Use of insulin pumps by children and young people in the management of type 1 diabetes mellitus

Thesis submitted with the requirements of the University of London for the degree of Doctor of Philosophy by

Fatemah Mohammad Alsaleh

Department of Practice and Policy
The School of Pharmacy
University of London

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PLAGIARISM STATEMENT

This thesis describes research conducted in the School of Pharmacy, University of London between March 2007 and January 2010 under the supervision of Professor Felicity Smith and Professor Kevin Taylor. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publication.

Signature

27-06-2011

Date

To my parents,

For loving me unconditionally and helping me to make this dream a reality…

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Dedicated with love to All who have supported me

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Abstract

Background

Insulin pump therapy or continuous subcutaneous insulin infusion (CSII) was introduced in the UK in the 1970s as a method for achieving strict control of blood glucose concentrations in people with type 1 diabetes mellitus (T1DM). The advancements of medical technology over the years and the research documenting clinical effectiveness have led to the worldwide growth of pump therapy. In the UK, the use of CSII in children is limited and there is little evidence regarding how the management of the condition on their life and that of their families is compared with the injection therapy.

Aim

To describe the experiences of children using CSII and, their parents, including glycaemic control, use of pump technology and flexibility in lifestyle for children of different ages and durations of pump therapy.

Methods

The study was conducted in the Paediatric Diabetes Clinic at University College Hospital (UCH), London. All patients (N=42) using insulin pumps, and their parents, were invited to participate. Semi-structured interviews were conducted with parents of all children, and children aged 5 years or older. Measures of glycated haemoglobin A1c (HbA1c) values from 6 months prior to, and after pump therapy were also obtained from medical records. Quantitative analysis of structured data was undertaken using the Statistical Package for the Social Sciences (SPSS). Qualitative data were analysed by an iterative process employing a constant comparative approach.

Results

Both the parents and the children found it easier to maintain glycaemic control within their target range with insulin pumps compared to injections. This was supported by HbA1c measures and the reported frequency and severity of hypoglycaemic episodes. Whilst participants generally found the device itself easy to use and more acceptable than injections from the start, variable lengths of time were required to develop

confidence in carbohydrate counting and dose calculation. Parents and children reported an overall increase in flexibility in lifestyle and their ability to participate in daily activities. This was attributed to more flexible eating patterns and diabetes control, and was manifested by more normal lives at home and schools, and improved socialisation.

Conclusion

Parents and children using insulin pumps found it easier to lead normal lives by being able to maintain glycaemic control and accommodate a more flexible lifestyle, which is a central goal of health policy for children and young people in the UK.

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List of abbreviations

ADA	American Diabetes Association
BG	Blood glucose
BMI	Body mass index
C	Children and young people
Carb	Carbohydrate
CGMS	Continuous glucose monitoring system
CI	Confidence interval
CIT	Conventional insulin therapy
CSII	Continuous subcutaneous insulin infusion
DCCT	Diabetes Control and Complications Trial study
DQOL	Diabetes quality of life measure
DKA	Diabetic ketoacidosis
DNA	Deoxyribonucleic acid
DSME	Diabetes self-management education
DSN	Diabetes specialist nurse
EDIC	Epidemiology of Diabetes Interventions and Complications study
FDA	Food and Drug Administration
FPG	Fasting plasma glucose
HbA1c	Glycated haemoglobin A1c
HBGM	Home blood glucose monitoring
Hypo	Hypoglycaemia
IFG	Impaired fasting glycaemia
IGT	Impaired glucose tolerance
IOB	Insulin on board
IPA	International Pharmaceutical Abstracts
JDRF	Juvenile Diabetes Research Foundation
LEA	Local Education Authority
LSA	Learning support assistant
Maths	Mathematics
MDI	Multiple daily injection
MRI	Magnetic resonance imaging radiation

MSII	Multiple subcutaneous insulin injection
N.A	Information was not available
NeLM	National electronic Library for Medicines
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPH	Neutral Protamine Hagedorn
NPSA	National Patient Safety Agency
NSF	National Service Framework
OGTT	Oral glucose tolerance test
P	Parents
PCT	Primary care trust
PDA	Personal digital assistant
PDM	Personal diabetes manager
PE	Physical education
PG	Plasma glucose
RCT	Randomised controlled trial
RT	Real time
SD	Standard deviation
SEIQoL	The Schedule for the Evaluation of Individualized Quality of Life
SENs	Special educational needs
SF 36	36-Item short form survey
SH	Severe hypoglycaemia
SMBG	Self-monitoring of blood glucose
SPSS	Statistical Package for the Social Sciences
TA	Teaching assistant
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TU	Technosphere unit
U	Units
UCH	University College Hospital, London
u/hr	Unit per hour
UKPDS	UK Prospective Diabetes Study
Uni	University

VDC	Volts of direct current
WHO	World Health Organisation

Preface

Why use insulin pumps in paediatrics?

There is an overall increase in the incidence of type 1 diabetes mellitus (T1DM) in children and young people worldwide. In the UK, there has been both the highest number of children diagnosed with diabetes in Europe and the lowest number of children attaining good glycaemic control (Department of Health, 2007b). Over the past few years, advances in medical technology have made insulin pumps an attractive option for managing the condition in paediatric population. However, the overall users of insulin pumps in the UK comprise fewer than 5% of diabetic patients compared to the USA (35%) and other European countries (e.g. France, Sweden and the Netherlands) where 15-20% of diabetic patients are using insulin pumps (Pickup, 2009). This percentage is even lower (0.1%) in UK children and young people (Department of Health, 2007a). Recent government policy in the UK has emphasised that disease management for children and young people should endeavor to allow them, and their families, to lead normal lives (Department of Health, 2007c). To date, there is limited evidence from users' perspectives demonstrating the benefits and problems of using insulin pumps.

Overview of the project

The project is a study of the management of T1DM by children/young people who have been switched from multiple daily injections (MDIs) to insulin pump therapy. The study was conducted in collaboration with University College Hospital (UCH), London. Semi-structured interviews were conducted with children/young people and their parents, with data regarding glycated haemoglobin A1c (HbA1c) levels collected from medical records. The study aimed to examine the change of therapy in terms of clinical management, use of the technology and impact on daily home and school lives. This will reveal the perceived benefits, needs, and problems that arise in the context of pump therapy and will permit recommendations for future practice to be made. Qualitative and quantitative analytical approaches were employed.

Organisation of the thesis

The thesis is divided into several sections. The first section comprises the introduction which includes a review of the literature and ends with the aim and objectives of the study. The introduction is followed by a methodology section where the study design, sampling strategy, and data collection methods are described, together with the analytical procedures undertaken on the data. The characteristics of the sample and response rate are described in a separate section.

Results of the study are presented in 5 chapters **(Chapters 4 to 8)**, illustrating the findings on: 'glycaemic control and safety,' 'management at home,' 'management at school,' 'impact on family life' and 'perspectives on services provided by the hospital.' In the final chapter, the study findings are discussed in relation to the literature and policy implications.

CHAPTER 1 – Background

Chapter 1: Background

Chapter 1 provides a background for, and an introduction to, the research questions of this project. It is divided into 5 major sections, providing an overview of: diabetes mellitus, including T1DM in children and young people; insulin pump therapy and how this method of treatment was developed over the years; the literature search with regard to research concerning insulin pumps in children and young people and the aim and objectives of the study.

1.1 Overview of diabetes mellitus

Diabetes mellitus is defined by the World Health organisation (WHO) as 'a metabolic disorder of multiple aetiologies, which is characterised by a chronic elevation of blood glucose levels with concomitant disturbances in the metabolism of carbohydrates, fat and protein due to defects in insulin production, action, or both' (World Health Organisation, 1999). As a result of chronic elevation of blood glucose (hyperglycaemia), chronic damage or dysfunction of several organs occurs, mainly: the heart, kidneys, eyes, blood vessels and nerves.

The vast majority of cases of diabetes fall into 2 major categories: T1DM and type 2 diabetes mellitus (T2DM). T1DM, which is also described as juvenile-onset or ketosis-prone diabetes, is the most common type of diabetes in children and adults aged younger than 30 years, though it can occur at any age (Yarborough and Rodgers, 2001). Although most affected children have T1DM, this type of diabetes accounts for only 5-10% of all individuals diagnosed with diabetes (American Diabetes Association, 2010). T1DM is caused by a destruction of beta cells of the Islets of Langerhans in the pancreas elicited by an autoimmune reaction in the body, which usually results in absolute deficiency in insulin secretion. The rate of destruction of beta cells varies, being rapid in some (mainly infants and children) and slow in others (mainly adults). Patients diagnosed with T1DM are predisposed to ketoacidosis, due to the accumulation of ketone bodies resulting from the breakdown of fats in body tissues and fluids, and are dependent on insulin replacement for survival. Multiple genetic predispositions and environmental factors underlie the autoimmune destruction of the cells in the pancreas, however, the latter are still poorly defined. The presence of obesity is not incompatible with the diagnosis, though patients are rarely obese when they present with this type of diabetes. Patients diagnosed with T1DM are more susceptible to other autoimmune disorders, such as Graves' disease, Addison's disease and Hashimoto's thyroiditis.

T2DM is described as adult-onset diabetes as it is usually diagnosed in people aged greater than 30 years old. However, it can occur at any age (Yarborough and Rodgers, 2001). T2DM accounts for 90-95% of patients diagnosed with diabetes mellitus and females are more commonly affected with this type than males, especially women with a history of diabetes during pregnancy (American Diabetes Association, 2010). Individuals with hypertension or dyslipidemia are at increased risk of developing the condition. In T2DM, the autoimmune destruction of beta cells does not occur and insulin secretion from the pancreas can be increased, decreased, or remain normal. In spite of the amount of insulin secreted, this type of diabetes is commonly associated with insulin resistance and hyperinsulinemia which eventually leads to glucose intolerance and subsequent hyperglycaemia. Obesity itself, which is a common characteristic of patients in this type of diabetes, can cause hyperinsulinemia. In contrast to T1DM, patients with T2DM are not prone to ketosis, except during periods of severe stress, such as surgery or infection (Yarborough and Rodgers, 2001; American Diabetes Association, 2010). If this type of diabetes is neither controlled nor treated, it may result in hyperosmolar non-ketotic syndrome, leading to coma and eventually death (Yarborough and Rodgers, 2001). At least initially, and usually throughout life, patients with T2DM do not need insulin treatment for survival, but rather pharmacological treatment is used for the management of the condition.

For decades, either fasting plasma glucose (FPG) or the 75 g oral glucose tolerance test (OGTT) were used for the diagnosis of diabetes (American Diabetes Association, 2010) **(Table 1.1)**. Recently, the International Expert Committee (2009) recommended the glycated haemoglobin A1c (HbA1c) as an indicator for the diagnose of diabetes at a threshold of ≥6.5%, as it is associated with prediction for the prevalence of retinopathy, as are the diagnostic thresholds for FPG and 2-hours plasma glucose (PG). Moreover, the test is widely used for monitoring patients with diabetes, as it is a standard biomarker for the adequacy of glycaemic control (reflecting average blood glucose levels over 2-3 months) and correlates well with microvascular and macrovascular complications.

As the study presented in this thesis is based in the UK and the focus is on children and young people with T1DM, **Section 1.2** will provide a comprehensive overview of the

problem in the UK, its health and economic consequences as well as different methods for the management of the condition.

Table 1.1: WHO and ADA criteria for the diagnosis of diabetes (World Health Organisation, 1999; World Health Organisation, 2006)

	WHO 1999	ADA 2003
Diabetes		
Fasting glucose	≥7.0 mmol/l (126 mg/dl) **OR**	≥7.0 mmol/l (126 mg/dl) **OR**
2-h glucose*	≥11.1 mmol/l (200 mg/dl)	≥11.1 mmol/l (200 mg/dl)
IGT		
Fasting glucose	<7.0 mmol/l (126 mg/dl) (if measured) **AND**	Not required
2-h glucose	≥7.8 & < 11.1 mmol/l (≥140 & < 200 mg/dl)	≥7.8 & < 11.1 mmol/l (≥140 & < 200 mg/dl)
IFG		
Fasting glucose	6.1 to 6.9 mmol/l (110 to 125 mg/dl) **AND (if measured)**	5.6 to 6.9 mmol/l (100 to 125 mg/dl)
2-h glucose	< 7.8 mmol/l (140 mg/dl) (Measurement recommended)	Measurement not recommended (but if measured should be < 11.1 mmol/l; 200 mg/dl)

WHO= World Health Organisation; ADA= American Diabetes Association; IGT= impaired glucose tolerance; IFG= impaired fasting glycaemia.

IGT and IFG represent an intermediate group of people whose glucose levels although not high enough to be considered as diabetes are nevertheless significantly different from normal.
* Venous plasma glucose 2-h after ingestion of 75 g oral glucose load

1.2 T1DM in children and young people

1.2.1 Disease burden in the UK and the health/economic consequences

T1DM is one of the most common chronic conditions affecting children and young people. There is a global rise in the incidence of the disease in paediatric patients worldwide, with the greatest increase in children younger than 5 years (Gardner et al, 1997; Department of Health, 2007b; National Institute for Health and Clinical Excellence, 2008a). In the UK, 1 every 700-1000 children and young people is diagnosed with T1DM, giving a population of 25,000 under the age of 25 (Diabetes UK, 2010). Local authorities and primary care trusts (PCTs) might expect 100-150 children with diabetes to live in their areas.

T1DM takes a severe toll on those who develop it, having significant short-term consequences on health and being associated with major long-term complications and reduced life expectancy. Short-term complications are manifested by acute metabolic emergencies which can be life-threatening, such as diabetic ketoacidosis (DKA) (a consequence of high blood glucose levels; hyperglycaemia) and hypoglycaemia (caused by the treatment). Severe hypoglycaemia (SH), in which a person needs assistance and may be accompanied with coma and loss of consciousness, can cause cognitive impairment, especially in children aged less than 5 years (National Institute for Health and Clinical Excellence, 2008a). Uncontrolled diabetes and subsequent chronic elevation of blood glucose levels result in microvascular complications affecting eyes, kidneys, nerves (e.g. retinopathy and blindness; nephropathy and renal failure; neuropathy) and macrovascular complications, manifested by ischaemic heart disease and stroke (Department of Health, 2007b). Although macrovascular complications may not be a problem for children and young people with diabetes in their childhood, they are very likely to occur in adulthood, because of the duration of time the children had lived with their diabetes. T1DM reduces life expectancy by 20 years, with kidney diseases estimated to account for 21% of deaths (Diabetes UK, 2010). Within 20 years of diagnosis, all people with T1DM are expected to develop some degree of retinopathy. There are concerns that 30-40% of children and young people with T1DM will develop microalbuminuria (i.e. leakage of small amounts of albumin protein into the urine) which is an early indicator of renal damage, and that 25% of them will require laser treatment for retinopathy (Department of Health, 2007b).

It has been estimated that 10% of the National Health Service (NHS) budget is spent on diabetes (for treatment, prevention and screening), costing around £9 billion a year (Diabetes UK, 2010). However, the presence of diabetes complications increases that cost more than 5 fold, as it increases the chance of hospital admissions (Diabetes UK, 2010). People with diabetes are twice as likely to be admitted to hospital, and at time, at least 1 in 10 people in hospital has diabetes. Effective management of T1DM is therefore essential and has been shown to reduce the risk of disease-associated complications: new eye disease by 76%; worsening eye disease by 54%; early renal dysfunction by 54%; late renal dysfunction by 39% and neuropathy by 60% (Department of Health, 2007b).

1.2.2 Disease management

T1DM is a lifelong condition in which the both morbidity and treatment affect quality of life. In the UK, the National Service Framework (NSF) for children (Department of Health, 2003) states that:

> *'Children and young people with type 1 diabetes should receive care that is integrated and coordinated around their particular needs, and the needs of their family. They, and their parents, should be treated with respect, and should be given support and information to enable them to understand and cope with the diagnosis of diabetes and the treatment needed. They should be encouraged to be active partners in decisions about their health and care, and, where possible, be able to exercise choice.'*

Thus, the diabetes healthcare team in addition to providing medical care, should provide appropriate education and psychosocial support to children/young people and their families. Within this context, in 2004 the National Institute for Health and Clinical Excellence (NICE) published guidelines and recommendations about the management and care for children and young people with T1DM at diagnosis, and during ongoing therapy (National Institute for Health and Clinical Excellence, 2004).

Medical management of T1DM requires lifelong replacement of insulin in order to compensate for the lost amount of insulin in the body. Different types of insulin regimens have been used and studied. Based on treatment goals, child's age and general health, selection of the most appropriate treatment regimen should be made. In this chapter, the focus will be only on the medical therapy of the condition; insulin therapy.

1.2.2.1 Insulin therapy and challenges in the management of children and young people

Since its discovery in 1921, insulin replacement therapy has been the mainstay treatment for people with T1DM. According to the mode of administration, insulin therapy has been classified into conventional and intensive insulin therapy **(Table 1.2)**.

Conventional insulin therapy (CIT), also called 'split and mixed regimen,' consists of once or twice daily injections of short-acting insulin (acts as a bolus dose to prevent post-prandial hyperglycaemia) and intermediate-acting insulin (acts as a basal insulin dose to hinder daytime elevation of blood glucose), which are administered usually before meals **(Table 1.3)** (DeWitt & Hirsch, 2003; Bhatia & Aggarwal, 2007).

Table 1.2: Comparison of conventional versus intensive insulin therapy (Bhatia & Aggarwal, 2007)

	Conventional regimen	Intensive regimen
Principle	- Attempts to provide basal and meal related bolus of insulin - HBGM as far as possible - Insulin dose adjustment	- Separate basal and meal insulin - Frequent HBGM - Insulin dose adjustment
Goals	- HbA1c < 8% - Fasting glucose 80-160 mg%	- HbA1c < 7% - Pre-meal glucose 80-130 mg% - Post-meal glucose < 160 mg%
Advantages	- Easier for subjects to manage - Fewer resources required - Less risk of hypoglycaemia	- More flexibility in lifestyle - Lower risk of microvascular complications
Disadvantages	- Less flexibility - Higher risk of microvascular complications	- More resources necessary - Increased risk of hypoglycaemia
Qualified team	- Not required	- Necessary
Regimens	- Twice daily regular and NPH insulin - HBGM 2-3 times/day - Insulin dose supplementation and adjustment	- MSII or CSII - HBGM 4-5 times/day - Insulin dose supplementation and adjustment

HBGM= home blood glucose monitoring; MSII= multiple subcutaneous insulin injection; CSII= continuous subcutaneous insulin infusion; NPH= Neutral Protamine Hagedorn

The total daily dose is usually divided into 2/3 pre-breakfast and 1/3 pre-dinner (Yadav & Parakh, 2006). This regimen requires strict consistency in the timing of dose administration and meal ingestion. Moreover, the amounts of meals, snacks and exercise should be fixed and remain relatively constant. With this regimen, mid-morning snacks are usually required to prevent hypoglycaemia. This method of insulin delivery is usually prescribed for newly diagnosed patients with T1DM, who are still producing endogenous insulin before they progress to complete beta-cell failure (DeWitt & Hirsch, 2003). The time for complete loss of pancreatic production of insulin varies greatly, and it is shorter in children and young people compared to adults (American Diabetes Association, 2010). In general, CIT restricts lifestyle, as the timings and amounts of meals, snacks and exercise have to be fixed to achieve target blood sugar values.

Children and young people consume multiple snacks during the day and perform different physical activities. Therefore, using prandial insulin (e.g. aspart, lispro, regular) for each meal (in intensive insulin therapy) with separate basal insulin (e.g.

NPH, lente, ultralente, glargine) gives flexibility to the regimen by allowing children to skip meals or change mealtimes (DeWitt & Hirsch, 2003) **(Table 1.3)**.

Table 1.3: Classifications of insulin preparations with time action profiles (Yarborough & Rodgers, 2001; Dejkhamron et al, 2007)

Classification	Onset (h)	Peak (h)	Effective duration (h)	Variability in absorption/duration
Rapid-acting				
- Lispro	<0.25	0.5 – 1.5	4-6	Minimal
- Aspart	<0.25	0.5-1.5	4-6	Minimal
- Glulisine	Rapid	1	4	-
Short-acting				
- Regular	0.5-1	2 - 3	8-10	Moderate
Intermediate-acting				
- NPH (isophane insulin suspension)	2-4	6 – 10	10 – 16	High
- Lente (insulin zinc suspension)	3-4	6 - 12	12 - 18	High
Long-acting				
- Ultralente (extended insulin zinc suspension)	6 – 10	10 – 16	18 – 20	High
- Glargine	2-4	None	20 – 24	Minimal – Moderate
- Detemir	1	1.5	Dose Dependent	-

NPH= Neutral Protamine Hagedorn

In intensive insulin therapy, also known as a 'basal/bolus regimen,' the total daily dose of insulin is divided into a basal dose of about 25%-30% of the total dose in younger children (e.g. 2-3 years) and 40%-50% of total dose in older children, administered at bedtime to suppress glucose production between meals and overnight (Yadav & Parakh, 2006). The remaining dose is divided into 3 pre-meal bolus (prandial) doses to prevent post-prandial hyperglycaemia. If a large snack is consumed between meals (a typical habit for children and young people), an extra injection of rapid-acting insulin is necessary. To be successful, intensive insulin therapy requires frequent blood glucose monitoring (4-5 times a day). Moreover, adjustments of basal and bolus doses should be undertaken based on blood glucose values, food intake (carbohydrate counting) and exercise.

Intensive insulin therapy, given by multiple daily injections (MDIs) or continuous subcutaneous insulin infusion (CSII); insulin pumps, is considered an excellent method of achieving diabetes control and allowing greater flexibility in the timing and amount

of food ingested. However, the risk of hypoglycaemia and need of greater motivation, financial resources and experienced specialised healthcare team are high **(Table 1.2)**. Results from the Diabetes Control and Complications Trial study (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) study showed that intensive treatment of T1DM achieved better metabolic control than conventional therapy and reduced the development and progression of diabetes-induced microvascular and macrovascular complications in adults and young people (Diabetes Control and Complications Trial Research Group, 1993; Diabetes Control and Complications Trial Research Group, 1994). Recent recommendations support the trend towards using a basal/bolus regimen, as CIT cannot generally maintain the target HbA1c values in 50-70% children and young people with T1DM (Silverstein et al, 2005).

Special considerations should be taken in to account when managing children and young people with diabetes. Many children newly diagnosed with T1DM enter a honeymoon phase several weeks after the initiation of insulin therapy, during which a temporary rise in insulin secretion from the pancreas occurs. As a result, the insulin dose must be reduced to less than the initial daily requirements of 0.5-1.0 u/kg/day to ensure blood glucose levels are tightly controlled (Silverstein et al, 2005). During the honeymoon period, the child may require very small amounts of intermediate or long-acting insulin, which may be combined with minimal amounts of rapid or short-acting insulin. Nevertheless, the destruction of beta cells of the pancreas continues during this phase and a subsequent increase in insulin dose is required to maintain tight diabetes control.

Achieving diabetes control for younger children is usually difficult, due to erratic feeding and activity, and inability to express early symptoms of hypoglycaemia (Bhatia & Aggarwal, 2007). As a result, SH may be associated with long-term cognitive impairment (Rovet and Ehrlich, 1999). During puberty, hormonal changes and subsequent insulin resistance is one problem facing young people. As a result, the body requirement of insulin changes making diabetes control challenging. Prolonged periods of poor glycaemic control are usually associated with increased risks of microvascular complications, exposing children at this age to diabetes-induced problems (Bhatia & Aggarwal, 2007).

1.2.2.2 Recent advances in insulin therapy

Over the years, there have been great advances in insulin therapy for managing diabetes, including developments in insulin preparations, insulin delivery devices and blood glucose monitoring systems.

1.2.2.2.1 Enhancing insulin pharmacokinetics and pharmacodynamics

Over the past decades, advances in insulin therapy have made the development of insulin analogues possible. Insulin analogues are modified molecular versions of natural animal and human insulin, which are produced by a slight alteration of the amino acid sequence within the original molecule, using recombinant DNA technology (National Institute for Health and Clinical Excellence, 2004; Dejkhamron et al, 2007). The aim of producing insulin analogues is to develop insulin with distinct properties that imitate physiological pancreatic secretions, with more predictable time course and dose response than traditional injected insulin. Two types of insulin analogues have been designed using recombinant DNA technology: rapid-acting insulin analogues (e.g. aspart, lispro and glulisine) which mimic post-prandial bolus insulin release to compensate for meal-related need of insulin and correct post-prandial hyperglycaemia, and long-acting insulin analogues (e.g. glargine and detemir) which serve to mimic natural basal insulin secretion to maintain stable blood glucose levels between meals and overnight **(Table 1.3)**.

Compared to regular insulin, rapid-acting insulin analogues have an onset that occurs within a few minutes following administration, give sharper and earlier peak activity and have a shorter duration of action. Accordingly, this makes them ideally suitable for post-meal boluses (Sherr et al, 2009). Rapid-acting insulin analogues are usually administered before meals, though their very fast action permits their usage within 15 minutes after meals, which may be of a great value for those patients with unpredictable eating habits, such as infants and pre-school children (National Institute for Health and Clinical Excellence, 2004). Several studies have shown that rapid-acting insulin analogues improved post-meal glucose control and/or reduced the frequency of hypoglycaemic episodes when compared to regular insulin (Anderson et al, 1997b; Brunelle et al, 1998; Anuzzi et al, 2001; Siebenhofer et al, 2006).

Glargine was the first long-acting insulin analogue approved by the US Food and Drug Administration (FDA), and is licensed for use in children with T1DM aged 6 years or

older (Silverstein et al, 2005). The long duration of action arises from the fact that it forms aggregates when injected under the skin (i.e. subcutaneously) at physiological pH, leading to slow release into the blood circulation and subsequent long duration of action (Bhatia & Aggarwal, 2007). The advantages of this insulin over the traditional long-acting ultralente insulin and intermediate-acting NPH insulin in that it is peakless (i.e. relatively constant concentration/time profile in the plasma over 24 hours) with a 24-hour duration of action, and hence can be administered once daily; usually at bedtime (Silverstein et al, 2005). There is a small elevation in the effective action of glargine, which usually occurs 3-5 hours following initial administration. Consequently, it may be expected that the risk of nocturnal hypoglycaemia in children and young people is reduced if the drug is administered in the morning or shortly prior to the evening meal. In 2003, a randomised cross-over trial showed that a basal/bolus regimen, using glargine/lispro insulin analogues resulted in a significant reduction in the risk of nocturnal hypoglycaemia, compared to a NPH/regular insulin regimen (Murphy et al, 2003). Insulin detemir is another basal insulin analogue which has slow release and long duration of action. As with glargine, insulin detemir gives more stable and less variable blood glucose profile with less hypoglycaemic episodes compared to intermediate-acting NPH insulin (Hermansen et al, 2004).

Insulin analogues have a major advantage over traditional insulin products (e.g. NPH, lente, ultralente) in that the variability in absorption from the injection site is minimal. Therefore, the use of technology for the synthesis of insulin analogues provides an opportunity for implementing physiological insulin replacement therapy (a bolus/basal regimen). Nevertheless, they have the disadvantages of high costs and limited data for their long-term safety and teratogenicity (Bhatia & Aggarwal, 2007).

