Friday, and then when I went to diabetic nurse on the Friday and she gave me the new pen and that.....because the pen I had only went up in units but that goes up in half units."

(Kerry: id. 249, pg. 36)

5.7.6.5 Conflicting preferences: GP not always the preferred option

Approximately half of all participants described receiving advice to seek follow-up care. Most were advised by ambulance clinicians to follow-up with their GP. But some participants had definite preferences about who they preferred to consult with. James refused to follow-up with his GP as he perceived care there to be deficient after previous unhelpful experiences. However, later, when probed, it became apparent that he would have been comfortable making an appointment with his DSN as an alternative. Both Lisa and Kerry were very specific in whom they preferred to consult about their diabetes control.

"[James]: When I phoned one day I wasn't feeling good, I phoned up regarding the...cannot mind who I spoke to...one of the girls up there, and I says, 'Can I speak to the nurse?' 'What is it about?' I tell her everything, that I've taken two hypos because I've reduced my insulin. 'She'll come back to you.' I'm still waiting for the phone call. [Interviewer]: Right, and how long ago was that? [James]: About four months ago. [Interviewer]: Four months ago. [James]: I'm still waiting for the phone call. [Interviewer]: And this is from your GP? [James]: GP, aye."

(James: id. 221, pg. 10)

"[Interviewer]: Did they [the ambulance clinicians] give you any advice about...did they leave anything? [James]: Go down to the GP.....but I never done it, because nobody knows anything and they'll no bother their backside about you son. [Interviewer]: Sure. Who would you have contacted, if we had suggested somebody else? [James]: I'd have contacted that diabetic nurse (based in the diabetes specialist centre)...she's a nice enough wee girl...I saw her there, 'Who are you?' diabetic nurse ...the diabetic...the nurse that's [inaudible 30:39]... the doctor's sent her up from the Monklands, but she's never come back, but you know, she is well known. I'd rather be on my own. I'm trying to help myself, you know what I mean, son?"

(James: i.d. 221, pg. 19)

"[Interviewer]: And how easy do you find it to make an appointment? [Lisa]: I would have thought it would be quite difficult because it's the bit about it in an emergency if not it's you want to follow-up? It would be maybe two or three weeks to get something. And I wouldn't do a GP because all they'll do is refer me on. [Interviewer]: Who would you like to speak to about that? [Lisa]: It would probably be the consultant because I haven't had the need or I haven't perceived the need to hassle them then..."

(Lisa: id. 242b, pg. 8)

"[Kerry]: Uh-huh. It was half eight. Because they'll say...or I'll phone down, appointment for Doctor S, oh we've

not got any, Kerry. We've got Doctor F. I went no. Doctor R or W. Either. I says but Doctor F, no way."

(Kerry: id. 249, pg. 34)

5.7.6.6 Confusion around information sharing

As has been illustrated in previous extracts, for some participants who did follow-up, this was purely coincidental as they already had an appointment organised a day or two after the emergency event. These forthcoming routine appointments with diabetes carers seemed to have influenced some participants' behaviours on actively seeking short-term follow-up care. In some instances participants appeared to be comfortable to wait for weeks or months to inform their care provider about their recent hypoglycaemic event. For a number of participants there was a lack of urgency in seeking follow-up care in the days after the event.

"[Interviewer]: Sure and you were also saying earlier on that you had a number of hypos in a row just recently, but every time you've remained at home afterwards you've not been transported to hospital? [Andrew]: No, no. [Interviewer]: Did you follow-up with your nurse or GP afterwards, did you contact, did you feel a need to contact? [Andrew]: No they told me to do that of course, they tell you to contact your nurse. I go to my nurse every three month, I get whatever, I'll tell her then, I don't need to tell her the next day or phone up. [Andrews wife]: Do you tell her? [Andrew]: Aye I do tell her, I do tell her, I say I've had a couple of hypos and, blaa, blaa, blaa, do you know what caused it, of course I know what caused it."

(Andrew: id. 165, pg. 6)

5.7.6.7 "I don't know whether they contact them or they contact him"

Earlier, it was noted that participants' awareness of communication between services was lacking which created confusion around what information the DCP would have. This lack of knowledge had resulted in some perhaps presuming that the diabetes care providers would be made aware of the event and if there were any perceived problems they would automatically contact the patient. The inference here is that the responsibility for organising follow-up care lies with the diabetes care providers. The assumption that some participants made therefore is that information was being transferred from the ambulance clinician to the DCP, if there was any problem with control then they would have been contacted by their

DCP, and because they have not been contacted by their DCP then everything must be fine and they can wait until the following month where there was a routine appointment organised.

"[Interviewer]: And so the next day or so, would you think of going to your GP or your diabetic nurse specialist or contacting somebody to let them know? [Peter]: I've never actually...I've always thought [Inaudible 54:29]? waited then getting information back from the doctor at hospital. [Peters' wife]: He doesn't, even if...well he's had quite a few hypos with the paramedic being out but nothing after that, because once they go away, they go away and then you don't hear anything else from the doctor, from the diabetic nurse. I don't know whether they contact them or they contact him...I don't know but they just don't, you know...[Interviewer]: And do you take them down to your doctor to...? [Peters' wife]: We did that last time, he went up to the doctor's after it once. [Interviewer]: And that's to let them see? [Peters' wife]: Uh-huh .[Interviewer]: So do you do that usually? Contact your doctor, your diabetic nurse and let them know that you've had the Emergency Services out? [Peter]: I've only done it once or twice because I know that I'm going to get, what was it word from the diabetic specialist nurse, I know I'm going to get word from her and I know, I actually know next month that's April. [Peters wife]: She'll probably have a copy of it."

(Peter: id. 120, pg. 23)

Ronan suggested that he often went for routine diabetes care but was able to describe a more positive experience than others. He spoke of the different grades and professions and how some can be more receptive than others. There was also a suggestion that the routine of follow-up care can become a little relentless and that sometimes he felt it necessary to have a break. This resulted in him deliberately missing some appointments.

"[Ronan]: One of the two nurses is also diabetic, where there is a radical idea of diabetics in charge of diabetic services. She is very, very good and the other nurse probably learns quite a lot from her colleague as well."

'No generally the DNS is a lot easier to speak to than the consultant, in general terms that's the case and I've yet to meet a diabetic nurse who hasn't been quite good at listening, not always particularly good at responding, but there are a number of medics at doctor level staff they don't just listen at all, not even slightly interested unless you're saying what they want to hear, that is not reflected, certainly quite differently, diabetic nurses, obviously there is a varying in standard but the route to become a DNS in many ways is quite a lot harder than becoming a Diabetologist at a junior level and then obviously you've got to qualify as a doctor, which is an incredibly difficult thing to do, but once you are there.'

"But I mean it's the way of the world and it's just about kind of slowly getting there, I missed my last appointment I was just so pig sick with the whole thing, I just actually couldn't face it, so I need to rebook that and go back, there is no point in dipping out of the system at all, it doesn't get you anywhere, you just need to take wee holidays from it."

(Ronan: id. 119, pg. 3)

Stephen clearly stated that he perceived little benefit, or value, in short-term follow-up care. Stephen, who lives with his wife, and who has experienced numerous severe hypoglycaemic events requiring ambulance service assistance, has adopted a laid-back approach to hypoglycaemic events and their follow-up. He paraphrases, stating that his GP would not be changing any medication. In his mind, there was little point in going to see anyone. There are several physicians involved in Stephen's care, from both public and private sectors, each giving advice that appears to be conflicting.

"[Stephen]: If I went up to Doctor 'B' and said, 'I had a hypo, what do you think?' He would probably say, 'Take less insulin and more sugar.' What more can he say? I don't see what he can say. [Interviewer]: So when you do go and see him again later, do you tell him then? [Stephen]: I've got a letter saying, 'This is your last warning, come and see us so we can sort out what Doctor 'G' said.' I'm that blasé, I need to do it. [Interviewer]: You would get that letter...not that but...[Stephen]: Well, the practice has written to me three times saying, 'You went to see Doctor 'G', you need to come and see the GP to get things sorted.' [Interviewer]: And that's a standard follow-up care, not for anything specific. [Stephen]: I got one the other day saying if you don't come we're not going to write to you again. [laughs] But I mean, I spoke to Doctor 'G', there's not anything in my prescription he's going to change."

(Stephen: id. 146, pg. 30)

5.7.7 Summary

It is apparent that not many participants have engaged in short-term follow-up care. Although many did suggested ambulance clinicians advised them to seek follow-up care, as with follow-up in the ED, few actually went. For those who did describe their follow-up, it was perceived as being variable. For a few there was a feeling of helplessness, these thoughts were reinforced when their care providers told them there was little else they could

do to help. Few participants knew about the lack of information sharing between ambulance services and NHS services. This influenced help seeking behaviour in at least one individual who presumed that information was shared and that as he had not heard from his DCP everything must be fine.

5.8 Discussion

5.8.1 Introduction

No previous qualitative study had investigated patients' experiences of hypoglycaemic care provided by ambulance clinicians. This study has described the patients' experiences using a qualitative and inductive approach. This discussion section concentrates on three aspects of the findings that are important in terms of improving services and reducing the frequency of hypoglycaemic events; i) why the ambulance was called ii) the polarised experiences of follow-up care, and iii) the current systems for hypoglycaemia care. It also considers the relevant psychological theories that help to explain participants' and relatives' actions before, during and after the event. The integration of these findings with relevant theories, policies and research will provide potentially helpful explanations of behaviours and inform the development of interventions as well as other future studies.

5.8.2 Perception of hypoglycaemia

Impaired awareness was clearly identified in many participants and was the most important clinical feature contributing to the development of severe hypoglycaemia (section 5.5.1). The reported frequency of impaired awareness was of concern due to the long established links between impaired awareness and severe hypoglycaemia (De Galan *et al*, 2006; Gold *et al*, 1994; The Diabetes Control and Complications Trial Research Group, 1991). While some participants reported experiencing 'text book' symptoms of hypoglycaemia, many with impaired awareness either misinterpreted the early symptoms or simply had no warning symptoms at all. Without treatment, neuroglycopenia developed, impeding their ability to self-treat. Subsequently the mild hypoglycaemic event would escalate into a severe event

requiring third party assistance (via relative or ambulance). This association emphasised the importance of the role relatives play with the identification and then treatment of hypoglycaemia. Fortunately, when assistance was required, relatives and friends were familiar with the signs of hypoglycaemia and intervened (section 5.5.2). But despite relatives or friends being near-by, identification of hypoglycaemia was often delayed and as a result relatives frequently found themselves managing an unconscious 'patient' (sections 5.5.2.3 to 5.5.2.9). Descriptions of such events also confirmed the rapid onset and unpredictability of the condition. This would be considerably more dangerous in the absence of relatives, friends or others.

5.8.2.1 Carer Support

Several factors appeared to affect the relative's ability to cope and provide assistance. Although for some there was an intimation of support from diabetes care providers through the prescribing of glucagon, this injectable antidote was rarely used, and was often unavailable. The emotions of fear and anxiety experienced by relatives often prevented the administration of glucagon (when it was available) and impeded their capacity to treat (section 5.5.2.6 and 5.5.2.10). Indeed a past study established that non-diabetic relatives expressed greater fear of hypoglycaemia than the patients' did themselves (Gonder-Frederick *et al*, 1997). However, fear was not present in all cases within the current study. One participant described family support systems that were so well developed that only once had they needed to call for an ambulance (section 5.5.2.9). This account suggested that treatment and support provided by relatives may be a viable alternative to the existing default position of the ambulance call-out.

A recent review recognised the challenges faced by carers in providing support during severe hypoglycaemic events and recommended continuous education on the use of glucagon (Kedia, 2011). Similar broad recommendations are included in current NICE guidelines on diabetes care (NICE, 2012). Neither are explicit in the provision of clear

recommendations on the content and type of education needed. The importance of adequate guidance and support should not be underestimated; past research demonstrated that despite education almost 70% of carers experience handling difficulties during administration of glucagon (Harris *et al*, 2001). Another study found that some patients have treatment preferences; some preferring intranasal glucagon to intramuscular or subcutaneous (they presumed their carers would too) (Yanai *et al*, 1997). An example of this was also found in the current study (see section 5.7.1.2 pertaining to glucose gel). The use of alternative, less invasive treatments could help in reducing fear or anxiety and enhance the carer's ability and willingness to provide treatment. Such education and support may usefully be considered for future interventions aimed at improving the provision of care by relatives. However, providing treatment is only a small part of the considerably larger system of care required to assist a person experiencing a severe hypoglycaemic event. The effectiveness of any practical intervention is dependent on the ability of both the patient and relative to identify the illness. Without this, no treatment would be initiated.

5.8.2.2 Impaired awareness

The patient's susceptibility to hypoglycaemia and the relative's capacity to act appear linked to their ability to recognise the condition. The ability to identify illness is one of the key measures of Leventhal's Common Sense Model of Self-regulation of Health and Illness (Leventhal, 1998). Of all the social cognition models, Leventhal's model is the most developed and the only one to include an element on illness 'identity', more specifically, the signs and symptoms associated with a condition (Marks *et al*, 2011). The manner in which an illness is represented allows individuals to determine the nature of the health 'threat' (Leventhal *et al*, 1998). Leventhal stated: 'The model is based on three simple propositions:

"1) people are active problem solvers; they define and construe their worlds in their own way, select and develop coping procedures to manage health threats, and change the way they represent problems in the face of disconfirming information.

2) *problem-solving processes occur in context.*

3) *the motivation to prevent and cure disease is directed to what is perceived as the most immediate health threat and is limited by resources and a satisfaction rule”*

(Leventhal *et al*, 1998 pg. 718)

The first property of the model pertains to the content of the representation of the illness, and the second, the organisation of these representations. The ‘content’ refers to the nature of the health threat and consists of five elements (also known as constructs): identity, cause, time-line, consequences and curability/controllability. The organisation of the representation of the illness refers to features such as ‘patterns’ or ‘cyclical’ conditions or presentations of the illness (Leventhal *et al*, 1998). The model determines that a person can only respond to an illness once they have assigned a label or identity to it. The importance of ‘identity’ is that it becomes the representation of the illness and, if perceived as a threat, a coping strategy will be developed to assist a return to status quo. Only when a specific representation of an illness is stimulated can a behaviour change be initiated.

A recent study investigated impaired awareness in people with Type I diabetes using semi-structured interviews (Rogers, De Zoysa and Amiel, 2012). Participants were separated into two groups. Group 1 (n = 4) had significant concerns about their impaired awareness and Group 2 (n = 13), the greater proportion, seemed unconcerned about impaired awareness or expressed any fear of hypoglycaemia. They applied Leventhal’s model (1998) to their findings post hoc and found that those with high identity for impaired awareness were in Group 1 and those with poor identity for impaired awareness were in Group 2. Those in Group 2 also appeared to lack knowledge in the causes of impaired awareness.

In the current study some participants had recognised the early symptoms of hypoglycaemia, believed these to represent a threat and acted to counter the threat through the ingestion of carbohydrate. However, in those with impaired awareness, no threat was recognised or perceived and, as a result, no action was taken. Consequently they developed severe hypoglycaemia. Where relatives or friends were present however, the unique changes in the person's behaviour, or the reduction in level of consciousness associated with hypoglycaemia, were identified as a threat. These were acted upon by the relative through either attempts to treat or by calling for an ambulance. Leventhal's model (1998) could therefore provide a useful theoretical platform on which to further investigate this element of illness perception. Post hoc application of this model suggests that, if all participants had been able to attach an identity (symptoms of hypoglycaemia) to the illness, preventative action could have been taken to prevent a mild event from progressing to a more severe event.

Whilst Leventhal's model (1998) may help explain the link between impaired awareness (the absence of illness identity), the hypoglycaemic event and the subsequent ambulance call-out, there were other aspects of the participants' behaviours that may be better explained through alternative psychological models.

5.8.2.3 Perception of no need for follow-up

Despite many participants' accounts of ambulance clinicians advising patients to seek follow-up care, either immediately within the ED or with their DCP following recovery, few followed this advice (known in the literature as non-compliance). Although emergency care was perceived as being excellent, the advice provided by ambulance clinicians prior to their departure was generally ignored. Many patients remained at home post treatment. This reflected earlier results presented in both the scoping review (chapter 3) and the retrospective analysis (chapter 4). The study by Daniels *et al* (1999) included only those patients with insulin dependent diabetes and found that only 37% of those followed up with

their DCP. Indeed in the West of Scotland almost 71% of patients who had recovered from hypoglycaemia remained at home post event (see section 4.4.4.3.).

Importance of follow-up

Follow-up care for patients who have experienced a severe hypoglycaemic event is important for several reasons: Firstly, previous research (Walker *et al*, 2006) reported that around 50% of patients who attended for follow-up received medication changes, and all received education on their condition. The findings in the current study suggested that, for many, self-care was sub-optimal. This may have contributed to fluctuations in glycaemic control and perhaps even the hypoglycaemic event. Secondly, as previously described, many participants reported impaired awareness (see section 5.5.1.2). To restore awareness of hypoglycaemia meticulous avoidance of hypoglycaemia is required for a period of 2-3 months (Graveling and Frier, 2010; Dagogo-Jack, Rattarasarn and Vryer, 1994). Such care requires individualised advice and on-going support. There were no accounts from participants of on-going clinical support from DCP's in the days after the event; perhaps because so few had attended for follow-up care. Participants were unaware that their lack of symptoms were preventable and so failed to instigate any personal measures to regain awareness. Thirdly, both the scoping review (chapter 3) and the retrospective cross-sectional observational study (chapter 4), demonstrated that repeat and recurrent events were not unusual in this patient population. The review found that 2-7% of patients experienced a repeat event within the first 48 hours of initial treatment (see section 3.7.4). Analysis of data from the West of Scotland Ambulance Control Centre found 3.1% of patients experienced a repeat event with 48 hours; 10% of recurrent events (those beyond the 48 hour time period) occurred within 14 days of the initial call (see section 4.4.4). For some, therefore, immediate follow-up care was essential.

Lastly, although structured diabetes education programmes such as DAFNE, BITES, BERTIS, and DESMOND (NICE, 2012; SIGN, 2010) have demonstrated improvements in

HBA1c, they have had no impact on the frequency or severity of severe hypoglycaemic events. However specific, focussed education programmes for those with significant problems with hypoglycaemia have also been developed: HAATT, BGAT and BGAT (Cox *et al*, 2006). These have had some degree of success in reducing hypoglycaemic events with minimal impact on HBA1c (Cox *et al*, 2006). This is encouraging, however if the DCP is unaware of their patients severe events then patients most in need will not be targeted with these bespoke educational interventions. The knowledge of additional evidence-based interventions to support care and prevent hypoglycaemia is encouraging and emphasises the need to inform patients about the importance of follow-up care. Ultimately, the lack of follow-up care, or a personal management plan, may have placed participants at increased risk of a repeat or recurrent severe hypoglycaemic event. This underlines the importance of developing an understanding as to why some people do not follow-up their care with their DCP.

Reasons for non-compliance

Most participants reported a prompt recovery from severe hypoglycaemia with little immediate consequence. With the exception of headache, tiredness and hunger there were few reports of significant side effects. In fact one of the few consequences reported was the development of tension between relative and patient in those who refused follow-up (see section 5.7.4.6). A small number of participants' relatives expressed concern about the risk of repeat or recurrent events. As Leventhal *et al* (1998) suggested, behavioural change is instigated through the perceived threat of illness. Some relatives clearly perceived a repeat event as a threat. However, in terms of illness representation, the identity of the illness is manifest through the physiological signs and symptoms of hypoglycaemia experienced by the patient. For those who had developed impaired awareness, this may have prevented any 'identity' being attached to the condition. Furthermore, on recovery, any signs or symptoms directly associated with hypoglycaemia would have diminished as a result of treatment. With the exception of some limited side-effects, as noted above, there were few

symptoms that could be linked specifically to hypoglycaemia or any specific health 'threat'. A state of normal health had returned. Additionally, the duration of the illness was short, it was easily treated (for most) and there were no significant consequences to the event.