1.2.2.2.2 Enhancing blood glucose monitoring

Recently, a new technology to measure blood glucose levels continuously; continuous glucose monitoring system (CGMS) or continuous glucose sensors has been introduced.

Self-monitoring of blood glucose (SMBG), by measuring capillary blood glucose, is an integral component of intensive diabetes management. Nevertheless, it has the disadvantages of being cumbersome, inconvenient and expensive (Burge et al, 2008). Most importantly, it only provides a 'snapshot' of blood glucose readings measured at the time of the blood testing procedure, without giving any details about the direction or

change of blood glucose levels. Such limitations pose obstacles against attaining target blood glucose levels for many patients, despite constant and frequent SMBG. In comparison, CGMS represents a revolution in the era of blood glucose monitoring, as it provides: real-time glucose values and glucose trends (measured as interstitial fluid glucose concentration), short-term feedback of the effectiveness of diabetes treatment (e.g. insulin) and alerts for unusually high or low blood glucose levels. From glycaemic data provided by CGMS, patients are allowed to explore the relationship between day-to-day activities (e.g. exercise and food) and patterns of glycaemic changes. The system is composed of 3 parts: a disposable sensor that is inserted subcutaneously to measure blood glucose concentrations; a transmitter that is connected to the sensor and transmits information wirelessly to a receiver and a receiver that displays and stores blood glucose information which is then converted into estimated mean glucose values standardised to capillary blood glucose levels measured during calibration. On long-term use, the data can be downloaded to a computer.

Devices for continuous glucose monitoring emerged in the 1970s. These were limited to providing retrospective glycaemic data. Subsequent generations of sensors have evolved, but with variable results (Torres et al, 2010). The first real-time CGMS introduced to the market was the GlucoWatch G2 Biographer® produced originally by Cygnus, USA, which was non-invasive. However, the device was withdrawn from the market because of difficulty of usage, lack of precision and skin irritation (Diabetes Research in Children Network Study Group, 2005; Torres et al, 2010). Currently, there is a new generation of real-time minimally-invasive glucose sensors available on the international market **(Table 1.4)**. The concept by which these devices operate depends on the premise that the concentration of glucose in the interstitial fluid correlates with plasma glucose levels. Therefore, these systems are regarded as 'minimally invasive' because of the insertion of a fine needle into subcutaneous tissue to measure the glucose in the interstitial fluid directly or by an external sensor (as in GlucoDay® device). In most of the currently available CGMS devices, the blood glucose concentration in the interstitial fluid of subcutaneous tissue is continuously measured using an amperometric sensor that is linked to an electro-chemical enzymatic process (Torres et al, 2010).

The clinical application of continuous glucose monitoring devices has not yet been well established. Regardless of the fact that these devices can be helpful in determining

Table 1.4: Features of current available real-time glucose sensors on the international market (Burge et al, 2008; Danne et al, 2008; Torres et al, 2010)

Feature		Guardian-RT®, Paradigm-RT®	GlucoDay ®	FreeStyle Navigator ®	Seven System ®
Picture			N.A		
Company/origin		Medtronic MiniMed; USA	Menarini Diagnostics; Italy	Abbott Laboratories; USA	DexCom; USA
Year approved (by FDA)		2005 (Guardian-RT) 2006 (Paradigm-RT)	N.A	2008	2007
Range of glucose values (mg/dl)		40-400	40-400	20-500	40-400
Sensor	**Mechanism**	Amperometric sensor glucose oxidase	Microdialysis glucose oxidase	Amperometric sensor glucose oxidase	Amperometric sensor glucose oxidase
	Location	Subcutaneous arm	External	Subcutaneous arm	Subcutaneous abdomen
	Life span (d)	3 in USA, 6 in Europe	2	5	7
Calibrations frequency (h)		Every 12 h	One point	Post insertion: 72h (latest system)	Every 12 h
Frequency of testing (min)		5	3	1	5
Glucose data display		Real time	Retrospective and real time	Real time	Real time
Alarm		Yes	N.A	Yes	Yes
Integration with pump		Yes (paradigm-RT)	No	No	No
Advantages		- Alarms for both hypo/hyperglycaemia	- High precision and reliability even in low levels of glucose	- Alarms for both hypo/hyperglycaemia - Update glycaemic data every 1 min - Information is transmitted as trends of glucose values	- Alarms for both hypo/hyperglycaemia - High precision (latest; Seven Plus System)
Limitations		- Life span of 3 days (USA) - Updates glycaemic data on screen every 5 min	- Large system - Life span of 2 days - Skin irritation	-Large sensor and transmitter - Calibration time programming required - Must use FreeStyle strips for calibration - High cost	- Update glycaemic data on screen every 5 minutes

RT= real time; N.A= information was not available

patterns of glycaemic changes over 24-hours and in detecting glycaemic excursions, their uptake in clinical practice is still relatively poor. This is due to controversies regarding their capacity to improve the glycaemic control, high price and paucity of data from good randomised controlled trials (RCTs) showing long-term glycaemic benefits compared to SMBG using capillary measurements (Kerr & Fayers, 2008). There is a growing body of literature indicating that CGMS is a promising tool contributing to improved glycaemic control in adults and/or children with T1DM, although not all studies have found significant difference between CGMS and SMBG (Sachedina & Pickup, 2003; Garg et al, 2006; Maia & Araújo, 2007; Golicki et al, 2008; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, 2009). Recently, a meta-analysis of RCTs was performed to compare CGMS and SMBG in patients with T1DM (Chetty et al, 2008). Although non-significant reduction in HbA1c was observed across all the patient cohorts, there was a significant reduction in HbA1c in favour of CGMS when the analysis was performed in the paediatric population separately.

The currently available CGMSs have the limitations of being invasive (sensor inserted subcutaneously under the skin), having the risk of secondary local skin irritations and requiring frequent calibrations (Burge et al, 2008). Moreover, many investigators have studied their accuracy and reported limited sensitivity, particularly in the detection of hypoglycaemia (Burge et al, 2008; Torres et al, 2010). The FDA indicates that the glucose sensors should not replace SMBG, however, they should be used in conjunction with patient-self monitoring. With continued advancement in medical technology and continuous research improving their accuracy and reliability, the future application of continuous glucose sensors may become crucial as a component of the 'closed loop' insulin delivery system, discussed in **Section 1.3.3**.

1.2.2.2.3 Enhancing insulin delivery methods

Insulin is delivered most commonly through subcutaneous injection. Inconsistencies in subcutaneous absorption of the drug, depending largely on the site of injection, volume injected, type of insulin and route of administration, result in variation in insulin action and subsequent erratic glycaemic control (Bhatia & Aggarwal, 2007). Attempts have been made to improve insulin delivery systems. Subcutaneous insulin administration via a needle and syringe forms the original method through which insulin is delivered to diabetic patients. However, it is not the most commonly preferred means of

administration for many patients, especially if intensive regimen (i.e. MDIs) was used, due to pain, needle-fear, inaccuracy and risk of contamination. As an alternative, insulin pens which are small pen-sized devices are a more convenient means of administering insulin accurately (Al-Tabakha & Arida, 2008). However, they are more expensive than syringes. More recently, subcutaneous insulin infusion via a pump has become a feasible approach for intensive therapy for managing patients with T1DM, including children and young people. Detailed description of the technology is provided in **Section 1.3**.

Novel routes of insulin delivery are an area of interest in the management of diabetes, given that insulin injection therapy is burdensome for many patients. There have been many attempts to develop effective insulin delivery systems that are needle-free. However, their success has been limited until the development of improved delivery devices and formulations of short-acting regular insulin that are well absorbed from the lungs became a reality. Pulmonary insulin delivery provides a novel route of insulin administration with faster and more uniform absorption compared to the subcutaneous route (Gerich, 2002). The advantages of this novel route arise from the anatomic structure of the lungs, having a well-perfused large surface area for absorption and lacking peptidase enzymes that degrade insulin (Rajput & Bhansali, 2006). Moreover, it has a high acceptance from users compared to injections (Cefalu et al, 2001; Skyler et al, 2001). Inhaled insulin can be delivered into the lungs as aerosols by nebulisers, or as dry powder delivered via specially designed inhalers, which are connected to a drug-holding chamber to deliver measured doses of insulin (Gerich, 2002). Over the last 20 years, a competition between pharmaceutical companies occured to produce suitable devices for pulmonary delivery of insulin. Nevertheless, the bioavailability of inhaled insulin via such devices varied greatly (from 10% to 46%), as much of the drug was retained in the device or in the oropharynx or upper airways (Patton et al, 2004).

Many trials examined the efficacy and safety of inhaled insulin products in the management of T1DM compared to subcutaneous injections (Hollander et al, 2004; Patton et al, 2004; Skyler et al, 2005; Garg et al, 2009) **(Table 1.5)**. However, various results were obtained which could be related to variability of insulin formulations and type of insulin used in the subcutaneous insulin injection regimens. Exubera® was the first inhaled insulin marketed by Pfizer and approved by the FDA in late 2006

(Seikmeier & Scheuch, 2008; Mastrandrea, 2010). Although the glycaemic efficacy was not inferior to that of injection therapy, the drug was withdrawn from the market following a year of production, due to poor sales and acceptance and increased risk of lung cancer in patients with smoking history (Seikmeier & Scheuch, 2008). While the concept of inhaled insulin is attractive, the great developments of subcutaneous insulin delivery (e.g. insulin pumps) for intensive diabetes care and concerns regarding pulmonary function, health and cost-effectiveness make the future developments in this area uncertain.

Other trials have been conducted for developing other non-invasive insulin delivery systems, such as oral, intranasal and transdermal insulin. However, issues of bioavailability and safety are still major obstacles to their application in clinical practice (Rajput & Bhansali, 2006; Yadav & Parakh, 2006; Al-Tabakha & Arida, 2008).

Table 1.5: Inhaled insulin systems (Mastrandrea, 2010)

Inhalation system	Insulin formulation	Insulin equivalents*	Inhaler device	Device benefits	Current status
Exubera®	Dry powder, blisters	1 mg = 3 U 3 mg = 8 U	Mechanical	Collapsible	FDA-approved, off-market
AERx iDMS®	Liquid insulin, blisters	1AERx unit = 1U	Electronic	Downloaded capability	*No further development*
AIR®	Dry powder, capsules	6mg = 2 U 9 mg = 6 U	Mechanical	Small size	No further development
Technosphere®	Dry powder, microsphere, cartridges	6TU = 1.56 U 12 TU = 3.12 U 24TU = 6.24 U	Mechanical	Placebo formulation	Phase III trials, FDA-new drug application

TU= technosphere unit
* Compared to regular insulin

1.3 Insulin pump therapy

In recent years, insulin pumps have been increasingly marketed and used worldwide. This section provides detailed overview of the technology.

1.3.1 Historical evolution of pump technology

In the early 1960s, the idea of continuous insulin delivery emerged in the USA with the work of Arnold Kadish who designed the first closed-loop insulin pump device that worked by providing continuous insulin to the body, together with automatic blood glucose sensing (Lee, 2003; Input Newsletter, 2006; Alsaleh et al, 2010). This artificial

pancreas comprised a large pump with an autoanalyser, operated to measure blood sugar with an on-off servo-mechanism that controlled the pump function when blood sugar was outside normal ranges (Kadish, 1963; Kadish, 1964; Input Newsletter, 2006). Unfortunately, little attention was given to Kadish's device due to its impracticality for daily use, with its size similar to 'an army backpack' **(Figure 1.1)**.

Figure 1.1: The first insulin pump; Kadish's device (Lee, 2003)

Greater attention was directed to the first computer controlled closed-loop insulin pump, named Biostator which was developed in 1974 **(Figure 1.2)** (Albisser et al, 1974a; Albisser et al, 1974b; Pfeiffer et al, 1974). This was designed to simulate the function of normal pancreatic cells and consisted of: a pump which controlled continual withdrawal and mixing of blood; a glucose analyser for continuous analysis of blood glucose concentration; a computer programmed with a set of algorithms to calculate the amount of insulin or dextrose to be infused based on blood glucose level; a computer-operated infusion pump for insulin or dextrose delivery and a printer/plotter for minute-by-minute blood glucose recording (Fogt et al, 1978). As with Kadish's device, long-term use of the Biostator was restricted by its complexity, cumbersome size and intricacy, and so it was only used in short-term research studies (Input Newsletter, 2006).

The pursuit of more practical means of insulin delivery led investigators to use continuous intravenous insulin delivery systems. Pioneering research was undertaken in Paris by Slama et al (1974), who showed good control of blood sugar levels in patients with diabetes, using an open-loop pump (i.e. the rate of insulin delivery was not

Figure 1.2: Biostator; a computer-based glucose-controlled insulin infusion system (Fogt et al, 1978)

automatically adjusted to blood glucose levels) with intravenous insulin infusion over 1–5 days. The pump was worn in a shoulder bag and delivered insulin at a basal rate and a 15- fold higher rate at meal times. In spite of encouraging results from Slama's et al study, the use of an open-loop intravenous infusion system was restricted because of the risks of thrombosis, phlebitis, and infections associated with the infusion through the intravenous route (Input Newletter, 2006).

Rigorous clinical testing for CSII was introduced in the UK in the late 1970s (Alsaleh et al, 2010). Pickup et al (1978a; 1978b) from Guy's Hospital, London reported successful and practical use of a portable insulin pump device for CSII in patients with T1DM. This was confirmed by others, showing that CSII when used with continuous glucose monitoring, could produce precise glycaemic control for long periods (Kadish, 1963; Kadish, 1964; Albisser et al, 1974a; Albisser et al, 1974b; Pfeiffer et al, 1974; Slama et al, 1974; Fogt et al, 1978; Pickup et al, 1978a; Pickup et al, 1978b; Felig et al, 1979a; Felig et al, 1979b; Tamborlane et al, 1979; Torrance et al, 2003). The CSII pump was the Mill Hill Infuser which was adapted from a pump designed by Parsons et al (1977) at the National Institute for Medical Research, Mill Hill, London for infusing hormones into animals. The prototype Mill Hill infuser was a portable, battery-driven, miniature syringe pump, weighing 159 grams. It was a dual-rate insulin delivery system giving a basal rate and an 8-fold higher prandial rate, which was engaged by pressing a small button on the side of the pump **(Figure 1.3)** (Parsons et al, 1977; Pickup et al, 1978a).

Figure 1.3: The Mill Hill infuser (Saudek & MacCormick, 2004)

Following their introduction in the late 1970s, insulin pumps started to receive global acceptance by the medical community. By the early 1980s, many pharmaceutical companies began to invest in the development of insulin pumps (Alsaleh et al, 2010). One of the first commercial insulin pumps marketed in 1978 was the Autosyringe®, also named 'Big Blue Brick' which achieved early sales of 600 pumps per month **(Figure 1.4)** (Hauge, 2003). In the early 1980s, the first custom designed microprocessor-controlled insulin pump was introduced, which was designed by the Mill Hill and Guy's Hospital team (Input Newsletter, 2006). The product was licensed for commercial use in 1983 and was named the Nordisk infuser®. Subsequently, many leading medical and pharmaceutical companies introduced products of their own, which were designed only for their particular insulin products.

Figure 1.4: The Autosyringe® infusion pump (left) beside a smaller modern pump (Anonymous, 2008d)

Early commercial insulin pumps suffered from performance and reliability problems. They were large, being the size of a house brick and weighed up to 400 g; their batteries needed to be recharged frequently; they had limited safety alarms; lacked control of safe

insulin delivery; offered very little flexibility in the rate of basal insulin delivery; had infusion sets with metal needles and some required the use of a screwdriver for dosage adjustment (Hauge, 2003; Lee, 2003; Torrance et al, 2003; Anonymous, 2005). Additionally, many cases of syringe and tubing blockages, as well as needle dislodgement, were reported (Guilhem et al, 2006; Input Newsletter, 2006). As a result, clinical complications of diabetes such as hyperglycaemia, DKA and infection at the injection site were common with early pumps, causing limited acceptance and use of this technology throughout the 1980s by both healthcare professionals and patients (Alsaleh et al, 2010). Patients' resistance to the idea of being hooked to a large and heavy device was another reason for the limited uptake during the 1980s. For these reasons, use of the early pumps was reserved for a minority of difficult-to-manage cases, and even then they often gave unsatisfactory results (Lee, 2003).

The 1990s represented a new era in the development of insulin infusion pumps, where the technical problems of the early devices such as pump malfunction (either not working or releasing extra insulin; insulin leakage) and tubing occlusion were largely resolved (Weintrob et al, 2004a). Production began of more functional pumps with safety measures, for instance alarms and alerts for problems such as infusion set occlusion, as well as indicators for a low battery or low insulin reservoir (Alsaleh et al, 2010). Moreover, it was recognised that limiting the use of insulin pumps for difficult-to-manage cases during the 1980s was unrealistic and impeded their successful implementation (Reynold, 2000).

Today, patients/clinicians have a variety of devices to select from **(Table 1.6)**. The currently available pumps are miniature pager-sized devices (Skyler et al, 2007). They work by delivering a programmed basal insulin dose continuously throughout the day and overnight. Moreover, bolus doses are also required to be given by the user, usually before meals based on blood sugar concentration, food intake (amount of carbohydrates consumed) and physical activity. If blood glucose levels remain high after a meal, then a 'supplemental' or 'correction' bolus dose of insulin should be administered to achieve the target blood sugar level. The pump has an insulin reservoir and is connected to the body via a soft plastic tube that terminates with a fine, soft, and flexible cannula which is fixed by self-adhesive tape and inserted subcutaneously under the skin; usually in the abdomen area. Depending on patients' preference, the cannula attached to the device

Table 1.6: Features of the latest insulin pumps on the market (Eugster & Francis, 2006; Anonymous 2007a; Anonymous, 2007b; Anonymous, 2007c; Anonymous, 2008a; Anonymous, 2008b; Anonymous, 2008c; National Institute for Health and Clinical Excellence, 2008a; Skryabina et al, 2008; Takahashi et al, 2008)

Company	**Medtronic Minimed**	**Roche Disetronic Medical Systems**	**Animas (Johnson & Johnson)**	**Deltec (Smiths group)**	**Sooil**	**Nipro**	**Insulet**
Model	**Paradigm® 522/722 (REAL-Time System)**	**Accu-Chek® Spirit** (3 components) pump, meter, PDA	**Animas™ IR-2020**	**Cozmo® 1800**	**Dana Diabecare® IISG**	**Amigo®**	**OmniPod®** (2 components: Pod and PDM)
Dimensions (mm)	522: 51 x 79 x 20 722: 51 x 79 x 20	80 x 56 x 20	51 x 77 x 18	80 x 46 x 24	45 x 75x 19	55x 83x 24	pod: 41 x 61x 18 PDA: 66 x 110 x 26
Weight (g)	522: 99.2 722: 107.7	79.4 (empty), 136.1 (with battery, full cartridge, infusion set)	87.9	76.5	51 (empty)	96.4	OmniPod: 1.2 (full reservoir) PDM: 4.0 (with batteries)
Reservoir size (U)	176 or 300	315	200	300	300	N.A	200
Screen size (sq mm)	774	N.A	992	870	N.A	N.A	1,848 on PDA controller
Colours	Clear, smoke, blue, purple	Blue, with 30 pump skins in colours and styles	Blue, silver, black, limelight, pink glow	Volcano black, pacific blue, tropical green	Black, white, pink, green, grey	6 colours: yellow, white, pink, grey, blue, violet, dark blue	White

Table 1.6: Contd.

Basal	**Increment (U/h)**	0.05	0.1 to 25.0	0.025	0.05	0.01 and 0.1	0.05 up to 30	0.05, up to 30
	Total (U/day)	48	24	12	48	24	48	48
	Profiles *	3	5	4	4	4	4	7
	Interval	30 min	60 min	30 min	30 min	15 min	N.A	30 min
	Delivery	Varies, up to every 10 min	Every 3 min	Every 3 min	Every 3 min	Every 4 min	Every 3 or 15 min	N.A
Bolus	**Increment (U)**	0.1 visual, 0.5 or 1.0 visual or audio, remote extra	0.1, 0.2, 0.5, 1.0, 2.0	0.05 visual or audio, 0.1, 1.0, 5.0 audio	0.05, 0.1 visual, 0.05, 0.1, 0.5, 1.0 visual or audio	0.1-87	0.1 to 5.00	0.05, 0.1, 0.5, 1.0
	Type	Standard, extended, or combination	Quick, scroll, extended, multi-wave	Standard, extended, combination	Standard, extended, combination	Single step, extended, dual pattern	Normal, extended, layered	Meal, correction, meal & correction; normal, extended, combination
	Calculator	Yes, using IOB correction factor, current glucose, and carb input	On separate PDA	Yes, automatically calculates correction bolus based on personal settings by entering blood glucose reading	Yes, using IOB correction factor, current glucose, and carb input	Yes, must enter factors each time	Yes, using IOB correction factor, current glucose, and carb input	Yes, using IOB correction factor, current glucose, and carb input
Battery type		AAA for pump A23 for remote	AA x 1 Alkaline or Rechargeable	AA lithium x 1	AAA x 1	3.6 VDC x 1	CR2 battery	AAA x 2 (PDA)
Battery life		3 weeks	4 weeks	6-8 weeks	3 weeks	8-12 weeks	4 weeks	4 weeks

Table 1.6: Contd.

Memory**	4000 events, volatile (i.e. basal & history loss can occur): 24 boluses, 7 day totals	Non-volatile: 90 days (4,500 events); history recall of last 30 boluses, alerts, daily insulin totals, and temporary basal rate increases	Non-volatile: 600 bolus, 270 basals, 120 daily totals, 30 alarms, 60 primes	Non-volatile: 90 days (2000 events) of basals, carb boluses, correction boluses, alarms	Static memory stores last 100 boluses, last 100 daily totals, last 100 primes, last 100 alarms, carb amounts	90 days on screen and stores 1 year of history, even in the absence of a battery	90 days of data (up to 4500 records)
Safety features	- Alarm - Key lock function	- Alarm - Key lock function	- Alarm	- Alarm - Key lock function	- Alarm - Key lock function	- Alarm - Key lock function	- Alarm - Key lock function
Waterproof	No; Splash resistant	Up to 1 h	12 ft up to 24 h	Watertight	12 ft up to 24 h	1m for 35 min	Watertight (Pod)
Warranty	4 years	4 years	4 years	4 years	4 years	N.A	4 years
Price (Pounds)***	£ 2750	£ 2375	£ 2600	£ 2750	N.A	£ 2777	N.A

PDA= personal digital assistant; PDM= personal diabetes manager; U= units; IOB= insulin on board; Carb= carbohydrate; VDC= volts of direct current.

* Current insulin pumps allow users to program different basal rates within a day.

** Memory of insulin pump devices can either be volatile (i.e. has the tendency to be lost) or non-volatile (i.e. does not have the tendency to be lost).

*** Prices as of 2008.

can also be inserted into the arm, thigh, or lower back. It has been possible to manufacture devices with enhanced safety measures and long-life batteries, which can be provided with plastic catheter infusion sets to reduce the problem of site infection (Alsaleh et al, 2010). Depending on each manufacturer's instructions, the infusion set which is composed of the tubing and the cannula must be changed routinely, usually every 2 to 3 days, for hygiene purposes.

Recent insulin pumps are equipped with advanced features making them attractive treatment options for users. They allow patients to program several different basal rates to be used in one day to accommodate diurnal changes in insulin needs (Prasek et al, 2003; CIGNA Healthcare Coverage Position, 2004; Skyler et al, 2007). Based on the use carbohydrate intake, most modern insulin pumps can calculate bolus doses as well as doses needed to adjust high blood glucose values when needed (Skyler et al, 2007). Some recent pumps, termed 'smart pumps,' have built-in dosage calculators (called pump Bolus Wizard®) to perform an automatic estimation of insulin remaining active from a previous bolus, and can estimate the amount of insulin that should be administered based on several factors, such as blood glucose concentration and anticipated amount of ingested food. For more advanced treatment strategies, some pumps offer the ability to change the shape and/or duration ('square wave' or 'dual wave') of the boluses to accommodate the variable needs of insulin based on lifestyle. A 'square wave' bolus mode is used to deliver a single bolus dose of insulin over an extended period of time, while a 'dual wave' bolus mode is used to deliver two boluses; one immediately and another a few hours later. The continuous technological development has enabled the production of pumps with additional features, such as programmable memory, safety lockout features and remote control. Currently, there are 7 manufacturers in the international market supplying insulin pumps worldwide **(Table 1.6)** (Alsaleh et al, 2010). The insulin pump market today is growing by approximately 50% per year, indicating that the technology fills a genuine need and has proven capability (Hauge, 2003).

1.3.2 Principles of insulin pump therapy

1.3.2.1 Which insulin and what dose?

Several studies have shown that rapid-acting insulin analogues (insulin lispro, aspart and glulisine) produce a more physiological profile than buffered human regular insulin

when used in CSII, by providing bolus/basal insulin secretion without increasing the risk of hypoglycaemia or DKA in well trained individuals (Colquitt et al, 2003; Radermecker & Scheen, 2004). Furthermore, no observed differences were demonstrated among rapid-acting insulin analogues when used in CSII (Bode et al, 2002c; Hoogma & Schumicki, 2006). However, although Di Bartolo and colleagues (2006) have shown that there was no difference between insulin aspart and lispro in glycaemic control and episodes of hypoglycaemia, insulin aspart provided an improvement in infusion set lifetime with consequent improvement of insulin predictability, compared with insulin lispro (Becker, 2002).

A variety of guidelines are available for the calculation of basal and bolus insulin doses for pump therapy. However, these guidelines are based mainly on managing the treatment of adults with diabetes and do not necessarily apply to children and young people (Torrance et al, 2003). Upon initiating pump therapy, the pre-pump total daily dose of insulin is usually reduced by 25-30% (Reynold, 2000; Bode et al, 2002a; Torrance et al, 2003). The reason behind tapering the pre-pump insulin dose is to allow improvement of insulin sensitivity which is usually increased with CSII and the use of rapid-acting insulin analogues. The pump total daily dose is then divided: 50% as the total daily basal dose, which also can be calculated as 0.22 u/kg, and 50% as the total daily bolus dose (Bode et al, 2002a). The bolus dose is split over meals based on the carbohydrate content of the ingested food. For younger patients, pump therapy is usually started with 40% basal and 60% bolus doses.

When commencing pump therapy, it is recommended that a single basal rate is administered, which can be followed later by a second basal rate (Bode et al, 2002a). During the 2-4 weeks after the initiation of pump therapy, snacks must be avoided to allow proper establishment of the basal rates. Bolus doses are calculated based on the carbohydrate-to-insulin ratio, which indicates the size of bolus to be injected based on the amount of food ingested.

Ongoing monitoring of blood glucose levels (conducted before meals, 2 hours after eating, at bedtime, midnight and at 3:00 AM) is extremely important, as basal and bolus doses are adjusted accordingly (Bode et al, 2002a; Bode et al, 2002b). Basal insulin dose is usually adjusted by 0.1 u/h increment or drop. This helps to maintain pre-meal

and overnight blood sugar values within 2 mmol/l (36 mg/dl) glucose excursion from baseline glucose levels, which in turn prevents nocturnal hypoglycaemia that usually occurs between 2:00 and 4:00 AM, and hyperglycaemia that occurs on waking. Adjustments of basal dose should be done during the day when significant glucose excursions persist for more than 4 hours post-meal bolus.