Leventhal *et al* (1998) also speaks of the 'organisation' of the illness and describes these as features such as 'patterns' or 'cyclical' conditions representing the illness. For some participants, the cyclical nature of repeat or recurrent hypoglycaemia events may have allowed the individual to identify patterns in the recovery process. In the participant interviews there were often no mention of serious side-effects, no protracted responses to treatment and no clearly defined symptoms reported post recovery. The absence of any clearly defined illness means that a behavioural change was neither likely nor required. Leventhal *et al* (1998) also suggested that representation of illness can be 'bi-level': individuals may treat the disease or simply focus on treating the symptoms. For the few participants who did experience symptoms and identify hypoglycaemia as an 'illness', most appeared to treat the symptoms rather than developing any strategy to prevent further events.

Application of Leventhal's model (1998) suggests that, as an illness, hypoglycaemia may lack identity particularly in those who have impaired awareness. When hypoglycaemia occurs it is of short-duration, very treatable and recovery is rapid with few significant side effects. There are therefore few stimuli to motivate any change in behaviour. The lack of illness identity, the cumulative effect of past experiences and the absence of consequences may then explain the reluctance by many to agree to any follow-up care. Leventhal's model therefore is useful in helping to explain the links between illness perception and behaviour in terms of follow-up care. However other aspects of care, such as past experiences, may also have influenced participants' compliance around follow-up care. These elements cannot be explained by Leventhal's model (1998).

5.8.2.4 Polarised experiences of follow-up care

Alternative explanations for non-compliance with referral advice may be explained through other health behaviour models. One candidate model is the Health Belief Model (HBM) (Rosenstock, 1966). The HBM preceded some of the newer models such as Protection Motivation Theory (Rogers, 1975), the Theory of Reasoned Action (Fishbein, 1967) and the Theory of Planned Behaviour (Ajzen, 1991). Its origins lie within Subjective Expected Utility Theory (Edwards, 1954). The HBM was developed to predict preventative health behaviours but has also been used to predict behaviours in response to acute illness (Ogden, 2007). As such the HBM is a suitable model to be considered and applied within the context of the current findings. The HBM suggests that patients' behaviour is influenced by their core beliefs, developed through past experiences (Ogden, 2007). It suggests the likelihood of following up care (the 'behaviour' in the current study) may be influenced by a number of variables. An understanding of these variables may therefore help predict health behaviour.

Two variables within the model, 'Benefits' and 'Costs' could help to explain participants' follow-up care behaviours. The costs and benefits variables can be clearly linked to the home vs hospital theme developed from the findings of the qualitative interviews. The absence of any adverse incidents during home recovery may also be linked to the perceived 'severity' of the condition and the person's recovery.

Participants' experiences of follow-up care were clearly polarised i.e. positive home recovery v's negative ED/DCP follow-up. For example, in terms of ED recovery, although one or two participants reported positive care experiences, there were many whose experiences had been negative (see section 5.7.4). Occasionally, the explicit recommendation made by ambulance clinicians to follow-up care offended the patient as it conflicted with their preferences. This was particularly the case where there was a lack of confidence expressed in their DCP. Others felt a little patronised by some of the advice provided. Where such specific advice conflicted with the participant's preference it may have acted as a barrier not

a facilitator. Reports of care from DCP's were also variable; some participants reporting their DCP lacked interest in their condition or implying there was nothing more they could do. Conversely most participants who remained at home reported a predictable and uneventful recovery with a return to normality.

The broader literature on diabetes care clearly describes the many challenges faced in providing support to individuals with impaired awareness (Nam *et al*, 2011). Many barriers between the diabetes care provider and patients were identified. These included the provision of inadequate support by clinicians, lack of adherence to guidelines, clinicians' attitudes, communication and the patient-clinician relationship. Many of these barriers were also described by participants taking part in the current study suggesting that participants' experiences in the study by Nam *et al* (2011) were not unique. These negative experiences clearly impacted on participants' willingness to attend for follow-up care.

Conversely, relatives and friends provided bespoke care and support, elements of recovery valued by participants. The reliability and predictability of home recovery without adverse incident provided a stark and clearly positive contrast to care received in the ED or with Primary Care follow-up. Collectively these elements were likely to have influenced follow-up compliance and participants' behaviours. However, there were other aspects of the process of care that afforded the opportunity to influence patient compliance with follow-up, particularly the advice provided by ambulance clinicians before they left the patient.

5.8.2.5 Compliance with follow-up advice

Local and National Ambulance Service Clinical Guidelines (Scottish Ambulance Service, 2005; Basics Education Scotland, 2004; JRCALC, 2006) recommend ambulance clinicians advise follow-up care for those who have experienced a hypoglycaemic event. The previous section (5.8.2.3) explained why follow-up was important. However, once a non-transportation decision has been made, local guidelines hand over the responsibility for

referral to the patients who then become responsible for arranging their own follow-up care. No direct communication between ambulance clinicians and DCP/primary care occurs. The interview findings suggest that ambulance clinicians advice pertaining to follow-up was minimal, but did regularly consist of verbal advice to follow-up care either to the ED or Primary Care. Most participants suggested they ignored this advice.

The psychological models discussed earlier are unable to inform the relationship between the advice provided and patient 'compliance' with follow-up care. However Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995; 1981) may provide a helpful insight to this behaviour. Ley and Llewelyn (1995; 1981) suggests that compliance with advice can be predicted through the effects of recall, understanding and satisfaction on a patient's understanding.

Earlier work by Ley (1972) demonstrated that individuals who were given health information, recalled the information they received first, followed by the information perceived to be important. In the current study most participants specifically recalled verbal advice recommending follow-up care. This implied that ambulance clinicians may have provided this information to the patient early after recovery, and that participants attached some degree of importance to this advice. However Ley and Llewelyn (1995) suggested that verbal information alone had limitations and that other techniques to aid compliance should be considered. The use of written information, for example, has been found to increase compliance and improve outcome (Ley and Morris, 1984). Ley and Llewelyn (1995, pg. 85) stated, "*for the benefits of written information to be realised, the materials have to be noticed, read, understood, believed and remembered*". SAS clinical guidance recommends that ambulance clinicians hand over written documentation to patients, however few participants reported receiving this. Even in the few instances where paperwork was reportedly received, it was subsequently misplaced or discarded by the patient. This suggests that such

information was unlikely to have had any importance attached to it, gone unnoticed, unread, and would as a result have had minimal impact on compliance.

A participant's ability to understand the significance of the information within the context of their illness was important too (Ley and Llewelyn, 1995). There is likely to be a degree of cognitive impairment after a severe hypoglycaemic event (Warren and Frier, 2005). This is precisely when important information was likely to be passed onto patients. However, the timing of this may have affected their ability to recall the first piece of information they were told (Ley, 1972). Indeed among the small number of participants who were unable to recall receiving any advice, one denied knowledge even of the ambulance clinician's attendance. The process of cognitive recovery may have impacted on an individual's capacity to understand and will therefore impact on their compliance (Ley and Llewelyn, 1995; Ley, 1981; Ley, 1972). The timing of information aimed at providing an understanding of the importance of follow-up care is therefore crucial, particularly in those who may have a degree of cognitive impairment. Current information sharing practices by ambulance clinicians are not helpful therefore in promoting understanding and compliance in participants.

No participant indicated that ambulance clinicians had provided any rationale for the need for follow-up care. Similarly, none reported being informed about the possibility of a repeat or recurrent event, this despite there being a reasonable chance of occurrence. As was mentioned earlier (see section 2.5.1), there are no formal referral mechanisms or systems embedded in ambulance clinician's practice. However a small number of participants wrongly presumed that information was formally shared between ambulance clinicians and diabetes care providers. It was possible that this misunderstanding had evolved from the lack of relevant information provided by ambulance clinicians. Consequently, some participants presumed that 'no contact' from their diabetes care provider corresponded to 'no problems' with diabetes control. An understanding of the risks of non-compliance i.e. repeat/recurrent events, and clarity on the systems of care, particularly around the

responsibility to follow-up care being that of the patients, may have positively influenced compliance with any advice (Ley and Llewelyn, 1995).

This discussion section would not be complete without also mentioning the possibility of non-compliance of ambulance clinicians. Few appeared to issue the appropriate T&R paperwork or provide adequate follow-up guidance. Such non-compliance was also reported in the study by Cain *et al* (2003) where documentation on follow-up advice was only apparent in 55% of cases. This is counter to SAS T&R policy. There was also some evidence to suggest ambulance clinicians were trivialising follow-up care (see section 5.6.4.2) and that they reinforced the use of the ambulance service through their safety netting (see section 5.5.2.11). However, as the actual behaviour of the ambulance clinicians was not objectively measured, it is entirely possible that patients did not recollect the ambulance clinicians behaviours accurately. Nevertheless, this finding was important. Beyond Ley's (1972) cognitive hypothesis there are several factors that may influence the ambulance clinician's ability to provide adequate referral advice; for example, they may forget, they may not have to carry the written material with them, or as was found in a previous study, they may prefer to have patients sign refusal forms which reduces the amount of paperwork required (Dalgleish, Colver and Fitzpatrick, 2008). Nevertheless, some accounts of advice provided by ambulance clinicians raise significant concerns, particularly where insulin adjustment was advised; this is beyond the scope of current paramedic practice. Further education may be required to enable paramedics to provide appropriate advice.

5.8.3 Considerations of the predictive validity of proposed psychological theories

This discussion section has introduced a number of mid-range theories and considered their relevance to the study's findings post hoc. These theories could provide a useful basis for the development of future interventions. However in order to do so, it is important that their predictive validity and general utility is considered.

Three key theoretical models (or constructs from within these) were identified as potential explanatory theories for participants' behaviours before, during and after severe hypoglycaemic events: Leventhal's Self-Regulatory Model of Illness Perceptions (Leventhal *et al*, 1988); the Health Belief Model (Rosenstock, 1966); and Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995; 1981). This section of the thesis examines the predictive validity of each theory or model to describe their respective abilities in explaining and predicting behaviour, and aims to develop an understanding of what each respective theory or model's contribution to a future intervention could be. Table 20 provides a summary of exemplar studies that describe the predictive validity of each of the respective theories. The constructs of relevance to the behaviour of patient's with hypoglycaemia are described and are set in bold type. However, other constructs are also included to provide an overall view of each of the models. It is possible that these remaining constructs may become more important and relevant as understanding of each model/theory is improved. A more detailed discussion of the predictive validity of each theory within the context of each of the key behaviour's identified within the qualitative chapter then follows.

Table 20: Summary of the predictive validity of selected theories

Theory/Model	Self-Regulatory Model of Illness Perceptions/Common Sense Model (CSM)			
Study Title/Author (Year)	Adherence to asthma treatment (Halm, Mora and Leventhal, 2006).	Improving self-management in diabetes (Khunti <i>et al</i> , 2012).	Meta-analysis CSM (French, Cooper and Weinman, 2006).	
Results of constructs measured	<p><i>Poor illness identity</i></p> <p>Less likely to adhere to treatment (OR [CI] 0.35 [0.19–0.64]; p = 0.0005)</p> <p>Less like to attend routine asthma clinic (OR [CI] 0.54 [0.30-0.97]; p = 0.04)</p> <p>Less likely to feel important to use medication (OR [CI] 0.38 [0.19-0.74]; p = 0.004)</p>	<p><i>Improved overall perception of their condition</i></p> <p>Timeline (OR [CI] 0.87 [0.24 to 1.49]; p = 0.01)</p> <p>Personal responsibility [control] (OR [CI] 0.49 [-0.004 to 0.99]; p = 0.005)</p> <p>Consequences [seriousness] OR [CI] 0.77 [0.23 to 1.30]; p = 0.01)</p>	<p><i>Demonstrate predictive validity of CSM (included 4/5 constructs) on attendance at cardiac rehab.</i></p> <p>Time line (<i>r</i> 0.016; <i>p</i> = 0.680)</p> <p>Cure/control (<i>rc</i> = 0.119; <i>p</i> < 0.05)</p> <p>Consequences (<i>r</i> = 0.093; <i>p</i> < 0.05)</p> <p>Identity (<i>r</i> = 0.131; <i>p</i> < 0.05)</p>	
Theory/Model	Health Belief Model (HBM)			
Study Title/Author (Year)	Meta-analysis to determine predictive validity of HBM (Carpenter, 2010).		Intervention on promoting healthy eating behaviour (Orji, Vassileva and Mandryk, 2012).	
Results of constructs measured	<p><i>Variance in behaviour</i></p> <p>Barriers 33.8%; <i>r</i> = 0.30</p> <p>Benefits 31.7%; <i>r</i> = 0.27</p>		<p><i>Predictive ability of an extended HBM</i> <i>Added constructs to modified HBM</i></p> <p>Barrier (β = -0.42, <i>p</i><0.01)</p> <p>Benefit (β = 0.02, <i>p</i>≤ 0.01)</p> <p>Susceptibility (β = 0.06, <i>p</i>≤ 0.01)</p> <p>Severity (β = 0.05, <i>p</i>≤ 0.01)</p> <p>Cue to action (β = 0.08, <i>p</i>≤ 0.01)</p> <p>Importance (β = 0.32, <i>p</i>≤ 0.01)</p> <p>Consideration (β = 0.20, <i>p</i>≤ 0.01)</p> <p>Future Consequences (β = 0.20, <i>p</i>≤ 0.01)</p> <p>Self-identity (β = 0.37, <i>p</i>≤ 0.01)</p> <p>Appearance concern (β = 0.10, <i>p</i>≤ 0.01)</p>	
Theory/Model	Ley’s cognitive hypothesis model of communication			
Study Title/Author (Year)	Meta-analysis to measure effect of education on compliance (Mazzuca, 198a).	Intervention leaflet developed to alter patient's antibiotic use when diagnosed with acute bronchitis (McFarlen <i>et al</i> , 2002).	Cochrane review measure effectiveness of interventions to increase screening uptake (Everrett <i>et al</i> , 2011).	Communicating with patients. Ley (1988)
Results of constructs measured	<p><i>Patient education (positively affected)</i></p> <p>Compliance (effect size = 0.67 over control; <i>p</i> < 0.05).</p> <p>Physiological progress (0.49, <i>p</i> < 0.01)</p> <p>Health outcomes (0.20; <i>p</i> 0.05)</p>	<p><i>Intervention leaflet</i></p> <p>Significantly fewer took antibiotic in intervention group (n=49 [47%] v's control group n = 63 [62%]) (risk ratio 0.76, 95% CI 0.59 to 0.97, <i>P</i> = 0.04)</p> <p>Intervention reduced antibiotic use by almost 25%.</p>	<p><i>Intervention Letter</i></p> <p>Significantly higher uptake vs' usual care or no invitation letter (RR = 1.44, 95% CI: 1.24 to 1.52).</p> <p><i>Telephone invitation</i></p> <p>Significantly higher uptake of screening than those in the control group (RR= 2.16, 95% CI: 1.70 to 2.74)</p>	<p><i>Phone or Mail</i></p> <p>Reminders made by phone or mail increased compliance in appointment keeping by 17.2% (SD = 7.2%).</p>

5.8.3.1 Leventhal's Self-Regulatory Model of Illness perception

Many participants interviewed in the qualitative study appeared to have impaired awareness of hypoglycaemia (where they do not experience any symptoms during onset) and most recovered from the hypoglycaemic event quickly without any significant side-effects. It was likely therefore that they would lack a clear illness identity stemming from poor symptom perception. The only theoretical model that included the construct 'illness identity' was Leventhal's Illness Perception Model (1988) (see section 5.8.2.2.). Leventhal (1988) proposed that the construct and representation of 'illness identity' enabled an individual to determine the nature of the health threat but, in its absence, any illness would lack representation. It was hypothesised by Leventhal that the degree of representation would influence the patient's health behaviour.

The illness perception model, known also as the Common Sense Model (CSM), led to the development of the illness perception questionnaire (Weinman *et al*, 1996). This has been tested and subsequently updated in a substantial number of behavioural change studies (Marks *et al*, 2011; Haggard and Orbell, 2003). According to the CSM (Table 21), illness identity is one of five key cognitive constructs within the model required to elicit a behavioural change (Leventhal *et al*, 1988), along-side the concept of 'coherence' representing the clarity of the linkages between each construct.

Table 21: Common Sense Model: cognitive constructs

Identity	signs or symptoms and the illness label
Consequence	perceived physical, social and economic consequences of the disease and the felt emotional consequences
Causes	perceived cause of the disease/illness.
Time line	perceived time frame for the development and duration of the illness threat.
Cure/Control	extent to which the illness is responsive to treatment.

The predictive validity of the construct 'identity' is relevant to this thesis as so many participants appeared to have impaired awareness. The study by Halm, Mora and Leventhal (2006) applied the CSM to test associations between illness identity with adherence to treatments in asthma. In their study of 198 patients, they hypothesised that those with the perception that asthma was only present during a 'flare up' and were disease free at other times, would have poorer compliance with long-term therapy. They confirmed that those with this perception did indeed have significantly poorer adherence to a number of the self-management behaviours. For example, when this group were asymptomatic they were significantly less likely to adhere to medication treatment (OR [CI] 0.35 [0.19–0.64]; $p = 0.0005$), attend for routine asthma visits (OR [CI] 0.54 [0.30-0.97]; $p = 0.04$) or feel it was important to use their medication (OR [CI] 0.38 [0.19-0.74]; $p = 0.004$). Moving attention beyond the construct 'identity', another single study measured the predictive validity of the CSM remaining constructs (Khunti *et al*, 2012). They tested an intervention to improve diabetes education and self-management. They measured behaviour using the CSM questionnaire amongst others at three years comparing the intervention group to the control group. For aspects related to the CSM, the study determined a statistically significant improvement ($p < 0.01$) in 3 out of 4 tested CSM constructs; timeline (OR [CI] 0.87 [0.24-1.49]), personal responsibility [control] (OR [CI] 0.49 [-0.004-0.99]), and consequences [seriousness] (OR [CI] 0.77 [0.23-1.30]). Although biological outcomes were not improved, they confirmed that aspects of illness perception were altered positively to improve understanding of the condition diabetes.

A highly cited meta-analysis of the CSM was undertaken by French, Cooper and Weinman (2006). They demonstrated the predictive validity of 4 out of 5 of the constructs of the CSM. In their meta-analysis on cardiac rehabilitation care, eight studies were included with data from 906 individuals. The study excluded the construct

'cause'. The initial analysis of all eight studies determined only one construct (cure/control) reached statistical significance in predicting attendance at rehabilitation ($p < 0.05$) representing a small effect size ($rc = 0.119$).¹ However, once two studies were removed, on the grounds they had affected the heterogeneity of the meta-analysis, three of the four included HBM constructs were found to be statistically significant ($p < 0.05$) in their effect on promoting following-up care. Their respective effect sizes were; identity ($r = 0.130$); consequences ($r = 0.084$); cure/control ($r = 0.119$).² The effect of time line was non-significant ($p = 0.680$; $rc 0.016$). The review, therefore, provided evidence that three out the four tested constructs of illness perception in the CSM (identity, consequences, cure/control) had a small size effect on predicting attendance at follow-up care.

In another highly cited meta-analysis Hagger and Orbell (2003) sought to determine if there was consistency in people's cognitive representations of illness and whether these representations were associated with coping behaviour. Forty-five studies using the CSM were included. They reported that those individuals with strong illness identity viewed their condition as being "*uncontrollable*" (Hagger and Orbell, 2003, pg. 146). Moderate correlations were also established between illness identity and avoidance/denial ($rc 0.23$, $p < 0.05$).³ This somewhat is contradicted by the findings by French, Cooper and Weinman (2006) who determined the construct illness identity

¹ In statistics the presentation ' r ' represents the correlation calculation that measures the linear relationship between two continuous variables (Knock, 2009). Where ' rc ' is presented, this donates a statistical process referred to as corrected correlation undertaken to correct for artefacts (Knock, 2009).