Bolus insulin doses are adjusted based on blood glucose values measured 2 hours after meals. At initiation of the therapy, boluses are usually monitored every 2 days to maintain blood sugar values within an acceptable range (i.e. <10 mmol/l; <180 mg/dl 2-hours after a meal) (Bode et al, 2002a). As target blood glucose is achieved, bolus insulin doses may be modified by calculating the carbohydrate-to-insulin ratio of each meal, which varies from 1 u/5g carbohydrate to 1 u/30g carbohydrate. As insulin pump therapy is associated with frequent blood glucose tests (4 times a day or more), especially at therapy initiation as well as carbohydrate counting, careful selection and preparation of the patients is the cornerstone for successful implementation of the therapy.

1.3.2.2 Who should be considered for using insulin pumps?

Appropriate patient selection is the key factor for successful implementation of insulin pump therapy. However, there are limited data to guide clinicians about the ideal candidates for insulin pump therapy, and current guidelines for selecting patients are largely dependent on consensus or experts' opinions (Lenhard, 2006). Patients with inadequate glycaemic control, unexplained glucose excursion or frequent and unexpected hypoglycaemic attacks together are recommended to receive insulin pump therapy (Fisher, 2006a; Lenhard, 2006).

Bode and colleagues (2002b) suggested that the best candidates for insulin pump therapy are patients who undertake diabetes self-management, including regular monitoring and recording of blood glucose levels, carbohydrate counting and regularly attend the hospital. Good candidates for starting pump therapy are those who have the motivation to achieve tighter glucose control and show a willingness to learn the general principles of diabetes self-management as well as dosage calculations and adjustments (Skyler et al, 2001). Patients must be willing to adhere strictly to the prescribed treatment plan set by the diabetes healthcare team and follow the pump manufacturers' instructions, especially those regarding changing the infusion set. For children and

young people who are not responsible for their everyday medical care, a motivated and well trained parent/carer is vital for success with CSII (Nebesio & Eugster, 2006). Even when candidates fulfil the requirements for pump therapy, it is crucial for the success of the therapy that initiation is overseen by a team of healthcare professionals who are knowledgeable, skilled and trained in all aspects of diabetes management and CSII (Fisher, 2006a).

In the UK, NICE proposed guidelines in February 2003 for the use of insulin pumps in the management of diabetes (National Institute for Health and Clinical Excellence, 2003). This guidance was applicable to all patients with T1DM, including adults, children, young people, pre-pregnant and pregnant women. It was recommended that CSII is a treatment option for patients for whom MDIs have failed (i.e. attempts to achieve target HbA1c levels results in disabling hypoglycaemia or HbA1c levels remain high; 8.5% or above despite diligent diabetes care), providing that those patients show the commitment and competence to use therapy effectively. Moreover, it was a requirement of NICE that therapy should be initiated by a trained diabetes team and all candidates must undergo a specific training programme for pump use and diabetes management. Two years later, a paper by Hammond (2005) recommended the need to re-appraise NICE guidance on insulin pump therapy, because although the number of pump users had increased since publication of the NICE guidelines (from below 1000 to approximately 2500), this number still represented fewer than 1% of patients with T1DM in the UK.

In 2008, the initial NICE guidance (2003) about the use of CSII was replaced. The new guidance recommends much wider use, with children (under 12 years old) no longer required to fail on MDIs in order to start insulin pump therapy (National Institute for Health and Clinical Excellence, 2008a).

1.3.3 Future directions in pump technology

The future of insulin pump therapy is promising. Current pumps **(Table 1.6)** are based on an open-loop insulin infusion system, where the rate of insulin delivery is not automatically adjusted to the current blood glucose concentration (Weintrob et al, 2004a). With existing insulin pumps, the patient (or parent/carer) has to decide the basal insulin infusion rate throughout the day and calculate boluses to be administered before

each meal. This can make the process of diabetes control difficult, stressful and open to non-optimal dosing. Thus, a closed-loop system offers many advantages.

The ideal 'closed-loop' system should work as an artificial pancreas, allowing real-time communication between an infusion pump and a glucose sensor (Liberatore & Damiani, 2006). In the artificial pancreas, insulin is delivered by the insulin pump according to real-time sensor glucose data, as instructed by a control algorithm rather than rates programmed by the user (Shalitin & Phillip, 2006). Furthermore, the closed-loop system should react to variations in measured glucose values, respond quickly to cover insulin needs, and must be capable of recognising and correcting spurious readings. For example, when blood glucose values go beyond normal levels, the closed-loop operated pump must be able to either modulate or interrupt insulin delivery and when necessary to inject counter-regulatory hormones such as glucagon. Operating together, an insulin pump and glucose sensor will in effect serve as an artificial pancreas, mimicking the role of pancreatic beta cells and freeing patients from the tedious efforts related to continuous blood glucose monitoring and adjustments of food intake, as well as calculation of insulin doses (Weintrob et al, 2004a; Shalitin & Phillip, 2006) .

Efforts to connect the CSII system with real-time glucose sensors have been made in animal models and in some human trials (Weintrob et al, 2004a; Renard et al, 2006; Sahlitin & Phillip, 2006). However, the available glucose sensors are still the limiting factor in the development of commercially acceptable closed-loop pumps, due to the lack of satisfactory characteristics of reliability and/or accuracy (Hovorka, 2006). Moreover, the relatively slow absorption of rapid-acting insulin analogues through the subcutaneous route compared to rapid variation in blood glucose concentrations especially post meals, and inaccurate control algorithms have contributed to hindering the progress towards the development of fully automated closed-loop system (Hanaire et al, 2008).

1.4 Literature review of the studies conducted in the context of insulin pump therapy in children and young people

Before deciding the research topic for this project, an extensive literature search was undertaken to reveal areas of research in the context of using insulin pump therapy in paediatric patients. This section therefore, describes the search process undertaken to review the current literature relating to insulin pump therapy in children and young

people with T1DM. A systematic search was undertaken using electronic databases. The search of the literature was conducted throughout the period from March 2007 and continued until the completion of this thesis (November 2010).

1.4.1 Search language

In order to explore previous studies conducted in the context of pump therapy in paediatrics, a wide range of search keywords have been used to cover all relevant articles in this aspect: 'children,' 'toddlers,' 'adolescents,' 'young people,' 'teenagers,' 'parents,' 'carers,' 'diabetes,' 'T1DM,' 'insulin pumps' and 'continuous subcutaneous insulin infusion.' Some of these words were used in combination with other wards: 'glycaemic control,' 'blood glucose control,' 'metabolic control,' 'efficacy,' 'safety,' 'quality of life,' 'cost-effectiveness,' 'psychosocial impact,' 'experiences', 'views,' 'concerns,' 'school nurses,' 'nursing role,' 'school management,' 'parental experience,' and 'parental reflections.'

1.4.2 Search databases

Several electronic databases were accessed and searched for the relevant literature: Cochrane Library, PubMed (from 1950-2010), Ovid, Embase (from 1980-2010 week 43), National Electronic Library for Medicines (NeLM; from 1998 to 2010), International Pharmaceutical Abstract (IPA; from 1970-October 2010) and Medscape. In some instances, electronic journals from websites (e.g. ScienceDirect, Wiley online library and NHS library) were accessed and searched for the topics of interest. Also, reference lists from identified papers were hand-searched for further articles of relevance. Where appropriate, these were identified and reviewed.

1.4.3 Excluded studies

All studies with topics of interest, including randomised, non-randomised, observational, or pilot studies, comparing insulin pumps with injection therapy (CIT or MDIs) were reviewed. Research concerning the use of insulin pumps for managing patients with T2DM was excluded. As the experiences and needs would be diverse from those of children and young people, studies related to adults and pregnant women were beyond the scope of this project and hence were not reviewed. The views and perspectives of school nurses and other healthcare specialists on using insulin pumps to manage children/young people with T1DM were not included. In addition, case studies were excluded from this review of the literature. All included studies were those in

which portable subcutaneous insulin pumps were used, whilst those involving intravenous or implantable insulin pumps were not reviewed. The search was limited to include studies in the English language only.

1.4.4 Results

Eighty three studies were identified in the literature with children of different ages using insulin pumps to manage T1DM. The identified studies ranged from the very old (e.g. 1979) to very recent (conducted in 2010). Searching the literature identified the richness of research in the context of efficacy, safety, quality of life and psychosocial impact (77 studies) **(Appendix 1)**: 59 examined effectiveness of achieving metabolic control and/or safety; 18 evaluated quality of life and/or psychosocial impact and 1 assessed cost-effectiveness. Of those, 16 involved both young people and adults, while the rest (61 studies) included children in different age groups. Seven studies were systematic reviews and 5 were meta-analyses.

Many studies were found evaluating the clinical and therapeutic outcomes of using insulin pumps to manage T1DM in children and young people **(Appendix 1)**. Only 6 studies were identified to examine the use of insulin pumps from the perspectives of users themselves (i.e. qualitative studies) **(Table 1.7)**. These studies mainly focused on: introduction to the pump; reasons for the transition to pump therapy from injections; advantages and disadvantages of this treatment method and impact on quality of life.

Parents and/or children reported that they learned about insulin pump therapy either formally from a healthcare professional or informally from a friend or the internet (Maniatis et al, 2001b; Sullivan-Bolyai et al, 2004; Wilson, 2008). Many reasons were identified for the transition, the most important being the pursuit of stable and controlled blood glucose levels and the desire for a more flexible lifestyle (Maniatis et al, 2001b; Low et al, 2005; Olinder et al, 2007; Wilson, 2008). Participants highlighted the advantages and/or disadvantages of insulin pumps (Low et al, 2005; Olinder et al, 2007; Barnard et al, 2008; Wilson, 2008). The greatest positive impact of the pump on the users' lives was in improved blood glucose control and enhanced quality of life, as they provided children more flexible lifestyles especially with regard to meals and socialisation. In contrast, psychosocial issues, such as pump visibility and physical restrictions were highlighted as disadvantages. Issues like day-to-day management were also discussed (Mainatis, 2001b; Sullivan-Bolyai, 2004; Low et al, 2005).

Table1.7: Studies explored experiences of using insulin pumps to manage T1DM in children and young people

Study/country	Description	Participants/ N	Design/tool
Maniatis et al (2001b) USA	- Described reasons for initiating therapy and management issues - Assessed parental involvement and anxiety	- Children/ young people (7.6-23.6 years); N=52 - Parents; N=52	Semi-structured interviews (for needle fear issues)
Sullivan-Bolyai et al (2004) USA	Described experiences of parents	Parents only (of 16 children aged less than 12 years); N=21	Descriptive study, semi-structured interviews
Low et al (2005) USA	Explored psychosocial issues related to therapy	- Young people (11-18 years); N=18 - Parents; N=21	Descriptive study; interviews
Olinder et al (2007) Sweden	- Investigated reasons for starting therapy; opinions and concerns - Evaluated metabolic control and safety	Young girls (7-15 years); N= 12	Aged matched controlled, then follow-up study for 2 years; questionnaires
Barnard et al (2008) UK	Identified major component of quality of life and assessed impact on life	- Children (9-17 years); N=15 - Parents; N=17	Exploratory study; telephone interviews using SEIQoL
Wilson (2008) UK	Examined experiences of parents	Parents (of children aged 1-6 years); N=44	Exploratory study; Self-completion questionnaires

SEIQoL= the schedule for the evaluation of individualised quality of life

Reviewing these studies revealed that they were mostly small scale-studies (sample size:12 to 52), with variable methodology: 2 used questionnaires (Olinder et al, 2007; Wilson, 2008) and 4 used interview techniques (Maniatis et al, 2001b; Sullivan-Bolyai et al, 2004; Low et al, 2005; Barnard et al, 2008). In addition, insulin pumps of different makes and models were used in these studies, which might have played a role in the users' perceptions and opinions. In some cases, pump type was not even mentioned (Sullivan-Bolyai et al, 2004; Low et al, 2005; Wilson, 2008). The ages of children/young people varied and only 2 studies were identified in the literature that explored experiences of children as young as 7 (Maniatis et al, 2001b; Olinder et al, 2007). Children as young as 5-6 years old were not asked to comment on their experiences of using insulin pumps in any of these studies, instead their parents were asked to provide the necessary data.

The views of children and young people were not analysed with reference to age to investigate if there were certain issues raised by each age group. In addition, there was lack of evidence about the views of children versus those of parents about the use of insulin pumps compared to injections.

Although the majority of studies reported the participants' views or expectations on improving glycaemic control using CSII compared to injections, clinical evidence of blood glucose control, represented by HbA1c values, was absent in all but 2 studies (Maniatis et al, 2001b; Olinder et al, 2007). Furthermore, questions about the use of pumps at schools, social interaction, mechanical dependency and child's autonomy in carrying out management tasks in relation to age have not been adequately addressed in the existing literature.

As there is scarcity of published studies on the experiences and views on the use of insulin pumps, and as the number of pump users in the UK is still limited regardless of the growing data supporting their safety and efficacy, further research in this context is recommended. The NSF for children and young people aims to promote high quality services to children/young people and their families through the setting of national standards (Department of Health, 2007c). One of these standards requires agencies to take into account the views of children/young people and families in the planning, delivery and evaluation of healthcare services. Conducting studies that explore the experiences and perspectives of children and their parents on the use of insulin pump therapy is therefore crucial.

1.5 Aim and objectives of the main study

1.5.1 Research aim

To document the experiences of children/young people with T1DM and their parents in managing the condition using insulin pumps, and to examine the extent to which switching to pumps enables health policy goals (i.e. improved glycaemic control, self-management and supporting normal lives) to be achieved. This will reveal the benefits, needs and problems that arise in the context of pump therapy, from the patients' and their families' perspective, and permit recommendations to be made for the provision of health services.

1.5.2 Research objectives

1. To document changes in glycaemic control immediately prior to and following the transition from injections to insulin pump therapy.
2. To identify problems associated with the use of the pump technology.
3. To identify how the day-to-day management responsibilities for diabetes were shared between children and their parents, and ways in which use of insulin pumps promoted or hindered children in assuming greater responsibility for management of their condition.
4. To identify, within the context of school life, how the management responsibilities were undertaken and what problems were experienced. Also, to examine forms of support and barriers pertaining to using insulin pumps at school.
5. To investigate how insulin pump therapy impacts on the daily lives of children and other family members.
6. To examine the experiences of children/young people and their parents at different stages of therapy.
7. To make recommendations, from the children/young people's and their parents' perspectives, on the support they receive with University College Hospital (UCH), London.

CHAPTER 2 - Methods

Chapter 2: Methods

Chapter 2 describes processes by which the study methods and procedures were devised and undertaken. It includes a report of the preliminary fieldwork, research design, sampling, data collection and analysis.

UCH, part of University College London Hospitals NHS Foundation Trust, is a major centre in London providing insulin pump therapy for children and young people, and hence was chosen as the setting for the study. This setting has a wide geographical catchment area and would thus enable the recruitment of families from a range of social-cultural backgrounds. Meetings were held with the Paediatric Diabetes Team at UCH to help inform the structure of the main study **(Section 2.1)**.

2.1 Preliminary fieldwork

2.1.1 Aims of the preliminary fieldwork

The preliminary fieldwork had 4 major aims. These were:

1. To gain insight into the programme of insulin pump therapy conducted at UCH, London.
2. To establish issues that might be of importance for clinicians and nursing staff at the hospital, for inclusion in the interview schedules of the main study.
3. To discuss how the children/young people and their parents would be invited and recruited to the study and how the medical records would be accessed for the collection of clinical data.

2.1.2 Meetings with the Paediatric Diabetes Team at UCH

Meetings were arranged with the Paediatric Diabetes Team at UCH, including diabetes consultants and Diabetes Specialist Nurses (DSNs) to discuss the focus of the main study. The meetings involved discussions regarding the programme of insulin pump therapy conducted at the hospital in terms of: patients selection criteria, educational courses and other services offered to the families. The most important areas of research in the context of pump therapy in paediatric patients were also covered and discussed. The meetings involved discussions on the most feasible and convenient methods for participants' invitation and recruitment to the study, and for the collection of clinical data from the medical records.

2.1.3 Impact of the preliminary fieldwork on the development of the main study

Preliminary fieldwork was conducted to help the structure and methods of the main study **(Figure 2.1)**. In relation to the study sample, information regarding the paediatric population receiving insulin pump therapy at the hospital was obtained, such as: number of children/young people, age ranges and types of insulin pumps used. The preliminary fieldwork also helped to plan the best way to recruit participants in the study which was most convenient for the diabetes team and the researcher. Accordingly, it was suggested that a package of all relevant documents (e.g. invitation letters, information leaflets and consent forms) should be prepared by the researcher for distribution, in collaboration with the DSNs at the hospital. All the documents were revised and assessed by the clinical team, whose comments and feedback were taken into consideration.

The preliminary meetings with the clinical team, especially the DSNs, helped the researcher to develop the instrument for the study. This was manifested by proposing questions and issues to be included in the instrument designed for data collection. Such issues were particularly relevant to the insulin pump programme conducted at the hospital and the services provided by the clinical team for the children and their families.

As the current study aimed to explore experiences of children having a wide age range, the clinical team helped the researcher to group children based on their ages. This was undertaken for methodological reasons to design a data collection tool suitable for each age group.

2.2 Methodological design

In order to meet the study's proposed aim and objectives, a cross-sectional study was employed using quantitative and qualitative procedures to explore the experiences of using insulin pumps in children and young people.

The quantitative procedures involved accessing medical records of patients to collect clinical readings (i.e. HbA1c). This would help to examine the clinical effectiveness of using the pumps and to relate that to the qualitative data.

Figure 2.1: Research methodology for the main study

The qualitative procedures involved conducting cross-sectional, semi-structured interviews. The use of interviews enables the presentation of full accounts of children's and parents' views in detail and separately from each other. Moreover, the semi-structured research technique is a flexible tool that has the advantages of maintaining a balance of structure and openness by permitting two-way communication. Such interviews allow the researcher to prepare a list of questions around the topics of interest prior to the interview and permit the interviewees to discuss their own experiences in response to questions and to raise issues of importance to them, adding both depth and validity to the data (Gillham, 2005). This flexibility would not have been achieved if either structured interviews or a totally unstructured interview approach had been employed, as the former lacks the flexibility in the two-way communication between the interviewer and the interviewees, while the latter would not ensure coverage of the topics of interest to all the respondents.

2.3 Sampling and recruitment

2.3.1 Sampling strategy and sample size

All paediatric patients receiving insulin pump therapy at UCH, London were regarded as eligible for this study. Accordingly, all children and young people (N=65) treated with insulin pumps for different periods of time and who attended the paediatric diabetes outpatient clinics, and their parents, were invited to take part. This sample size would permit analysis of the clinical data. Moreover, since the UCH is a major regional centre in London implementing insulin pump therapy for paediatric patients, inviting the whole population would include a sample with a wide range of social and cultural backgrounds, age groups and durations on insulin pump therapy.

The study aimed to recruit children and young people of different ages, who were diagnosed with T1DM, who had transitioned from injection therapy to insulin pump therapy and who attended outpatient clinics at the hospital, and their parents. The inclusion and exclusion criteria used in the study reflected this and are listed below:

- A diagnosis of T1DM
- Age 0-17 years old
- Attending paediatric diabetes clinic at UCH, London
- Receiving insulin pump therapy
- Previously transitioned from injection therapy to insulin pump therapy

The exclusion criteria were:

- Children/young people who started insulin pump therapy directly after diagnosis
- Children/young people or parents who did not consent to take part in the study

2.3.2 Sampling procedures

Initially, a list of the names, number and ages of all paediatric patients receiving insulin pump therapy at the hospital who were eligible for the study was given to the researcher by the DSNs.

Children and young people receiving insulin pump therapy at the hospital have appointments with the diabetes consultants every 3 months. Accordingly, patient recruitment was conducted on a rolling monthly basis based on the clinic visits of each group of patients. For this purpose, a time schedule of the monthly visits to the paediatric diabetes outpatient clinics was prepared by the DSNs and given to the researcher at the end of each month, once data collection for the study had commenced. The schedule comprised information on: patients' names, dates and times of the medical appointment with the consultants.

2.3.3 Sample recruitment

A recruitment package containing a cover letter attached to a reply slip **(Appendix 2)**, information leaflets and consent forms were prepared for both the parents and their children/young people. This was important so that the child/young person would feel invited personally to take part in the research. Age-specific material was prepared for children and young people aged 0-7, 8-12 and 13-17 years. Accordingly, 5 versions of information leaflets **(Appendix 3)** and consent forms **(Appendix 4)** were designed: for parents of children younger than 5 years and parents of children aged 5 years and older, as well as for children aged from 5 to 7 years, 8 to 12 years and 13 to 17 years. The forms were designed to explain: the purpose of the study, what it would involve, time required from the participants, confidentiality issues, investigator's information and the participants' rights. Moreover, in the design of information leaflets and consent forms for children and young people, care was taken to ensure that the documents were presented and worded in a way that could be understood by the target age-group.

Patients were recruited in groups on a monthly basis according to the clinic visits they had at the hospital. So for each patient having a medical appointment at the clinic in a

certain month, a package with all correspondent documents were sent to their home address at least 2 weeks prior the appointment, so that the patients and/or their parents would have time to read the documents and send back the reply slip either with their agreement, or refusal, to take part in the study. On the occasions where a family had two children using insulin pumps, 3 packages were sent to the home address (one for each child and one for the parent). In most cases, parents filled in reply slips and their consent forms while children filled in their own consent forms. In cases where consent forms of parents or children were not signed and returned with the reply slip, the researcher would ensure receipt of the signed documents when meeting the children/young people and parents at the hospital/family's home for the interviews. On the receipt of a reply indicating that the young person and his parent(s) wished to take part in the study, the researcher contacted parents or, in rare cases, patients themselves (in the case of young people) by telephone, answered any questions that they might have had, and arranged an appropriate time for interviews, one with the child and another with the parent(s).

From reply slips that indicated a decision not to take part in the project, patients' information such as: name, age, sex, number of years since the diagnosis of the condition and duration of using insulin pumps (which were included in the reply slips filled by the respondents) were recorded and collated at the end of the study.

If there was no response, a 'reminder letter' was sent to those families, usually within a month of sending the information packages to the home addresses. This method was usually combined by the researcher attending the diabetes outpatient clinics run at the hospital to talk to the parents and/or young people about the study, to answer any questions and to clarify what was required from them if they agreed to take part. On the occasions where the medical appointments were cancelled; patients and their parents did not attend UCH for the appointments; or the researcher could not attend the clinic because of conducting an interview on the same day with another family, only a reminder letter was sent to those families which did not return back reply slips.

Recruitment of the participants in the study commenced in July 2008 and continued for 12 months (until June 2009).

2.4 Data collection methods

Quantitative measurements and descriptive procedures were undertaken for characteristics of respondents and clinical data. HbA1c values were collected retrospectively from the medical records of children and young people for 6 months prior to commencing pump therapy and for all subsequent readings achieved whilst using insulin pumps during the time course of the study.

Qualitative, semi-structured interviews were undertaken to explore views and perspectives of children/young people, and their parents about using insulin pumps to manage T1DM.

2.4.1 Review of patients' records

The first method for collecting data in this project involved reviewing the medical records of the children and young people for HbA1c values. The HbA1c measure is the most commonly used internationally recognised assay to predict blood glucose control for patients with diabetes since its introduction more than 25 years ago (Nathan et al, 2007; American Diabetes Association, 2009). The aim of obtaining such data was to determine the clinical outcomes immediately prior to and following the switch to pump therapy. These data could also be related to the qualitative data obtained from the interviews in an attempt to put clinical change into the context of users' own experiences. Additionally, exploring glycaemic control would help assess the clinical significance of using insulin pump therapy compared to using injections, and to support any recommendations that could be made for the provision of health services with regard to managing T1DM in children and young people.

Accordingly, for all families who consented to participate in the study, data concerning HbA1c values for 6 months prior to the commencement of insulin pump therapy (when injections were used) to the latest reading achieved whilst using insulin pumps were recorded from the children/young people's medical records. For children aged less than 5 years, their parents consented on their behalf.

2.4.2 Interviews

2.4.2.1 Development of an instrument (interview schedules)

For the purpose of this study, age-specific interview schedules (5 versions) were devised by the researcher and reviewed by the project supervisors for content and layout **(Appendix 5)**. Care was taken with respect to the language and content so that the questions could be understood by the age-group for whom they were designed.

The content of the interview schedules was created to reflect the aim and objectives of the project. Reviewing the literature of similar works and the preliminary fieldwork helped the researcher to design some of the questions. The interview schedules comprised open-ended and closed-ended questions. The open-ended questions were designed to gather information about children/young people's and parent's experiences and views on using insulin pumps compared to injections in the management of T1DM, while the closed-ended questions were designed to gather some information with regard to medical regimens and demographics.

The parents' interview schedules included questions on: general experiences and views about using insulin pumps; day-to-day management issues at home; issues of using insulin pumps at schools; effectiveness for achieving glycaemic control; safety; impact on family life; insulin pump therapy programme and other services provided at the hospital. Moreover, some medical (e.g. insulin regimen, pump type, diabetes/pump therapy duration) and personal (e.g. age, sex, ethnicity and year at school) information was included. For children and young people aged 8-17 years, the interview schedules included similar questions to those of the parents, but with simplified language suitable for the age range of each group. For younger children (aged 5-7 years), the interview schedules were further simplified, therefore some detailed questions were not included. These included information on: insulin regimens; incidence of pump problems in the month prior to the interview day; opinion on different services at hospital and ethnicity. All interview schedules contained similar prompts and probes which were written in italics and a smaller font to help the researcher to gain information on specific issues in the areas of interest.

After conducting the first 6 interviews (3 with the children and 3 with the correspondent parents), some minor additions were introduced to the interview schedules, as illustrated in **Section 2.4.2.3**.

2.4.2.2 Conduct of interviews

Upon receipt of a reply slip indicating willingness to participate in the study, parents (or rarely young people) were contacted by telephone and were asked about the location and time they wished the interview to take place. As the study aimed to explore and describe participants' experiences in the context of their social lives and daily activities, initially it was intended that all interviews would be conducted in patients' homes. It was considered appropriate to carry out the interviews in patients' homes as this would help to create a comfortable and relaxed atmosphere for the children and the parents to express their views and concerns. However, the interviews were conducted depending on the parents' preferences either at their homes to which the researcher travelled, or at the hospital at the next medical appointment. On the occasions when the interview was scheduled for the next clinical appointment which usually was more than 2 weeks from the initial contact with the family, the researcher telephoned the family a day before that appointment in order to remind them.

At the beginning of the study, it was intended that the children/young people (aged 5-17 years) and their parents would be interviewed separately, so as to ensure free and open discussion without the influence of the presence of the other which might affect participant's response. However, in practice, in some cases either the child or the parent(s) requested to attend the other's interview. Moreover, for many of the interviews (N=9; out of 17) that were conducted at the hospital, the parent(s) and/or children attended each others' interview. This was because only one room was provided for the researcher to conduct the interviews, and the interviews were sometimes conducted on a different floor to the clinic, therefore parents and their children preferred to accompany each other during the interview process. It is important to highlight that children aged less than 5 years were not interviewed, but instead the interviews were conducted with their parents, as it would be almost impossible to gain information from children aged less than 5 years. Moreover, where two parents wished to be interviewed, they were interviewed jointly, with the questions addressed to both parents and answered by either.