² Effects sizes were defined as small $r = \pm 0.1$, and medium $r = \pm 0.3$ (Cohen, 1992)

³ When the classifications of small, medium, and large effect sizes are transformed to a correlation coefficient, as in this study, the analogous values translate to 0.10, 0.25 and 0.37, respectively (Lipsey and Wilson, 2001).

was predictive of follow-up care behaviour, not avoidance. However, Hagger and Orbell (2003) also determined the control/cure constructs were positively correlated with cognitive reappraisal (changing perception of illness) ($r_c = 0.20, p < 0.05$). So whilst strong illness identity may correlate with avoidance/denial strategies, those with a strong belief in cure /control can positively alter their illness perceptions. Developing a strong illness identity, in some cases, may in fact inhibit follow-up care behaviour as individuals avoid or deny their illness. However a weaker, but not absent, illness identity is associated with the more positive adaptive outcomes and therefore helpful changes in behaviour (Hagger and Orbell, 2003).

The predictive validity of the construct identity has been demonstrated to be consistent overall, but the effect size is small (± 0.2). The results presented by Hagger and Orbell (2003) were noteworthy in that strong illness identity was associated with avoidance and denial strategies. However, individuals with a strong belief in cure/control also demonstrate more positive adaptive outcomes.

The importance and relevance of the CSM constructs included to the current study are twofold. Firstly, without any illness identity, it is unlikely that the patient will take any action at all. The evidence from the study by Hagger and Orbell (2003) suggests that it is important to avoid developing a strong illness identity, as this may have a negative effect on prevention strategies. Secondly, even if only weaker illness identity could be achieved (perhaps via a subtle identification of the impaired awareness via a validated tool), and subsequently linked to the belief of 'cure or control' (demonstrated to be a stronger predictor of positive behaviour change) then patient follow-up care behaviour may still be improved. Indeed Hagger and Orwell (2003) demonstrate the importance of considering other constructs in the model, not just the one construct identified.

Therefore, any intervention designed to improve identification of impaired awareness (illness identity) should consider the utility of, and relationship between, the other constructs within the model. In doing so, an intervention may be developed specifically to encourage links between the construct identity, with the construct control/cure. It may be as straightforward as identifying impaired awareness with a validated tool, informing patients they have the condition and of its reversible nature and that they can therefore control/prevent future severe hypoglycaemic events. This may have a positive effect in improving patient attendance at follow-up care.

5.8.3.2 Health Belief Model

The findings presented in chapter 5 (section 5.8.2.3) suggested that the Health Belief Model (HBM) could be useful in explaining the relation between participants' past experiences of care and influences on their core beliefs. In this study, the hospital v's home care theme was comparable to 'cost/barriers' v's 'benefit' in the HBM; specifically, the negative hospital or GP follow-up care experience v's the comfortable and positive home recovery experience (sections 5.7.1 to 5.7.7).

The ability of the HBM to predict behaviour has been evidenced in many studies (Janz and Becker, 1984). However, some found evidence that the Health Belief Model (HBM) has been shown to have weak predictive ability, predicting only around 20% of variance in health behaviour (Taylor *et al*, 2006). This limited predictive ability being attributed to poorly defined constructs and lack of explicit guidance about appropriate grouping of variables and their relationships (Orji, Vassileva and Mandryk, 2012). However, a recent meta-analysis measuring the effectiveness of the HBM constructs in predicting any health behaviour delivered more promising results (Jones *et al*, 2014; Carpenter, 2010). Specifically, 'benefits' and 'barriers' were shown to be strong predictors of behaviour; benefits demonstrating 31.7% and barriers 33.8% of the

variance in behaviour (Carpenter, 2010). Carpenter (2010) however, does underline the overall variability in the effectiveness of each of the constructs as predictors.

In recognition of this variability and the previously outline limitations of the constructs, some have extended the HBM in an attempt to improve its predictive ability (Orji, Vassileva and Mandryk, 2012). By carefully complementing the basic HBM model with selected constructs from within a specific health context, in this case healthy eating behaviour, the adapted HBM model led to a 78% increase (from 40% to 71%) in predictive capacity when compared with the original HBM model. Within the context of changing post-hypoglycaemic follow-up care behaviour, the use of additional constructs may therefore be valuable in enhancing the models predictive ability in the context of hypoglycaemic emergencies.

Another recent meta-analysis evaluated the effectiveness of the HBM in improving adherence behaviour (Jones *et al*, 2014). Unlike the study by Carpenter (2010) this meta-analysis focused specifically on 'adherence' health behaviour, rather than 'any' health behaviour. They determined that 83% (n = 15) of the included studies reported a statistically significant effect of the intervention on improving adherence (Jones *et al*, 2014). And, 86% (n = 6) of studies reported an overall positive effect on adherence in studies using health professional-led interventions. Six studies (86%) produced effect sizes that were moderate (d > 0.5) to large (d > 0.8) with the remainder demonstrating small (d > 0.2) to moderate effects.¹ However, the findings contradicted those of Carpenter (2010). It was established that the success of the interventions were

¹ An error in the 'd' value scale published in the paper by Jones *et al* (2014) was identified by the author of this thesis after direct contact with Jones *et al* (2014). Cohen's d is used to describe the standardised mean difference of an effect. The correct effect size of the scale is as follows: small (d = 0.2), medium (d = 0.5), and large (d = 0.8). The incorrect values published were: small (d = 0.02), medium (d = 0.05) and large (d = 0.08).

unrelated to any of the core constructs in the HBM. Of interest was that two of the three studies demonstrating statistical significance, and a large effect of intervention on adherence ($d > 0.79 - 1.00$), were those that used a written intervention design (discussed in the section on compliance, section 4.8.2.3). Jones *et al* conclude by suggesting the variation in findings between their results and Carpenter's (2010) may be due their focus on the construct 'adherence' and the lack of definition, measuring and operationalization of the constructs of the HBM (Jones *et al*, 2014). Better definition of the HBM constructs will be necessary. This need will extend to any bespoke construct added to extend the model, in a bid to improve its predictive ability. The selected studies have demonstrated that the constructs of the HBM can be effective in predicting health behaviour. Questions remain however, about the model's utility in the development of complex interventions, and specifically, adherence behaviour (Jones *et al*, 2014). The identified discrepancies in construct definition, measurement and operationalization, as well as the lack of firm descriptions regarding interventions, all may adversely affect results. Additionally, the core constructs within this model may be beyond the control of the ambulance service. That is, the costs/barriers identified in the qualitative study are not within the domain of SAS care. However, by communicating these findings to primary carer's and improving services via a process of co-construction, it may be possible to limit or reduce these barriers thereby improving the likelihood that patients will wish to attend for follow-up. Irrespective of the variability between studies, it is important to acknowledge that a significant proportion of behaviour can be predicted using this model, with and without additional constructs. There is therefore merit in pursuing the use of this model within the context of a collaborative approach to improving patients' experiences of care.

5.8.3.3 Ley's cognitive hypothesis model of communication

It was identified in the qualitative interviews that many participants reported receiving little advice from ambulance clinicians on the importance of follow-up care. This was

noteworthy as there is currently no direct communication link between ambulance clinicians and diabetes care providers; the responsibility being placed on the patient to comply with the ambulance clinician's advice to follow-up their care. Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995; 1981) was thought to be beneficial in understanding the link between information/follow-up advice and promoting compliance. The suggested utility of this model was based on the existing lack of information or advice provided to patients on the need for follow-up care, and concerns about the effect of post-hypoglycaemic cognitive impairment on recall and understanding of such advice (section 5.6.4.).

The core elements of this model of communication are relevant to the compliance of both the clinician and patient. However this section focusses on patient compliance.¹ The ability of education/information to improve diabetes outcome has been demonstrated through a previous meta-analysis of 82 studies which looked at the effect of education on patient outcome in diabetes (Brown, 1990). They measured the effect of education on a number of specific outcome variables. Brown et al found that the effect size of education on knowledge ranged from $d = 0.49$ to 1.05 , self-care behaviour from $d = 0.17$ to 0.57 , metabolic control from $d = 0.16$ to 0.41 , and psychological outcome $d = 0.27$ (Brown, 1990).² This follow-up study reinforced the findings of their earlier meta-analysis (Brown, 1988) that determined education had a moderate to large effect on patient knowledge and metabolic control outcome measures.

¹ The inclusion of clinician compliance is based on the evidence presented by Ley and Llewelyn (1995) that demonstrated non-compliance with health and medical care practitioners ranged from 12% to 95% ($m = 60\%$; $SD = 27\%$). Any intervention aimed at improving patient compliance must therefore apportion sufficient time and effort to the element of clinician compliance.

² Cohen's d is used to describe the standardised mean difference of an effect. The scale is as follows: small ($r = 0.2$), medium ($r = 0.5$), and large ($r = 0.8$).

The mode of delivery of such education is also important, particularly when existing ambulance service guidance that appears to be ignored by ambulance clinicians at present, recommends that patients should receive written information encouraging self-referral to follow-up care. As there may be a degree of post-hypoglycaemic cognitive impairment when verbal information is handed over by ambulance clinicians, the need for advice at a later stage in care is evident. The use of both written and verbal information to change patient behaviour has been studied in a variety of clinical settings. Morris and Halperin (1979) pooled the data from a number of studies that measured the effect of written information on medication knowledge and adherence. They reported that written and verbal information increased patients' knowledge and adherence to medication, but failed to support this statement with any statistical analysis or meta-analysis.

Other research has demonstrated that written information can affect patient behaviour on medication use. The study by McFarlane *et al* (2002) developed an information leaflet to alter patient's antibiotic use when diagnosed with acute bronchitis, found that the use of the leaflet reduced antibiotic use by almost 25%. A recent Cochrane systematic review (Everrett *et al*, 2011) undertaken to determine which interventions benefitted the uptake of cervical screening found pooled data from almost 100,000 participants and found that "*women who received invitation letters to attend cervical screening programmes had a significantly higher uptake of screening than women who received usual care or no invitation (RR= 1.44, 95% CI: 1.24 to 1.52)*" (Everrett *et al*, 2011, pg. 12). Those who received a telephone invitation (pooled data from n = 2342 participants) had a "*significantly higher uptake of screening than those in the control group (RR = 2.16, 95% CI: 1.70 to 2.74)*" (Everrett *et al*, 2011, pg. 12). Additionally in some of Ley's own work, reminders made by phone or mail increased compliance in appointment-keeping by 17.2% (SD=7.2%) (Ley, 1988). Finally, reviews by Morris and

Halperin (1979), Morris and Groft (1982) and Ley and Morris (1984) found that written information increased compliance in approximately 60% of investigations.

These studies demonstrate that the use of both written and verbal information/education can be effective in altering health care behaviour. The use of education in improving compliance with post-hypoglycaemic follow-up care advice should be considered within the context of any future intervention being developed. The importance of education and written information in improving adherence was also described in the earlier section regarding the HBM (Jones *et al*, 2014). This may also support the greater integration of information/education (as per Ley's model) with other psychological/behavioural change models available.

5.8.3.4 Summary

It is clear from this review of the predictive validity of these theories and models that none is likely to be completely effective in eliciting the desired follow-up care behaviour in isolation. Behaviour change evidence increasingly suggests that more innovative approaches are required (Orji, Vassileva and Mandryk, 2012). Rather than using a single illness perception, lone construct from any of the theories, or educational intervention in isolation as a behavioural change mechanism, 'clusters' of these constructs should be considered and accurately measured (French, Cooper and Weinman, 2006).

Through the application of these multiple, but well defined constructs (from the various theories or models), a well developed and designed intervention may have a cumulative effect on improving compliance with follow-up care advice, thus enhancing post-hypoglycaemic follow-up care. An example of the application of these theories within the context of a proposed interventions will be provided in the final chapter (see section 6.2.5).

5.8.4 Limitation and Trustworthiness of the qualitative framework approach

There are inherent limitations and strengths with any research approach. The qualitative approach in this study permitted each participant to present their individual story. Each unique experience was treated with equal importance and these singular and combined experiences enabled the identification of common and uncommon themes. This approach has helped to increase understanding regarding the questions raised in chapter 4 on patient's behaviour before, during and after the hypoglycaemic emergency and is useful in informing future research and clinical practice. However, there are important elements of a study's strengths and limitations that are suitably considered within the context of 'trustworthiness'.

The Framework approach is a form of qualitative content analysis specifically designed for use in applied research (Spencer, Ritchie and O'Connor, 2008). When appraising the quality of this qualitative analytical approach, measures of reliability and validity, traditionally applied to the quantitative paradigms of enquiry are inappropriate (Lewis and Ritchie, 2008; Denzin and Lincoln, 2005). The quality of qualitative analysis, such as is carried out using the Framework approach, is based on the concept of trustworthiness. There remains some disagreement on the terminology used to describe and assess the trustworthiness of a study (Lewis and Ritchie, 2008; Mays and Pope, 2000). Guba (1981) describes trustworthiness by comparing the traditional positivist and naturalistic approaches to analytical rigour. He proposed four criteria required to ensure a trustworthy study (see Table 22).

Table 22: Comparison of terminology: quantitative to qualitative (Guba, 1981)

<i>Qualitative term</i>	<i>Quantitative term</i>	<i>Aspect</i>
Credibility	Internal validity	Truth value
Transferability	External Validity/Generalisability	Applicability
Dependability	Reliability	Consistency
Confirmability	Objectivity	Neutrality

Shenton (2004) further developed Guba's 1981 concept of trustworthiness in qualitative analysis, describing in detail these four characteristics (Shenton, 2004):

- **Credibility:** how the study demonstrates that it has accurately recorded the phenomena under scrutiny.
- **Transferability:** the extent that the study findings may be applied to other situations.
- **Dependability:** *the extent to which the study may be repeated, reproduced.*
- **Confirmability:** the extent to which the findings are representing the participants rather than the researchers.

Many of the strategies developed to underpin these key characteristics were adopted in this study. As many of these characteristics overlap they will now be collectively discussed within the setting of the qualitative framework approach used in this study (Spencer, Ritchie and O'Connor, 2008).

Study development

Credibility and dependability are two key characteristics of a trustworthy study (Lincoln and Guba, 1985; Guba, 1981). In an effort to establish credibility, this study aimed to use conventional and accepted procedures to gather, record and analyse data (Kuper, Lingard, Levinson, 2008; Spencer, Ritchie and O'Connor, 2008; Shenton, 2004). Earlier in this chapter a thorough overview of the study methods, including the

framework approach, described this process (see section 5.2.17). This particular approach lends itself to informing practice and policy and was therefore ideally suited to this study. However, as a novice researcher, advice and guidance was sought in the application of the Framework approach from experienced qualitative researchers (Gale *et al*, 2013). This helped refine the research questions and processes and provided greater credibility (Shenton, 2004).

The detailed description of the methods, inclusion of raw transcripts and examples frameworks/matrix (Appendix 16 and 17) also ensured a considerable degree of transparency, thus permitting replication. Lacey and Luff state that the framework analysis process “*provides systematic and visible stages to the analysis process, so that funders and others, can be clear about the stages by which the results have been obtained from the data*” (Lacey and Luff, 2009, pg. 19). Transparency is a key component of the concept ‘dependability’ and ‘credibility’ (Shenton, 2004). Although the provision of such detail would enable others to duplicate this work, methodologically, due to the nature of qualitative research, and the investigation of multiple realities, duplication of methods would not necessarily lead to duplication of findings.

Objectivity is explicitly linked to the concept of ‘confirmability’. Being objective ensures participants’ voices are heard. The interview process was aided by the topic guide which helped standardise questions and reduce bias (Parahoo, 2006). However, this does not guarantee objectivity or guard against against ‘selectivity’ (Parahoo, 2014). There are numerous other measures such as triangulation through multiple analyses and respondent validation for example, discussed shortly, that would reduce any selectivity bias (Shenton, 2004). Although a novice research, the author was an experienced paramedic, and as such had undoubtedly been influenced by the culture

of the organisation. This may have introduced bias to the development of the study. However, the long-term secondment to the NMAHP Research Unit (see personal statement, pg. x) had helped to ensure a distance between researcher and observed cultural elements, thus aiding a more objective approach (Shenton, 2004). An additional element necessary to ensure confirmability is the concept of reflexivity. This has previously been discussed in detail (see section 5.2.6) and will therefore not be repeated in this section.

The sampling strategy was also carefully considered (Kuper, Lingard and Levinson, 2008). Qualitative research places importance on the subjective realities of individuals. Those who agreed to participate may have held different views from those who declined. But, for those who did participate, a stratified purposive sample was used to ensure the range of salient issues needed to understand behaviours were covered. This was appropriate and although some recruitment difficulties were experienced, particularly of younger people in the 16 – 24 year age group, those within ethnic minorities and those in full time employment, a broad perspective of participant's views was achieved. The failure to recruit younger people, people from within minority groups, or the employed may have affected the study's findings. However, study time constraints meant that it was not feasible to extend the recruitment and data collection phase to try to alleviate these limitations. Consequently it was only possible to undertake 26 of the planned 30 interviews. Nevertheless, the use of a broadly representative sample ensured that many who had experienced the phenomena under study (hypoglycaemia) were included and their views subsequently represented through robust analysis: all elements being considered important in ensuring credibility (Shenton, 2004). As such, within these acknowledged limitations, the objective, reflexive and appropriate sampling of participants during the developmental stages of

this study added substantially to its credibility, confirmability and therefore trustworthiness (Kuper, Lingard and Levinson, 2008; Shenton, 2004).

Analysis

During analysis, the demographic data emanating from the qualitative and quantitative studies were compared using both 'methods triangulation' (Lewis and Ritchie, 2008) and 'sequential triangulation' (Creswell and Clark, 2011) (chapters 4 and 5). These triangulation processes showed that the participant demographics (with the exception of employment status) in both studies were very similar (see sections 4.4.3.2 and 5.3.3). This suggests that the participants in the qualitative interviews were representative of the population identified in the quantitative study (chapter 4); particularly those who experienced frequent repeat severe hypoglycaemic events requiring ambulance service support. The qualitative findings also provided credible explanations for a number of the key statistical results (see sections 4.4.4 and 4.4.5). These explained the reasons for repeat or recurrent calls, non-transportation behaviour, and the influences on follow-up care practices. This triangulation established a more objective view of accounts, again reassuring those reading of the credibility and confirmability of the research undertaken (Shenton, 2004; Lacey and Luff, 2007) as well as providing a degree of external validation (Lewis and Ritchie, 2008).

Corroboration is another important measure of a study's credibility and confirmability. It was recognised that patient participants may have forgotten, or that post-hypoglycaemic cognitive impairment may have affected their memory of the event. Some participants accounts had drawn on information received from friends or relatives, this more objective account from secondary parties, retrospectively or during interviews, assisted in confirming the participants' accounts.

The identification of corroboration (or not) between participants enabled a considerable degree of confidence to be placed on the established themes (see section 5.5.2.11 and 5.7.1.5) (Lacey and Luff, 2007; Shenton, 2004). Indeed, the ease through which the process of across-case analysis was undertaken is an acknowledged strength of the matrix used in the framework approach (Gale *et al*, 2012; Lewis and Ritchie, 2008). Although recent literature has provided excellent examples of corroboration (and triangulation) between patients and ambulance clinicians (Togher, Davy and Siriwardena, 2013) these clinicians were not the primary focus of enquiry in this study and, as such, were not included. Nevertheless, the presence of relatives in some of the interviews (46%, n = 12) did permit an unexpected, but welcome, degree of corroboration (and contrast) during these interviews. The inclusion of relative's responses not only enriched participants' accounts but also added to the credibility and confirmability of the findings (Shenton, 2008).

Once interviews are transcribed, some authors describe the importance of 'respondent validation' (Lewis and Ritchie, 2008; Lacey and Luff, 2007). The process permits participants to read and confirm their own interview transcripts and ensure accuracy, minimise misrepresentation and ultimately enhance the credibility of study findings (Lacey and Luff, 2007). This was considered at the outset of this study. However, the process is time-consuming, most interviews conducted were over an hour long which resulted in over thirty A4 pages of verbatim transcripts per participant. To request participants read over such a lengthy transcript would be a significant task which was felt to be unreasonable. It is also recognised that participants' views can be altered by their involvement in the research process itself, they may not remember what they said and they may deny some of the less attractive original responses they made (Long and Johnson, 2000). The duration of the research project would also have been

lengthened considerably. For these reasons, respondent validation was not adopted in this study.

Alternative strategies, however, were instigated during interviews and analysis to minimise any misrepresentation and bias. For example, the interviewer immediately clarified or confirmed any vague responses to minimise any reporting inaccuracies. This tactic ensured a higher degree of accuracy in the recorded transcripts. The recordings were also professionally transcribed verbatim. During transcript analysis, an additional two researchers (both supervisors) were involved in the reviewing, coding and development of the analytical framework. This triangulation through multiple analyses ensured a common understanding of findings (Lewis and Ritchie, 2008) and, as an iterative process, facilitated the agreement of final themes after review. The coding process was undertaken independently with attention paid to identification of disconfirming elements (Gale *et al*, 2013; Lacey and Luff, 2007). Additionally (linked again with credibility and confirmability) key terms, expressions and phrases were retained within the tables to ensure the findings remained grounded within the context in which they were constructed (see Appendix 17). Adopting these processes ensured that the meanings of the interviews were not lost in more abstract representations, and that concepts were more 'transferrable' (Shenton, 2004).

As has been described earlier in this thesis (see section 1.9.1) qualitative research is not undertaken for the purpose of generalising findings, as in positivist enquiry. However, what may be considered is the possibility of transferability (Shenton, 2004). The use of raw transcript data in what could be described as 'thick description' permits those reading to "*make an informed decision about whether or not the research may be applied to their own studies...*" and is considered "*...a key concern of transferability*" (Corwin and Clemens, 2012, pgs. 492-493). A number of elements enhanced the

transferability of the findings. Firstly, all interview transcripts were presented in their raw format, allowing the reader to view these as they were recorded (and constructed) during the interview process. Secondly, the participants' demographics were presented in Table 19, permitting the reader to consider the possibility of transferability inferences (Teddlie and Tashikkori, 2012; Shenton, 2004). Thirdly, the population demographics in this qualitative study were found to be similar to those of the larger quantitative study (chapter 4). As demographic data from the quantitative study were similar to those of studies undertaken in England, the concepts identified in the qualitative findings may therefore be transferrable beyond the study population drawn from the West of Scotland. Such cross-study comparison is an acknowledged advantage of a multiple or mixed methods approach (Teddlie and Tasikkori, 2012).

However, caution is still required in terms of the study's *temporal* transferability, that is "*the degree to which the inferences may be applicable in the future*" (Teddlie and Tashikkori, 2012, pg. 312). The pace of change in the world of the NHS is startling, as is the variability in services provided. Such changes or differences in the delivery of care and services may influence the transferability of certain elements of the findings beyond the West of Scotland where the study was conducted. Nevertheless, as can be seen from the discussion above, multiple strategies were employed during the different stages of this study to ensure the overall trustworthiness of the findings. Despite acknowledged limitations, readers should be able to place a considerable degree of confidence in the credibility, transferability, dependability and confirmability of the study findings.

5.8.5 Conclusion

Previous research on prehospital hypoglycaemic events had not investigated the patient's experience of ambulance care. However, studies in chapters 3 and 4 had identified that most patients did not attend the ED for immediate follow-up care and a

minority of patients experienced repeat calls. This led to the development of key questions around patients' experiences, perceptions and follow-up behaviours.

This study enabled patients to articulate their experiences of hypoglycaemia, their reasons for requiring the SAS and why they did or did not attend for follow-up care after SAS treatment. The framework analysis process facilitated the development of themes that led to the consideration of theoretical models to explain health behaviours. The post hoc application of relevant theoretical models (Leventhal, 1998; Rosenstock, 1974; Ley, 1981) has helped provide a number of plausible explanations for participants' behaviours.

A large proportion of participants reported impaired awareness. Application of Leventhal's model suggests that many of these individuals lacked the ability to recognise signs and symptoms of illness; without this, people lack the motivation to act or develop a coping strategy. Failing to recognise the onset of hypoglycaemia impedes self-treatment which results in further deterioration and severe hypoglycaemia. Conversely, the relative's ability to recognise signs and symptoms and/or patients' abnormal behaviour enabled them to render assistance. However, as many relatives reported struggling to cope, the motivation and strategy often developed into a telephone call to the ambulance service. Impaired awareness therefore contributed substantially to the development of a large proportion of severe hypoglycaemic events requiring assistance by the ambulance service. Leventhal's model (Leventhal *et al*, 1998) can also help explain participants' lack of motivation in seeking follow-up care within the context of recovery. Participants' appeared to perceive hypoglycaemia to be a condition of short duration, treated quickly and with few significant side effects. Association with any illness was therefore lacking. The absence of illness, and consequently illness identity, may contribute to participants' follow-up care behaviours.

The retrospective analysis (see section 4.4.5) determined that previous ambulance call-outs were a strong predictor of remaining at home post event. However this result is counterintuitive as both JRCALC and T&R guidelines recommend those who experience recurrent or repeat events require follow-up care. Clinical guidelines suggest that individuals who repeatedly require ambulance care are more in need of expert clinical support (Welsh Ambulance Service, 2006; Scottish Ambulance Service, 2005; BASICS Education Scotland, 2004). This preference for home recovery may be linked to illness perception as described before, but more likely can be explained through the 'costs v's benefits' reported by participants (see section 5.7).

For some participants the costs of being transported to the ED or of following up care with their DCP were considerable. Some reported prolonged waiting times, poor care and substandard discharge practices in terms of ED care. DCP's relationships with patients/carer were not always positive with some reports of DCP's lacking interest in their patient or declaring that nothing more could be done to help. These experiences appeared to directly influenced the participants' future follow-up care preferences. Alternatively, participants reported experience of the ambulance service was very good, they were comfortable at home; received bespoke care, and ate as they pleased. The experience of the benefits of home recovery far outweighed the experience or costs of ED recovery and care.

Finally, the importance of providing advice that can be remembered, understood and satisfies a patient's need, was recognised as a fact that influenced participant compliance. Despite verbal information being consistently provided, evidence suggests that, on its own, this was unlikely to be sufficient to encourage follow-up care. Ambulance clinicians appear to have failed to provide any rationale for follow-up care

to any of the participants. The apparent lack of formal written documentation or systems in place to reinforce the importance of follow-up care will clearly not aid participant recall. These findings are contrary to recommendations made within Ley's hypothesis (Ley and Llewelyn, 1995; Ley and Morris, 1984) that considers, along with patient's understanding of why and what is being asked, the need for the provision of excellent verbal and written information to improve compliance with advice.

Different elements of follow-up care behaviour can therefore be explained through a number of theoretical models (Leventhal *et al*, 1998 ; Rosenstock, 1966; Ley, 1981). The absence of any symptoms or illness meant few individuals perceived there to be a condition in need of treatment or support. They were not motivated to change their existing behaviours in terms of requirements for follow-up care. The rapid recovery, return to normality and comfortable surroundings of the familiar home environment was in stark contrast to some experiences of ED care. These collectively created an environment that was not receptive to follow-up care. Such factors are very likely to influence follow-up care preferences.

Overall these findings suggest that there is much that could be done to improve follow-up care for patients treated by ambulance clinicians for hypoglycaemia. These findings should provide a platform on which future research and service improvements could be made in terms of hypoglycaemic awareness and follow-up care. Until these problems are addressed patients will continue to receive suboptimal care for their condition. The implications of these finding are explored in chapter 6.

CHAPTER 6: OVERALL DISCUSSION AND CONCLUSION

This final chapter will begin with a summary of the key findings of the thesis emphasising the sequential development process, new contributions to knowledge, limitations, and the impact and implications of each study. Thereafter the strengths and limitations of the atheoretical, inductive and multiple methods approach are discussed. This is followed by a short discussion section that brings together the key findings within the context of the current systems of health care and health policies. The chapter concluded by describing the process required for developing complex interventions, along with clear examples of future research projects, that help to ensure this patient population receives the most appropriate care and improved health outcomes.

6.1 Key findings

An initial exploration of diabetes found it to be a condition with significant morbidity and mortality, with an increasing world-wide prevalence. Health care strategies to reduce the long-term consequences of the condition increase the likelihood of severe hypoglycaemic events but only a small proportion of these require ambulance service support. The factors contributing to both initial and subsequent hypoglycaemic events requiring ambulance support have been identified as impaired awareness and the relative's inability to cope. However, once treated, most patients prefer to remain at home and perceive no need for follow-up care. There are risks of repeat events in the aftermath of a severe hypoglycaemic event, irrespective of treatment by the ED or ambulance service. It is likely many of these subsequent events are associated with impaired awareness a condition that could be prevented by appropriate follow-up care. But a lack of illness identity and past negative experiences of DCP are impeding patients' perceptions and desire to seek help.

6.1.1 A scoping review to determine the safety of prehospital treatment of hypoglycaemic events

The scoping review determined that a small proportion of calls to ambulance services were for hypoglycaemic emergencies (0.57 and 5.2%) and that non-transportation rates were variable (25%-73%). Establishing the proportion of individuals remaining at home after a severe hypoglycaemic event, updated previous knowledge and confirmed that many patients recovered and did not attend for ED follow-up. However the scoping review showed that between 2-7% of post-hypoglycaemic individuals treated by ambulance clinicians experienced a repeat event requiring ambulance support within 48 hours. There were safety implications and risks associated with non-transportation for a small proportion of individuals. Despite there being insufficient data to determine the involvement of OHA's the literature suggested those treated with OHA's (particularly sulphonylureas) were at risk of repeat events. This knowledge, within the context of T&R, justified the recommendation to transport these patient groups to the ED (see section 3.8.2). But the lack of knowledge of patient characteristics within the Scottish context led to the investigation of hypoglycaemic emergencies using Scottish Ambulance Service data. Caution was advised in the interpretation of these results due to the variability in quality of studies and the absence of a formal quality appraisal process.

6.1.1.1 Research Impact

The scoping review was presented at the 2008 National Emergency Medical Services (EMS) Research Forum Conference where the work received an award for 'research most likely to influence practice' (JRCALC, 2009b). Shortly thereafter an adapted version of chapter three was published in the BMJ Emergency Medicine Journal (Fitzpatrick and Duncan, 2009). The scoping review informed UK Ambulance Service National Clinical Guidelines on Emergency Hypoglycaemic Care (JRCALC 2013)

where the explicit recommendations to transport individuals treated with specific OHA's, and those who experienced repeat calls within a 48hr period, were endorsed.

6.1.2 A retrospective cross sectional observational study of diabetes related emergency calls.

The population demographics of those requiring ambulance service assistance for severe hypoglycaemic events in Scotland were broadly similar to those described in other UK and international studies (Khunti *et al*, 2013; Farmer *et al*, 2012; Parsaik *et al*, 2012; Brackenridge *et al*, 2006; Leese *et al*, 2003; Mattilla *et al*, 2004). Few people were transported to the ED for immediate follow-up care. New evidence was generated on repeat call data where a small proportion (10.6%, n=140) of patients was found to experience repeat hypoglycaemic events within the first 14 days of the initial event (3.1% within 48 hours). This contributed to the existing knowledge on subsequent calls to ambulance services and confirmed that the SAS has a relatively low repeat call rate within 48 hours compared to other services. The identification of repeat calls in all studies recognised this as an international problem and not localised to Scotland or the wider UK. Despite this, no study of this size had specifically investigated any predictors of remaining at home using repeat call or deprivation category data (see section 4.5.7). However the current study, through regression analysis, established that prior calls to the ambulance service were the most significant predictor of remaining at home post-hypoglycaemic event. The identification of frequent repeat severe events, and the recognition that this aspect of care had not been addressed in any of the literature, reinforced the need to seek the patients' perspectives and experiences of care.

The retrospective approach and use of information from lay members of the public (recorded during 999 calls) were two important limitations to this study. The MPDS[®]

data lacked the clinical detail provided on the pPRF's but these were neither accessible nor accurate at the time of data collection. Concerns regarding the accuracy of the coding of hypoglycaemic calls, were mitigated through a cross reference of pPRF data with MPDS[®] call data (see chapter 4, section 4.3.2.2). This enabled confidence to be placed in the results presented.

6.1.2.1 Research Impact

The study reinforced and expanded on previous evidence developed from the scoping review (chapter 3). Most individuals who have been treated for a severe hypoglycaemic event remain at home and do not require further ambulance support. However a small proportion sought further ambulance support in the days and weeks thereafter, and these included those who had initially been transported to the ED. This highlighted that transportation to the ED for follow-up did not necessarily prevent repeat or recurrent events. This study currently represents one of the largest retrospective cross-sectional observation studies undertaken on hypoglycaemic emergencies call data and has directly informed Government Policy (Diabetes in Scotland, 2013; Scottish Executive, 2010).

6.1.3 Investigating patients' experiences of prehospital hypoglycaemic care

Impaired awareness (see sections 5.5.1.2.) seemed to contribute substantially to the development of severe hypoglycaemic events, with the absence of symptoms leaving many patients unable to self-treat. This shifted the responsibility of care on to relatives who described struggling to cope. This qualitative study found that participants' experiences of emergency ambulance care were overwhelmingly positive, however post recovery follow-up with DCP's appeared to be lacking. Most participants reported prompt recovery and that ambulance clinicians' verbally advised follow-up care. But few recollected receiving written information (counter to SAS T&R policy). The findings from the qualitative interviews supported the results from the retrospective analysis on

non-transportation rates where both studies found that few patients travelled to the ED after a severe hypoglycaemic event. However it was also established that few individuals attended for follow-up care with their DCP. Participant's behaviour was considered through the post hoc application of relevant psychological models (Leventhal *et al*, 1998; Ley and Llewelyn, 1995; Rosenstock, 1966). These suggest that tailored information delivered by ambulance clinicians may improve illness identity and subsequently improve follow-up care (Ley and Llewelyn, 1995; Leventhal *et al*, 1998). The benefits of staying at home and not following up their care appeared to outweigh the costs of either attendance at the ED or DCP for follow-up (Rosenstock, 1966). This suggests that some of the required changes may be beyond the control of the SAS.

6.1.3.1 Research Impact

As with the retrospective analysis, the findings of the qualitative study were presented and discussed at a Scottish Parliament, Diabetes in Scotland Round Table meeting and included in its subsequent publication (Diabetes in Scotland, 2013). The findings are also helping to inform the future development of care pathways within the SAS.

6.1.4 Strengths and limitations

Strengths and limitations of specific studies were reported within their relevant chapters (see sections 3.10, 4.5.8 and 5.8.4). This section focusses on the overall strengths and limitations of the inductive atheoretical and multiple methods approach.

6.1.4.1 Strengths and limitations of an inductive atheoretical approach

As discussed in chapter one, different levels of theory can be applied to research studies. Some levels are more abstract than others (see sections 1.9.1 to 1.9.3). At the epistemological level this thesis was undertaken from a pragmatic perspective, to provide meaningful answers to real world research questions, in order to ultimately inform clinical and organisational practices. At a more concrete level, in the absence

of sufficient evidence or any firm basis on which to select an appropriate mid-range theoretical approach, a decision was made to adopt an atheoretical and inductive approach to data collection and analysis. This approach to applied health services research has been adopted by others. Rogers, De Zoysa and Amiel (2012) undertook a similarly atheoretical qualitative study on hypoglycaemia contemporaneously with this research. The merits of this approach will now be discussed.

The strengths and limitations of the inductive atheoretical approach were presented in the introduction to this thesis (section 1.9.3). The author acknowledges that no approach can be truly atheoretical (McKenna, 1997). In considering this atheoretical approach to knowledge, the author has developed a greater appreciation and understanding of this statement by McKenna (1997). In this research programme it was more abstract, high-level epistemological theory that underpinned the process. The pragmatic approach (pragmatism) ensured the focus of enquiry remained grounded within the context of the original practical aims of the thesis.

The absence of any mid-range theory permitted each study within this programme of research to begin by attempting to adopt as “*open a mind as possible, aiming to allow the researcher an unrestricted view of any relationships between emerging concepts*” (Kramer, 1995, pg. 200). Each study therefore developed and evolved unrestricted by any particular mid-range theoretical lens. This facilitated an evidence-based exploration of those mid-range theories that would help explain, post hoc, some of the key behaviours identified within both the quantitative and qualitative studies.

The process of reflexivity, described earlier (section 5.2.6) enabled the author to acknowledge openly any professional and personal biases. This enhanced transparency in the decision-making and analytical processes throughout (Parahoo,

2014). This transparency helped to establish validity, reliability and trustworthiness, respectively throughout this thesis.

To reiterate earlier discussion on these theories, each theory is comprised of a number of constructs (see section 5.8.2.3 and 5.8.2.5). Had one single theory been selected from the outset, constructs from the other models would have been omitted, thus some of the key findings may have remained undetected. Selecting only one theory, or theories in the absence of evidence to guide such decision making would, therefore, have limited the identification of areas worthy of further investigation. This may have introduced significant flaws to the research process (Topping, 2010). Post hoc theoretical application suggested that applying multiple combined theories may be more effective in eliciting the behavioural change desired; in this case attendance at follow-up. Selecting theory (or theories) without supporting evidence would have therefore been unlikely to have contributed as meaningfully to the development of this understanding and negatively affected future intervention development.

Had there been a stronger and more developed evidence base on which to apply any single (or number of) theories a priori, this would undoubtedly have provided a firmer framework for this programme of research. This may have also, as some have suggested, produced results that were more transferrable or comparable to other studies that have used the same mid-range theoretical approach (Chinn and Kramer, 1995). This clearly is a limitation of the current thesis.

In summary, the pragmatic, inductive atheoretical approach permitted the freedom to investigate thoroughly without mid-range theoretical constraint. The post hoc application of mid-range theory identified that multiple theoretical approaches may be necessary in order to fully understand patients' behaviours. This pragmatic and

grounded approach therefore reinforces the need to carefully consider the appropriate use of theory from the outset. However, as the atheoretical approach led to the identification of potentially relevant theories, future research projects, including the development of theory based interventions to improve follow-up care, can now be developed meaningfully on an existing evidence base.

6.1.4.2 Strengths and limitation of the use of multiple methods

The inductive approach using multiple methods in a sequential explanatory design provides flexibility (Creswell *et al*, 2003) and has been successfully used in other studies (Schillaci *et al*, 2004; Khunti, 1999; Larme and Pugh, 1998). As each study was completed, new knowledge was generated that helped to guide the development of the subsequent study. As previously stated (see section 6.1.4.1) this pragmatic approach supported the generation of clinically relevant research questions which were investigated using established, scientifically robust, research methods (Creswell *et al*, 2003). Both quantitative and qualitative data were required to thoroughly investigate the challenges faced by the prehospital hypoglycaemic patient population. However philosophical tensions do exist between the pragmatist paradigm and those of the positivist and constructivist which are associated with quantitative and qualitative research respectively (Creswell *et al*, 2003). Positivist and constructivist paradigms view mixed or multiple methods approaches as a methodological weakness (Morse, 2003). But, from a pragmatic perspective, using a multiple methods approach, it is possible to respect their individual epistemological groundings. As such these approaches are viewed as appropriate and entirely acceptable (Gray, 2009).

Although not completely aligned with the agreed typologies (see section 5.2.3), the multiple method approach adhered to the fundamental principles outlined by Morse (2003). This permitted the overall inductive approach, but unusually began with a quantitative study, followed by qualitative study. The studies in this thesis involved

sequential triangulation where “*projects are conducted one after the other to inform enquiry, with the first project informing the nature of the second project*” (Morse, 2003, pg. 190). This process generated new knowledge and informed the future direction of the investigation, a recognised benefit of the approach (Creswell and Clarke, 2011; Morse and Niehaus, 2009; Creswell *et al*, 2003; Morse, 2003). Sequential triangulation also helped provide clinically relevant explanations for previous findings. Each of the studies stood alone; another reported strength of this approach (Morse and Niehaus, 2009; Morse, 2003). Sequential triangulation permitted the pertinent points from the first study to be discussed, explained or developed within the context of the second, and then the first and second within the context of the third. Examples of the strengths of the sequential multiple methods approach can be found in the key findings. For example, the identification of repeat callers and the concerns around non-transportation, which emanated from the scoping review (see chapter 3) led to the cross-sectional retrospective study to examine the Scottish perspective (see chapter 4). And the confirmation of non-transportation and repeat calls in Scotland led to the development of the qualitative study (chapter 5) to provide explanations of patients’ behaviours. Alternative epistemological stances would have restricted the progression of the thesis by affording less flexibility in its development. These may not have enabled as comprehensive a description or interpretation of results as has been provided using the multiple methods approach (Morse, 2003).