Efforts were made by the researcher to relax the child/young person and parents before the interview process. Children and young people were reminded prior to the commencement of each interview that the interview was not an exam and that no answer was correct or wrong, but rather the researcher wanted to know how the child felt about managing diabetes with the pump. Parents were reminded that the researcher was independent from the hospital and that all participants' names and information obtained during the interviews would be made anonymous and confidential, respectively. Where a signed consent form was not obtained with the reply slip, children and/or parents were asked to sign a consent form **(Appendix 4)** before the interview process took place and were reminded again about the nature of the research and that they were free to withdraw at any time. Consent to audio-record the interview was also obtained at this point. A 'thank you' letter was sent to the families which participated in the research.

The average duration of interviews (patients and their parents) was anticipated to be 30-45 minutes, depending on the respondent's views and concerns.

2.4.2.3 Piloting and amendments introduced to the interview schedules

After conducting the first 6 interviews with the families (3 interviews with the children and 3 with the correspondent parent), the instruments and procedures were reviewed (i.e. piloted). The aim of this piloting was to make sure that the design of the interview schedules was sufficient in terms of content, format and wording to gain the required amount of information that commensurate with the research aim and objectives. In other words, to make sure that the tool designed for the study was suitable to answer the research questions and to introduce any refinements if needed before conducting the rest of the interviews. Therefore, the transcripts of the first 6 interviews were read and then discussed in a meeting which was held between the researcher and the project supervisor(s).

In terms of the content, the questions of the interview schedules were found to be sufficient to collect comprehensive data around the topics of interest. With respect to the format, minor modifications were made by introducing prompts to some of the questions in the interview schedules (see bold words in **Appendix 5**):

- The prompts 'carbohydrate counting' and 'other family members' were added to 'question 9' of interview schedules of children aged less than 5 and to 'question 7' of the interview schedules of the other participants.
- The prompt 'impact of using insulin pumps on other family members' was added to 'question 11' of interview schedules of children aged less than 5 and to 'question 9' of the interview schedules of the other participants.

Moreover, some issues were discussed in the meeting, such as whether the wording of the questions was sufficiently clear for the children and young people to understand. Some words such as 'transition' in 'question 14' of the interview schedules were found to be difficult for some children to understand (as shown by interviews with 2 children aged 8 years) therefore, the researcher had to use alternative words, such as 'switch' during the interviews. However, it was decided by the researcher and supervisor(s) to keep the same word 'transition' in the interview schedules of children aged 8-12 and if necessary, rewording and further clarification would be done during the interview process.

Because no significant changes were introduced, these 3 pairs of interview transcripts were retained in the data set.

2.5 Ethical approval

Before commencement of any data collection for the project, approval from the Ethics Committee was sought. As the study was to be carried out at UCH, London a submission for ethical approval was made to two health authority committees: the Joint UCL/UCLH Biomedical Research (R & D) Unit and the Joint UCL/UCLH Committee on the Ethics of Human Research, Committee Alpha. Applications were submitted with the research protocol, invitation letters, interview schedules and all other relevant documents on 14th December 2007.

A letter of approval from the R & D Unit was received on 10th January 2008 **(Appendix 6)**. The Ethics Committee's meeting was held on 17th January 2008, where the researcher and one of the supervisors attended a meeting of the committee and a letter of response was received on 29th January 2008, which provided a favourable ethical opinion of the research, subject to the submission of some additional information and minor amendments. Amendments were introduced to the relevant documents as

requested and a reply letter enclosed with the revised documents was sent to the Committee on 12th February 2008. The Committee's final decision was obtained on 10th March 2008 **(Appendix 7)**, giving a favourable ethical opinion after revising the amended documents.

2.6 Data processing and analysis

2.6.1 Analysis of HbA1c readings

The aim of this part of the project was to examine clinical outcomes of pump use. HbA1c values were collected from all children's and young people's medical records (N=42) for 6 months prior to the commencement of insulin pump therapy (i.e. during injection therapy) up to the last reading whilst using the pumps. For some patients (N=6), the readings of HbA1c on injections were absent from the files kept at the hospital. Most of these patients (N=5) were referrals (i.e. did not start insulin pump therapy at UCH). Moreover, for 2 patients, no test was undertaken to measure HbA1c values for the first 6 months post-pump therapy. In such cases, readings were recorded as 'missing.'

Initially, all HbA1c readings pre and post-pump therapy were entered into an Excel spreadsheet with the dates of HbA1c testing. Data were anonymised. Details regarding patients' ages and durations on insulin pump therapy were also included.

Quantitative analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 13. To test the statistical significance of using insulin pumps to achieve the glycaemic control compared to the injections, HbA1c values for 6 months pre and post-pump therapy were entered into the SPSS program, then mean values were calculated and paired data were analysed using the parametric t-test. A paired t-test is usually used to compare mean values of the same participants, which were collected in two conditions or at two points in time (Bryman & Cramer, 2001). The rationale for using a parametric test was the following:

1. The sample was tested for normality. The mean, median and mode were equal and the sample distribution curves for the HbA1c readings pre and post-pump therapy showed normal distribution.
2. There was significant correlation between the mean HbA1c values pre and post-pump therapy.

The sample in this study involved children and young people who have been using the pump for various durations of time ranging from 5-84 months. Therefore, the clinical significance of using the pump over long periods of time was also investigated. This was achieved by testing the mean HbA1c values of 6 months prior to pump therapy against the mean HbA1c values of the following durations post-pump therapy: 0-6 months, 7-12 months, 13-18 months...etc. The parametric paired t-test was used to perform such examination. All reported results were two-tailed and were considered significant at $P<0.05$.

Descriptive statistics were undertaken to illustrate the trend of glycaemic control over time. Graphs were drawn using line segment statistical graphs where mean HbA1c for 6 months before pump therapy and then per case averages at each 6 month interval post-pump therapy were plotted.

Because children and young people were of different ages and had been using insulin pumps for various durations of time, further analysis was undertaken to investigate if there was an association between children's age or duration on insulin pump therapy with the changes in glycaemic control. For this purpose, a weighted linear regression test was undertaken to quantify the association between 2 continuous variables (Dupont, 2009).

Following examination of the clinical data, the interview transcripts were investigated in an attempt to relate the clinical results to the information provided by the parents and/or their children/young people. Moreover, the transcripts were also scrutinized to find justifications and explanations for the results obtained from the clinical data.

2.6.2 Analysis of interviews data

All interviews were audio-recorded (Olympus WS-331M Digital Voice Recorder) after obtaining participants' permission. Audio-recorded data from the open and closed questions were transcribed verbatim to enable the qualitative analytical procedures. The process of transcribing the interviews was usually carried out directly after finishing the interview, or within 24-hours, as that helped the researcher remember the details of each interview. Field notes were also taken and typed up directly after completion of interviews to ensure accurate documentation of all data. They included information on: other attendants with the participant during the interview; any interruptions made during

the interview process; facial expressions and side conversations with the participants before or after the start of the interview. All transcripts were given an identifying number which reflected the order of the interviews; parents' interviews were numbered first then the children's interviews. This enabled the researcher to analyse parents' interviews separately from the children's and young people's interviews and allowed comparisons to be made.

As noted by Miles and Huberman (1994), computer programs can provide assistance to the researcher in the analysis of qualitative data, as they can reduce analysis time, cut out much hard work, make analysis more systematic and clear, and permit easier retrieval of data. For this purpose and due to the large volume of the qualitative data in this study (72 transcripts; 38 for parents and 34 for children), the software package MAXQDA 2007 was used. This software allowed many functions to be carried out, including coding segments of text, storing the transcribed data in an organised form, searching and retrieval of particular segments of texts for inspection, linking relevant data to form categories, writing memos, counting frequencies of words or phrases, conclusion drawing and verification, as well as concept building. Before being entered into MAXQDA, each transcript was revised by re-listening to the audio-recorded tapes at least once to ensure accuracy of the data captured and that all data were recorded and typed verbatim. For confidentiality reasons, factors identifying participants, such as names of children/young people, parents, or other individuals mentioned during the interviews as well as names of hospital staff were made anonymous.

The transcripts were organised in the program so that the parents' and the children's interviews were grouped based on the age group of the children: children aged 5-7 years, children aged 8-12 years and young people aged 13-17 years. For children aged less than 5, only the parents were interviewed.

As indicated by Robson (1993), although there are different approaches to analysing qualitative data, the procedures undertaken in qualitative data analysis must be systematic. Approaches to analyse qualitative data vary depending on the focus of the study and nature of the qualitative enquiry (Spencer et al, 2003). For this research, a mixture of framework approach informed by research objectives, and grounded approach to accurately reflect experiences and perspectives of respondents was

undertaken for data analysis. The procedures carried out to analyse the transcripts in the current study involved 3 main steps: data management, data description and data explanation/ interpretation **(Figure 2.2)**.

2.6.2.1 Data management

At the beginning of the analytical process, data management was usually undertaken to reduce and sort data and hence make them more manageable. Within this context, the interview transcripts (raw data) were coded following their entry into the MAXQDA program **(Appendix 8)**. Coding of transcripts involves generating labels or themes to parts of textual data with similar meaning, as well as differentiating and combining the retrieved data, while keeping the relations between different parts intact. In this way, data from interview transcripts were categorised according to meaning and description, as part of a data-reduction process. In this research, coding of interview data started after conducting interviews with all respondents.

As described by Miles and Huberman (1994), a 'code' is a label or tag for a section of the text, which could either be a word, a phrase, a sentence or a whole paragraph. Codes can either be descriptive (i.e. involves little interpretation), interpretive or inferential (i.e. more explanatory). This allows efficient retrieval, analysis, and organisation of the data as well as a description of respondents' experiences and views in the context of their own settings, priorities and concerns. For the generation of the codes in the current study, a list of codes was developed in advance based on the study's aim and objectives and the literature view and additional codes were included in the list as new issues were raised by the participants during the interviews.

From the interviews with the parents and children, 9 major themes/codes were generated **(Table 2.1)**. Demographic and medical information of participants were also given the codes 'demographic information' and 'medical information,' respectively.

As the process of entering transcripts into MAXQDA and the process of coding continued throughout textual data, additional sub-codes were identified and created under each major code or theme **(Appendix 9)**. For example the code 'day-to-day management issues at home' included many sub-codes, such as roles in partnership, dependency/independency and partnership on injection therapy. It is important to

Figure 2.2: A hierarchy illustrating the analytical procedures undertaken for the qualitative analysis of the interview data

Table 2.1: A list of themes/subthemes of the current study and origins of the major themes *

No	Code	Origin
1	**Transition period**	Interviews
2	**General experiences and views**	Study's aim and objectives
3	**Glycaemic control**	
4	**Safety**	
5	**Management of diabetes with pump therapy at schools**	
6	**Hospital services**	
7	**Day-to-day management issues at home**	Study's aim and objectives as well as literature review
8	**Advantages and disadvantages of pump therapy**	
9	**Impact on family life**	

* Sub-themes under each major theme were mostly generated from issues raised by respondents during the interviews

mention that on the formation of a new code or sub-codes, all transcripts were searched systematically for similar codes or sub-codes which then were added. This describes an iterative approach in which the constant comparison method, as described by Lincolin and Guba (1985), was used throughout the data analysis. By this method, the data were constantly revisited after initial coding until it was clear that no new themes were emerging.

By the use of MAXQDA software, memos were written to aid in the analytical process. They were attached either to the 'text browser' to record any ideas or comments which occurred to the researcher during the coding process, or to the 'code system' to provide definitions and clarification for some of the themes and sub-themes. For instance, for the code 'management at home,' the sub-code 'roles in partnership' was explained by a memo as: 'partnership that existed between parents and their children/young people in the day-to-day management tasks that accompanied using insulin pumps.'

2.6.2.2 Data description

The number of interviews conducted with children/young people and their parents was relatively large (N=72), which generated a huge amount of textual data. Consequently, the researcher undertook a descriptive analysis of the findings. The aim of this stage of qualitative analysis was to display data in a way that is conceptually pure and provides content that is illuminating, which would subsequently allow organisation, comparison and linking of views of various groups of participants. The process of describing the data involved looking within a theme across all the cases in the study (i.e. parents, children and young people) and noting perceptions and views which have been tagged as a part of that theme. This was applied, theme by theme, to all the 9 major themes generated or identified for the study **(Table 2.1)**, noting that for each individual theme, data from parents were displayed first, followed by those of children/young people. At this stage of analysis, the descriptions made by the researcher stayed close to the original data obtained from the parents and their children/young people.

2.6.2.3 Data explanation/interpretation

The process of data description was then followed by deeper analysis whereby descriptive data underwent further merging, refinement and abstraction. This stage of analysis involved interpretation of the data by detecting patterns, giving explanations (by answering 'why' and 'how' questions) and developing theoretical models or fitting results to frameworks/theories.

The researcher aimed to identify patterns in the descriptive data set by examining if there were any linkages or associations that occurred repeatedly across the data set or within a particular group of participants in the study. In some cases, the explanations were apparent to the researcher, where the participants themselves gave reasons to explain certain issues. In other cases, the explanations were implicit, where the researcher inferred them by: identifying common contexts between cases; applying analytical concepts or relating findings to a theoretical framework, as will be presented in the result chapters.

Using such methods to analyse the interview data allowed the researcher to answer the research questions and make recommendations regarding the use of insulin pumps for the provision of health services. It is important to consider that analytical procedures are not linear **(Figure 2.2)**, as iterative and constant revision of the original or synthesised

data are required to search for new clues, to check some issues, or to identify other factors.

2.7 Reliability and validity of the study

Reliability and validity are important issues that should be considered in all types of researches including qualitative studies to ensure that the processing and analysis of the data are rigorous. This section discusses the reliability and validity of the study in relation to aspects of conduct of interviews, data processing and analysis.

When conducting this study, attention was paid to issues of reliability and validity. 'Reliability' has been termed as the extent to which the findings are reproducible. This is applicable in quantitative studies where the sample should be representative of a larger population, however, it is addressed in different ways in qualitative research (Smith, 2005).

Reliability in qualitative research means how the data is internally consistent (Smith 2002; Smith, 2005). All responses from interviewees should be internally consistent and hence the interviewer should be able to identify any inconsistencies in the views of respondents and provide suitable explanations and reasoning for these elicited responses, so that a detailed understanding from perspectives of interviewees is obtained. Accordingly, it is important that the researcher makes sure that all data relevant to the subject of interest are collected during the interviews, otherwise difficulties in data processing and analysis will arise.

In this study, issues of reliability of the data were taken into consideration:

1. Clarity of questions in the interview schedules was achieved by having the supervisor(s) reviewing and modifying questions that were devised by the researcher. Also, questions with simpler language were used in the interviews schedules of children and young people.
2. Piloting was done for the first 6 interviews (3 with the children/young people and 3 with their parents) to ensure consistency of the answers and clarity of questions for different groups of participants. See **Section 2.4.2.3**.
3. The interviews were conducted by the researcher only, and hence variations in the style of questioning carried out by different interviewers were excluded in this study.

4. The researcher attended preparation courses and read books to acquire the qualifications and skills to undertake interviews. Such skills included avoiding leading questions.
5. All conducted interviews were audio-recorded to enable quality assurance of the data and accurate transcription.
6. Coding for the first few interviews was carried out separately by the researcher and project supervisor(s), then comparisons and discussions on the generated codes were made.

With respect to reliability, Robson (1993) has identified the need of 'conformability' in qualitative research, which is defined as the process by which an outsider to the research can judge a study's findings. He advocated that qualitative data should be collected, recorded and analysed in such a way that an outside individual is able to follow the steps from which the findings have been reached.

In addition to reliability, issues of validity were also considered in this study. 'Validity' of an instrument is defined as the extent to which it measures what it was designed for (Smith, 2002). In qualitative interviews, questions are generally designed to be open-ended to allow the interviewees to raise issues of importance to the topic of concern, and the role of the interviewer in that case is to explore these issues in greater detail. Therefore, data collected from qualitative interviews might be seen as possessing inherent content validity as they are guided by responses of interviewees rather than following the agenda of the interviewer. Steps were undertaken in this study to ensure the validity of the findings:

1. Use of the computer package MAXQDA assisted in the validation process by ensuring that all references to a particular topic were identified and coded in the transcripts. Also, topics were searched throughout all transcripts to enable checking of a topic being mentioned throughout all transcripts.
2. Findings of this research were examined in relation to the findings of previous work and consistencies in findings were noted. This has been termed 'cumulative validity' (Smith, 2002).
3. The data were searched by the researcher for cases that were inconsistent with the main findings from the data. This has been defined as 'argumentative validation' (Smith, 2002).

4. A method of triangulation process was used in which the findings from qualitative data 'views on metabolic control achieved by pump compared to injections' were considered in conjunction with the quantitative data 'HbA1c measures before and after initiation of insulin pump therapy.'
5. Alongside qualitative analysis, the frequencies by which different issues were reported by respondents were recorded. This was done to enable identifying issues of priority from respondents' perspectives and inform inferences from issues where the majority agreed or disagreed. Incidences of missing data were also documented to ensure that responses for all participants were accounted for.

Factors that could affect the validity of the study, such as location of the interviews, independence of the interviewer and confidentiality issues were all taken into consideration when planning and conducting the study (Smith, 2005). With regard to study location, initially all the interviews were intended to be conducted at the participants' homes as that would confer comfort and a relaxed environment to express views. Moreover, the interviewees were assured that the interviewer was independent from the hospital (a PhD student), all the participants will be made anonymous and all information will be confidential. This would ensure that the participants would provide detailed accounts of their experiences and concerns.

Sample characteristics and response rate are described in the next chapter, after which results of the quantitative and qualitative data obtained and analysed by the methodology described in this chapter are presented.

CHAPTER 3 - Response rate and sample characteristics

Chapter 3: Response rate and sample characteristics

In this chapter, a description of the sample and response rate is provided. Rates for non-participants and non-respondents are also documented. The terminology used in this chapter: respondents, non-participants and non-respondents refers to parents and/or children/young people who agreed, declined, or did not reply back to the invitation for taking part in the study, respectively. The response rates for children/young people and/or parents taking part in the study are represented in this chapter by the response rates of the families.

3.1 Rates of respondents, non-participants and non-respondents

The methodology used for recruiting children/young people and their parents was described in **Chapter 2.**

Of the 65 invitations sent to the home addresses of the families, reply slips were received from 57 (88%), among whom 13 families (20%) declined to be involved in the study (non-participant families). Forty-four families agreed to participate in the study (with the child only, parent(s) only, or both), giving a response rate of 68% (respondent families). However, the interviews were not undertaken with 2 of these families, because they could not be conducted within the time scheduled for data collection. Despite sending 'reminder letters,' no responses were received from 8 families (12%; non-respondent) (**Table 3.1**).

Table 3.1: Summary of rates of respondent, non-participant, and non-respondent families (N=65)*

Families	N
Families which agreed to take part in the study **(respondents)**	44
Families which refused to take part in the study **(non-participants)**	13
Families which did not respond **(non-respondents)**	8

* The number of families was calculated according to the number of children using insulin pumps. Four families in the sample had 2 children using insulin pumps. Accordingly number of families was counted as 8)

The following techniques were used to enhance response rates of families during the time course of the sample recruitment and data collection: sending reminder letters alone; attending clinics alone; both sending reminder letters and attending outpatient

clinics. The impact of each of these techniques on the response rate is illustrated in **Table 3.2**.

Table 3.2: Impact of sending reminders only, attending outpatient clinics only, or both on the response rates of families which did not send back reply slips (N=44)

Response	Sending reminders only	Attending outpatient clinics only*	Both sending reminders and attending outpatient clinics**
Agreed to take part	-	13***	- Sending reminders then attending clinics: 4 - Attending clinics then sending reminders: 8
Refused to take part	1	7	Attending clinics then sending reminders: 3
No-response	3	2	Attending clinics then sending reminders: 3

* Six families reported that they have not received any packages through the post
** Four families stated that they have not received any packages through the post
*** The interview was not done with one of those families, because they could not be undertaken within the time scheduled for the study

From **Table 3.2**, it is evident that talking to the families at the clinic alone, or combined with sending reminders to home addresses, was the most effective method of boosting response rates of the participants, by almost 20%. Sending reminders only was the least effective method in attracting patients and their children/young people to participate in the study. Non-respondents in this study formed 12% (N=8) of sample, even following reminders, or speaking to participants at clinics, or using both techniques.

3.2 Characteristics of children/young people who participated in the study

The interviews were initially planned to be conducted separately with the children/young people and their parents, and consent forms had to be received from both. However, either the child or the parent(s), in some families, participated in the study, while the other did not wish to **(Table 3.3)**.

Table 3.3: Families which were interviewed in the study (N=42)

Member(s) interviewed		N
Child and both parents		4
Child and mother		27
Child and father		2
One parent only	**Mother**	7*
	Father	1
Child/young person only		1**

* In 4 families, children's ages were less than 5 years and hence the interviews were conducted with the parent(s) only

** A 17-year old girl told the researcher that she was responsible for everything related to the management, and her parents were no longer involved apart from taking her to the hospital for medical appointments

The characteristics of children/young people who were interviewed are illustrated in **Table 3.4**. Some medical information for children and young people on injection and pump therapy is also described, as reported by parents and/or children during interviews, or collected from the medical records **(Table 3.5)**.

3.3 Characteristics of children/young people who agreed to take part, but were not interviewed

Two families which sent reply forms back to the researcher reporting that they are willing to take part in the study, were not interviewed. The child in the first family was a 6-year old girl who had diabetes for 3½ years and had been using the pump for a year. The other family had a 14-year old boy who was diagnosed with diabetes 12 years ago and had been using the pump for almost 2 years.

3.4 Characteristics of children/young people and their parents who were non-participants in this study

Thirteen families sent reply slips back to the researcher indicating unwillingness to participate in the study and hence were regarded as non-participants. Reasons for not participating were not asked at the request of the Ethics committee. However, 4 parents proposed some reasons which included: previous participation in similar studies or a busy lifestyle.

Table 3.4: Characteristics of children and young people who were incorporated in the study, classified according to the age ranges, as reported by children/young people and/or their parents (N=42)*

Age ranges (years)	Number in each group	Sex	Diabetes duration (years)	Duration on pump therapy	Country of birth (N) **	Ethnic group***
< 5	4	**Male:** 1 **Female:** 3	**Range:** 2-4 **Mean:** 2.6	**Range:** 5 months - 3 years **Mean:** 1.4	England: 4	▪ White: 3 ▪ Mixed: 1
5-7	2	**Male:** 2 **Female:** 0	**Range:** 3-4 **Mean:** 3.7	**Range:** 1-4 years **Mean:** 1.9	England: 2	▪ White: 1 ▪ Mixed: 1 (half English and half Turkish)
8-12	23	**Male:** 15 **Female:** 8	**Range:** 4-11 **Mean:** 6.7	**Range:** 5 months -5 years **Mean:** 2.5	England: 19 Germany: 1 Poland: 1 South Africa: 1	▪ White: 20 ▪ Mixed: 1 ▪ Other: -Turkish: 1
13-17^	13	**Male:** 7 **Female:** 6	**Range:** 3-14 **Mean:** 9.2	**Range:** 2-7 years **Mean:** 3.7	England: 11 Canada: 1	▪ White: 8 ▪ Asian British: 1 ▪ Black British: 1 ▪ Mixed: 1 (half Burmese and half White) ▪ Other: - Caucasian: 1

* In the case of children aged less than 5 years (N=4), the interviews were done with the parent(s) only. In the group of children aged 8-12, 3 interviews were done with the parents only, while in the group of children aged 13-17 years, 1 interview was done with the young person only without parent(s)

** Data on 'country of birth' are missing for one child aged 8-12 years and one young person aged 13-17 years

*** Data on 'ethnicity' are missing for one child aged 8-12 years and one young person aged 13-17 years

^ One young person was aged 19 years by the time of interview. After the discussion with the project supervisor(s), the researcher decided to include the patient in the study.

Table 3.5: Some medical information on insulin injections and pump therapy, as reported by children/parents and/or recorded from medical files

Patient groups	Injection therapy		Insulin pump therapy		
	Insulin type	**Frequency ***	**Place of commencing CSII/N**	**Current pump/N****	**Insulin type/N *****
Children aged < 5 years (N=4)	Short-acting/ intermediate-acting and long acting insulin	2 times/day → MDIs	UCH: 4	▪ **MiniMed Medtronic Paradigm** - 522: 4	Novorapid: 4
Children aged 5-7 years (N=2)			UCH: 2	▪ **MiniMed Medtronic Paradigm** - 512: 1	Novorapid: 2
Children aged 8-12 years (N=23)			UCH: 22 South Africa: 1	▪ **MiniMed Medtronic Paradigm** - 502: 1 - 512: 2 - 515: 1 - 522: 12 - 722: 3 - Unknown: 3 ▪ **Animas:** 1	Novorapid: 19 Humalog: 2
Children aged 13-17 years (N=13)			UCH: 9 USA: 3 Canada: 1	▪ **MiniMed Medtronic Paradigm** - 512: 4 - 522: 3 - 722: 4 - Unknown: 1 ▪ **Animas:** 1	Novorapid: 12 Humalog: 1

* One patient aged < 5 years, 2 children aged 8-12 years and one young person aged 13-17 years started on MDI directly after the diagnosis. A child aged 8-12 years was moved directly from 2 injections/day regimen to insulin pump therapy.

** Data regarding 'current pump type' are missing for one child aged 5-7 years

*** Data regarding 'insulin type on pump therapy' are missing for 2 children aged 8-12 years. Novorapid and Humalog are trade names for insulin aspart and lispro, respectively.

Characteristics of children/young people and their parents who were regarded as non-participant in the study, as reported by their parents (in the reply slips) are shown in **Table 3.6**. Sampling bias was excluded from the current study (the total population was invited to participate), however, bias may be imposed by the non-participants. No apparent differences were identified in the characteristics of non-participants compared to those who participated in the study.

Table 3.6: Characteristics of children and young people who were non-participants in the study, as reported by their parents (N=13)*

Age ranges	N	Sex	Diabetes duration (years)	Duration on pump
< 5 years	1	**Male:** 1 **Female:** 0	2	6 months
5-7 years	1	**Male:** 1 **Female:** 0	4.5	2 years, 3 months
8-12 years	3	**Male:** 0 **Female:** 3	**Range:** 8-10 **Mean:** 8.8	**Range:** 1 month-2 years** **Mean:** 1.1
13-17 years	5	**Male:** 3 **Female:** 2	**Range:** 4-13 **Mean:** 7.5	**Range:** 7 months - 6 years **Mean:** 3.3

* Three parents reported their refusal to take part in the study verbally at the clinic
** One parent in this group reported that the child was no longer on insulin pump therapy

3.5 Conduct of interviews

Interviews were initially planned to be conducted at patients' homes. However, the interviews could be conducted in the clinic on the next medical appointment if parents/young people preferred. Of the interviews conducted with the families (N=42), interviews with 25 families were done at their home, whilst interviews with 17 were conducted at the hospital.