However the use of sequential triangulation also has limitations. It was not possible to make explicit links between the findings of the retrospective cross-sectional observation study and the qualitative study. This was because the samples were separated by a number of years. As such, the timing of these studies may have impacted on the findings. But the part-time nature of the study, the data cleaning process and analysis of quantitative data took considerable time. Although the SAS

had not changed care delivery within the context of T&R over this time, other services may have. It is possible then that developments in general diabetes care and management may have influenced the proportion of individuals remaining at home, and as such, the reasons provided for non-transportation may vary over time. The qualitative study may have been strengthened by the involvement of ambulance clinicians and DCP's and by within study triangulation. Similar recent qualitative work provides an excellent example of how this process can develop a richer and broader understanding of the topic under investigation (Togher, Davy and Siriwardena, 2013). Involvement of health professionals may also have helped to provide deeper explanations for the findings of the quantitative chapter.

The prehospital hypoglycaemic knowledge base has been usefully developed using the multiple methods approach and in the absence of mid-range theory. This demonstrates that this particular approach can be beneficial. The use of multiple methods permitted each study to remain uncompromised and true to their respective paradigms. As such, the use of multiple methods is likely to have strengthened the quality of the overall thesis, rather than weakened it (Morse, 2003). The ability to retain an overall inductive drive, and not conform to existing typologies (i.e. QUANT – QUAL = deductive), strengthens the argument by Bryman (2006) who suggested that the existing typologies were too tight and prescriptive for the diversity required by multiple methods studies. Similarly, use of an atheoretical approach produced coherent and meaningful results contradicting the views of some (Giacomini, 2013; Moody, 1990) while adding weight to the views of others (Chinn and Kramer, 1995).

There were a number of ways in which the research problem identified at the beginning of this thesis could be approached. Although an a priori approach would be preferred, the theoretically based approach was not the only way to tackle these particular set of

research problems. This thesis demonstrates that an atheoretical approach offers an alternative and, importantly, can still produce meaningful results. This thesis has therefore contributed to the growing evidence-base that supports the pragmatic application of an inductive atheoretical approach using multiple methods. These results suggest there is the potential also for methodological growth in this area.

6.2 Final discussion

6.2.1 The diabetes challenge

Diabetes is a complex long-term condition and a global health challenge that continues to place a considerable burden on the provision of health care across the world (WHO, 2009). Projected figures state that between the years 2000 and 2030 the world wide prevalence of diabetes for all age groups will grow from 2.8% (N = 171,228,000) to an estimated 4.4% (N = 366,212,000) (WHO, 2009). The incidence of diabetes in the UK is 4.6%, with three million people currently diagnosed with the condition (Diabetes UK, 2012a). This figure is expected to rise to four million by 2020 (NICE, 2012; Wild *et al*, 2004).

These changes have placed immense pressures on the NHS, particularly EDs and ambulance services. However, the long and short-term complications of diabetes make managing the condition challenging. Existing strategies, introduced to avoid patients experiencing the long-term complications of diabetes (see section 2.4.1), have increased the likelihood of patients experiencing the short-term consequences of severe hypoglycaemia (Leese *et al*, 2003; The Diabetes Control and Complications Trial, 1997).

Whilst the literature suggests that ambulance assistance is only required for severe hypoglycaemic events in around 10% in those with Type I diabetes and 33% in those

with Type II (Donnelly *et al*, 2005), it is a global challenge. Internationally, between 0.57% to 4.7% of all emergency calls are for hypoglycaemic emergencies (see Table 16). The growing prevalence of both Type I and Type II diabetes in the UK could feasibly lead to an increase in ambulance calls for hypoglycaemia (Donnelly *et al*, 2005; Leese *et al*, 2003). Diabetes will therefore continue to challenge ambulance services and the greater NHS for the foreseeable future, thus emphasising the importance of the development of systems that deliver safe and effective care for those individuals affected.

6.2.2 Reducing demand on Emergency Departments

Government policies (Department of Health, 2005a; Scottish Executive, 2005a; Scottish Executive, 2005b; Scottish Executive, 2003a) aim to reduce demand on EDs and stimulate the development of non-transportation guidelines by ambulance services (Snooks *et al*, 2005; Dalglish *et al*, 2008; Colver, 2013). These changes signalled a partial deviation from the Anglo-American model, to the Franco-German model of ambulance care, where care and treatment were provided at home avoiding transportation to the ED (see section 1.6). The studies presented in chapters three and four demonstrated that T&R guidance (or similar) for hypoglycaemia appear to have been effective at avoiding unnecessary transportation. Furthermore, the patients' experiences of emergency ambulance care were generally positive: the SAS responded quickly, provided prompt treatment and recovery was generally swift. From a policy perspective, ambulance services and patients, T&R could be perceived as a success. However, home recovery is perhaps not without consequence (see sections 3.8.1 and 2.4.3).

6.2.2.1 Concerns over the safety and effectiveness of T&R systems

Despite the apparent success of the T&R system, a number of quality and safety issues were identified. Locally produced T&R guidelines (JRCALC, 2006, Welsh

Ambulance Service, 2006; Scottish Ambulance Service, 2005) represented a return to regional variation and the inconsistencies that had previously received much criticism (British Broadcasting Corporation, 2000). Whilst the scoping review had impacted on national guidelines (JRCALC, 2013), concern still remained about variation in the locally developed T&R guidance. Furthermore additional, broader concerns about the quality and safety of patient care remained. In particular, the recurrence of hypoglycaemia in those previously treated was a concern. This problem was not confined to Scotland, with repeat and recurrent events confirmed in all studies conducted within and outwith the UK. Both the retrospective analysis (chapter 4) and previously published data (Goh *et al*, 2009; Cain *et al*, 2003; Socransky *et al*, 1998) demonstrate that repeat and recurrent events occur irrespective of the place of discharge. This suggests that discharge practices and follow-up systems from both ED's and the ambulance service were ineffective for some. The qualitative interviews highlighted the involvement of impaired awareness in initial and subsequent hypoglycaemic emergencies (see section 5.5.1). This was already known to cause and increase the likelihood of developing severe hypoglycaemia (Gravellin and Frier, 2010; Frier, 2007). Impaired awareness is also known to be very treatable (Cranston *et al*, 1994; Dagogo-Jack *et al*, 1994; Fanelli *et al*, 1994), further emphasising the importance of appropriate follow-up care.

The evidence, therefore, suggests that neither ED follow-up care, nor ambulance care are best placed to deal with these specific problems. The factors contributing to repeat calls such as impaired awareness may be better resolved through patients' diabetes care providers who have the expertise, detailed knowledge of the individual's condition and access to the appropriate referral and support networks. The identification of impaired awareness also reaffirmed the rationale for the follow-up care being most appropriately delivered by the diabetes care provider.

The frequency of repeat events (and associated clinical risks) identified within the context of T&R are related to fundamental problems previously recognised in the broader diabetes literature for which evidence-based management strategies already exist (NICE, 2012; SIGN, 2010). It was concerning to learn that, despite the persistence of the government policy drivers (Department of Health, 2005a; Scottish Executive, 2005a; Scottish Executive, 2005b; Scottish Executive, 2003a) and the introduction of consensus based T&R guidance, essential and individualised care appeared to be lacking. Existing emergency and unscheduled health care systems do not appear to be configured to deal effectively with these particular problems. These gaps in care provision are exposing particular patient groups sub-optimal care. If referral processes could be improved, patients likely to experience severe hypoglycaemic events may receive appropriate medication alteration and personalised advice. They may also be directed to, or enrolled in specific evidence-based educational programmes known to reduce the frequency and severity of hypoglycaemic events (Cox *et al*, 2006). However, many patients appear to accept hypoglycaemia as an unpreventable aspect of their condition and consequently lack sufficient motivation to act to prevent its occurrence. There were a number of barriers that precluded appropriate follow-up care from being sought or provided (see sections 5.7.2, 5.7.4 and 5.7.6). The identification of these will allow for possible solutions to be developed and evaluated in the future.

6.2.3 Future Developments

The concept of providing the 'hospital at home' is an attractive one, particularly within the current economic climate, however to achieve success services must be joined-up. At present they are not. The existence of repeat and recurrent calls, patients' perceptions of the SAS and the absence of clear linkages between services (see sections 4.4.4 and 5.6.5) were evidence of this fragmented system. Whilst the initial

phase of care, such as the emergency response and treatment, seem effective from all perspectives, the system of care once the patient has recovered appears to be inadequate. Interview data (see section 5.6.5) suggests that patients do not reliably pass on details to their DCP. Consequently the DCP will be unaware of the severe event. Clearly then, there is little that can be done to improve individual's care if care providers are unaware of the problem.

In recognition of the evidence provided, both services and patients must now consider how information sharing can be improved. Although ambulance services could improve some of their working practices and perhaps influence some of the behaviours identified, much of the clinical care required is beyond their current skill set. Emergency Care Practitioners (extended trained paramedic) demonstrate that ambulance services and clinicians can be flexible in care provision (Hill *et al*, 2013; Ball, 2005; Mason *et al*, 2006, 2003). But their efficacy has yet to be fully established (Hill *et al*, 2013). Where a DCP already exist, the needs and benefits for the delivery of such care by ambulance clinicians is questionable. An extended role for ambulance clinicians may therefore be unnecessary. However DCP's were not perceived positively by the majority of participants that were interviewed. This led to patients' reluctance to follow-up their care. If patients are to increase their attendance at DCP's, then these services will need to adapt in order to provide a more bespoke and valued service to their patients. Otherwise patients are likely to maintain their current behaviours.

The delivery of joined up care and services would not be without challenge. Many of these services are not accessible out of hours (established as the time when more hypoglycaemic events requiring ambulance support occur (see section 4.4.4.4 and section 4.5.4). Existing patient care record systems mean that such information is not

easily shared between SAS and the broader NHS. And whilst the success of such systems may alleviate the pressure on ambulance services, this would undoubtedly increase the pressure on DCP and primary care.

6.2.4 Towards an evidence base to improve post-hypoglycaemic follow-up care

The studies (chapters 3, 4 and 5) reported in this thesis have identified that patients who have repeat severe hypoglycaemic events and are attended to by the ambulance service may be experiencing preventable emergencies and frequently lack follow-up care. As ambulance clinicians are often the only health care professionals to come into contact with many of these individuals, they may be in a unique position to promote and improve follow-up care. This, however, would require a novel form of follow-up intervention.

The quantitative results presented in chapter 4 and qualitative findings presented in chapter 5, identified a number of key areas of patient behaviour that may help inform the design of such an intervention, through the targeted application of existing theoretical models. A number of candidate theories were suggested which could inform the development of a potentially effective intervention to promote follow-up care (Leventhal *et al*, 1998; Ley and Llewelyn, 1995; Rosenstock, 1966). However, shifting from this post hoc application of explanatory theory into the development phase of any clinical intervention is a complex process with multiple elements and therefore requires a careful and informed approach.

The nature of ambulance service unscheduled and emergency care, the lack of integration of health care communication systems, and elements pertaining to the behaviour of ambulance clinicians, diabetes care providers and patients, suggest that

a complex intervention will be required to improve the frequency of patients following up their care. Complex interventions have been defined as “*interventions that contain several interacting components*” (Medical Research Council, 2008, pg. 7). In 2000 the Medical Research Council (MRC) recognised the need for guidance on developing and testing complex interventions (MRC, 2000). Whilst developed initially as only draft guidance, it gained considerable popularity as *the* process to follow. The original guidance (MRC, 2000) provided a stepped, sequential process. This was later updated (Anderson, 2008) and presented the process as a number of iterative stages (see Figure 13). Discussing the framework, Craig *et al* state that:

“Best practice is to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach, starting with a series of pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory and then a definitive evaluation.”

(Craig *et al*, 2008, pg. 980)

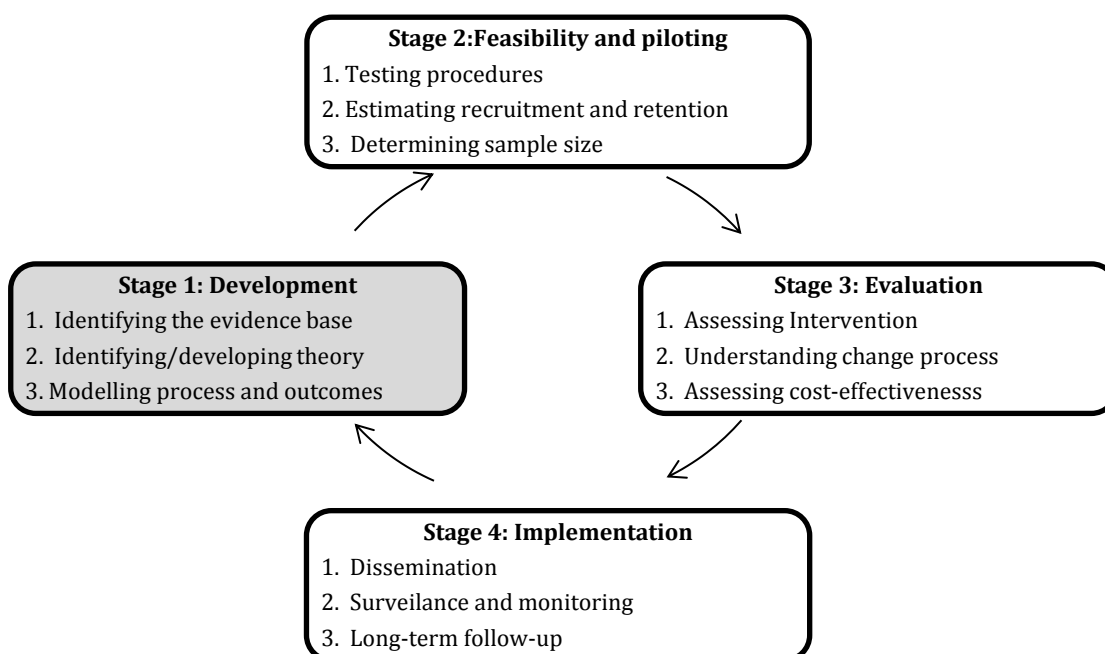
According to the framework (Anderson, 2008) two key questions are central to the development of a complex intervention: 1. Does it work during routine practice?; and 2. How does it work? The studies that form this thesis focus on the development process, specifically steps one and two (see grey ‘Stage 1: Development’ box in Figure 13).

6.2.4.1 Developing the evidence

The three studies presented in this thesis (chapters 3, 4 and 5) have identified and developed the evidence base relating to prehospital hypoglycaemic care. The scoping review (chapter 3) acknowledged the dearth of prehospital studies on the hypoglycaemic population treated by ambulance clinics and led to the undertaking of

primary studies using a multiple methods approach (chapters 4 and 5). Findings from both the retrospective review (chapter 4) and the qualitative study (chapter 5) built on the previously identified literature and collectively informed step two of the development process; identifying and developing theory.

Figure 13: MRC Framework (Anderson, 2008)



6.2.4.2 Identifying and developing theory

A number of theories or models were identified as potentially useful in informing future intervention development (Leventhal *et al*, 1998; Ley and Llewelyn, 1995; Rosenstock, 1966) (see section 5.8.3). This suggested that interventions based on these theoretical models (Leventhal *et al*, 1998; Ley and Llewelyn, 1995; Rosestock, 1966) are likely to be useful in informing the development of future interventions.

6.2.5 Research recommendations

6.2.5.1 Recommendation 1: An intervention to improve self-referral to primary care should be developed.

Rationale: Two factors identified within this thesis highlight the need for an evidence-based intervention to improve self-referral. Firstly, although the effectiveness of existing T&R follow-up advice has not been objectively measured, the current process appears to be suboptimal and ineffective (see sections 5.6.4 to 5.6.5). Ambulance clinicians reportedly fail to comply with current best practice guidance on providing advice on the need for follow-up (JRCALC, 2006; Scottish Ambulance Service T&R, 2005). Many participants therefore perceived there to be little need for follow-up attendance (see section 5.7.4 and 5.7.6). The reported lack of specialist diabetes follow-up of patients who have a hypoglycaemic emergency is concerning (see sections 4.4.4.3 and 5.7). Improving self-referral to primary carers would mean that patients receive the necessary support to prevent future events (Walker *et al*, 2006). Secondly, impaired awareness may be a contributing factor in many who developed severe hypoglycaemia requiring ambulance care (see sections 5.5.1.2. and 5.8.2.2). This condition is identifiable and preventable and would benefit from prompt follow-up care (see section 2.4.2.3). Over half interviewed in the qualitative study appeared to have developed impaired awareness. This is much higher than the 8-25% reported in other studies on the mainstream hypoglycaemia population (Pramming *et al*, 1991; Hepburn *et al*, 1990). Post hoc application of Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995) and Leventhal's Common Sense Model (Leventhal, 1988) suggests that inadequate referral advice the absence, or lack of illness identity, may be influencing follow-up care behaviour. Therefore, a two phase study is recommended:

Phase 1: A national prevalence study of impaired awareness of hypoglycaemia in people who require ambulance support for severe hypoglycaemic events.

Given the indications of a higher rate of impaired awareness in the qualitative study, it is important to objectively measure whether the population who use the ambulance service for severe hypoglycaemia have a higher prevalence of impaired awareness. Understanding the degree to which impaired awareness affects this population will help inform and focus the development of any behavioural change interventions that follow.

Phase 2: The development and evaluation of a patient centred educational and behavioural change intervention. This intervention should be informed using Leventhal's Common Sense Model (Leventhal, 1988) and Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995) aggregated for accumulative effect. A future intervention may, for example, consist of a two component model:

- **Component one:** would be informed by two key constructs of Leventhal's Common Sense Model: illness 'identity' and 'cure/control' (Leventhal, 1988). The assessment to identify impaired awareness may be undertaken by ambulance clinicians, once patients have recovered, using an established and validated tool (Gold, 1994). Illness representation (impaired awareness) would therefore be realised in affected individuals. Subsequently, ambulance clinicians would inform patients of its reversible nature. This would permit identity or representation of the condition but would, through ambulance clinician's assurance of its reversible nature, ensure the crucial link with the perception of cure/control; important in affecting positive behaviour change (see section 5.8.3.1). Both constructs have demonstrated a small to medium size effect on changing behaviours (see section 5.8.3.1).

- **Component two:** would consist of the delivery of an educational intervention aimed at reinforcing the need for follow-up care and should be consistent with the evidence provided by Ley's cognitive hypothesis model of communication (Ley and Llewelyn, 1995). This aims to ensure recall, understanding and patient satisfaction. The effectiveness this type of intervention has been demonstrated in a number of studies (McFarlen *et al*, 2002; Brown, 1990; Morris and Halperin, 1979) (see section 5.8.3.3). Adding to this a reminder letter, or follow-up telephone call, may further enhance the intervention's utility and improve compliance with advice (Everett *et al*, 2011).

6.2.5.2 Recommendation 2: Enhanced communication systems should be implemented between ambulance services and primary carers to ensure timely and appropriate follow-up care.

Rationale: Participants' positive perceptions and experiences of the ambulance service lay in the Scottish Ambulance Service's immediate and reliable response and the prompt intervention by ambulance clinicians. Treatment usually resulted in rapid recovery and non-transportation for most (see section 5.7.1.1 to 5.7.1.4). Some perceived the SAS as a 'crutch' (see section 5.6.2) which was a very useful analogy. The knowledge that they can achieve a dependable 'quick fix' from the ambulance service, and the comforts associated with home recovery, may therefore also be influencing patients' perceptions about the need to follow-up their care (Rosenstock, 1966). Patients seemed comfortable using the ambulance service as a means of care, a life-line. Participants created their own short-term solutions, but in doing so maintained the status quo. Despite this immediate and seemingly valued solution to the problem, some patients went on to experience repeat or recurrent events resulting in a poor health outcomes (see section 4.4.4). Furthermore, despite some receiving

advice and education on the importance of follow-up, they were so profoundly affected by their negative past experiences of ED or DCP care (or tensions between particular DCP's) (see section 5.7.6.4 and 5.7.6.5) that self-referral was extremely unlikely. But without any change in follow-up care behaviour, longer term issues are not addressed.

Identifying the ineffective nature of the self-referral system was important (see section 5.6.4). As was the evidence that more emergency calls for hypoglycaemia fall outwith normal working hours for diabetes care providers (see section 4.4.4.4 and 4.5.4). This highlights the need to develop systems that enable effective communication and patient support within and outwith normal hours. There are many elements of care that fall outwith the immediate control of the ambulance service.

Therefore, to support and perhaps reinforce the previously described educational or behavioural change interventions (recommendation 1), enhanced, timely communication systems between ambulance services and primary and unscheduled care services must be improved and tested. This will ensure professionals with expertise in diabetes care are notified when a person with diabetes experiences a severe hypoglycaemic event. This will provide diabetes services with important clinical information about the patient's on-going clinical condition and may enable professionals to encourage patients to participate in follow-up care.

6.2.5.3 Recommendation 3: Develop and test a carer-based intervention to assist in the management of severe hypoglycaemic events.

Rationale: There will always be individuals for whom severe hypoglycaemia can neither be predicted nor prevented. Inevitably a severe event will occur that will require third party assistance. Often it is a relative that finds the patient unconscious or

in need of external assistance. The qualitative study (chapter 3) found that many relatives were fearful of such occurrences and described struggling to cope both physically and emotionally (see section 5.5.2). This contributed to the need for ambulance call-out (see section 5.5.2). The quantitative study (chapter 4) also evidenced that 70% of patients were not transported to the ED (see sections 4.4.4.3) and the standard pharmacological treatment provided by ambulance clinicians is often the same as that which has been issued to many people who experience severe hypoglycaemic events; glucagon. Conversely, there was some evidence to suggest that where carers were present and educated in the management of severe hypoglycaemia, an ambulance call was often completely averted (see section 5.5.2.9). An educational intervention to help carers deliver appropriate and timely care may increase carer confidence and reduce the rate of hypoglycaemic emergencies. The need for new interventions to support carers of people who experience hypoglycaemic emergencies has recently been acknowledged by other researchers (Lawton *et al*, 2013).

6.2.6 Conclusion

The use of a pragmatic and inductive applied health services research approach has generated an evidence base and identified plausible candidate theories, upon which future interventions can be developed. This thesis has demonstrated that the treatment of hypoglycaemic emergencies by the SAS is generally effective. The condition is improved in the short-term, hospital attendance and admissions are avoided and patients remain at home, something they report to prefer. However, a sub-set of this population may experience future severe hypoglycaemic events. In the absence of sufficient evidence to the contrary, it is considered safer to transport patients receiving OHA's to the ED. Patients who remain at home to recover require additional support to improve glycaemic control and successfully prevent further

hypoglycaemic emergencies. The SAS has a role to play in providing this support but cannot achieve this in isolation. A combination of interventions, such as those described earlier, may promote improved care and health outcomes. Significant research, as described, is required to establish a range of effective interventions for this patient and carer group.

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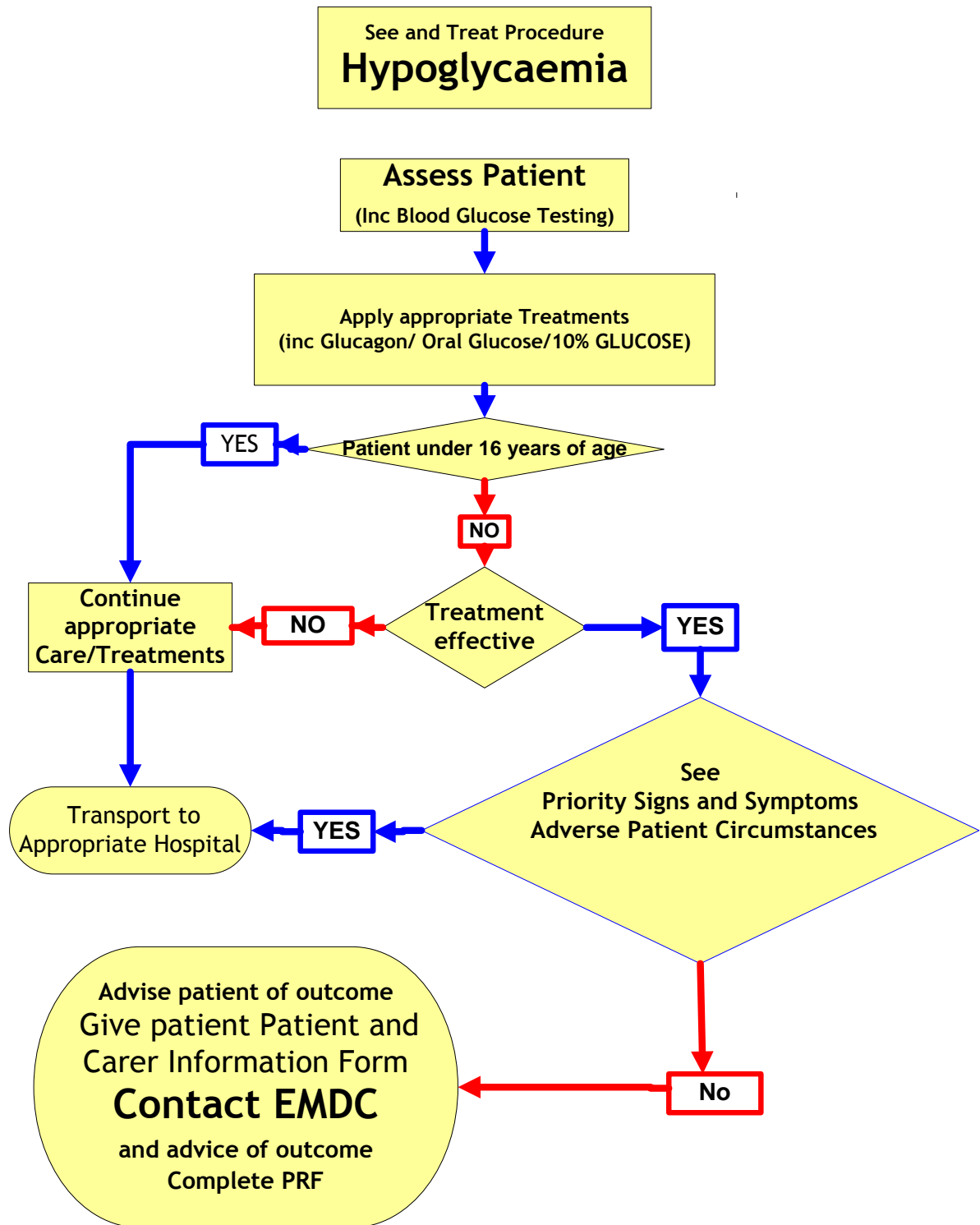
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APPENDICES



Hypoglycaemia

Priority Signs and Symptoms

Episode lasted more than 30 Mins after treatment
Unusual trigger/ cause
Injury incurred during episode
Seizure during/after episode
History of neurological injury secondary to Hypoglycaemia
Recent frequent/ prolonged Hypoglycaemic episodes

Adverse Patient Circumstances

Patient Educationally Challenged
Patient not physically well
Inadequate supply of own medication
No access to family support/Telephone/GP

If further Medical advice is needed

Contact NHS 24
0845 4 24 24 24

Appendix 2

Paramedic Extended Skills Course

IDDM: Hypoglycaemia: Paramedic Guidelines for Home Treatment

Presenting complaint

Disturbance in conscious level likely to be due to hypoglycaemia

History of Presenting Complaint

Onset of symptoms compatible with a hypoglycaemic episode recognised as such by the patient and/or anyone in attendance. The patient has previously experienced such an episode

The episode is short-lived (<30 minutes)
No unusual triggers (e.g. febrile illness)
No injury incurred during episode
No seizure activity

Past Medical History

No history of neurological injury secondary to hypoglycaemia
No recent history of frequent or prolonged "hypos"

Medications & Allergies

NB!!! The patient is NOT on oral hypoglycaemic agents

Family & Social History

Adequate social circumstances
Carer is well briefed
Home treatment (e.g. "hypostop" and/or glucagon) is available

Systems Enquiry

Ask about headache, confusion, sweating, disturbance of the special senses, sensorimotor dysfunction

APPENDIX 3: WELSH T&R GUIDELINE - HYPOGLYCAEMIA

Ymdäiriédolaeth GIG Gwasanaethau Ambiwlaens Cymru Welsh Ambulance Services NHS Trust

Patients in the following categories should be transported to the nearest suitable A&E unit

- Any patient who is not in the care of a responsible adult
- All patients over the age of 65
- All patients taking oral hypoglycaemic medication
- All patients with significant co-morbidity such as current chest infection, unstable angina, liver or kidney disease
- All patients with complicating factors such as renal dialysis, cardiac arrhythmia, seizures or focal neurological signs
- All patients without a previous history of diabetes
- All patients whose blood glucose reading after treatment remains less than 5mmol/l
- All patients whose mental status has not returned to normal within 10 minutes of administration of Dextrose or Hypostop
- All patients who have been treated with Glucagon
- All patients who are showing the effects of alcohol
- All patients in police custody

If these patients refuse transport, the Refusal of Treatment or Transport policy should be implemented.

Every effort should be made to arrange alternative care.

Patients who have responded to treatment and do not fall into one of the above categories can be discharged from care provided:

- Blood glucose level is 5mmol/l or greater
- GCS is 15
- The patient is fully orientated (time, place person)
- The patient is in the care of a responsible adult
- The cannula has been removed and a suitable dressing applied

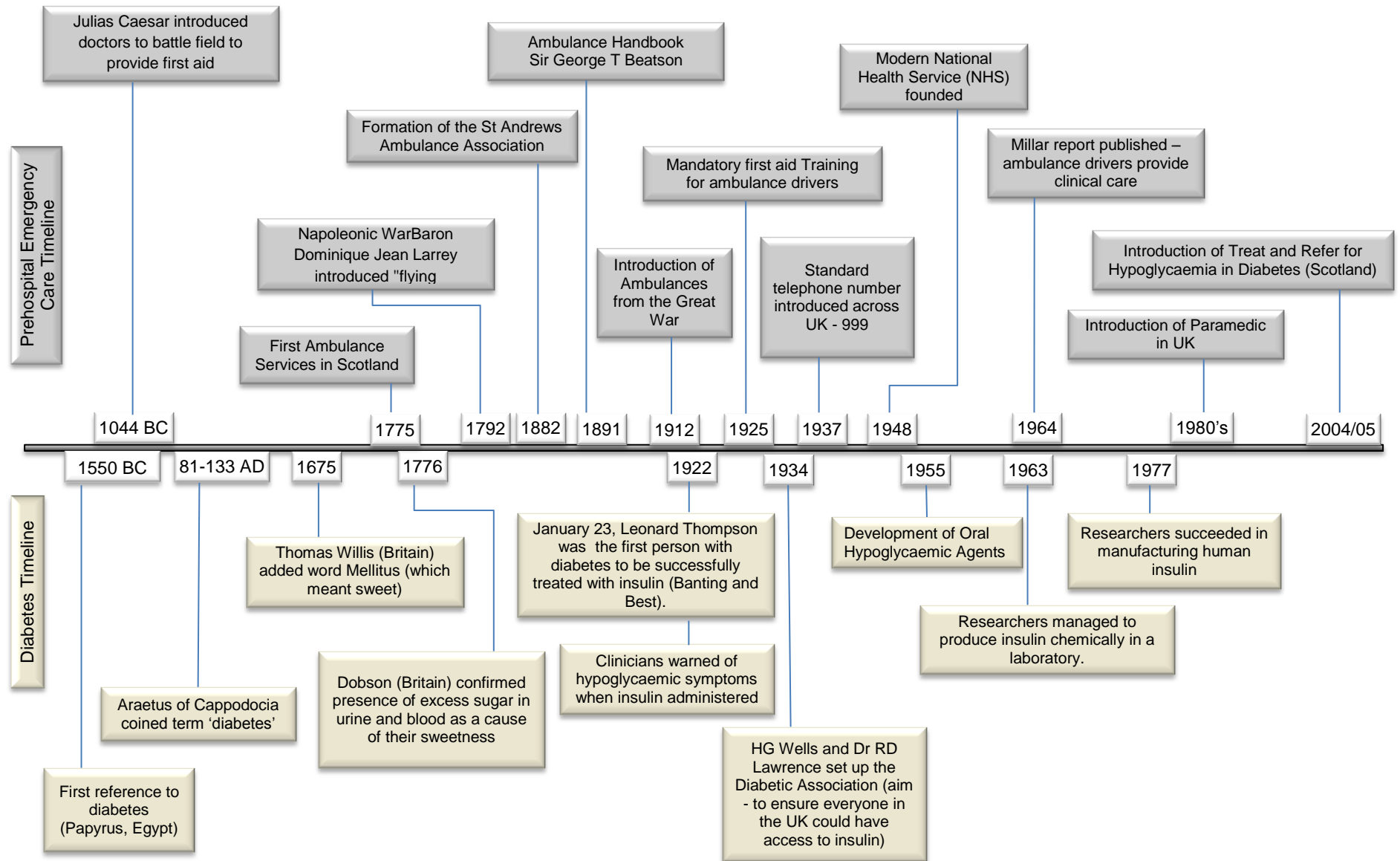
For these patients

- Complete a PCR and leave the bottom copy (yellow) with the patient
- Advise the patient to make an appointment to see their GP or Nurse Practitioner to discuss the hypoglycaemic episode and to hand over the copy of the PCR
- Ask control to inform the patient's GP (or the out-of-hours deputising service) about the hypoglycaemic episode, the full recovery of the patient, and their discharge from the care of the ambulance service. It is NOT necessary for the GP to attend the patient
- Advise the patient and carers to dial 999 should symptoms of hypoglycaemia return
- Document these actions on the Refusal of Treatment or Transport form

The patient is suitable for discharge but requests transport to hospital.

- Transport the patient to hospital.

APPENDIX 4: TIME LINE OF DIABETES/PREHOSPITAL CARE



APPENDIX 5 ORAL DIABETES MEDICATION

- Thiazolidinediones (pioglitazone): enhance insulin sensitivity: activate specific receptors in adipose tissue. This results in alteration in adipose tissue metabolism and distribution.
- Biguanide (Metformin): Acts independently of the pancreas. It acts on the liver decreasing glucose output and thereby reducing blood glucose levels.
- Sulphonylureas: close pancreatic cell potassium channels leading to enhanced insulin secretion.
- Alpha glucosidase inhibitor (acarbose): slows down the absorption of starch from intestine.
- Prandial glucose regulators: also stimulate pancreas to secrete insulin but is shorter acting than sulphonylureas and, like some insulin's, is taken approximately half an hour before a meal.
- Incretin mimetics: increases level of hormones 'incretins'. Helps the body to produce insulin 'on demand' and reduce gastric digestion and emptying.
- DPP-4 inhibitors (gliptins). Like incretin mimetics, help the body produce insulin 'on demand'.

APPENDIX 6: PATIENT REPORT FORM

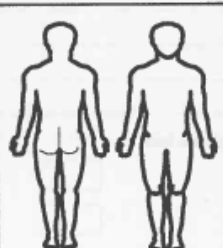
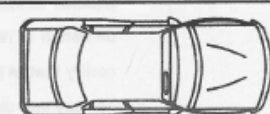
SCOTTISH AMBULANCE SERVICE - PATIENT REPORT FORM

CCS INCIDENT No. <input type="text"/>										Date <input type="text"/>	
Last Name <input type="text"/>										Time of Call <input type="text"/>	
First Name <input type="text"/>										Time at Patient <input type="text"/>	
Location <input type="text"/>										Time Left <input type="text"/>	
Age <input type="text"/>										AMPDS Code <input type="text"/>	
Sex <input type="text"/>										AMPDS Revised <input type="text"/>	
D of B <input type="text"/>											

Airway Clear <input type="checkbox"/>	Suction <input type="checkbox"/>	N/OPA <input type="checkbox"/>	ET <input type="checkbox"/>	LMA <input type="checkbox"/>	Successful ? <input type="checkbox"/>	C-spine Injury <input type="checkbox"/>
Breathing <input type="checkbox"/>	Rate <input type="text"/>	BVM <input type="checkbox"/>	Ventilation <input type="checkbox"/>	Successful ? <input type="checkbox"/>	Paralysis <input type="checkbox"/>	Fitting <input type="checkbox"/>
Pulse <input type="checkbox"/>	Rate <input type="text"/>	CPR <input type="checkbox"/>	IV/IO <input type="checkbox"/>	Fluids <input type="checkbox"/>	Successful ? <input type="checkbox"/>	ECG <input type="text"/>

Despite the above unable to

Clear airway Detect breathing Detect pulse

Injury Site	Wound #	Pain #	Splint	Dressed	 RTA <input type="checkbox"/> Trapped <input type="checkbox"/> Ejected <input type="checkbox"/> M / cyclist <input type="checkbox"/> Cyclist <input type="checkbox"/> Pedestrian <input type="checkbox"/> >20 min. Extricate <input type="checkbox"/>	 Allergies <input type="text"/> Medication <input type="text"/> Assisted by and Name - <input type="text"/> Doctor <input type="checkbox"/> Nurse <input type="checkbox"/> Other <input type="checkbox"/>
Head	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Neck	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Chest	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Abdomen	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Back	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
R/Arm	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
R/Leg	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
L/Arm	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
L/Leg	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		

Time	Pulse	Resp	BP	C / Refill	SpO2 %	GCS	Lpupil	Rpupil
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Time	Fluid/Drug/Gas	Dose	Unit	Route	Effect	Rhythm	No. Joules	Repeat	Result	Rhythm
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Condition at hospital Pulse Breathing Conscious Time at Hospital

History and Additional Information

Working assessment Diagnosis Code

Crew Name 1 Grade

APPENDIX 7: MPDS® CARD – DIABETES CODE 13

13 DIABETIC PROBLEMS

KEY QUESTIONS		POST-DISPATCH INSTRUCTIONS	
<p>Unconscious (per Case Entry)</p> <ol style="list-style-type: none"> Is s/he completely alert (responding appropriately)? Is s/he behaving normally now? Is s/he breathing normally? (≥ 8) Can I speak with the patient personally to verify her/his condition? <ol style="list-style-type: none"> (Yes) Did you verify her/his condition? 		<p>13-D-1</p> <ol style="list-style-type: none"> I am organising help for you now. Stay on the line and I'll tell you exactly what to do next. (Patient medication requested and Alert) Remind her/him to do what her/his doctor has instructed for these situations. (Combative and ≥ 8) If it's safe to do so, observe her/him continuously and protect her/him from her/himself. <p>* Stay on the line with caller if her/his condition seems unstable or is worsening.</p> <p>DLS * Link to X-1 unless:</p> <p>Combative X-8</p> <p>Unconscious ABC-1</p> <p>INEFFECTIVE BREATHING and Not alert ABC-1</p>	
LEVELS	# DETERMINANT DESCRIPTORS	CODES	RESPONSES
D	1 Unconscious	13-D-1	
C	1 Not alert 2 Abnormal behaviour 3 Abnormal breathing	13-C-1 13-C-2 13-C-3	
A	1 Alert and behaving normally without 1st party verification	13-A-1	
Ω	1 Alert and behaving normally with 1st party verification	13-Ω-1	

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Concurrent Problem Suffix	Axioms	Hypoglycaemia/Insulin Coma (rapid onset)
<p>The suffix code is added whenever the patient appears to be combative or aggressive. It allows for different response assignment and provides for awareness of the situation:</p> <p>C = Combative or Aggressive</p>	<ol style="list-style-type: none"> Diabetes is a "diagnosis" that EMDs may accept at face value because of its high degree of accuracy. A significant potential for error is to confuse alcohol or drug intoxication with low blood sugar from too much insulin (insulin shock). An early sign of low blood sugar is abnormal behaviour, which may include agitation, aggressiveness, confusion, and/or combativeness. 	<p>Too much insulin has depleted the body's available blood sugar. Since the brain's most usable fuel is sugar, it is the first organ at risk. This is more serious if the patient is not alert, and is commonly confused with alcohol intoxication.</p>
<p>Coma</p> <p>A state of unconsciousness from which the patient cannot be aroused.</p>		<p>Diabetic Ketoacidosis (gradual onset)</p> <p>Pre-coma state resulting from insufficient insulin. Unable to use sugar as fuel, the body burns its own tissue (fat, muscle). The ketoacids (acetones) produced are "toxic" to the patient and cause a slowly increasing illness state. This is not considered a prehospital medical emergency if the patient is alert, but requires medical evaluation and treatment.</p>
<p>Rules</p> <ol style="list-style-type: none"> Determining the level of consciousness is the key to correctly assigning the prehospital response. EMDs should not advise administration of oral sugar to symptomatic diabetics. There is no clinical evidence of improved outcome by such EMD intervention, while the potential for airway obstruction in the not alert patient is high. The airway of an unconscious patient must be constantly maintained. If the caller asks whether the patient should be given their medication now, the EMD should only give instructions included in the protocol. 		<p>Diabetic Coma (later onset)</p> <p>Unconsciousness or decreased level of consciousness occurring later in untreated diabetic ketoacidosis. Without an accurate history, this problem may be difficult to tell from insulin shock. Airway control is the first priority in Post-Dispatch Instructions if the patient is unconscious.</p>

13 DIABETIC PROBLEMS

APPENDIX 8: E-MAIL TO PROFESSOR KHUNTI

From: Khunti, Kamlesh (Prof.) [kk22@leicester.ac.uk]
Sent: 12 June 2013 13:41
To: Fitzpatrick David (SCOTTISH AMBULANCE SERVICE)
Subject: RE: Prehospital Emergency Hypoglycaemia Calls - additional information request on published study

|Dear David

Great to hear you are doing similar work - a lot more needs to be done on this! Unfortunately this is all the data that the ambulance staff collected.