Where the interviews were undertaken at the hospital, a private room was sought by the researcher with the help of the DSNs. In some instances, the researcher had a time limit after which time the room had to be emptied. In these cases, the researcher shortened

the interview by omitting some of the probe questions. In other instances, the clinics ran late, which in turn shortened the time available for the family's interviews. Hospital interviews were sometimes interrupted by the nurses, for example looking for the families to see the consultants, or by other staff looking for an empty room. For these reasons, 2 interviews with parents were not completed and hence information on some questions was regarded as 'missing' when analysing the data.

Conducting interviews at patients' homes provided a more relaxed atmosphere where participants and the researcher communicated interactively without the obvious time limitations. However, interruptions were made sometimes in such interviews by the presence of siblings, other family members, or visitors. Of interviews at families' homes (N=25), 16 were done separately with the parents and the child/young person. However, in some cases (N=9), the parent requested to attend the child's interview.

In general, the duration of the interviews conducted at homes was longer than those conducted at the hospital. At the former, parents' interviews had a duration of time that ranged from 20-105 minutes, while the length of children's and young people's interviews ranged from 15-75 minutes. In contrast, the duration of interviews conducted at the hospital ranged from 25-95 minutes for the parents, and from 15-40 minutes for the children/young people.

As described in **Chapter 2**, UCH was chosen as the setting for conducting this study, as it has a wide geographical catchment area and thus would enable the recruitment of families with different social and cultural backgrounds. The distance (in miles) between the hospital and homes of families who agreed to take part in the study (N=44) was measured. This was done by entering postcode of the hospital and that of families' home into a 'Google map' search engine, and then calculating the mean ± standard deviation (SD): (24.06 ± 28.4; range: 2.6-169 miles).

CHAPTER 4 – Glycaemic control and safety of using insulin pumps

Chapter 4: Glycaemic control and safety of using insulin pumps

Chapter 4 explores the effectiveness and safety of using insulin pumps compared to injections to manage T1DM in children and young people.

4.1 Effectiveness of insulin pumps in achieving glycaemic control compared to injections

4.1.1 HbA1c readings from medical records

HbA1c measures reflect the average glycaemia over 2-3 months and it is a strong predictive indicator for diabetes complications (Diabetes Control and Complications Trial Research Group, 2002). From patients' medical records (N=42), HbA1c readings were collected retrospectively by the researcher for the 6 months period prior to commencing insulin pump therapy (i.e. when children were on injection therapy) to the last reading on insulin pump therapy collected within the time course specified for the data collection for the study **(Chapter 2)**. Statistical analysis was undertaken to determine: the effectiveness of insulin pumps to control blood glucose levels compared to injections, whether the control was maintained over time and if there was an association between 'children's age' or 'duration on insulin pump therapy' and the change in the glycaemic control. All statistical analysis was undertaken using the software SPSS, version 13. Reported results were two-tailed and were regarded statistically significant at $P < 0.05$.

The changes in HbA1c levels over time for the whole sample are shown in **Figure 4.1**.

Figure 4.1: Glycaemic control before and after transition to insulin pump therapy for children and young people (N=42).* The number of subjects included at each time point (N) is indicated above the corresponding month. P-values (P) represent comparison between pre-pump HbA1c values with those post-pump at each 6-month increment. The figure only represents mean HbA1c versus time for readings with at least 3 cases.

* Data were missing from 6 children/young people who did not have pre-pump HbA1c readings

A general reduction trend was found in the HbA1c readings over time. The mean ± SD of HbA1c values of the children/young people fell from 8.18 ± 0.77 to 7.63 ± 0.82% after 6 months of initiating insulin pump therapy. This 0.55% drop in HbA1c levels was statistically significant with P< 0.05 (95% CI, 0.26-0.68).

To investigate whether the long-term benefits of insulin pump were significant compared to injections, mean HbA1c readings for all children and young people for 6 months pre-pump versus various durations post-pump (at each 6-month increment) were compared using a paired t-test **(Figure 4.1)**.

The significant improvement in the glycaemic control was sustained throughout the first 3 years following pump commencement with mean value of 7.56 ± 0.76 (P= 0.025; 95% CI, 0.07-0.86) at year 3. After 3 years, HbA1c values remained less than that pre-pump therapy; however further changes were not statistically significant. The number of children decreased as the duration of follow-up increased, therefore the sample size was small for more long-term analysis (i.e. HbA1c pre-pump readings versus 6 month-increments post-pump). Accordingly, the interpretation of the results on this aspect should be undertaken with care.

Descriptive statistics were undertaken to identify those children and young people who showed improvement, deterioration, or no change in HbA1c values following 6 months of commencing insulin pump therapy **(Figure 4.2)**.

Figure 4.2: Patients' response following 6 months of insulin pump therapy (by changes in the HbA1c values).
N=34 out of 42 (data for 6 months pre and post-pump therapy were absent for 6 and 2 patients, respectively)

The majority of children and young people showed improvement in glycaemic control after 6 months of starting insulin pump therapy. Patients who showed 'no change' or 'deterioration' in the blood sugar readings on the pumps are reported in **Table 4.1**.

Table 4.1: Children/young people who showed worsened (N=7) or no change (N=3) in glycaemic control 6 months after starting pump therapy

Patient	Age (years)	Pump duration (months)	Mean HbA1c %	
			Pre-pump	Post-pump
Pt 8	5	43	8.3	8.4
Pt 11	10	14	8	8.6
Pt 13	12	43	8.6	9.2
Pt 14	8	41	8.1	8.4
Pt 29	10	19	7.4	7.8
Pt 33	16	36	8.2	8.5
Pt 41	15	27	7.2	7.8
Pt 36	11	62	8.7	8.7
Pt 15	10	25	8.3	8.3
Pt 17	8	5	8.1	8.1

Children and young people who showed worsened glycaemic control (by elevation in mean HbA1c readings) 6 months following pump initiation were from various age groups (1 was in the group of children aged 5-7 years; 7 were 8-12 years and 2 were 13-17 years) and had various durations on insulin pumps (from 5 to 62 months). The elevation in those patients with worsened control was by 0.3%-0.6%. The 3 children whose mean HBA1c values for 6 months pre and post-pump therapy did not change were in the age group of 8-12 years.

Because the sample was of wide age ranges and duration on insulin pump therapy, a possible association between the children's age or duration on pump therapy and the glycaemic control was investigated. For this purpose, the sample was grouped as follows: children aged 0-8 (N=9), 9-12 (N=18) and 13-17 years (N=9). Weighted linear regression testing was performed and showed no significant association between duration on insulin pump therapy (β= -0.45; P= 0.17) with the changes in glycaemic control (measured as mean HbA1c values). Regarding age, there was no significant association between post-treatment time for groups aged 0-8 and 9-12 years and change in HbA1c values (P= 0.37 and 0.08, respectively). With participants aged 13 years or older, there was a significant negative relationship (β= -0.85; P= 0.002).

In order to relate the results from the clinical data with those of the qualitative data, all transcripts from parents' and children/young people's interviews were scrutinized carefully to explore perspectives of participants on the effectiveness of using insulin pumps, compared to injections, to maintain blood glucose levels of children and young people within normal target ranges.

4.1.2 Reports of parents and children/young people on overall glycaemic control

All parents (N=38) and children/young people (N=34) were asked during the interviews to describe their perspectives with regard to the effectiveness of insulin pumps to control blood glucose levels‡ compared to injections (**Table 4.2**).

Table 4.2: Perceived glycaemic control on insulin pumps compared to injections, as reported by parents (N=38) and children/young people (N=34)

Role	Groups based on children's age (years)								
	< 5	5-7		8-12		13-17		Total	
	P N=4	P N=2	C N=2*	P N=21	C N=20^	P N=11	C N=12	P	C
Improved	4	1	-	18	18†	9	12	32	30
Same	-	-	-	-	-	-	-	-	-
Worsened	-	1**	-	3	-	2	-	6	-

P= parents; C= children and young people

* Parents who attended children's interviews reported their children would not be able to answer the question, because they were young on the injections. Children, on the other hand, stated that the pump keeps them controlled. One of them added that the control was not achieved at night

** The parent stated that the difference between the pump and injections was 'marginal'

^ Data are missing from 2 children; they answered 'I don't know'

† Three children could not remember time on injections as they were young, however, they answered based on what they thought

‡ Parents and children/young people gave ranges for the blood glucose levels they aimed to target, which were between 4-10 mmol/l

In most cases, insulin pump therapy was reported to improve glycaemic control for the children and young people compared to insulin injections. However, the control was not consistent throughout the day. This was manifested in some families as the child having morning hyperglycaemia or experiencing some days of bad control:

> *"We still have quite a big rise* [blood glucose level] *in the morning after breakfast, but for the rest of the day it is fairly stable and the night times are a lot more stable as well."*
> [Mother of a girl aged 3 years; interview no: 27, lines 191-192]

Few cases were identified in the sample where the blood glucose readings on the injections were better than those on insulin pump therapy. Such reports were only made by parents, while all of the children and young people thought that the control with insulin pumps was better than with the injections. This discrepancy in the opinions of parents and children could be due to most of the children in the sample being either young at diagnosis, or they had been using insulin pumps so long that they might not remember control with injections as well as their parents did. Moreover, parents might be expected to be more precise and accurate than the children when reporting their views.

Justification for the better control on the injections was related to having a longer than normal honeymoon period during the injections. As a result, the body requirements of insulin were minimal:

> *"She had a longer than normal honeymoon, that's what the doctors were saying, so we probably are not comparing with a realistic normal set of levels you know. Her levels were normal; blood sugar levels* [on injections]. *They were perfect for the first couple of years. So now* [on the pump] *I think we are more in the form of diabetes with all ups and downs, so that is why we do not have enough of the test period to compare them you know."*
> [Father of a girl aged 14 years; interview no: 2, lines 263-266]

Moreover, in some cases the difference in metabolic control between the two therapies was marginal (as stated by a parent of a 5-year old boy) or the control was starting to be gained by the pump (reported by a parent of a 10-year old girl).

Although glycaemic control was not achieved in a few cases, insulin pumps were preferred over injections due to the advantages they had in terms of enhancing lifestyle.

Within this context, the impact of insulin pump therapy on family life will be discussed in detail in **Chapter 7**.

4.1.3 Reports from parents and children/young people on glycaemic control during the transition period

Some parents and children/young people also described the blood glucose control at onset of commencing insulin pump therapy; the transition period. The transition period refers to the very beginning of pump use when children and young people had just transitioned from injection therapy to insulin pump therapy (**Table 4.3**).

Table 4.3: Glycaemic control on insulin pumps during the transition period, as reported by some parents (N=24) and children/young people (N=11)

Role	Groups based on children's age (years)								
	< 5	5-7		8-12		13-17		Total	
	P N=4	P N=2*	C N=2*	P N=12	C N=4	P N=8	C N=7	P	C
Improved	1	-	-	2	-	3	2	6	2
Same	-	-	-	-	-	-	-	-	-
Worsened	3	-	-	9	4	4	5	16	9
Others	-	-	-	1**	-	1^	-	2	-

P= parents; C= children and young people

* Data are missing from 2 parents and 2 children (aged 5-7 years)
** A mother of 2 diabetic sons reported that blood sugar readings of the younger son were improved once started CSII, while those of the elder son were worsened
^ A parent could not remember blood glucose control during the transition period

Commencing insulin pump therapy was associated with a period of blood glucose level deterioration, where the control was erratic, difficult to achieve and many hypoglycaemic episodes were experienced. Different estimations, however, were given (by some parents and children) for the time needed to gain glycaemic control. In many families, the duration was from a few weeks to a few months (2-6 months) and in one family, it was a year. Where the control was improved at pump start, the change in blood glucose readings was immediate.

From the clinical data and interviews, insulin pumps were effective in controlling blood glucose levels compared to injections. Moreover, children who did not improve when using pumps were from various ages and durations on pump therapy **(Table 4.1)** and this was consistent with the qualitative data where the parents (N=6) who reported worsened blood glucose readings on insulin pumps, were those caring for children of various ages (5-17 years) who have been using the pump for different durations.

4.2 Reasons why 'good' control was not achieved using pumps for all patients and at all occasions

From the quantitative and qualitative data presented in **Section 4.1**, insulin pump therapy was an effective method of achieving and maintaining metabolic control for the majority of patients in the sample. However, in some patients the blood glucose readings either deteriorated or remained the same. Even with those who showed an overall improvement, the control was not consistent at all times, as days of poor control were occasionally experienced. In addition, the start of pump therapy was usually associated with erratic blood glucose levels.

Accordingly, the transcripts of all children and young people whose blood glucose readings did not improve with using pumps, and those of their parents, were initially revisited in an attempt to identify any factors that impeded good blood glucose control. Likewise, the transcripts of the remaining patients and their parents were revised systematically to explore why days of poor blood glucose control had occurred at the start of insulin pump therapy or later throughout the management. No differences were identified in the reasons given by families in which the glycaemic control was not improved with insulin pumps, and by those who showed an overall improvement, but experienced occasions of bad control **(Table 4.4)**. The reasons given by the families were related to the transition period, ongoing therapy, or both the transition period and thoughout the course of the therapy. Moreover, most of these reasons were not linked to insulin pumps per se, but rather related to diabetes or other external factors.

Table 4.4: Reasons why insulin pumps failed to control blood glucose in some patients, or on some occasions, as reported by parents and children/young people

Reason	Transition period		Ongoing therapy	
	P N=12	C N=5	P N=28	C N=13
Basal insulin needed adjustments	9	2	-	-
New to technology	3	2	-	-
Timing of transition	1	-	-	-
Changes in routines	-	-	7	2
Other illnesses	-	-	6	-
Emotional factors	-	-	4	1
Insulin sensitivity	-	-	1	-
Site failure	-	-	1	1
Monthly period	-	-	1	-
Insulin resistance	-	-	-	1
Puberty	1	-	17	4
Non-compliance	1	1	4	4
Mistakes	2	1	4	1
Unknown reasons	-	-	7	-

P= parents; C= children and young people.
Numbers in the table refers to the frequency the 'reason' was mentioned

4.2.1 Reasons for not attaining glycaemic control during the transition period

Three reasons were identified for patients not attaining control at the period of starting insulin pump therapy. The most commonly mentioned reason was the need to work out and adjust basal insulin:

> *"It was not straightforward, it was not like someone put a pump on them and then miraculously their levels were so much better. I was drawn to the situation of trying to get things right and then realising once you got it right for this situation, change that situation and you need to then get it right for the other one. So very quickly I realised that they needed pattern* [of basal dose] *for school and pattern for weekend."*
> [Mother of diabetic sons aged 8 and 12 years; interview no: 17, line 251]

Using insulin pump therapy requires pump users to learn how to operate the pump correctly. Being new to the technology was one of the factors impacting on glycaemic control. Moreover, selecting the appropriate time for the transition is vital, as some families stated that their children were started on the pump just before going on a holiday, when they were still new to the pump and children were out of the routine they were used to:

> *"But that's because we were trying to learn how to use it. So I would say it took about 2 weeks for some calmness to come back. This was slightly mitigated by the fact that they started Easter, two days after they went on the pump, so we are talking about large amounts of chocolate you know. So that quite complicated things a little bit."*
> [Mother of diabetic sons aged 9 and 12 years; interview no: 17, line 257]

4.2.2 Reasons for not attaining control during ongoing therapy

Many participants provided reasons for having poor glycaemic control during ongoing management with insulin pumps. Insulin pumps allow users less regimentation in diet and activities. Accordingly, change in daily routines was one of the factors proposed as affecting blood sugar control compared to injections where lifestyle was more rigid:

> *"At the moment it is really hard* [to achieve glycaemic control by pump] *because he is out of routine. It is ok when you are on routine but when you are out of routine... because he has finished school and his brother is home from Uni* [university] *and they are going for tennis, they are going for squash, they are going for football, they are annoying each other and brothers fight. So at the moment his counts are just completely unpredictable."*
> [Mother of a boy aged 16 years; interview no: 37, lines 218-219]

The presence of other medical conditions (e.g. hypothyroidism) could also have played a role in disturbing metabolic control, resulting in a changed body requirement for insulin. In several cases, the treatment regimen was strictly followed and no apparent reasons were proposed for not having good control, hence the causes were uncertain (i.e. unknown reasons).

Other factors were identified, in some families, as possible reasons for having days of poor glycaemic control with insulin pump therapy, including: emotional factors (e.g. stress and excitement), insulin sensitivity/resistance, site failures (because the cannula was kept in the site longer than recommended, so the insulin would not be delivered anymore) and monthly periods for girls.

4.2.3 Reasons for not attaining glycaemic control at the transition period or during ongoing management

Many parents and/or children/young people reported similar possible reasons for not achieving glycaemic control with insulin pumps, whether that was at therapy initiation or later on in the management. Puberty was one of the most frequently reported issues impeding the attainment of target glucose values. Puberty is usually associated with hormonal changes that modify body requirements of insulin and hence make blood

glucose control challenging for young people with diabetes (Shashaj & Sulli, 2009; Amiel et al, 1986). This was raised by children/young people aged 8-17 years and their parents during the interviews:

> *"So I think it is probably just to do with his age, you know the hormones are sort of raging up and down and sometimes he burns off the insulin really quickly and other times it does not seem to go anywhere."*
> [Mother of a boy aged 16 years; interview no: 24, line 219]

Children's non-compliance was one of the reasons proposed to affect glycaemic control, whether at the initiation of pump therapy or later. Two types of non-compliance were identified from the interviews: food and regimen related. Non-compliance with food was manifested mainly at the transition period, which was identified by situations where the children craved all kinds of food that were restricted on the injections:

> *"I remember the first couple of weeks, I went a bit crazy because it was getting to the point where I was not eating* [on the injections] *because I did not want to inject ... And then I got onto this pump and I was like 'I can have a Snickers bar now and I can have a snack now and I can eat this now and I can eat that now,' so I was just going to this 'I'm going to eat everything I can' and I put on like a couple of pounds like in 3 weeks."*
> [A girl aged 17 years; interview no: 72, line 199]

During ongoing therapy, the non-compliant behaviour of children was mainly related to the treatment regimen (e.g. not doing finger pricks, forgetting to give bolus doses):

> *"To some degree at certain times she is not compliant in doing the management as it should be, the regimen of taking it at its time, doing the checks at its time."*
> [Father of a girl aged 14 years; interview no: 2, lines 277-280]

> *"I have not been using my pump properly because I have been doing finger pricks, but not typing them into the pump* [i.e. not entering blood glucose values into pump needed for calculating insulin bolus doses for meals]. *And due to my ignorance, I thought I was still corrected above 10* [blood glucose reading in mmol/l] *rather than 8, so that was also affecting* [blood glucose control]. *"*
> [A girl aged 17 years; interview no: 72, line 205]

Such attitudes of the young people was explained by the fact that they were passing through a stage of denying the reality of being diabetics and hence did not care about the management, as stated by a mother of a 15-year old boy:

> *"It* [blood glucose value] *went down considerably because I was doing it. As I said my son just does not want diabetes at the moment. He does not care about his management, so his HbA1c has gone up from 8.6 and it went up to 11, and this is the highest he has ever been."*
> [Mother of a boy aged 15 years; interview no: 38, lines 201-202]

Besides puberty and non-compliance, management mistakes were one of the reasons related to not attaining glycaemic control with insulin pumps. At the onset of pump therapy, the management mistakes were made by the hospital. For instance, 2 families in the sample reported that their children were started on relatively high basal insulin rates. However, both of these families were some of the earliest to receive the service at the hospital:

> *"And the basal was about 50%, too high and by the time we got home, she was in a very deep deep hypo* [hypoglycaemia]. *That took us about 4 hours to get her up, by giving her literally juice and sweets and hypo stops and glucose tablets and it took about 4-5 hours to get her sugar up back to about 4. And what happened was that she suffered massive massive rebound and after that point about the next year, every time her sugar started to fall quickly or did, she would have an autonomic rebound and she would release cortisone which would effectively put her sugar up a few hours after the hypo and it would then put her up into the 20* [blood sugar level in mmol/l] *the next 12 hours or more."*
> [Father of a girl aged 12 years; interview no: 4, line 174]

On the other hand, mistakes in the management throughout the course of pump therapy were usually made by the patients and/or their parents (e.g. not counting carbohydrates properly or wrong basal insulin), which also affected control:

> *"So I think it is more the case of the carbohydrate counting is not quite there sometimes with some of the meals and that is why may be the control may be not as good as with the injections."*
> [Mother of a girl aged 10 years; interview no: 34, line 176]

4.3 Safety of insulin pumps

In the UK, the National Patient Safety Agency (NPSA) which aims to improve patient safety by enabling the NHS to learn from patient safety incidents, published reports for safer administration of insulin (National Patient Safety Agency, 2010) and use of infusion devices (National Patient Safety Agency, 2004). In the latter, the NPSA had sponsored a project which covered six pilot sites to determine the causes of infusion device incidents. Three hundred and twenty one incidents were recorded which were variable (e.g. devices failures, users' errors, prescription errors...etc.). Accordingly, recommendations were made to avoid their recurrence and hence improve health, reduce death and enhance cost-effectiveness. Within this context, examining safety of using insulin pumps in this study is important.

Parents and children/young people were asked during the interviews to report if using insulin pumps was associated with any clinical problems, such as hypoglycaemic

episodes or problems at the cannula-insertion site (e.g. allergy or infection). Other clinical problems, such as weight loss/gain or problems at the site of inserting the infusion set (e.g. pain, redness and lumps) were identified from the transcripts, and are reported in this section. In addition to the clinical problems, parents and children/young people were asked to describe any mechanical problems experienced when using insulin pumps.

4.3.1. Clinical problems

4.3.1.1 Hypoglycaemic episodes

All parents (N=38) and children/young people (N=34) stated whether the frequency and/or severity of developing hypoglycaemic episodes on insulin pumps were less, the same, or more than those when injections were used to manage T1DM (**Table 4.5**). In this study, any blood glucose reading < 4 mmol/l was regarded as a hypoglycaemic episode.

Table 4.5: Frequency and/or severity of developing hypoglycaemia on insulin pumps compared to injections, as reported by parents (N=38) and children/young people (N=34)

Hypoglycaemia		Groups based on children's age (years)								
		< 5	5-7		8-12		13-17		Total	
		P N=4*	P N=2*	C N=2^	P N=21**	C N=20^^	P N=11*	C N=12†	P	C
Frequency	**Less**	2	2	-	14	10	6	7	24	17
	Same	1	-	-	-	-	2	1	3	1
	More	1	-	-	5	2	3	4	9	6
	Other	-	-	-	-	7	-	-	-	7
Severity	**Less**	2	1	-	13	6	8	7	24	13
	Same	1	-	-	3	2	1	1	5	3
	More	-	-	-	3	-	1	1	4	1
	Other	-	-	-	-	2	-	-	-	2

P= parents; C= children and young people.
'Other' refers to cases where children had hypoglycaemic episodes that were not severe and they were usually experienced after exercise. However, the situation on injections could neither be compared nor remembered.

* Data are missing from 1parent on severity
** Data are missing from 2 parents on frequency and severity
^ Data on frequency and severity are missing from 2 children (question was not asked because children were young and did not remember injections, as reported by their parents)
^^ Data on frequency are missing from 1 child, and on severity are missing from 10 children
† Data on severity are missing from 3 young people

The majority of parents and children/young people reported fewer and less severe hypoglycaemic episodes with insulin pumps compared to injections. In a few cases, hypoglycaemic episodes either remained the same or increased with using pumps compared to injections. When they were increased, the difference in blood glucose readings was marginal and the episodes were usually explainable:

> *"I don't think they* [the frequent hypoglycaemic episodes] *have been because of the pump, it is you know have been because something I did, but nothing to do with the pump. On the injections there were not as many, but then again I would have been recently diagnosed and my blood sugars were in a higher range as I said than now, because I'm in better control now. But I'm not saying that my hypos now are very frequent."*
> [A girl aged 15 years; interview no: 59, lines 214-219]

Where the frequency was less on injections, over-feeding the children with sweets and food was a necessity to prevent the development of hypoglycaemic episodes, as reported by a parent who cared for a 10-year old boy.

Three parents reported that incidents of low blood glucose levels on the injections were either more difficult to deal with, or the children took a longer time to recover from them. This was related to the long-acting insulin used with the injection regimen:

> *"It is a problem. We had times it* [long-acting insulin] *was running for 24-hours even when no additional insulin was administered, and we could not get his blood sugar above 2* [mmol/l]. *My son was sick of Mars bars, chocolate and ice cream."*
> [Mother of a boy aged 8 years; interview no: 9, lines 315-316]

Reasons why some families had frequent or severe hypoglycaemic episodes on insulin pump compared to injections are listed in **Table 4.6**.

Table 4.6: Reasons for developing hypoglycaemic episodes on insulin pumps, as reported by some parents (N=12) and children/young people (N=7)

Reason	Parents (frequency)	Children (frequency)
Overdosing	6	2
Change in routine	4	6
Aiming for lower blood glucose target	2	-
Illness	1	-
Non-compliance	1	-
Forgetting to set pump on 'temporary basal setting' when exercising	-	1
Unknown reasons	-	1

The commonest cause for developing hypoglycaemic episodes on the pump was overdosing. Overdosing was usually caused by: miscalculation of insulin doses; trying to oppose a high blood sugar reading; trying to adjust the basal insulin or a wrong reading given by the glucose sensor:

> *"The one that was the worst was when she believed the sensor and then administered a bolus dose. Then we said 'have you checked your BG* [blood glucose readings]*?' 'No,' and when she checked the sensor, she said it was something like 20 and BG was actually about 12 at the time or 10, and then she went out to 2 and that was bad. So that was over-bolusing rather than anything else."*
> [Mother of a girl aged 12 years; interview no: 12, lines 232-233]

Another common cause for developing hypoglycaemic episodes was related to changes in daily routines (i.e. the activities the children engaged in, such as exercise). Moreover, aiming for lower blood glucose targets with insulin pumps compared to injections was another reason for experiencing frequent episodes:

> *"May be quite a little bit more now* [hypos on the pump] *because we are aiming for lower* [blood glucose readings], *so she does sometimes go lower and sometimes she is more likely to have a hypo."*
> [Mother of a girl aged 2 years; interview no: 5, line 200]

Some parents and children reported other causes for developing low blood glucose episodes on insulin pumps, which included children's non-compliance with diet (e.g. forgetting to eat when delivering a bolus) or with the treatment regimen (e.g. not setting temporary basal rates when exercising):

> *"That* [a hypoglycaemic episode on the pump] *was rare as well, and it happened after like exercise or when I had forgotten to set the temporary basal."*
> [A boy aged 12 years; interview no: 53, line 481]

Although this study did not aim to investigate the effect of insulin pumps on hypoglycaemic awareness (i.e. feeling the symptoms of getting into an incident of low blood glucose level), it was one of the issues that emerged from the interviews. Some children and young people reported that the awareness was markedly improved with pump use (reported by 7 parents and 1 young person):

> *"One thing I should have been said earlier; that she is much more aware of her blood sugar levels on the pump which is an advantage. It means that if she is going down* [low blood sugar] *she feels the symptoms much more quickly, while on the injections she would not know. That is why she would blackout and none of us would know* [when the girl was using injections]."
> [Mother of a girl aged 16 years; interview no: 16, lines 153-158]

In one case, the improvement did not only involve hyoglycaemic episodes, as the child's awareness of hyperglycaemia had also become better with using insulin pumps:

> *"And then he started to feel very high. Before, he used to have to go to bed with his blood sugar about 18* [on the injections], *just to get through the night. Whereas within a week or two* [of being on the pump] *he felt high if his blood sugars were 8 or 9, as very quickly his body adjusted."*
> [Mother of a boy aged 16 years; interview no: 24, lines 85-86]

This was not the case for all the families, as hypoglycaemic awareness did not improve in 6 children using insulin pumps, as reported by their parents. Moreover, 3 parents stated that the hypoglycaemic awareness of their children was always good on the pumps and injections, while only one stated that the awareness was bad on both treatment methods. Further investigation with this regard is needed.

4.3.1.2 Allergy or infection at the cannula-insertion site

Using insulin pumps requires users frequently to change the infusion set and rotate the cannula-insertion site to avoid problems, such as infection or allergy. Based on manufacturers' recommendations, infusion sets should be changed every 2-3 days. In this section, parents and children reported if they experienced such issues when using the pumps **(Table 4.7)**.

Table 4.7: Development of allergy and/or infection at the cannula-insertion site of insulin pumps, as reported by parents (N=38) and children/young people (N=34)

Problem		Groups based on children's age (years)								
		< 5	5-7		8-12		13-17		Total	
		P N=4	P N=2	C N=2	P N=21	C N=20*	P N=11	C N=12	P	C
Allergy	**Never**	4	2	2	17	16	9	7	32	25
	Yes	-	-	-	4	3	2	5	6	8
Infection	**Never**	4	1	2	16	15	8	8	29	25
	Yes		1**	-	5^	4	3^^	4	9	8

P= parents; C= children and young people

* Data are missing from 1 child on 'allergy' and 'infection'
** The parent stated that the infection was 'not bad'
^ One parent stated that child had one superficial infection and another serious one
^^ One parent reported that the child had 2 incidents of serious infections

The majority of participants believed that using the pump was safe against developing allergy and/or infection. On occasions where incidents of allergy or infection at the cannula-insertion site were experienced, the causes of such problems were identified. Allergies usually developed to: adhesives used on the infusion set of the pump or sensor; materials used as a barrier between the skin and the adhesive tapes to protect skin against allergy (e.g. Cavilon™ Spray) or to the alcohol wipes used for cleaning the site before insertion of the cannula.

The ways the families handled this problem were reported by 5 parents and 7 children/young people during the interviews. In most cases, a film barrier (e.g. Duoderm® and Tagaderm® dressings) was used to prevent direct contact of the adhesive tapes to the skin. In other cases, anti-allergic or steroid creams prescribed by consultants were used. Site rotation or changing the types of the product (e.g. wipes) were other solutions employed by some families.

If these problems were unresolved, treatment non-compliance and consequently discontinuation could result. For example, one mother reported that the allergic problem of her son was due to the sensor's adhesive. Accordingly, the sensor was disconnected and not used subsequently.

Infections secondary to using the cannula could result in a disturbance in the blood glucose concentration. In one case, puss from an infection blocked the tubing of the infusion set. As a result, site failure and subsequent elevation of the blood glucose readings occurred.

Reasons for developing infections were only identified in 2 interviews where poor hygiene or not changing the cannula according to the manufacturers' recommendations was the cause. The infection was usually managed with prescribed antibiotic creams (e.g. Bactroban®). In other situations, rotating the site, bathing the infection with a salty solution, or keeping good hygiene at the site was usually followed.

In the month prior to the interview, one parent and one young person reported having the experience of allergy, and 2 parents and one young person reported the development of infection. In contrast, no such problems were reported by the rest of the sample (data were missing from 1 parent and 4 children.

4.3.1.3 Other clinical problems related to using insulin pumps

In addition to hypoglycaemia, allergy and infection, other problems associated with pump use were identified, most of which were related to the infusion set and body weight (i.e. weight gain/loss).

The cannula insertion procedure was sometimes painful, resulting in soreness and an uncomfortable feeling at the insertion site (reported by 4 parents and 7 children/young people). In some cases, the pain was caused by the sensor's cannula, not the pump's (reported by a parent and a 5-year old child). Families used different methods to relieve the pain at the site: using creams to relieve soreness or to numb the site before the insertion; rotating the site when inserting the cannula and using an inserter to aid in inserting the cannula rather than doing it manually.

Consequences of using insulin pumps on the body weight were identified in some interviews. Two parents reported that managing diabetes of the children and young people affected their body weight. One reported weight gain, whereas the other reported loss of weight. In contrast, no cases of changes in body weight were reported by the children and young people themselves.

Other kinds of problems were also highlighted by many participants (**Table 4.8**).

Table 4.8: Other problems related to using insulin pumps and frequencies, reported by parents (N=22) and children/young people (N=11)

Problem	Parents (frequency)	Children/young people (frequency)
Redness	9	6
Scars/marks	5	2
No site for rotation	4	1
Lumps	3	-
Diabetic ketoacidosis	2	1
Change of skin colour	1	-
Insulin resistance	1	-
Overdosing by child	-	1
Pressing buttons accidently	-	1

The most common problems reported by parents and/or children were skin problems related to inserting the cannula, such as redness and scars/marks. Moreover, a mother of a 13-year old boy reported that her son's skin colour had changed since he started pump therapy. However, no confirmation could be made as to whether the change was related to the pump or not. In most cases, skin-related problems (e.g. redness, lumps and scars) were managed by rotating the sites, using another type of cannulas (shorter ones) or using relieving creams (e.g. Bactroban® or Tetrix™).

Unavailability of a site to rotate the cannula was one of the problems associated with using the pump. This problem was usually manifested in families with very young or thin children, and on occasions where two catheters needed to be inserted into the body; one for the pump and another for the sensor. Such a problem had led some families to abandon the use of the sensors.

Other problems were related to the technical use of the pump, such as pressing buttons accidently or overdosing by the child without the parent's knowledge:

> *"Child: Once I was giving myself insulin, too much insulin, and I had a fit and it was quite disappointing when I started to give myself too much but everything was alright from there.*
> *Interviewer: Why did you give yourself too much insulin?*
> *Child: I was high and I gave myself I think...I think I guessed, I had a lot then when I went over sick and at night I had a fit and I did not do it again."*
> [A boy aged 12 years; interview no: 55, lines 265-268]

4.3.2 Mechanical problems

In addition to clinical problems, insulin pumps suffered mechanical malfunction. From the answers obtained from participants, mechanical problems were classified into problems related to the technical use of the pump and infusion set-related problems. The latter was further divided into cannula and tubing problems (i.e. the tube of the infusion set) **(Table 4.9)**.

Table 4.9: Mechanical malfunctions associated with using insulin pumps, as reported by parents (N=38) and children/young people (N=34)

Problems		Parents and children/young people		Resolving the problems
		P N=21*	C N=24*	
Technical	Pump stopped working	6	8	- Pump was replaced - A spare pump/ injections were used until a new one was received - Problem was solved by a manufacturer's engineer - Set was changed - A new battery was put in and pump was switched off then on so it worked
	Rewinding/priming problems	5	8	- Pump was replaced - Injections were used until a new pump was replaced - Problem was fixed by mother
	Pump breaking	4	2	- Pump was replaced
	Buttons 'frozen'	3	1	
	Bolus-delivery problems	2	1	
	Pump did not stop alarming	-	1	
	Had problems but could not remember what they were	1	3	
	Insulin reservoir problem	-	1	
	Battery-related problems	2	2	- Batteries were replaced
		P N=12	C N=5	
Infusion set: **1. Cannula**	Site failure	4	1	- Cannula was changed - The method of cannula insertion was changed (not following instructions from the manual) - Put bandage around chest to absorb sweat
	Cannula removed (by sweating, pulled off)	4	2	
	Blocked/stuck	2	-	
	Set change did not work	1	-	
	Folded	1	-	
	Blood in cannula	-	2	
	Bleeding when inserted wrongly	-	1	
2. Tubing	Air bubbles	3	1	- Air bubbles were primed (taken out from the tubing)
	Tube broken down	3	-	

P= parents; C= children and young people.
All problems were reported by frequency.
* 17 parents and 10 children/young people never experienced any mechanical problems

Seventeen parents and 10 children/young people reported they had never experienced mechanical problems that affected the function of insulin pumps. The rest of the participants on the other hand experienced technical problems and/or infusion set-related problems.

In terms of the technical issues, occasions where the pump stopped working were one of the most commonly reported. Different reasons were given in explanation (e.g. exposure to magnetic resonance imaging radiation; MRI and locking the pump accidently). The latter was reported by a family when a Learning Support Assistant (LSA) did something with the settings of the pump that resulted in the pump malfunctioning and ceasing to work.

The second most frequently reported technical problem with insulin pumps was rewinding or priming problems. 'Pump rewinding or priming' refers to the time when the pump is primed after filling the reservoir with insulin or after changing the infusion set, so the insulin can get through the tubing. Many parents as well as children and young people agreed that they experienced many occasions where the insulin was not going into tubing of the infusion set after such procedures:

> *"Well only once* [the child experienced an incident of no insulin going through the tubing of the infusion set], *but my brother gets it a lot, it is like 'no delivery' my brother gets this a lot usually after a set change. And it is actually rather annoying when it goes off to say 'no delivery' because...I don't actually know why it does that because may be there is a problem with it or something."*
> [A boy aged 9 years; interview no: 52, lines 211-212]

Pump malfunction, battery-related problems (e.g. running out or breaking down of the screw cap of the battery chamber), bolus-delivery problems (e.g. pump did not record that the bolus was delivered), or pump buttons becoming 'frozen' were other issues reported by both parents and children. For instance, 2 children reported that their pumps were broken either because the pump was dropped or because it was shaken and hence lost its waterproof properties so when children went swimming, the pump was broken:

> *"We were playing cricket. I smashed it when a real cricket ball went around...and just I thought it hit it, but did not smash it but then I looked at it, it was like ink all over, it was not actually ink but you could not press anything to see."*
> [A boy aged 9 years; interview no: 44, line 263]

One parent reported that they had a situation where the alarm on the pump did not stop and one child reported a problem related to the insulin reservoir.

Problems associated with the pumps' cannulas were documented by some participants who experienced situations where the cannulas were blocked, stuck, folded, or came out (e.g. due to twisting in the bed while sleeping or due to sweating). Site failure (where insulin does not get delivered to the site) or bleeding at the cannula insertion site, which happened if cannula was not inserted properly into the body, were other problems faced using insulin pumps. The former was explained in relation to not changing the cannula as frequently as recommended:

> *"I think it has happened occasionally, but I think that is more due to the fact he has not made sure there is enough insulin in it, probably not changed the cannula as regularly as he should have done, trying to be a bit lazy and it has caught up with him or the patches run out."*
> [Mother of a boy aged 6 years; interview no: 37, lines 228-229]

Apart from catheter problems, difficulties due to tubing problems (e.g. air bubbles or tubing breaking down) were also encountered by some families.

Most of the mechanical problems described were managed by replacing the old pump with a new one, after calling the hospital or directly calling the pump manufacturer. In some cases a spare pump or injections were used until a new pump was shipped and received. Problems related to the infusion set were managed mostly by replacement.

It was important to find out how often these problems were encountered. Therefore, all parents (N=38; data were missing from 1 parent as the interview was not completed) and children/young people (N=34) were asked whether any relevant problems were experienced in the month prior to the interview. All parents reported that the children did not experience any problems related to the pump functionality. Similarly, most of children and young people (N=26) did not experience problems. One young boy reported that his pump stopped working the day before the interview and another young girl reported that she did not experience any mechanical problems of the pump, however, the cannula came out twice when it was not meant to. Data were missing from 6 children (the question was not asked to 4, while the question was not part of interview schedules of 2 children aged 5-7 years).

4.4 Discussion

The cornerstone for the management of diabetes is to improve and maintain glycaemic control within normal ranges. HbA1c testing is an international, standardised test for the diagnosis and the assessment of diabetes, as it is an indicator for long-term control and a strong predictor of diabetes complications (Diabetes Control and Complications Trial Research Group, 2002).

In the light of the clinical findings presented in this study, insulin pump therapy is an effective means of achieving short-term and long-term control of diabetes in children and young people. A significant reduction in the average HbA1c values was sustained for the first 3 years following starting pump therapy after which the reduction continued, but was not significant (compared to the mean value taken 6 months pre-pump therapy). Findings presented in this thesis were consistent with the results of many studies in the literature where pre and post-intervention comparisons revealed that using insulin pumps compared to injections (MDIs) attained immediate and sustained (up to 4 years) glycaemic control in children and young people with T1DM (Weinzimer et al, 2004; Sulli & Shashaj, 2006; Pankowska et al, 2007). On the other hand, in the study by McVean et al (2007), 62% of children/young people who used insulin pumps for at least 6 months did not attain metabolic control. The sample size for the long-term analysis of HbA1c readings was small (i.e. the number of patients decreased as period of follow-up increased), therefore interpretation of the long-term effect of insulin pumps must be undertaken with care. Accordingly, performing similar analysis with a larger sample is recommended.

The DCCT and UK Prospective Diabetes Study (UKPDS) clearly demonstrated that there is good correlation between glycaemic control and incidence of late complications in type 1 and type 2 diabetes (Diabetes Control and Complications Trial Research Group, 1994; Stratton et al, 2000). Based on these previous studies, the current study suggests that the 0.4-1.0 **(Figure 4.1)** reduction in HbA1c value observed within the period of 3 years follow-up (compared to 6-month pre-pump readings) with CSII treatment is of clinical relevance and would be predicted to reduce by 15-37% and 8-21% the probability of developing diabetes microvascular complications and death, respectively (Stratton et al, 2000).

The trend of glycaemic change **(Figure 4.1)** over time for the whole cohort showed that, there was an increase in the readings in the first 6 months of the second year followed by fluctuations in the readings in subsequent years; but levels were lower than the pre-pump value. This is most likely to be due to the period of greater 'freedom' and less attention in the following years after the initial period of strong motivation and commitment to the new therapy. Moreover, the involvement of other factors over the years, such as less parental involvement, non-compliance and puberty should also be taken into consideration.

Findings from this study showed that there was no significant association between duration of being on CSII and achieving the target HbA1c values. Similarly, there was no relationship between age (for children aged 0-8 and 9-12) and the change in glycaemic control, whereas with children aged 13 or older, there was a significant negative linear relationship with the change in HbA1c readings (i.e. as they got older, control decreased). This is controversial to what was expected, as in other studies (Anderson et al, 1997a; Palmer et al, 2004) non-compliance and less parental involvement that were characteristics of children in this age group were associated with less diabetes control. However, in this study, the improved control in children aged 13-17 years could be related to that the parents continued to be involved to some extent in the management of their children, as it will be described in Chapter 5. Moreover, the degree of involvement of other factors (e.g. baseline HbA1c values) should be investigated. Only one recent study, by Wiebe et al (2010), has examined the association between metabolic control and duration of insulin pump use by young people with T1DM. A positive association was shown in young people who were using insulin pumps for less than 2 years, while no association was seen in those receiving therapy for longer durations. With regard to age, 2 studies; one by McVean et al (2007) with children and another by Pickup and Sutton (2008) with adults and children, were found where the association between age and probability of meeting HbA1c goals were tested. The results from these 2 studies varied greatly. McVean et al (2007) demonstrated a significant reduction in meeting HbA1c goals with increasing age, while Pickup and Sutton (2008) showed that mean age was not related with the changes in HbA1c values.

Although this study included a paediatric population of a wide age range who have been on insulin pump therapy for various durations of time, the study was retrospective based on a pre/post-intervention design and the cohort was small in size (N=42; 6 were excluded from quantitative analysis due to lack of data). Within this context, there are few RCTs and the need for more is recommended (Jeitler et al, 2008; Pickup & Sutton, 2008; Pankowska et al, 2009). Moreover, the differences in sex and its relation to metabolic control were not investigated in the current study therefore, further investigation is suggested.

This study aimed to examine the effectiveness of insulin pumps for controlling diabetes and to relate that to the perspectives of parents and children/young people obtained from the interviews. Few studies were identified in the literature documenting parents' and/or children/young people's views on the control attained by insulin pumps compared to injections. In this study, most of the parents caring for different age children, as well as the children themselves, reported improved glycaemic control with insulin pump therapy. These findings are consistent with other studies where the majority of parents and/or children reported improved metabolic control post-pump therapy (Sullivan-Bolyai et al, 2004; Low et al, 2005; Olinder et al, 2007; Wilson, 2008), however, the sample size (N=38 parents; N=34 children/young people) and/or age ranges (0-17 years) were greater in this study. Whilst the current study included the views of both the children and their parents, this was the case only in one of the 4 studies identified in the literature (Low et al, 2005), while the remaining 3 studies only focused on either parents' or children's perspectives (Sullivan-Bolyai et al, 2004; Olinder et al, 2007; Wilson, 2008).

As reported in the literature, children and young people with T1DM may have difficulties in controlling night time blood sugar levels. This could be due to difficulties of matching insulin requirements with blood glucose concentrations or due to the release of counter-regulatory hormones (e.g. growth hormone, cortisone and adrenaline) leading to a morning rise in blood glucose levels (i.e. down-phenomenon) (Torrance et al, 2003). Insulin pump therapy, however, has proved to be effective in reducing glycaemic instability and down-phenomenon in children and young people (Colquitt et al, 2004; Kapellen et al, 2007). In relation to the current study, only a few participants reported that morning hyperglycaemia and poor nocturnal glycaemic control were still

experienced after the switch to insulin pumps, regardless of the improvement in metabolic control. For instance, 2 mothers caring for children aged less than 5 years reported that the blood sugar readings with the insulin pump were high at certain times of the day, such as in the morning, and a 5-year old boy in the sample stated that his blood sugar was still not controlled with the insulin pump at night.

Findings presented in this study suggest the importance of parental involvement in achieving and maintaining glycaemic control, especially for young people (aged 13-17 years) where compliance issue could impact on treatment outcomes. This issue was obvious in a family in the sample where the mother of a 15-year old boy stated that the blood sugar readings remained under control only when she undertook the management tasks herself. This was explained by the fact that the boy was passing through difficult teenage years when he did not care about being diabetic, and hence did not comply with the treatment regimen. In agreement with this study, previous studies indicate that greater parental involvement in management tasks fostered improved glycaemic control (Anderson et al, 1997a; Palmer et al, 2004; Wiebe et al, 2010).

In the current study, the views of participants regarding glycaemic control in the transition period where children and young people had just switched from injections to insulin pumps, were also identified and described. In the majority of cases, starting insulin pump therapy was associated with a period of deteriorating metabolic control, while immediate control was only achieved in a few patients. In most cases, a period of a few weeks to a few months was needed for blood glucose readings to stabilise and return back to normal. To our knowledge, no studies have previously been done to explore children's and/or their parents' views on blood glucose control in the period immediately following the commencement of pump therapy.

Based on the data, many factors were proposed to explain why insulin pumps failed to achieve good metabolic control for all patients or on all occasions. Some of these related to the onset of pump use, whereas others related to ongoing therapy. Moreover, some of the factors were shared between the two periods. With regards to treatment onset, the most commonly reported reasons were the need to adjust basal insulin and to learn how to use the technology and the associated management tasks. Others included: timing of the transition (e.g. during holidays or puberty years) and child non-

compliance. To our knowledge, no studies were found in the literature that identified parents' and children's views on the factors that might have affected glycaemic control during the transition period. One previous study, however, tested changes of insulin requirement across children of different ages during the switch from injections to insulin pumps, and demonstrated a reduction in the insulin requirements with the transition which was associated with age-differences between children (Shashaj & Sulli, 2009). This in turn emphasises the importance of adjusting basal insulin during the transition period, taking into consideration age-related differences in insulin requirements. None of the parents or children in the present study justified poor glycaemic control in relation to the need for adjusting prandial insulin (i.e. bolus insulin delivery for every meal), although the mealtime insulin delivery was identified as the key to achieving metabolic control for individuals with diabetes (Crawford et al, 2000).

Insulin pump therapy requires users to gain special knowledge and skills in order to deal with the pump. Being new to the technology was one of the reasons proposed for worsened glycaemic control at the transition period. Therefore, the healthcare team should provide adequate knowledge to the families, who should also acquire the skills enabling them to deal with and use this technology. The selection of families in which insulin pump therapy will be started for their children should be considered, requiring highly motivated and trained parents/caregivers. Within this context, NICE recommends insulin pumps for patients who are willing to undertake the commitment and competence for using this treatment option effectively (National Institute for Health and Clinical Excellence, 2003).

Commencement of insulin pump therapy should be considered at an appropriate time taking into account family circumstances and the effect of children's age on the requirement for insulin when setting and adjusting insulin doses. From the current study, bad timing (e.g. puberty years) was one of the issues raised by participants as affecting glycaemic control at the transition period. This was articulated by parents who thought that starting insulin pump therapy during the puberty years was not appropriate.

Identifying factors linked to glycaemic control in the transition period is pivotal for the appropriate and effective use of this therapy in children/young people with T1DM. Furthermore, greater knowledge of the factors that could play a role in patients having

days of poor glycaemic control during therapy may help to obtain optimum conditions and hence achieve the best control. Several factors were identified from participants' views to explain reasons for days of poor glycaemic control while using pump therapy, even for those patients who showed significant reductions in HbA1c values. Only few studies have tried to elucidate individual factors that predict metabolic control in paediatric populations using CSII (Bode et al, 1997; Maniatis et al, 2001b; Plotnick et al, 2003; Nabhan et al, 2006). Puberty and the subsequent impact of growth hormones were one of the factors linked to glycaemic control in the current study, as reported by parents of children aged 8-17 years and by the children of similar ages. Similarly, Nelson et al (2009) proposed this as an explanation for young people who did not demonstrate good metabolic control pre and post-CSII. In the growing body of literature, it has been established that insulin resistance and dawn-phenomena due to hormonal changes (increased production of growth hormone and sex steroid hormone) are typical characteristics of puberty years, which as a result modify the insulin requirements of the young person (Amiel et al, 1986; Shashaj & Sulli, 2009).

Despite intensive therapy, metabolic control is usually more difficult to achieve in the paediatric population than in adults, due to variable eating patterns and high physical activity. In the current study, changes in daily-routines, or inconsistencies in daily activities (i.e. food and activity-wise) were explanations given for children having days of poor metabolic control on insulin pumps. Research has shown that irregular diet patterns are associated with poor glycaemic control in patients with T1DM, including children and adolescents (Wolever et al, 1999; Øverby et al, 2007). Furthermore, exercise has been found to improve diabetes control and reduce exogenous insulin requirements. However, attention must be given to the duration and intensity of such activity (Admon et al, 2005). Results from this study emphasise the necessity of following the dietary guidance recommended by dieticians and diabetes healthcare team in order to improve dietary habits and subsequent blood glucose readings in paediatric patients. Moreover, consensus guidance should be proposed for the optimal use of insulin pumps during exercise and physical activity.

Non-compliance was an issue identified in the young people population (aged 13-17 years) of the sample in the current study (whether at onset of CSII or during therapy). It was related either to non-compliance to dietary recommendations or to treatment

regimen (e.g. poor care and forgetting to bolus/count carbohydrates). Similar findings were reported in the meta-analysis by Hood et al (2009) and others (Wilkinson et al, 2010), where compliance with the treatment regimen was associated with improved glycaemic control in young people. Moreover, Burdick et al (2004) concluded that missed meal insulin could be the major cause for suboptimal diabetes control in children receiving insulin pump therapy. As recommended previously, the need for continuous parental/carer involvement to achieve treatment compliance and subsequent glycaemic control is important. Within this context, further research should be conducted to identify factors that affect young people's compliance in order to address them and improve treatment outcomes.

The beneficial effects of intensive glycaemic control on reducing the risks of long-term complications in patients with T1DM were firmly established in the DCCT (Diabetes Control and Complications Trial Research Group, 1993; Diabetes Control and Complications Trial Research Group, 1994). There is an extensive body of literature supporting the safety of using CSII compared to injections in the paediatric population, including very young children (Plotnick et al, 2003; Sulli & Shashaj, 2003; Weinzimer et al, 2004; Mack-Fogg et al, 2005; Hanas & Adolfsson, 2006; Sulli & Shashaj, 2006). However, limited studies have reported parents' and/or children's views on the clinical and/or mechanical problems as a part of their experience when using insulin pumps. This study explored and described the clinical (e.g. hypoglycaemia, allergy, infection and DKA) and mechanical problems encountered when using insulin pumps by reporting perspectives of the parents and their children. Similar problems were reported elsewhere by parents and/or young people (Sullivan-Bolyai et al, 2004; Low et al, 2005; Olinder et al, 2007; Wilson, 2008). However, the frequency of reporting these problems was not investigated in most of these studies (Sullivan-Bolyai et al, 2004; Low et al, 2005; Olinder et al, 2007; Wilson, 2008) and in some, there were cases of pump discontinuation due to allergy to adhesive tapes or pain from the infusion-set needle (Olinder et al, 2007). In this study, cases of pump discontinuation were not reported.

In terms of hypoglycaemia, it is important to notice that the definition of hypoglycaemia varies between studies. However, in this study, a hypoglycaemic episode was regarded as any blood glucose reading less than 4 mmol/l. Most of the parents and many of the children in the current study reported less frequent and/or severe hypoglycaemic

episodes on insulin pumps compared to injections. However, when experienced, the hypoglycaemic episodes were usually explainable by overdosing, exercise, or non-compliance. This was supported by the literature where extra insulin or excessive exercise resulted in the development of hypoglycaemia in children receiving insulin pump therapy (Admon et al, 2005; Hanas & Adolfsson, 2006). In this study, some parents and children commented on the awareness of hypoglycaemic episodes on insulin pump compared to injections, and gave mixed opinions. It has been shown that recurrent hypoglycaemia leads to hypoglycaemic unawareness due to defects in the counter-regulatory hormone responses in children and young people, even in those with good glycaemic control (Fanelli & Rossetti, 2006). Further research is required to investigate if such an effect can be reversed by the use of insulin pumps.

Results from this study demonstrated that most of the patients neither experienced infection nor allergy at the cannula-insertion site. A few parents, as well as children, reported redness and scars at the site. Developing infection in this study was explained by parents by not following hospital's or manufacturers' recommendations for changing the infusion set. This finding was confirmed elsewhere in the literature where lack of adherence to the recommended instructions for changing the insulin pump infusion set was shown to be associated with infections (Pietri & Raskin, 1981; Mecklenburg et al, 1984) and a subsequent elevation in blood glucose levels (Thethi et al, 2003). Different mechanical and technical problems were experienced when using the pumps, which included the pump not working/breaking down, rewinding problems, button problems and problems related to the pump batteries. However, these problems were not frequently experienced and none of the parents or children expressed their frustration or disappointment in encountering them. Moreover, none of the participants reported difficulties in replacing the pump from the pump manufacturers when needed. In all of the reported problems, parents were usually responsible for resolving them. Findings from this study suggest that insulin pumps were safe to be used in children and young people. However, families should be aware of the possible problems that accompany pumps, and should be educated in the best ways of avoiding them, and dealing with the occasions when pump failure or malfunction is experienced.