Happy to look at the analysis when done and good luck with the PhD

Best wishes

Kamlesh

From: Fitzpatrick David (SCOTTISH AMBULANCE SERVICE) [david.fitzpatrick@nhs.net]
Sent: 12 June 2013 11:43
To: kk22@le.ac.uk
Subject: Prehospital Emergency Hypoglycaemia Calls - additional information request on published study

Dear Professor Khunti,

I am currently in the last leg of writing my PhD thesis (on emergency hypoglycaemic care/patient experience etc etc) and I am drawing on your paper in terms of the demographics of the hypoglycaemia population (and other recent papers by Farmer *et al* 2013 and Leese *et al*, 2006). I have undertaken a retrospective analysis of MPDS® call data for the West of Scotland (population of over 2.1 million Hypo calls n=1300). I understand there are limitations with this data set, however the data is broadly comparable with another Scottish Study published by Leese *et al* 2006.

My reason for contact was to ask whether you held additional data on the time periods within which emergency calls were made? Specifically the calls not received during night-shift hours i.e. your paper stated 27.6%. Our data suggests that 37% of calls were made during night shift hours (2300-0700), 36.4% back shift and 26% during day shift. We too found that during night shift hours patients were less likely to be transported to the ED, however the results were not significant (p=0.081). It would be incredibly useful if I could find some comparisons for our data. Additionally we took a slightly different approach and used regression analysis to look for patient predictors for remaining at home (rather than being transported to the ED). Analysis is almost complete and I (we) hope to be able to share this data soon.

I would be incredibly grateful for any information, advice or assistance.

With kindest regards and best wishes.

David

David Fitzpatrick DipIMC RCSEd | Paramedic Clinical Research Specialist | Scottish Ambulance

APPENDIX 9: STUDY PROTOCOL

Investigating patients experiences of hypoglycaemic emergencies

(Full title: Improving self-referral to diabetic care services following hypoglycaemic emergencies: the development and initial assessment of a research-based intervention.)

Study Protocol

Final Version

20th October 2009

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Stratification of sample.....	6
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Aims and objectives

This study forms phase one of a larger study which aims to improve the follow-up care given to people who have a diabetic hypoglycaemic emergency and are treated at home by ambulance clinicians. During phase one, we will develop (a) a prompt card that ambulance staff can leave with people to encourage follow-up at their diabetic care service; and (b) a follow-up phone call from the ambulance service. Development of the prompt card and phone call will be informed by interviews with people who have experienced a hypoglycaemic emergency to find out what support they need, want and prefer. We will investigate both whether the prompt card and phone call are acceptable to people with diabetes and ambulance clinicians.

Sample/population

We will conduct in-depth interviews with approximately 30 adults who have had a diabetic hypoglycaemic emergency and been attended by ambulance clinicians. The study sample size (n=30) will be drawn from the catchment area of the West of Scotland Emergency Medical Dispatch Centre (ACC) Cardonald, Glasgow. A sample size of 30 was selected as it is anticipated that this will allow sufficient number of patients to generate a broad range of information about their experiences.

Potential participants will be identified from a weekly review of emergency calls²¹. To achieve this, the research paramedic (David Fitzpatrick) will:

- I. Obtain the phone number, name, sex, age, address/post code and nature of emergency call (code 13) of all potential participants
- II. Obtain and cross reference corresponding Electronic Patient Report Form (EPRF) details.
- III. Confirm that the call was for hypoglycaemia. This can be determined by blood glucose reading recorded as <4mmol.

An inclusion and exclusion criteria will then be applied to all potential participants as described below:

Inclusion Criteria:

²¹ DF, who is a staff member of SAS will be identifying participants. Approval has been granted for this purpose from the SAS Caldicott Guardian and data protection lead. DF is a state registered paramedic a must adhere to regulations laid down by the Health Professions Council with respect to patient confidentiality. The Scottish Ambulance Service complies with NHS and Data Protection Laws.

- 1) Patients with Type I or II diabetes.
- 2) Have required assistance from the Scottish Ambulance Service for hypoglycaemia defined as blood glucose , <4mmol/l.
- 3) ≥16 years of age.
- 4) had a recent (within 3 months) diabetic hypoglycaemic emergency;

Exclusion criteria:

- 1) All individuals aged below 16 years of age (current Scottish Ambulance Service Policy/Guidelines do not authorised ambulance clinicians to Treat and Refer this age group)
- 2) Where patients have communication difficulties and cannot communicate.²²

Stratification of sample

The remaining potential participants will be stratified to ensure we identify the full range of salient issues. Our sample will include people who belong to groups that are likely to have different experiences and attitudes relating to diabetes care. The following will all be represented: men/women; people with Type I/people with Type II diabetes; treated at home/taken to hospital; people aged under 65/people aged 65 and older.

Randomly select approximately 5 participants from the following age groups:

- 16-25 (2 males/3 females)
- 26-35 (3 males/2 females)
- 36-45 (2 males/3 females)
- 46-55 (3 males/2 females)
- 56-65 (2 males/3 females)
- ≥ 66 (3 males/2 females)

Recruitment and process of obtaining written consent

Potential participants will be contacted via telephone within 7 days of their hypoglycaemic emergency. They will then be invited to participate in the study. If they agree

²² We are unable to ensure inclusion of people from a variety of ethnic cultural backgrounds as this information is not routinely gathered. However participants who speak little English will not be excluded, interpretation service will be offered to ensure representation.

- I. Send a written cover letter, study information sheet and consent form to those who express interest and invite to return confirmation and completed consent form indicating that they are willing to be contacted by a member of the research team to arrange an interview to discuss their hypoglycaemic emergency, the care they received and the ways in which follow-up care might be improved in the future.
- II. If no response is received send reminder pack at 2 weeks.
- III. Contact the participant by telephone to arrange the interviews at mutually agreeable location.
- IV. Send confirmation letter with date, time and location.
- V. Send letter to GP to confirm patient's participation.

Telephone Protocol

Potential participant called via telephone.

Example introduction:

'good afternoon Mr/Mrs/Miss..... my name is, I'm a Clinical Research Paramedic employed by the Scottish Ambulance Service. I wondered if you would be able to spare a few moments to discuss a research study which we are currently undertaking which involves patients who have recently had a hypoglycaemic event and required ambulance service assistance.

We have contacted you as our record show that you have recently had a hypoglycaemic event and required assistance from the Scottish Ambulance Service. I am phoning about a research study which aims to improve the follow-up care given to people who have had a diabetic hypoglycaemic emergency and treated at home by ambulance clinicians.

You are under no obligation to take part but I'd like to ask if you would you be happy to receive documentation which includes information on the study (a cover letter, information sheet and consent form should you decide to take part).

Contact details are provided on the information sheet should you wish to discuss any aspects of your participation.

Thank you for your time.

Conducting interviews

The interviews will be conducted in a conversational style and should last no more than an hour. They will be supported by a topic guide to ensure key issues are covered regarding the

emergency event, attendance by ambulance clinicians, consequent actions taken by the participant and issues relating to follow-up care. The interviews will be digitally recorded and transcribed verbatim. Interviews will be conducted in a mutually agreeable location.

When interviews are conducted in a participants home the researcher undertaking the interview will ensure a telephone call is made to the principle investigator immediately prior to and after interviews. This will ensure researchers are 'clocked in' and 'clocked out' and their location is known at all times. If no call is received by the principle investigator, he will call the research assistant. If no response is attained after the two calls the principle investigator will call the police and raise his concerns to ensure their safety.

Consent

Prior to interview the participant will again be asked if they have any questions with regards to the study. The interviewer should emphasise that the participant is free to withdraw at any time.

Interview analysis

A thematic content analysis will be conducted in the following manner:

- a) After familiarisation with five interview transcripts, three members of the research team (DF, ED & VE) will develop a preliminary coding scheme to organise the data according to domains of interest. This coding scheme will then be applied to two interviews, checked with other members of the research team and refined as necessary before being systematically applied to the other interview/transcripts.
- b) The coding scheme will then be systematically applied to the remaining interviews/transcripts by the research assistant.
- c) For each domain of interest, summary charts will be used to record the relevant experiences/beliefs/attitudes/behaviours etc. expressed by each individual. These will facilitate both within case and across case analysis.
- d) Analysis will be particularly focused on identifying the range of factors that need to be addressed to encourage and enable patients to attend for and receive appropriate follow-up.
- e) Attention will also be paid to the language that participants use, and this will inform the development of the intervention.

Research Governance

All electronic data will be stored on a password protected hard drive based at the Nursing Midwifery and Allied Health Professions Research Unit (NMAHP RU), University of Stirling. All paper based data or personal information will be stored in a locked, metal cabinet in the NMAHP RU. Personal details will only be made available to DF (SAS employee and Clinical Research Paramedic). These will be held separately in another locked metal cabinet.

Timetable

Tasks	Months											
	Se	Oc	No	De	Ja	Fe	Ma	Ap	Ma	Ju	Ju	Au
Year 1 (Sep 2009-Aug 2010)												
R&D approval	x											
Baseline data collection from SCI-DC & ACC	x	x	x	x	x	x						
Conduct exploratory patient interviews			x	x	x	x	x	x				
Analysis of patient interviews			x	x	x	x	x	x	x	x	x	x
Intervention development											x	
Stakeholder group meetings												x

Costs

To complete objective 1: Costs of travel to conduct the in-depth interviews. These costs have been calculated on the basis of 30 * 68 miles (return journeys) between the University of Stirling and Hamilton (a large town in central Lanarkshire). Employment costs are sought for a research assistant (RA) (Grade 7) for 18 hours/week for 8 months to conduct the interviews and participate their analysis. A RA is required so that participants feel free to talk to an independent (ie. non SAS) person about their experiences and ideas regarding the proposed intervention. Support is requested for stationary (100 original invitations and 100 reminders) to recruit participants as follows:- 200 study information leaflets and consent forms; 200 A5 windowless envelopes; 200 pre-paid envelopes; and 2nd class postage for questionnaires and reminders; Costs are requested for the transcription of 30 interviews each lasting approximately one hour, and for £10 gift vouchers for 30 participants with diabetes representing reimbursement for their time and inconvenience.

APPENDIX 10: TELEPHONE PROTOCOL

Telephone Protocol

Example phone call script for initial contact phone call:

'good afternoon Mr/Mrs/Miss..... my name is, I'm a Clinical Research Paramedic employed by the Scottish Ambulance Service. I wondered if you would be able to spare a few moments to let me tell you about a research study which we are currently undertaking which involves patients who have recently had a hypoglycaemic event and required ambulance service assistance.

We have contacted you as our records show that you have recently had a hypoglycaemic event and required assistance from the Scottish Ambulance Service. Our research study is very interested in the experiences of people who have recently had a diabetic hypoglycaemic emergency and treated by ambulance clinicians. You are under no obligation to take part but I'd like to ask if you would you be happy to receive documentation which includes information on the study (a cover letter, information sheet and consent form should you decide to take part) so that you can read more about it and see if you would be happy to participate.

Contact details are provided on the information sheet should you wish to discuss any aspects of the study further. Thank you for your time.'



Nursing,
Midwifery
and Allied
Health

Investigating patients experiences of hypoglycaemic emergencies

Participant Information Sheet

Invitation

You have been invited to take part in a research study about the emergency care you received for your hypoglycaemic event. Before you decide whether to take part it is important you understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If you wish to take part in the study can you please respond within two weeks.

Background to the study

The Scottish Ambulance Service responds to over 3000 emergency calls for hypoglycaemia each year with almost 2500 of these patients being left at home after the event. Many of these patients go on to have another hypoglycaemic event in the hours, weeks and months after the initial event. Patients who are left at home should be advised to attend their usual diabetic care provider as soon as possible. This information is not always given, and few patients follow-up their care when advised. This suggests that many people are missing out on reviews of their diabetes management that might help prevent future emergencies. Any hypoglycaemic event places a patient at risk of becoming unconscious which can ultimately lead to far more serious consequences, so it is vital that patient's receive appropriate follow-up care to ensure treatments are up-to-date. This study is the first in a series of studies that aim to increase the number of people who follow-up their care after a hypoglycaemic emergency.

Who is funding this study?

The study is being funded by Diabetes UK and is being undertaken by researchers from the Universities of Stirling, Dundee and Edinburgh, and the Scottish Ambulance Service.

Why have I been invited?

Scottish Ambulance Service records show that you have recently required assistance for a hypoglycaemic event. We would like to ask for your help as we want to know about what it is like to have a hypoglycaemic emergency, what your experience of being attended by ambulance clinicians is, and what sort of information you would find useful to have been given. We believe that the patient's perspective is essential in the development of any intervention and it is for this reason that you have been approached.

Interpretation services can be offered to promote inclusion of people who speak little English.

Do I have to take part?

You are under no obligation to take part in this study. By not responding to this letter and any reminders you may receive we will know that you have declined. You are free to withdraw from this study at any time. Should you decline to participate or choose to withdraw this will not have any implications on your standard treatment.

What am I being asked to do if I decide to participate?

You are being asked to take part in a face-to-face interview where you will be asked questions about your recent hypoglycaemic event, the care you received, and the ways in which follow-up care might be improved in the future. The interview will be digitally recorded and will last no longer than one hour and will take place in a mutually agreed location.

Will my participation in this study be kept confidential?

All information will only be viewed by authorised individuals within the research team. No identifiable information will be produced in any of the study reports, papers or other outputs. All information will be treated as confidential and stored securely at the NMAHP Research Unit, University of Stirling in accordance with data protection laws. Data will be retained for a period of 10 years and may be accessed for use in future studies, thereafter it will be disposed off securely. We will notify your doctor in writing that you are taking part in this study, no other information will be provided. If you would rather we

didn't notify your doctor then please acknowledge this by ticking the appropriate box in the accompanying consent form.

Ethics

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by a Research Ethics Committee.

What should I do now?

If after reading this information sheet you decide you would like to participate in this study please complete the enclosed consent form, place it in the, pre-paid addressed envelope and return it **within 2 weeks of receipt of this letter** (or future reminder). Once we have received your completed consent form you will be contacted by a member of the research team to arrange an interview. A mutually agreed location and time will be organised and you will receive travelling expenses where appropriate.

Diabetes UK (Scotland) offer counselling services and advice to patients with diabetes via a care line. They have agreed be a contact point for participants in the study for any support required. The contact telephone number is: 0845 120 2960 or e-mail: carelinescotland@diabetes.org.uk

APPENDIX 12: PARTICIPANT CONSENT FORM



Investigating patients' experiences of hypoglycaemic emergencies.

Participant Consent Form

Please initial box

1. I confirm that I have read and understand the information sheet coded (PI_sheet_v2_01/12/2009) for the above study

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. Should you decline to participate or choose to withdraw this will not have any implications on your standard treatment.

3. I consent/do not consent to my GP being informed of my participation in this study.

4. I agree/do not agree to this interview being audio recorded.

5. I agree to take part in the above study

Name of participant

Date

Signature

Researcher

Date

Signature

1 for researcher; 1 for participant



**Nursing,
Midwifery
and Allied
Health
Professions
Research
Unit**

Investigating patient's experiences of hypoglycaemic emergencies.

GP Consent Form

Please initial box

I confirm that I am happy for you to send a letter to my General Practitioner informing them that I have agreed to participate in the above study.

Name of participant

Date

Signature

Researcher

Date

Signature

1 for researcher; 1 for participant

APPENDIX 14: GP LETTER

Ref: Investigating patients experiences of hypoglycaemic emergencies

Dear Dr....

Re: (Patients name, D.O.B. and address)

We are undertaking a research study which aims to improve the follow-up care given to patients with diabetes who have had a hypoglycaemic emergency and are treated at home by ambulance clinicians. The study is being funded by Diabetes UK and is being undertaken by researchers from the University of Stirling, Dundee, Edinburgh and the Scottish Ambulance Service. The study has been given Research Ethics Committee approval (insert ethics approval number here).

As part of this study we required to contact patients with diabetes who have recently required ambulance service assistance for a hypoglycaemic emergency. Patients were invited to take part in face to face interviews where we asked them about their recent hypoglycaemic event, the care they received and the way in which follow-up care may be improved in the future.

As the above patient General Practitioner we are informing you they have agreed to take part in this study. Consent was provided prior to sending you this letter.

If you should have any questions in relation to this study please do not hesitate to contact me.

Yours sincerely

**Topic guide – Investigating patients experiences of
hypoglycaemic emergencies**

About this guide

This guide is intended to help ensure that the key topics are covered in all interviews. Each interview will be conducted in a conversational style, and the wording and order of questions about these topics will vary depending on what the respondents say and how.

A few illustrative ‘opener’ questions are included here, but these are not fixed scripts. Researchers will use careful ‘probe’ questions to ask (for example) for clarification, further details, illustrative examples or contrasting experiences to help gain an in-depth understanding of participants’ views.

This guide may be annotated or edited by research team after reflection on practice, pilot and early interviews to ensure it facilitates good coverage of the key issues for women and health care staff.

Interview Topics

Pre Interview

- Got info OK? – any questions
- Anon and Confidential
- Not affect care – not contact with Health Prof
- Consent Form
- Recording – are you happy?
- Time schedule – stop/ break

Diabetes

I'm coming as a follow-up to your recent hypoglycaemic event.

- Would you start my telling me a bit about your diabetes and how you manage it?
- How does it affect your life?
- What about your health care professionals? (Who do you see about your diabetes? How do you get on with them? How supportive do you feel they are?)
- How do you usually control your diabetes?
- How well do you feel you control your diabetes?
- What are the main issues for you in managing your diabetes? (ie things you need to do and things you have difficulty with)
- How does that compare with how your diabetes care providers think about how you control your diabetes?

Hypoglycaemia

- What about hypoglycaemic attacks?