CHAPTER 5 - Diabetes management within the home

Chapter 5: Management of diabetes within the home

Chapter 5 explores the experiences of parents and their children in the management of diabetes at home using insulin pumps, by describing day-to-day management responsibilities and partnerships. The impact of using insulin pumps compared to injections on autonomy of patients in self-management is also explored.

5.1 Patterns of partnership between parents and children when performing diabetes management tasks using insulin pumps

The term 'partnership' is used in this chapter to describe different styles of cooperation and sharing of responsibilities in the management of diabetes at home. Any cases where inconsistent views occurred are highlighted.

Parents, children and young people were asked questions about their roles concerning 6 major activities of managing T1DM: calculation of insulin doses, carbohydrate counting, blood glucose testing, equipment operation, infusion-set changing and cannula-insertion site checking. Other roles of the parents such as 'reminding' their children were revealed during interviews with the families, and hence have also been described. By analysis of the interview data, it was possible to describe the partnerships that existed as being 'parent(s) mostly,' 'shared,' or 'child/young person mostly.' This was achieved by reviewing the views within each case and across all cases (children of different ages and their parents) on how the management responsibilities associated with insulin pump therapy were undertaken. Then, the individual data for each task/partnership were considered and displayed separately; from the views of parents and children/young people.

5.1.1 Calculation of insulin doses

All parents (N=38) and children aged 5-17 years (N=34) were asked during the interviews to describe their roles when calculating insulin doses, such as insulin boluses and insulin correction doses **(Table 5.1)**. This applies to situations where the calculation was done manually using specific equations, or using the insulin pump Wizard. Pump Bolus Wizard® is software within the pump device that calculates insulin doses for each meal automatically by entering the blood glucose value and carbohydrate counts.

Table 5.1: Calculation of insulin doses, as reported by parents (N=38) and children/young people (N=34)

Role	Groups based on children's age (years)								
	< 5	5-7		8-12		13-17		Total	
	P N=4	P N=2	C N=2**	P N=21*	C N=20*	P N=11*	C N=12	P	C
Mostly by parent(s)	4	2	-	3	1	1	-	10	1
Shared	-	-	-	13	16	3	5	16	21
Mostly by child/young person	-	-	-	4	2	6	7	10	9

P= parents; C= children and young people

* Data are missing from 1 parent/child
** Data are missing from 2 children

From **Table 5.1**, it can be seen that no inconsistencies were identified in the views of the majority of parents and their children/young people regarding this role. All parents caring for very young children (7 years or less) were responsible of calculating insulin doses. Due to their young age, children aged 5-7 years could not give an answer to the question; however the tasks would be predicted to be done by their parents. The situation was different in families of older children (8-17 years). For children aged 8-12 years, the task was undertaken in most cases as a shared role. Parents and children/young people defined the role as being shared in different ways: shared in terms of 'task component' and shared in terms of 'occasions.'

'Task component' was related to situations where parents either calculated insulin doses (manually) or weighed food and informed children what entry to make into the pump:

> *"Usually my parents tell me what to put in and they usually ask me to show it to them so that I don't make a mistake or anything on it."*
> [A boy aged 10 years; interview no: 57, line 82]

'Occasions' related to situations when parents undertook the task at night and children did it during daytime, or parents undertook the task at home and children did it at school:

> *"I do that. I do that in the day and my parents do it in the night."*
> [A girl aged 12 years; interview no: 42, lines 143-144]

Not until age 13 and older, did the parents sometimes not have a role, as the young people showed greater capability to perform the task alone. Only one mother in the sample of parents caring for young people aged 13-17 years reported that she was still completely responsible for performing all management tasks, including calculation of insulin doses. She justified this in the context of her child passing through puberty, and that he was refusing to accept his diabetes, which made him careless about the management of his condition, which in turn forced his mother to deal with all the management issues.

5.1.2 Counting of carbohydrates

Carbohydrate counting is one of the day-to-day management tasks that accompanies insulin pump therapy. It involves estimation of the carbohydrate content of each meal or snack, for which equivalent insulin boluses should be calculated and subsequently administered (Table 5.2).

Table 5.2: Counting of carbohydrates, as reported by parents (N=38) and children/young people (N=34)

	Groups based on children's age (years)								
	< 5	5-7		8-12		13-17		Total	
Role	P N=4	P N=2*	C N=2*	P N=21**	C N=20*	P N=11^	C N=12	P	C
Mostly by parent(s)	4	1	1	11	10	1	-	17	11
Shared	-	-	-	4	8	-	6	4	14
Mostly by child/young person	-	-	-	1	1	8	6	9	7

P= parents; C= children and young people

* Data are missing from 1 parent/child
** Data are missing from 5 parents
^ Data are missing from 2 parents

Carbohydrate counting was usually undertaken by parents caring for very young children (7 years or less). Parents considered the task required greater mathematical ability than many children (aged 8-12 years) possessed. Therefore, the task was mainly

performed by parents of children in this age group. However, children in this age range were in the process of learning:

> *"Well we calculate his carbs and he has just started to kind of learn that, what carb value is different for him to have so he has got more involved with that."*
> [Father of a boy aged 10 years; interview no: 21, line 95]

> *"They tell me how, they will count my grams of carbohydrates, but I'm learning now how to calculate it myself."*
> [A boy aged 10 years; interview no: 57, line 84]

Some children in this group shared the task of carbohydrate counting with their parents. Sharing the task encompassed situations where the parents undertook the counting for the main meals and the child did it for snacks. This could be because counting carbohydrates for snacks is easier as all the nutritional information is usually displayed clearly on packaging, while for home-cooked food, some estimation is required. Sharing the task also applied to occasions where children did the counting for regular foods and sought parent's help for foods that did not contain nutritional information, such as fruits, or for meals where complicated mathematics were required:

> *"She knows how many carbs in each kind of major food that she eats and how much insulin she needs to take. But if you were to say to her for example 'today we have Fruit Corner' which is not something she eats that often and on the thing* [food pack] *it says 'per 100 g, 14.7 units of carbohydrates and the pack was 175 g.' she does not, her maths is not good enough yet that she knows how to convert, so I will help her with that."*
> [Mother of a girl aged 10; interview no: 36, lines 98-99]

At the age of 13 and older, parents generally considered young people able to undertake this role for themselves. However, not all the young people did so. Only half of the young people undertook this task themselves, while the other half shared it with their parents. The difference in the perspectives of parents and young people could be explained by the way parents and young people defined how the role was undertaken. Parents regarded the role to be done 'mostly by young people,' although they provided help sometimes at home (e.g. weighing food) or when necessary (e.g. giving advice if the young person was unsure). The young people, by contrast, considered the task as 'shared' if there were occasions where parents undertook carbohydrate counting at home (especially if meals were home cooked), while young people did it outside home (e.g. at school).

Only one case was identified in the interviews where the young person (aged more than 13 years) was completely dependent on parents for undertaking management tasks associated with the pump:

> *"I tell my son how many carbs he is eating. Again, only because he is at the age at the moment where he is not bothering and we found that because his HbA1c values have gone up."*
> [Mother of a boy aged 15; interview no: 38, line 100]

5.1.3 Testing of blood glucose levels

One of the tasks that accompany insulin pump therapy is frequent blood glucose testing (finger pricking) **(Table 5.3)**.

Table 5.3: Testing of blood glucose values, as reported by parents (N=38) and children/young people (N=34)

Role	Groups based on children's age (years)								
	< 5	5-7		8-12		13-17		Total	
	P N=4	P N=2	C N=2*	P N=21*	C N=20*	P N=11	C N=12	P	C
Mostly by parent(s)	4	-	-	1	1	-	-	5	1
Shared	-	1	-	6	5	2	3	9	8
Mostly by child/young person	-	1	1	13	13	9	9	23	23

P= parents; C= children and young people
* Data are missing from 1 parent/child

For very young children (aged less than 5 years), parents mostly performed this task. However, among these, a mother caring for a 4-year old girl asserted that her daughter was capable of performing the task alone:

> *"She can and she knows how to work the pump and everything, she is very old fashioned that way she likes to do it* [finger pricks] *herself. If you let her, she will."*
> [Mother of a girl aged 4 years; interview no: 29, lines 114-118]

Children as young as 5 years were either able to test blood glucose alone or were involved in the procedure (i.e. shared task). In agreement with the parents' views, a 5-year old boy showed the researcher during the interview his ability to measure his blood

glucose level under parental supervision. From the age of about 8 years, the task was generally undertaken by the children and young people, and parents only assisted (i.e. shared the role) in special circumstances (e.g. at night or when blood glucose values were high).

Only in one family caring for an 8-year old boy, the parents were completely responsible for undertaking blood glucose tests, and responsibility transfer was thought likely to be considered by the age of 10 or 11. No apparent discrepancy was identified in the views of parents and children of different ages.

5.1.4 Operating the pump

Pump operation in this chapter refers to setting/resetting insulin basal rates (e.g. temporary basal rate) to suit different activities that the child might engage in during the day (e.g. sports), and to administering boluses (by entering carbohydrate counts and last blood sugar value for bolus calculation; when the pump Bolus Wizard® feature is used) **(Table 5.4)**.

Table 5.4: Operation of insulin pump, as reported by parents (N=38) and children/young people (N=34)

Role		Groups based on children's age (years)								
		< 5	5-7		8-12		13-17		Total	
		P N=4	P N=2	C N=2^	P N=21*	C N=20^^	P N=11**	C N=12†	P	C
Basal setting	**Mostly by parent**	4	2	-	12	10	1	1	19	11
	Shared	-	-	-	4	1	1	2	5	3
	Mostly by child	-	-	-	2	7	6	9	8	16
Bolus delivery	**Mostly by parent**	4	1	2	3	3	-	-	8	5
	Shared	-	1	-	6	1	1	2	8	3
	Mostly by child	-	-	-	11	14	7	9	18	23

P= parents; C= children and young people

* Data are missing from 2 parents on 'basal setting' role and from 1 parent on 'bolus administration' role. One parent reported 'basal setting' role was done by hospital

** Data are missing from 3 parents on both roles

^ Data are missing from 2 children on 'basal setting' role

^ ^ Data are missing from 2 children on both roles

† Data are missing from 1 child on 'bolus administration' role

All parents of very young children (aged 7 years or less) assumed complete responsibility for operating the pump, although children as young as 5 years reported that they were involved in insulin bolus administration under their parents' supervision:

> *"I cannot press anything except if someone helps me, except if anybody else tells me where the button is and which button to press."*
> [A boy aged 5 years; interview no: 61, lines: 103-104]

By the age of 8, children and young people were more involved in operating the equipment with their parents. However, the majority of children aged 8-12 years were still dependent on their parents when setting or resetting the basal rate to match daily activities. This could be related to the complexity of the task, as monitoring and thinking are required to perform such a role, and children at this stage might not have yet developed the skills to handle such complex issues. Moreover, it was reported earlier by the parents of this age group of children that the mathematical skills of their children were not sufficiently developed, and that could have affected their ability and willingness to undertake the basal setting/resetting role. Young people (aged 13 years or older) were more able to undertake the task alone.

5.1.5 Changing the infusion set and checking the cannula-insertion site

Insulin pumps are usually connected to patients via a tube that ends with a cannula (catheter) placed subcutaneously on sites rich in fatty tissues (e.g. buttocks for younger or skinny children; abdomen or arm for older children). For insulin pumps to work efficiently, the cannula should be changed frequently according to manufacturers' recommendations (every 2-3 days). This prevents the occurrence of problems, such as infection, allergy, swelling, or site failure (where the insulin does not get absorbed) **(Table 5.5)**.

With regard to children aged 7 years or less, the site changing/checking task was mainly performed by parents. In agreement with parents, a 5-year old child reported that his parents or nanny were the ones who changed his infusion set:

> *"Not me. It could be mother and daddy...or it can be M.* [the nanny]."
> [A boy aged 5 years; interview no: 61, lines 155-158]

For older children (aged 8-12 years), the parents were the ones who in most cases changed the infusion set or checked the cannula-insertion site. This was often because the cannula was inserted into children's buttocks where children could not reach:

> *"I do that* [changing the infusion set], *because it is on his bottom so he can't see."*
> [Mother of a boy aged 8 years; interview no: 22, lines 137-138]

Table 5.5: Changing infusion set and checking cannula-insertion site, as reported by parents (N=38) and children/young people (N=34)

Role		Groups based on children's age (years)								
		< 5	5-7		8-12		13-17		Total	
		P N=4	P N=2	C N=2*	P N=21**	C N=20^	P N=11**	C N=12	P	C
Changing infusion set	**Mostly by parent**	4	2	1	12	11	1	1	19	13
	Shared	-	-	-	9	9	3	2	12	11
	Mostly by child	-	-	-	-	-	7	9	7	9
Checking cannula-insertion site	**Mostly by parent**	4	2	-	16	12	2	-	24	12
	Shared	-	-	-	-	4	-	1	-	5
	Mostly by child	-	-	-	3	3	7	11	10	14

P= parents; C= children and young people

* Data are missing from 1 child on 'set-changing' role and from 2 children on 'site checking' role
** Data are missing from 2 parents on the 'site checking' role
^ One child stated that the 'site checking' role was not done by anyone

However, the children informed parents in cases where they felt something was wrong with the site (e.g. soreness):

> *"My Mum will usually notice it during either a set change or any other thing that involves sets, but if it is like hurting I usually mention it to them."*
> [A boy aged 9 years; interview no: 52, lines 112-115]

In some cases, the role of changing the infusion set was shared between the parents and children in this age group (8-12 years), with one performing the actual insertion of the catheter (child did it when it was in the abdomen), while the other prepared the set:

> *"The cannula, I do that manually in my tummy myself but sometimes they do it if it was in the bottom."*
> [A girl aged 12 years; interview no: 47, lines 113-116]

Only in a few families, did children undertake the role of site-checking themselves. Parents usually observed the sites, especially during infusion-set changing. Surprisingly, one child reported the catheter-insertion site was not checked by anyone. However, this

child justified this by reporting that he usually does not have any allergies or problems on the cannula site. Although no parents reported the task as being shared, 4 children thought they shared this role with their parents. This discrepancy in the views could be related to the way that both parties understood and answered the question (i.e. if children had a minor involvement, parents might regard that as done mostly by them, while children might regard the role as being shared).

Most young people (aged 13 or older) were able to change or check the cannula site themselves, whereas a few required help from their parents. Only 2 parents stated that the checking role was performed by them, and a mother agreed with a young person that the infusion set was usually changed by the parent. The former was because the cannula was located on the young person's back, and hence the site could not be seen or accessed by the young person. The latter was justified by the fact that the young person was passing through adolescence, where he paid no attention to anything related to the management of his condition, as described earlier:

> *"Well my son is going through puberty and would rather not have diabetes, so I pretty much manage his diabetes. I remember when the pump needs changing, I also withdraw up the insulin and I set, you know, the pump for him. It just saves the arguments. He can do it."*
> [Mother of a boy aged 15 years; interview no: 38, lines 93-94]

No differences were found in the views of the majority of parents and children of different ages when undertaking site-checking and changing roles.

5.1.6 Reminding

During the interviews, the 'reminding role' was identified by 11 parents and 7 children/young people as one of the day-to-day management roles performed by the parents. Most of those parents (N=8) reported that their role in reminding their children centred around blood sugar testing:

> *"Again my son needs to be reminded and sometimes he will go all the day without doing a blood sugar test if I'm not around, which again I keep telling him 'it is dangerous, it is irresponsible.' "*
> [Mother of a boy aged 15; interview no: 38, line 199]

Other reminding tasks centred around dose administration (reported by 4 parents), and changing the infusion set (reported by 2 parents). A mother stated that currently her only involvement in her daughter's diabetes management was to 'remind' her about

doing it. This was because the daughter was studying in a boarding school where she had to take full responsibility for her diabetes, and because she was into her teenage years where she was supposed to undertake the management herself:

> *"Basically reminding her, that is the primary thing I ask her to do: 'has she done her bolus,' 'has she done her finger,' 'what are her levels,' 'how is she feeling,' because you know she is 16½ now and because she had been in a boarding school where she had to do it on her own."*
> [Mother of a girl aged 16; interview no: 16, lines 113-114]

In agreement with the parents, children stated that the 'reminding role' of their parents included: reminding them to administer a bolus, to count carbohydrates and to change basal rates.

Almost half of the comments on the 'reminding task' were obtained from parents caring for children aged 13-17 years (N=6), while the rest were obtained from parents caring for younger children (8-12 years) (N=5). Similarly, the ages of children who stated that their parents were still reminding them to undertake management issues ranged from 8 to 17 years. This might be related to the fact that insulin pump therapy is accompanied with many tasks that should be done on a regular and frequent daily basis and children aged 8-12 years as well as teenagers were usually able to perform some of the tasks and were taking on more responsibility for their management, and hence required reminding by their parents.

5.2 Factors affecting the pattern of partnership that existed between parents and their children when managing diabetes with insulin pumps

In this section, the interview transcripts of parents and children/young people were analysed to identify if there were any factors that could have affected the type of partnership that existed between the parents and their children when undertaking such roles. This was achieved by applying the following approach: the views of all parents, children and young people on the type of partnership when performing the tasks were considered; the sample of parents and children were then grouped based on children's age, duration on insulin pump therapy, or type of task; the views of the majority of participants in each of the 3 groupings were finally identified.

By considering the views of the majority of parents and children about the type of partnership, 3 factors were initially hypothesised to have an effect on the pattern of partnership: child's age, complexity of task and the duration of insulin pump therapy.

5.2.1. Age

Regarding the effect of a child's age on the nature of the partnership, from the views of majority of children and parents **(Tables 5.1-5.5)** it was clear that: as growing older, the child becomes more able to carry out the task alone **(Figure 5.1)**. This is in agreement with the child's developmental stages theory proposed by Piaget (1971). Moreover, this concept was consistent for all of the tasks described in **Section 5.1**.

5.2.2 Task complexity

The second factor that was hypothesised to have an effect on the pattern of partnership was the complexity of the performed task. Tasks associated with the management via insulin pumps either require technical skills (e.g. blood glucose testing, bolus administration and infusion-set changing/checking) or cognitive thinking for dose calculation, adjustment and monitoring (e.g. calculation of insulin doses, counting carbohydrates and basal setting).

To identify if there was any effect of task complexity on the type of partnership, all the 6 tasks were arranged from simple to more complex as follows: testing of blood glucose (least complex), administering boluses, calculating insulin doses, counting carbohydrates, changing/checking infusion set, and setting/resetting basal rate (most complex). This classification was validated by using the Competency Level Scale described by Kaufman et al (2001), which is used to asses a patient's ability to undertake management roles accompanying insulin pump therapy. It has 8 ascending scales ranging from simple to complex, for which patients should acquire certain skills and knowledge to perform. Some of the tasks, such as bolus delivery and changing/checking infusion set were absent from the Kaufman's Scale and hence the classification in this case was based on the reports from some participants during the interviews when they described some tasks as being difficult or easy to learn/perform. Following this classification, the views of majority of parents and children on the type of partnership between them were recorded **(Table 5.6)**.

Figure 5.1: Relationship between children's age and type of partnership between parents and their children.

* Except for blood glucose testing task where the task was either shared or done by the child

** Majority of parents stated that the carbohydrate counting role was performed mainly by them, whereas half of the young people stated the task was shared and half reported it was mainly done by young people

Table 5.6: Patterns of partnership when undertaking management tasks associated with pump therapy, as reported by parents (N=38) and children/young people (N=34)

Tasks (from simple to more complex)	Mostly by parent		Shared		Mostly by child	
	P	C	P	C	P	C
Testing of blood glucose levels*	5	1	9	8	23	23
Bolus administration**	8	5	8	3	18	23
Calculation of doses ^	10	1	16	21	10	9
Counting of carbohydrates ^^	17	11	4	14	9	7
Changing of catheter/cannula†	19	13	12	11	7	9
Checking of cannula-insertion site ††**	24	12	-	5	10	14
Basal setting/resetting ‡	19	11	5	3	8	16

P= parents; C= children and young people.
Numbers in red refers to the views of the majority.

* Data are missing from 1 parent and 2 children/young people
** Data are missing from 4 parents and 3 children/young people
^ Data are missing from 2 parents and 3 children/young people
^^ Data are missing from 8 parents and 2 children/young people
† Data are missing from 1 child/young person
†† One child (of the 3 children from whom the data were regarded as 'missing') reported the task was not done by anyone
‡ Data are missing from 6 parents and 4 children/young people

From **Table 5.6**, the results from this study support the hypothesis that: as the task becomes more difficult, it is 'mostly performed by parents' **(Figure 5.2)**.

It is important to consider that checking the cannula-insertion site for problems (e.g. infection or swelling) is not difficult in itself, but rather because of the location of the cannula, this task was difficult for many children/young people to undertake alone. There was inconsistency between the views of the majority of parents and children with regard to 3 tasks (see numbers in red in **Table 5.6**): counting of carbohydrates, checking cannula-insertion site and setting/resetting the basal rate. This inconsistency in the views could be explained by the way participants defined 'partnership' when describing how management responsibilities were undertaken within the family. For instance, with regard to counting carbohydrates, the parents may describe the tasks as mainly

Figure 5.2: Relationship between task complexity accompanying insulin pump therapy and the type of partnership between parents and their children.

performed by them, although children could have provided help, or be in the process of learning, such that the children may have defined the partnership in such situations as shared. Also differences may be related to the way the participants defined the 'task.' For instance, basal setting/resetting role was regarded by the majority of parents to be performed usually by them. This was reasonable as the role requires adjustments and monitoring (i.e. cognitive thinking) which could be difficult for many children to undertake alone. Children on the other hand may define performing such a role in terms of the actual physical change of the basal dose on the pump, and not in terms of deciding or adjusting the dose.

5.2.3 Duration of pump therapy

Transcripts of interviews with parents and children/young people were analysed to identify whether the duration of pump therapy had any effect on the nature of the partnership. Accordingly, the sample was divided based on the duration of using insulin pumps into: using pumps for less than a year, 1-2 years and more than 2 years to represent short-duration, long and very long duration, respectively. Then the views of the majority of parents and children in each group on the pattern of partnership when performing management tasks were considered **(Table 5.7)** to investigate the following hypothesis: as the duration on insulin pump therapy increases, the partnership between parents and children becomes shared or mostly performed by the child.

Table 5.7: Effect of duration of using insulin pumps on the pattern of partnership, as identified from the views of the majority of parents and children/young people

Role	Duration on insulin pump therapy		
	< 1 year (N=7)	1-2 years (N=9)	> 2 years (N=26)
Dose calculations	**P interview:** CHILD **C interview**: SHARED	SHARED	**P interview:** SHARED/CHILD **C interview**: SHARED
Carbohydrate counting	PARENT	**P interview**: SHARED **C interview:** PARENT	**P interview**: CHILD **C interview:** SHARED
Blood glucose testing	CHILD	CHILD	CHILD
Bolus administration	CHILD	CHILD	CHILD
Basal setting	PARENT	**P interview:** PARENT **C interview:** CHILD	**P interview:** PARENT **C interview:** CHILD
Site changing	SHARED	**P interview:** PARENT **C interview:** SHARED	PARENT
Site checking	PARENT	**P interview:** PARENT **C interview:** CHILD	**P interview:** PARENT **C interview:** CHILD

P interview= parent's interview; C interview= child's interview
PARENT: Task performed mostly by parents
SHARED: Task performed as a shared role
CHILD: Task performed mostly by child

From reviewing views of the majority of parents and/or children (divided into groups based on duration on pumps), it was found that the hypothesis only held for some tasks, such as carbohydrate counting, basal setting and catheter-site checking. For instance, complicated tasks, such as carbohydrate counting were done mostly by parents of children who were using the pump for less than a year, while it was either shared or done by the child solely for families where children were using the pump for 1-2 years or longer.

In contrast, for tasks, such as blood glucose testing and bolus administration, regardless of the duration of insulin pump therapy, the tasks were done by the majority of the children alone, as agreed by most of children and parents. This might be explained by the fact that these tasks can be regarded as relatively simple and hence could be done by children alone once they had transitioned to pump therapy. In addition, blood glucose testing was a task that needed to be performed with injection therapy (CIT or MDIs) and hence children would be familiar with it, prior to starting pump therapy.

Moreover, the hypothesis described above did not hold for tasks, such as calculation of insulin doses and changing of infusion sets, where the views of the majority of parents and children varied greatly. For instance, regarding dose calculations, the majority of parents caring for children who had been using insulin pumps for less than a year reported children could calculate insulin dose alone, while the majority of parents caring for children who have been on the treatment for 1 year or more stated that the children either shared the task with them or did it alone. On other hand, the majority of children who have been using pumps for less than a year, 1-2 years and more than a year stated that they shared the task with their parents. This variation in the opinions could be related to the fact that some families calculated insulin doses manually which was difficult for some children alone, because they lacked the mathematical ability to perform such calculations. On the other hand, other families used the pump Wizard facility which represented a relatively easy method for automatic calculation of insulin doses, and hence enabled many children to handle such calculations themselves (by entering carbohydrate counts and blood glucose values into their pumps).

Regarding changing of the infusion set, the majority of parents caring for children who have been on pump therapy for a short duration (less than a year) stated that the task

was shared with the children, while the majority of parents caring for children who have been using pumps for a year or more reported that the task was done by the parent alone. The majority of children who have been using insulin pumps for 2 years or less agreed that the task was shared with their parents, while the majority of those who have been using it for longer than 2 years agreed that the tasks was done by the parent solely.

The non-applicability of the hypothesis described above regarding roles of: dose calculation, infusion-set changing, dose administration and blood glucose testing might be related to other factors that might have impacted on the type of partnership existed between parents and children, such as children's age and task complexity. For instance children aged 8-12 formed the majority of the group of children who had been using insulin pumps for more than 2 years, and hence many of them were not able to do many tasks alone, due to their young age and the degree of the task complexity, even though they had been using insulin pumps for a very long time **(Table 5.7)**.

By considering how the factors discussed above (child's age, task complexity and duration of treatment) may affect the type of partnership between parents, a model was developed **(Figure 5.3)**.

Figure 5.3: Factors* influencing the pattern of partnership between children and parents when undertaking management tasks using insulin pumps.
* These factors could be interrelated to each other.

There was strong evidence with respect to the effect of child's age and type of task on the nature of the partnerships within families. The evidence supporting the effect of duration on insulin pump therapy in the current study (based on reports from the majority of participants) was neither consistent nor strong. Further investigation is recommended.

5.3 Impact of using the pump on children's transition towards autonomy in self-management

This section explores whether insulin pump therapy allowed children and young people more autonomy in terms of the division of management responsibilities in relation to treatment (i.e. insulin pump versus injections). It starts by defining the concept of autonomy/self-management. Parents' and children's perspectives on the dependency of children on their parents to undertake diabetes management responsibility using the pump compared to injections, and factors underpinning such dependency are also explored. This section ends by identifying how the change in management responsibilities (partnership) between parents and their children/young people occurred over time.