- What is your general experience of hypoglycaemic emergencies?
- Can you clarify for me how, if at all, they vary in severity? (Mild, moderate, severe. Severe = requiring external assistance)
- Can you talk me through the hypoglycaemic emergency which led to the SAS callout?
- When, where what time? (index attack)
- Is this the usual pattern ? (range of severity; frequency; details of other severe attacks)
- Do you get any warning/signs/symptoms? What are the signs/symptoms you get when you are becoming hypoglycaemic?
- To what extent and how do your family/friends know when you are becoming hypoglycaemic?
- After a hypoglycaemic attack do you usually know why they happened? Would you talk me through what you remember or what you remember being told and by whom after your most recent hypoglycaemic attack?
- How do you treat a hypo? (Mild? Moderate?)
- What kinds of discussions have you had with any of your diabetes care providers about hypos in particular?
 - What triggered the discussions?
 - How helpful were they?
 - [Check] have you ever spoken to one of your diabetes care providers after having had a hypo? How did they respond? Some people have told us that health professionals have been negatively judgemental when they've told them about having hypos. Have you ever felt that way? [If yes, can you tell me about it?]

Education

- Can you tell me *how* you've learned what you know about your diabetes and how to manage it?
- What
- By whom

- Up dated
- How easy do you find it to discuss any issues you have with the management of your diabetes with your [diabetes care providers]?

Emergency services

- You mentioned that your friend/family called the ambulance. Would you tell me what, if anything, you remember about the way the emergency services treated you? How did you feel about it?
- When/if you were left at home – how did you feel about that?
- When/if you were taken to hospital – how did you feel about that?
- What happened in hospital ?
- Which would you prefer? Why?

Information – what, if any, information were you given from emergency services/ hospital about –

- Your hypoglycaemic attack
- About follow-up
- Was this information given to you or other
- Was it in writing or verbal

What, if anything, did you think was good about the information; what was less good? Was there any other information that you would have found helpful?

After recovery (Index attack)

- How did you feel
 - Physically/Mentally
 - About your treatment
 - Rebound hyper/hypo? Effect on control
 - About information given
- What did you do
 - Physically
 - About follow-up
 - With whom
 - By phone/App

- What do you tell/ discuss with your healthcare provider
- How easy was it to access follow-up
- What did you family/friend do/say?
 - That you are like
 - About the treatment

How do you see the roles of the ambulance staff fit in with or compare with the roles of your usual diabetes care providers?

Intervention – explain about study – normally if left at home given general diabetic leaflet and very general medical info

What do you think about the idea of a card and follow-up phone call ?

Written information

- Like/ dislike
- What would you like to see included/excluded
- Treatment + blood sugar – before/after
- Asking to think about what might have caused the attack – how did you feel – were there any signs that you might recognise that you are going hypoglycaemic
- Issues connected with driving
- Size
- Phone number – Diabetes UK/DNS – general or specific
- Mock cards

Phone Call

- Like/Dislike
- When/where – how many days/time of day
- Would you like paramedic to phone your health care provider for you

Follow-Up

- Would you talk me through what you remember or what you remember being told and by whom after a hypoglycaemic attack?
 - With whom

- What would make it easier
- Barriers
- Transport - SAS can arrange

APPENDIX 16: MAIN THEMES

Demographics (brown)

ID No	Age/Gender Employment	Living Arrangements (who is in house, works with/helps with/affected by/need to be considered in relation to the person's diabetes, esp hypos)	Notes about interview (interviewee, length)

Diabetes background (light green)

ID No	Type	Age when diagnosed (time since diag) Depcat	Usual strategies for diabetes control	Perception of control	Any issues in relation to control? Including pressure by patient on self to control BMs	Affect on life

Diabetes Care Providers (dark green)

ID No + Preferred Diabetic care provider	Frequency/Relationship/Pressure re Hba1c/content of communication /Primacy of contact		
	Secondary Care	Primary care	Other

Education about diabetes (light blue)

ID No	Education received around diagnosis	Education received subsequently	Education received by family	Perceived gaps in education / comments about what would like to learn about (patient)	Perceived gaps in education / comments about what would like to learn about (family)

Hypos (dark blue)

ID No	Warning Signs	Predisp Factors/Causes?	Kinds of Hypos	Aftermath of hypos (how they feel)	Thoughts/Feelings about hypos (pt & family)

Treatment of hypos and attitude (purple)

ID No	Self treatment	Partner treatment/other involved in day to day care	Thoughts/Feelings about self/family management

Call-outs & experience of SAS (Red)

ID No	Frequency & threshold for call-out + reasons	Experiences of service + “What you got”	Hospital/Home + preference	Info/educ from hospital /SAS + “What you got told you got”	Self management post SAS departure	Perceived link between SAS/DNS/GP

FU after SAS call-out hypos (Pink)

ID No	Has the participant been recommended by any healthcare provider that they should go for follow-up following hypos. Including family	Participants attitude towards idea of going for follow-up (whether suggested by a hcp and/or by the research interviewer)	Experience of going for FU with usual DCP post hypo if went	Families’ attitude towards idea of going for FU

Interventions (indicate if question prompted) (Orange)

ID No	Card			Phonecall		Other suggestions – other than relating to FU
	Feelings/perception	Info (about FU)	SIZE	Feelings and perception	Time scale	

Any Other Comments (Yellow)

ID No					

APPENDIX 17: SUB THEMES EXAMPLE

I.D.	Patients wishes	Partners wishes/conflict?	Ambulance clinicians wishes	Reason for staying at home	Experience of care in hospital
33	Won't go to hosp (p.21) Been once (p.21) (33)	Not discussed	Not discussed	Not discussed	"I was only there two hours and I was back home again."(pg.21) "They said to me the ambulance crew brought me round, and it was a waste of time sitting there." (pg 21)
52	Sometimes taken to hosp (index P.13) so sometimes I prefer to be in the house.(pg.29)	Sometimes taken to hosp – partner not happy with GP's care (index P.13) Aye she doesn't like going to hospital but sometimes she needs to if I can't get her round quick enough. (pg.29)	If you can't get dealt with in the house, you have to come to the hospital; (pg.31)	but in the house, like if I'm not feeling well I could even be lying on the couch and I can turn round and say to [Partner], go and make me a wee cup of tea or... But in the hospital you've got to wait till your certain times and...know what I mean like, so sometimes I prefer to be in the house. (pg.29)	General comment not specifically related to hypo. "I started getting angry and all the rest of it, because okay, they're busy and it's an admission ward you're getting taken into, but I lay...I was left there, I had no medication, I didn't even have a cover, I didn't even have a drink of water, for hours and hours..... Absolutely awful". (pg.14) Pt comments that they don't even check your bloods when you are in (p.17) (55)
60	prefers to stay to stay at home (p.18) (60) Taken to hosp once, generally left at home (p.18) (60)	Not discussed	"they give me the option, do I want to stay here or go to hospital, but I always just stay here to be perfectly honest with you, but they do give me the option". (pg 18)	I prefer just to stay here. (pg.18)	Not discussed
71	Didn't want to go into hospital (p.11) (71)	Not discussed	The folk wouldn't leave her "they things on her chest – they done all the stuff to her here – no they	Not discussed	Hospital gave her a sweetie and then left her – "they were very busy" (p.12) (71)

I.D.	Patients wishes	Partners wishes/conflict?	Ambulance clinicians wishes	Reason for staying at home	Experience of care in hospital
	Hospital gave her a sweetie and then left her – “they were very busy” (p.12) (71)		were great” Couldn’t get her blood up either (pg.12)		See how she went and then came back, they got her up to 6 something (pg.12)
74	Doesn’t like going to hospital (p.25) (74) Went to hospital – came round in hospital (contracts later) (p.7,8) Generally take her to hospital –(p.23) (74)	Partner would like her to go (partner (p.31) (74)	“But sure they really do take me to the hospital they keep saying I need to take you to hospital, I need to, I don’t want to go, I don’t want to go, I keep saying I don’t want to go, but they say listen you’re going to make yourself better if you go in”. (pg.26)	Generally take her to hospital –(p.23) (74) I don’t like hospital dinners.”(pg.27)	“I keep just giving into them and going.” (pg.27) “But sometimes when I go they keep me in for days and days and I don’t like it. I don’t like hospital dinners.”(pg.27)
75	Home – always prefers to stay home “I’d always prefer to stay at home under any circumstances.” (p.6) (75)	Partner (p.19) Wife also happy staying at home “I was happy because by the time the paramedics left he looked although he was coming... he looked completely different after that.” (p.6) Partner felt that for newer pt with diabetes it would be good to take them to hospital (75)	Not discussed	Pt doesn’t like going to hosp because they want to take insulin away from him and he loses control (partner) (p.24) Bad experiences (p.24) (75)	Not spoken about post hypo
114	Pt didn’t want to go but sister & paras persuaded him (p.10) (114) Went to hospital (p.10) Pt didn’t want to go but sister & paras persuaded him (p.10) (can’t find this in 74 or 75 or 114)	Sister prefers he goes to hospital – in case he has another one – didn’t realise what was happening – might fall on the floor & she couldn’t get him up (p.16) (114) Pt didn’t want to go but sister & paras persuaded him (p.10) (can’t find this in 74 or 75 or 114)	Pt didn’t want to go but sister & paras persuaded him (p.10) (114) If paras are happy for him to stay sister trusts them (p.17) (114)	Not discussed	Pt thought it was a waste of time (p.10) (114) “No he was let back out after ten o’clock at night. But if he was on his own he would have to stay in for the twenty four hours” (pg.11)
119	Much prefers to stay at home (119)	Much prefers to stay at home – as does wife (p.22)	the last time I was actually asked and I said no very forcefully (pg.22)	Feels he is better off at home because of difficulty in being allowed	I think it was about twelve hours until I responded, they had three glucose

I.D.	Patients wishes	Partners wishes/conflict?	Ambulance clinicians wishes	Reason for staying at home	Experience of care in hospital
	<p>Stayed at home (p.21) Only once been taken to hosp. 9 (119)</p> <p>kind of in general terms my wife would prefer that I was staying at home and I would prefer that I was staying at home. (22) (119)</p>	(119)		<p>to administer own insulin (p.22) – also vegan (p.23) (119)</p> <p>“as far as I’m concerned it’s not a hospitalisable thing or there are cases I’m sure it can be, but I only have experience of one of those” (pg.22)</p>	bags and I didn’t respond. (pg.22)
120	<p>Didn’t want to go to hospital (p.22x2) – but admits he maybe should go (p.22) (120)</p>	<p>Wife concerned that he could fall back into hypo after SAS leave – feels husband doesn’t understand that (wife) (p.3)</p> <p>Wife likes him to get checked out when the hypos has gone on longer (wife) (p.4)</p> <p>Wife wants him to go to hospital after hypo to get checked out – but pt won’t go(wife) (p.26) (120)</p>	<p>Paras want to take him but he doesn’t want to go (wife) (p.3) (120) “They’ll say to me, ‘Do you want to come up to hospital?’ pg.22)</p>	<p>And, honestly, I don’t want to go up to hospital, you know, maybe I should (pg.22)</p>	
124	<p>– pt didn’t want to go (wife)(p.5) (124)</p> <p>One time taken in to hospital (p.10). Only refused twice to go to hospital – because he thought he was coming out of it (p.12)</p>	Not discussed	<p>Paras wanted to take him Paras understand why he didn’t want to go (wife) (p.5) (124)</p> <p>No. Have got him to sign...well, they’ve got this thing now that you just press your finger, to sign to say that he didn’t want to go into hospital, that they’d offered.</p>	<p>Had had to wait 3 hours last time at hospital (wife) (p.5) Wife also happy with him being left at home – because he was coming out of it (wife) (p.12)</p> <p>If they take him to hospital they just bring him round & send him home (wife) (p14) (124)</p>	Not discussed
133	<p>Prefers to stay at home (133)</p> <p>Generally stays at home -</p>	Not discussed	<p>they gave me all the paperwork and recommended an appointment with my GP which one of them already,</p>	<p>doesn’t want to use hospital “for something that stupid” (p.42)</p> <p>Rather be at home to recover</p>	Not discussed

I.D.	Patients wishes	Partners wishes/conflict?	Ambulance clinicians wishes	Reason for staying at home	Experience of care in hospital
	hospitalised twice in teens (p.42) (133)		already set up and... (pg.16)	emotionally and physically (p.43) (133)	
146	<p>Glad that now he doesn't have to go to hospital – do always give option (p.13)</p> <p>Gave him option of hospital – hasn't been for couple of years because he feels fine (p.18) (146)</p>	Not discussed	<p>Glad that now he doesn't have to go to hospital – do always give option (p.14) (146)</p> <p>I'm probably not there, it's probably [wife] that deals with it. (pg.14)</p>	Pt feels that he can't earn anything new by going to the hospital (p.19/20) Prefers to stay at home because not taking up paras & Drs time (p.21) (146)	I haven't been to the hospital for a while now. There's not really much difference. Because before and now I was treated for the shortage of sugar before...I mean, I wasn't taken to hospital as a one, I was sorted out and then taken to hospital. (pg.21)
162	Went once – only checked blood & BP & said to go to consultant – let out when still sweating – had to make his own way home – so will ever go again (p.12) (162)	Not discussed	They've asked him loads of times to go to the hospital but he'll no go to the hospital [wife]. (pg.12)	Went once – only checked blood & BP & said to go to consultant – let out when still sweating – had to make his own way home – so will ever go again (p.12) (162)	Either that or they take you up and get admitted and then the doctors, the A and E doctors. (pg.15)
165	<p>Doesn't want to go – no point. Happier to be left at home, doesn't see need for hospital (165)</p> <p>Always stays at home (p.6,N12FK) (165)</p>	wife would like him to go (N12FK) He felt fine although partner suggested she would have been happier if he's gone to hospital (after recorder switched off) (N21DF) (165)	Left at home with verbal advice to follow-up with GP (pg.6) and notes DF	Happier to be left at home, doesn't see need for hospital, just discharged two three hours later. (N23DF) (165)	Remained at home
179	Asked if wanted to go to hospital but said he preferred to stay as he was fine by then (p.12) (179)	Wife died 3 years earlier	<p>Asked if wanted to go to hospital but said he preferred to stay as he was fine by then (p.12) (179)</p> <p>“we need to ask you this, are you wanting us to take you into hospital?” And I was like, that, no, I says, I'll be</p>	Not discussed	Not discussed

I.D.	Patients wishes	Partners wishes/conflict?	Ambulance clinicians wishes	Reason for staying at home	Experience of care in hospital
			fine now. (pg.12)		
187	Always goes to hospital – his choice – just to be on the safe side (p.12,p.22) (187)	"[about sons] I know they get frightened so I try to kid on, I say away up the stair I'm all right now and I sit here hoping for an ambulance to come" (pg.16)	Not discussed		"Up at the Western. Once I was on the drips and that got it levelled out. I said I can't, anytime this happens to me it seem to be always ten to fourteen days they keep me in for some reason"(pg.10)
221	"I prefer home" (pg 19, 21) (221)	Lives on own	Go down to the GP. (pg.19)	"I said, 'I don't need to go" (pg 24) Patient feels "There's somebody worse than me son, just get me out of the coma and then be away" (pg 19,21) (221) "Oh home...no son, I prefer home...I tell the ambulance men, 'There's somebody worse than me son, just get me out of the coma and then be away,' oh no, I never liked... hospitals, son."(pg.19)	I'm better at home, I can treat myself. In the Monklands you just lie there and you'll do what they tell you, and as I say, that's nothing. (pg.19)
222	prefers to be left at home (222)	Lives on own	"They asked me, and I said no. So I had to sign a form." (pg.15)	Manages herself "much better" at home (pg 15*) prefers to be left at home (pg 16, 19**) " <i>because they don't know how to treat you in hospital with diabetes</i> " (pg 16*, 19*) If general nursing staff were like DNS then would be happy to go into hospital post hypo (pg 21*) (222)	"But I was only in a couple of days....Well they just said they would review my insulin.....Because it was a bad hypo.."(pg.17) No follow-up with GP (pg18)

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237	Happy at being left at home (pg 17) (237)	Husband likes her to go into hospital (pg 17) (237) The fact that husband wants her to go in but she wants to stay at home makes her feel "angry" (pg 17/18) If there's a need for her to go in to hospital then she will (pg 20) (237)	"They had said to me, go down to the Victoria and get checked out, but I knew myself I was okay. Once my blood sugar's up I'm all right." (pg.15)	If there's a need for her to go in to hospital then she will (pg 20) (237)	"Only once, and the only reason I was taken to hospital was I couldn't stop shivering, I was frozen, absolutely frozen. It was that bad, that when I got to the Victoria they were going to give me a Cozy thing?" "I got home after a couple of hours." (pg18)
242	No – preferred to stay at home (p.20) (242)(Absolutely not in hospital because they do admit you to hospital when you're diabetic control anyway. We always have a bit of a discussion about it. (pg.6b)	Not discussed	Not discussed	Absolutely doesn't like being taken to hospital because feels they would admit her (p.6b) (242)	"they do admit you to hospital when you're diabetic control anyway. "(pg.6b)
249	Would rather stay in house (pg 30) (249)	Not discussed	"he says is this the first, and I went no, I said, this has happened quite regularly, and he went like that, well go to that (GP's name) tomorrow morning and just tell her...well, the receptionist, and just tell them you need to see Helen tomorrow morning." (pg.29)	Concerned about cost of ambulance call-out (pg 30) (249) but the money that it's taken for an ambulance to come here and then I'm not going in it...(pg 30)	Never taken to hospital post hypo
270	Prefers to remain at home. (270) Never taken to hospital after a hypo (pg 19) (270)	Not discussed	"[paramedics] can deal with it without having to take me to hospital or suggest it. This one, this last time, that was the first time where I was, shall we say, asked repeatedly, do you not want to go to hospital? " (pg.10)	Hospital food, experience of lack of choice, has an impact on his wish to remain at home. (pg 19) Feels he may sit there " <i>slightly bored out of my skull</i> " and would " <i>be occupying a bed that I didn't need to</i> "	Never taken in post hypo (pg.

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				(pg 20) (270)	
274	<p>Feel safer going to hosp (274)</p> <p>Taken to hospital (p.32) Feel safer going to hosp – because “never been in for anything mild” (p.34) – feels good that she has people who can sort the problem for her (p.35) (274)</p>	Not discussed	Transported to hospital (pg.34)	<p>Feel safer going to hosp – because “never been in for anything mild” (p.34) – feels good that she has people who can sort the problem for her (p.34) (274)</p>	<p>“I was having a drink of Lucozade and all sorts of thingsthey kept me in one of those wee partition rooms..... kept me there to see how I was getting on..... I was there a good few hours anyway..... I just came home, you know”(pg.34)</p> <p>No follow-up care arranged...daughter phoned DNS the next day (pg.35)</p>
303	<p>Didn't get taken to hospital as participant wanted to stay at home (pg 20) (303). If it happens again “<i>I would rather go into hospital</i>” (pg 31) (pg 20) Preference appears to have been influenced by need to look after husband before he died (pg 31, 38)(303)</p>	n/a	<p>Doesn't recall signing any forms (pg21) or being left any information (pg 35) (303)</p> <p>“Are you sure you don't want to get moved, no I'm no wanting to move, you know. (pg.19)</p> <p>[paramedics said] “Well if we don't move this we'll have to take you, if we can't get it moved” (pg.19)</p>	<p>“<i>I would rather go to hospital.....Or treated at home. Cause the, everyone treats me at home</i>” (pg 32) (303)</p>	Only had one hypo and left at home.
323	<p>Prefer to be taken home. left at home (pg 20). Didn't want to go but would have if ambulance crew had wanted him to (pg 18). Would not like to be taken to hospital for “mild ones” (pg 21) (323)</p> <p>If I was feeling alright [inaudible 27:28] to be lying in hospital if I was feeling fine. (pg.20)</p>	After second hypo neither Mum or girlfriend mentioned getting follow-up (pg.20)	I think they did ask me that [if he wanted to go to hospital] but I didn't want to go, and then they said if nobody's in we'll need to take you up. (pg.18)	Felt fine about being left at home (pg 18) (323)	

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328	They make sure she is all right and they ask her, do you want to go to the hospital and that and if she says no, she will sign the thing and that and they make sure she is all right,(pg.20)	Not discussed	They make sure she is all right and they ask her, do you want to go to the hospital and that and if she says no, she will sign the thing and that and they make sure she is all right,(pg.20)	Not discussed	Not discussed