5.3.1 Concept of autonomy versus self-management

Many terminologies were identified in the literature to describe the concept of self–management in children and young people with diabetes, including: self-mastery, responsibility transfer, independency, self-care, self-care independence and self-care competence (Wysocki et al, 1996; Weissberg-Benchell et al, 2007; Karlsson et al, 2008; Buchbinder, 2009; Comeaux & Jaser, 2010). In 2002, Schilling et al (2002) clarified the concept of self-management of T1DM in young people. They defined it as 'an active, daily and flexible process in which children and their parents share responsibility and decision-making for achieving disease control, health and wellbeing through a wide range of illness-related activities' (p. 92). They identified 3 essential attributes of the concept: i) process, which involves shifting and sharing responsibilities between parents and their children; ii) performance of activities, which involves undertaking a wide range of diabetes management tasks, ranging from simple to complex and iii) setting goals, which involves the engagement of children and their parents in the self-management process to attain blood glucose levels within normal ranges and to maintain the wellbeing of the children.

As documented by Monsen (1992), autonomy is believed to be an important developmental underpinning for self-care behaviour. Dashiff and Bartolucci (2002) defined autonomy as 'being responsible' and its development starts at birth and continues throughout the lifespan, and is especially central to adolescence. For the purpose of this study, the term 'autonomy' refers to 'the ability of the children to master diabetes management tasks using insulin pumps, alone or with minimal help from their parents, and it will be considered as a component of the wider term; self-management.

5.3.2 Respondents' views on autonomy and factors promoting or hindering it

The respondents' perspectives on the dependency of the children on their parents when insulin pumps were used to manage diabetes compared to when injections were used were identified. Factors that might have promoted or hindered the children's transition towards autonomy were also explored from the points of view of the participants and are illustrated in **Table 5.8**.

Almost half of the parents (N=16) and more than half of the children (N=18) felt that insulin pumps allowed the children more independence to master the diabetes management tasks compared to injections.

To explore the reasons behind why insulin pumps allowed children in some families greater autonomy than they did in others, the interview transcripts of all participants were reviewed to identify respondents' views on how the management responsibilities were undertaken when injections were used (e.g. insulin withdrawal, injection delivery and blood glucose testing). From the children's perspectives (16 children aged 8-12 years and 6 young people aged 13-17 years), parents were completely responsible for everything related to the management until the children reached the age where they were able to do it themselves. In other cases, the management tasks were carried out as a shared role (reported by 4 young people aged 13-17 years).

In terms of the parents' views on their child's mastery of diabetes management on the injections, the responses of the parents (caring for children aged 8 years or older) varied greatly. Some parents (N=7) reported that their children were able to administer the dose either directly or shortly after diagnosis of diabetes, whereas others (N=16) administered injections to their children until they reached a specific age where they were capable of doing it themselves. It was recognised from cases where children were

Table 5.8: Level of children's autonomy when using insulin pumps compared to injections, as reported by parents (N=38)* and children/young people (N=34)**

Autonomy on pump versus injections	Parents (N)	Parents according to age (years) group of children they cared for (N)	Children (N)	Children/young people according to age (years) ranges (N)	Reasons for more or less autonomy on pump compared to injections
More	16	▪ Children aged 8-12 **(N=10)** ▪ Children aged 13-17 **(N=6)**	18	▪ Children aged 8-12 **(N=11)** ▪ Children aged 13-17 **(N=7)**	▪ Young age of child when they started injection therapy which made parents completely responsible for management ▪ Parents were new to diabetes and its management at diagnosis (on injections) ▪ Rigidity of life on injection therapy (MDIs) (e.g. eating and administering insulin at fixed times) ▪ Children did not feel comfortable administering injections themselves ▪ Recent pumps can do all mathematical calculations for doses through the Wizard, rather than doing them manually ▪ Some insulin pumps have sensors which allowed parents to relax at night and allowed children to go out alone a lot more without parents accompanying them or worrying ▪ Pump is an easier method of delivering insulin ▪ Pump is always attached to the child and hence parents' 'reminding role' for bolusing and blood testing is less compared to injections
Same	13	▪ Children less than 5 and 5-7 **(N=4)** ▪ Children aged 8-12 **(N=7)** ▪ Children aged 13-17 **(N=2)**	6	▪ Children aged 8-12 **(N=2)** ▪ Children aged 13-17 **(N=4)**	▪ Young age of child when using injections or pump ▪ Frequent blood glucose testing, food weighing and carbohydrate counting were already done on MDIs ▪ Child always needed help due to hard-to-manage diabetes (e.g. pancreas removed)
Less	5	▪ Children less than 5 and 5-7 **(N=2)** ▪ Children aged 8-12 **(N=2)** ▪ Children aged 13-17 **(N=1)**	3	▪ Children aged 8-12 **(N=2)** ▪ Children aged 13-17 **(N=1)**	▪ High readings on insulin pump therapy cannot be predicted even if doses were calculated correctly ▪ Insulin pump therapy requires more work with regard to food and drinks ▪ Insulin pump therapy required more supervision and adjustments ▪ Carbohydrate counting was not done on MDIs ▪ Pump is more complicated

* Data are missing from 4: (2 parents were caring for children aged 8-12 years while 2 were caring for young people aged 13-17 years)
** Data are missing from 5 children (aged 8-12) & from 2 children (aged 5 years)

able to give injections shortly after diagnosis that the children faced many challenges that forced them to do so. For instance, 2 mothers reported that they told their children that they would not be able to go to their friend's houses alone, or to go to residential courses unless they were able to inject themselves. In other families, the children had to administer their injections at school themselves, which forced them to learn quickly. In cases where injections were done by children, sites such as the abdomen, or leg were used instead of the arms.

By analysing the transcripts systematically across all cases, it was recognised that factors promoted the transition towards autonomy were partly related to the pump technology. The most modern pumps had many features that enabled children more mastery of the management tasks, and hence made them superior to injections. This concept was emphasised by the views of the participants in some interviews. For instance, having modern pumps equipped with software that automatically calculates insulin doses by entering carbohydrate counts for an ingested meal and the last blood sugar reading (i.e. pump Bolus Wizard®), freed children from complicated and tedious dose calculations:

> *"The Bolus Wizard is a gift for a child, because my head used to do all the maths for them, because it is unfair to make them to do mathematics like huge calculations whilst in the middle of their school day."*
> [Mother of boys aged 9 & 12, interview no: 17, line 111]

Modern insulin pumps are equipped with sensors which constitute CGMSs, that measure blood glucose values over 24-hours. This feature of insulin pumps freed children and their parents from the frequent blood glucose testing, especially at night. Some parents (N=6) stressed the importance of the sensors and how they helped them in the management:

> *"Yes she has that* [the sensor] *and I could not do without that anymore. That is brilliant you can do a lot more tweaking and things and you can see patterns and things like that. It is just...it is just brilliant overall."*
> [Mother of a girl aged 9 years; interview no: 26, line 71]

In addition to advanced technology associated with insulin pumps, the technical aspects underlying insulin administration via a pump were considered superior to those of injections. Insulin dose delivery using pumps only involves pressing a few buttons, while with injection therapy, dose delivery involves insulin withdrawal from the vial (a

procedure requiring skills and accuracy) and needle sticking, which can be hard for very young and children fearful of needles. Moreover, the pump is like 'a gadget' and children could handle it better than injections. Such issues were articulated by many participants during the interviews:

> *"Probably pump fairly because it is just you don't really have to do the maths or something to figure out what your carb ratio is or the bolus things, but it is easier to use...this is like playing a video game you just have to hit a few buttons and just that."*
> [A boy aged 15 years; interview no: 63, lines 132-133, 136]

> *"Well on the injections my Mum had to do it all, because I could not put it in, I could not put the insulin inside the injection vial thing. With the pump, I can do more, I can do most of it. So this was probably because I was too young to understand how injections worked."*
> [A boy aged 11 years; interview no: 66, lines 152-154]

Other reasons promoting greater autonomy of children on the pumps may be explained by the age factor **(Section 5.1)**. The effect of age was emphasised by many parents who thought that the autonomy of their children on the pump was related to the fact that they are getting older, while they were young at the time of diagnosis and use of injections.

Although the use of insulin pumps allowed children and young people greater autonomy, it was not consistent for all families in the sample. Some parents and children thought that the autonomy was the 'same' or 'less' with pumps compared to injections **(Table 5.8)**. Factors that hindered autonomy on insulin pumps were proposed by participants and identified from the interviews. Cases where autonomy was claimed to remain the same on both treatment modalities (injections and pumps) were explained by: the young age of children so parental help was needed for both; hard-to-manage diabetes where continuous involvement of parents was essential; same management tasks were undertaken for both. Cases where using the pumps made children more dependent on parents were due to the workload associated with insulin pumps (e.g. frequent blood glucose testing, dose monitoring/adjustments and carbohydrates counting). Some families in the sample reported that no carbohydrate counting or dose calculation was undertaken when children were using MDIs:

> *"I was on injections for a year before anybody admitted that I needed to count carbohydrates. They told me to eat a plate of food, just to eat a healthy diet. I said 'do I need to count carbohydrates?' they* [local hospital] *said 'no don't do that' so I got really bad advice on the MDIs."*
> [Mother of a girl aged 15 years; interview no: 33, lines 194-196]

> *"We were on multiple injections and I was not really carb counting, because we have not really...we were suddenly spoken to 'come on you can do it' and I learned to carb counting in about two weeks, so I suppose that is why I was unsure, because I had not had time to get used to that."*
> [Mother of a boy aged 11 years; interview no: 18, line 167]

Findings from this study suggest that overall insulin pumps allowed children more autonomy and mastery of diabetes management compared to injections, and hence they encouraged a trend towards 'self-management.' Factors which promoted autonomy included: developments in technology, simple technical use and an older age of the child. In contrast, many factors hindered children's mastering of management tasks: young age and unstable clinical condition. Although the workload associated with management using a pump was a barrier against a child's transition towards autonomy, as claimed by some participants, using MDIs involves a similar workload. However, this was not systematic across all cases, as some families in the sample used fixed doses rather than counting carbohydrates and adjusting doses with MDI regimes.

5.3.3 Progress towards autonomy when managing diabetes using insulin pumps

Within the context of 'self-management' (defined in **Section 5.3.1**), findings of the current study entailed the division of responsibilities between parents and their children at home and identified patterns of partnership which existed between them. This study was conducted with children of wide age ranges (5-17 years), and their parents (including parents of children aged less than 5). Accordingly, participants' views on division of responsibility when performing the diabetes management tasks could be used to reveal the ways in which responsibilities within the partnership might change within time.

As reported in **Section 5.1**, very young children (less than 5 years) were completely dependent on their parents to handle their management tasks. As children grew older (age 5-7 years), they were involved in some tasks, but under supervision, while older children (aged 8-12 years) had more shared involvement with their parents or in many cases, had the ability to undertake some management tasks alone. Young people (aged 13-17 years) in the majority of the sample were almost fully responsible of their diabetes management using the pump, although parents' involvement in reminding and providing help, with some of the tasks, continued in many cases.

In the light of these findings, the transfer of responsibility from parents to children corresponds with the theoretical model of Buford (2004). Buford's model was developed by examining parents' and children's perceptions of the transfer of the responsibility from parent to child for the management of asthma **(Figure 5.5)**.

Figure 5.5: Buford's theoretical model for parent-child transfer of asthma management responsibilities (Buford, 2004)

This study was similar to that of Buford, where a cross-sectional design was undertaken. In contrast to the model proposed by Buford which was based on the 'time frame' where participants were asked about the management responsibilities starting from diagnosis to later on the therapy, this study applies the same concept, but based on 'management responsibilities undertaken by each age group' of the children and young people. Buford's model consists of 3 discrete stages: 'out of control,' 'autopilot' and 'letting go' and 2 transitional stages: 'gaining control' and 'empowerment.' The first discrete stage 'out of control' refers to an emotional response usually at diagnosis when parents and children were unable to gain control of the condition or its management. 'Autopilot' occurred when families had incorporated management issues into their routines and daily lives. The third discrete stage is 'letting go' where the children had complete independent self-management, without assistance from parents. In the transitional 'gaining control' stage, families began to master asthma management skills and the 'empowerment' stage describes the time at which the parents became aware that

they would not always be there to manage the children's condition and hence changed the organisation of roles between them and their children.

This research identified the process of transfer of diabetes management roles from parents to children over time, based on what had been highlighted by both parties with regard to the division of management responsibilities. Findings from the current study suggest that as the children grew older, a gradual transfer in the responsibility for management roles occurred. The application of Buford's theoretical model of transition to the findings of this study is shown in **Figure 5.6**.

Figure 5.6: Buford's modified model of child-parent responsibility transfer of diabetes management responsibilities with insulin pump therapy

The 'out of control stage' in Buford's model had been represented in this study by 'parents taking full responsibility' for diabetes management, where parents handled completely the overwhelming load of the management due to young age of the children. The ages of the children in this stage of the modified model is 7 years or less. With time and as children grew older (age of 8-12 years), the majority of children in this study started to take more responsibility and hence in many cases shared some tasks, which is represented in the modified model as 'children undertaking some responsibility' and 'starting to gain control.' This is equivalent to the 'gaining control' and 'autopilot' stages in Buford's model, where families started to gain greater mastery of managing

the chronic illness and consequently the management became a family routine, respectively. The final transitional stage 'empowerment' and the discrete stage 'letting go' in Buford's model, in which families realised that the children should learn to manage their own condition and hence started to change the organisation of roles with their children, leading to young people adopted independent self-management without assistance from their parents, has been replaced with 'young people taking near to full responsibility' and 'gaining more control.' In this study the parental involvement continued in many cases and did not 'let it go' as it was the case in Buford's model.

Asthma and diabetes are different chronic conditions which entail different management responsibilities. However, in the absence of a model for diabetes, use of the theoretical model of asthma was found to be applicable to diabetes. This is because both are lifelong conditions [although 30-60% of children diagnosed with asthma in early childhood experience remission, those whose symptoms persist require ongoing management into adulthood; (Sears, 1998)]. Moreover, both conditions involve use of devices (pumps for diabetes; inhalers or nebulizers for asthma) where training, skills and knowledge must be acquired.

Factors, such as the child's age, task complexity and duration on the pump were suggested to affect the type of partnership between parents and children **(Section 5.2)**. With this regard, these factors are proposed to affect the speed of responsibility transfer in the modified Buford's model **(Figure 5.6)**. For instance, in terms of 'task complexity' children as young as 5 in the current study were able to handle simple tasks, such as blood glucose testing and bolus delivery, but under supervision, while for more complicated tasks, such as basal setting and infusion-set checking, the older children in some cases, required help from their parents as they could not handle them alone.

5.4 Discussion

Self-management of T1DM, together with achieving glycaemic control, is the cornerstone for managing diabetes. Yet, for children and young people, developmental and cognitive maturity is required to handle the management tasks. Little is known about how children of different ages and their parents undertake responsibility for the management tasks at home. Recently, the use of intensive insulin therapy with insulin pumps has increased worldwide. However, insulin pump users and their families face

many daunting tasks that accompany diabetes management with this technology, such as learning how to work the device, setting and adjusting insulin basal rate, fitting and changing infusion sets. These add to the workload that is already required for intensive diabetes management (e.g. frequent blood glucose testing, monitoring and carbohydrate counting). Therefore, it was important in the current study to explore how children of different ages and their parents shared the management responsibilities at home.

In the light of the self-management concept proposed by Schilling et al (2002) **(Section 5.3.1)**, 3 attributes of self-management were identified: process, activities and goals. Results from this study broadened this concept by the description of 3 management patterns which existed between children/young people and their parents when managing diabetes with insulin pumps: 'mostly by parents,' 'shared' and 'mostly by child,' and by proposing a model for the transfer of the management responsibilities. Although similar patterns of partnership were explored and described between parents and youths using insulin pumps in a study by Schilling et al (2006), this study used a larger sample size (N=34 children; N=38 parents) and involved very young children (as young as 5 years old) compared to the Schilling et al study (N children=22; aged 8-19 years). Only two children aged 5 years in this study formed the group of children aged 5-7 years, and hence the actual capability of other children in this age group (aged 6 or 7 years) was not fully explored. Further studies concerning the capability of this age group children are, therefore, needed.

Findings from this study identified that factors, such as age, task complexity and duration of pump therapy could play a role in affecting the pattern of partnership that existed between parents and their children. Newbould et al (2008) suggested other factors to promote (e.g. school trips or staying the night with friends) or hinder (e.g. worsening of medical condition and parental relationship breakdown) the transfer of diabetes or asthma management responsibilities from parents to their children, as a response to specific occasions or circumstances. Similar issues (e.g. going to friends' houses or residential courses) were identified in this study as challenging factors for the children to take more responsibility, but only in situations where injections were used.

Regarding age in the current study, it was recognised from the data obtained from the majority of cases that partnerships become more child-dominant as children grow older.

For very young children (less than 5 years) and children aged 5-7, parents were mostly responsible for management tasks. Children aged 8-12 years were likely to undertake many of the management tasks with their parents, while young people aged 13-17 years had near to full control of most of the management tasks. These findings are consistent with the literature, suggesting that older age is associated with more involvement in diabetes management (Drotar & Levers, 1994; Schilling et al, 2006; Weissberg-Benchell et al, 2007). However, a 15-year old boy in this study did not care about his condition which forced his mother to act in and hold complete responsibility for his management. This might be related in the poor regimen adherence associated with this age group (Wysocki et al, 1996), in addition to the special circumstances through which this family had gone, as the mother reported that a divorce and separation from the father had occurred as a result of the tension created by the stress of the management tasks associated with insulin pump therapy. Findings from this study also showed that teenagers and some children aged 8-12 although having the ability to manage T1DM using insulin pumps, still needed reminding and some help from their parents. This is in agreement with previous studies which suggested that parents continue to play an important role when managing diabetes of early and mid adolescents using CSII, especially in relation to reminding and solving problems (Low et al, 2005; Schilling et al, 2006). It is important to highlight the need for continued parental supervision and reminding in the management of young people with T1DM, even if they are capable of managing many tasks themselves, as it can lead to better metabolic control (Anderson et al, 1997a).

In terms of task complexity, it has been reported that diabetes management tasks vary in their complexity and this in turn affects children's capability to perform the task (McNabb et al, 1994). In this study, the tasks were regarded as 'simple' or 'complex based on Kaufman's Competency Level Scale (Kaufman et al, 2001) and from descriptions given by many participants during the interviews. Children were able to handle simple tasks as soon as they started insulin pump therapy, such as blood glucose testing and bolus administration. On the other hand, more complicated tasks, such as dose calculations, carbohydrate counting and infusion-set changing were performed in many cases mostly by the parents.

The third factor that was proposed to affect the pattern of partnership in the management of diabetes with insulin pumps was the duration of using the device. Findings from this research suggested that as the time using pump therapy increases, children become more able to master their management tasks. However this was not the case for all of the tasks described in this study, due to other factors (child's age and task complexity) which can interrelate with the therapy duration. All these factors affected patterns of partnership and hence responsibility transfer from parents to their children. In addition, the distribution of children relative to their ages was not consistent across groups (i.e. most children using a pump for more than 2 years were aged 8-12 years, and hence their mathematical skills and knowledge were insufficient to undertake all management tasks themselves). No studies were found in the literature search that examined the effect of pump duration on the child's mastery of management tasks. Therefore, further research with this regard is recommended.

Although the current study suggested that factors, such as child's age, treatment complexity and duration of therapy could play a role in the pattern of partnership in the families, and on transfer of responsibility from parent to child (i.e. self-management), this study had a cross-sectional design and was only based on the information obtained from the interviewees' views. Longitudinal studies and further testing of such factors as the division of labour in the home and transfer of pump management responsibilities are recommended. Furthermore, the effect of other factors, such as sex, motivation and family variables (e.g. parental education level) on the transfer of the responsibility to children and hence self-management should be explored in children receiving insulin pump therapy.

This study broadened the concept of self-management proposed by Schilling et al (2002), by describing the process of responsibility transfer from parent to child, based on the information obtained from the interviewees with regard to the division of management responsibilities. A model was developed to describe the transfer process, by modifying a model proposed previously by Buford (2004) for describing responsibility transfer in the management of asthma. The responsibility transfer identified in this study was 'a gradual process' in which the responsibility transfers from parents to their children with more management tasks handled by children as they grow older. This model differed from Buford's model in that the latter was based on 'time

frame,' while the current study described the process over time, considering management tasks undertaken by children at different developmental stages (i.e. from early childhood to teenage years). Also absent from the Buford's model were factors described in the current study (child's age, task complexity and duration on pump) that affected the pattern of partnership and which were proposed to influence the speed of the responsibility transfer process in the modified model. The research presented in this thesis furthers the work of Buford (2004) by the application of the model in children using insulin pumps for managing diabetes. Moreover, the adapted model **(Figure 5.6)** in this study was created based on interviews with 34 children/young people and 38 parents, while the original model by Buford **(Figure 5.5)** was proposed based on interviews with only 14 young people and 14 carers.

Findings from this study suggest that insulin pumps allow children and young people greater mastery and autonomy of managing diabetes compared to injections. This opinion was reached by taking into consideration the views from half of the parents and their children. Parents who thought the workload was the same on either method of insulin delivery justified their views with respect to the young age of their children which made them solely responsible for the management, or because of the nature of their child's condition which was always hard to manage. The greater autonomy with insulin pumps was because they presented an easier method of insulin delivery, in addition to the fact that modern pumps were equipped with sensors and calculator software that made insulin dose calculations and blood sugar monitoring easier, such that these were not parental-restricted tasks. Findings presented with this regard were inconsistent with the results in a study by Weissberg-Benchell et al (2007), where parents and clinicians reported that insulin pump therapy-related tasks were more difficult for young people to carryout than MDIs-related tasks. This was explained by the fact that using MDIs only involved giving injections and counting carbohydrate content, whereas CSII required continuous adjustments of basal and bolus insulin doses in coordination with food intake, physical activity and changes in daily schedules. In addition, using insulin pumps required an individual be able to deal with technical aspects of the device and to change the infusion- set on a regular basis. Conducting the current study was crucial, as the concept of autonomy in children with diabetes mellitus with relation to the treatment modality (insulin pump versus injections) has been poorly investigated this far.

Together with achieving glycaemic control, an individual's autonomy in mastering management tasks is a key for managing diabetes in children and young people. There is increasing research regarding the involvement of children and young people with chronic illness in the process of care and self-management, however, studies on how medicines are managed at home are lacking (Smith & Gray, 2009). Findings presented in this study give an insight into the pattern of partnership that exists between children and parents when undertaking day-to-day diabetes management using insulin pump. They suggest a greater involvement of children in the management when insulin pumps are used rather than injections. This in turn acknowledges the importance for how children with diabetes can be best empowered to participate in the process of managing their condition and allows healthcare professionals proposing guidance and supporting parents caring for children of different ages using insulin pump therapy to facilitate the movement of management from being mostly performed by parents to mostly performed by children, without deteriorating metabolic control.

In the UK, NSF proposed Standard 3 'empowering people with diabetes' (Department of Health, 2001). This standard indicates that all patients with diabetes, including children and young people, should receive a service that encourages personal control over the day-to-day management of diabetes to guarantee the best possible quality of life and the development of a healthcare system in which self-management is adopted as the cornerstone of effective diabetes care. Likewise, the American Diabetes Association (ADA) in its National Standards for Diabetes Self-management Education (DSME) identified self-management as the keystone of care for all people with diabetes, to improve health-related outcomes (Mensing et al, 2002). Within this context, results from this study showed that insulin pumps promote greater autonomy compared to injections for children and young people with T1DM.

CHAPTER 6 - Diabetes management within schools

Chapter 6: Diabetes management within schools

Chapter 6 explores how the T1DM of the children and young people was managed at school using insulin pumps. It investigates problems experienced using pumps at school; how children with insulin pumps and their families were supported and the barriers against successful management of diabetes at school using the pumps.

6.1 Using insulin pumps at school to manage T1DM

6.1.1 Undertaking management responsibilities and children's autonomy at school

As demonstrated in **Chapter 5**, using insulin pump facilitated children's autonomy in self-management. Whether this was applicable to the school setting was investigated in this section. This was done by exploring participants' views on how the diabetes management responsibilities were undertaken at school. Examples were given around tasks, such as bolus administration, blood glucose testing, carbohydrate counting and cannula-site changing/checking **(Figures 6.1 & 6.2)**. Comparisons with the situation where injections were used were also highlighted **(Figures 6.3 & 6.4)**.

Due to their young age, very young children who went to nurseries were managed with the help of nursery staff. Nursery personnel checked blood glucose levels at times specified by parents and delivered a bolus for snacks only, but not meals, using pump Wizard. Infusion-set changes and bolus delivery for lunch were mostly done by the parents. This may be because these tasks needed greater skills, knowledge and practice. As a result, children were not staying for lunchtime at nursery.

Children aged 5-7 were able to do blood tests, but under supervision, at schools. Insulin boluses were delivered by the staff (using pump Wizard for carbohydrates that were counted in advance by the parents), who also checked the cannula-insertion site for unusual signs. More involvement was shown by older children (aged 8-17 years). Children aged 8-12 years and their parents agreed that in most cases the blood tests were done by the children in the medical office, where they also administered boluses calculated for carbohydrates counted previously by the parents, i.e. children bolused for what they consumed. In case of developing hypoglycaemic episodes, children in this age group showed the ability to manage the situation themselves by administering hypo-stop aids. Parents were sometimes called for double checking and advice. Young people (aged 13 or older) were able to check blood glucose levels and to administer insulin

Figure 6.1: Quotes from parents' interviews illustrating how children and young people managed diabetes at schools using insulin pumps. Numbers between brackets refer to the interviews' number and lines from which quotes were extracted, respectively.

Figure 6.2: Quotes from children's interviews illustrating how children and young people managed diabetes at schools using insulin pumps. Numbers between brackets refer to the interviews' number and lines from which quotes were extracted, respectively

Managing diabetes at schools by using injections

Parents of children aged less than 5

No quotes [all children in this group (N=4) did not use injections at nurseries; started nurseries while on pumps]

Parents of children aged 5-7

Children in this group (N=2) started school (reception) with pump therapy. However one of them used injections at nursery, but the child stayed only for 2-3 hours daily, so all injections were administered at home:

"He was there for about 2-3 hours so he had an injection before he went and an injection the moment he got home. They used to do one blood test for me but they never administered the insulin for that, which was worse for him because he was not having the insulin that he needed in the morning."
[Mother of a boy aged 5 years; interview no: 11, line 186]

Parents of children aged 8-12

"Once he started doing injections, I think I spent 2 or 3 years going over to the school doing them and then we managed to get him doing them himself and then they covered it at school, but they could not help him with it, rather they had seen him doing them to make sure he had them."
[Mother of a boy aged 11 years; interview no: 18, line 78]

"She used to go to a private place everyday because she used to pull her trousers down, so she did not like that. She had a friend with her but she would not allow the friend to look, so she had the door closed and nobody surrounding."
[Mother of a girl aged 10 years; interview no: 8, line 166]

Parents of children aged 13-17

"When she was in the junior school she had to go to a separate place, because they would never have needles in the classroom, but at the senior school she could just carry a kit around with her, so that it was not such a problem. She used to do it at the dinner table or in the classroom and when she needed it."
[Mother of a girl aged 15 years; interview no: 33, line 251]

"When she was on injections I used to sit outside the school or go into school, because she was 10 when she was diagnosed, so I would go in to school and give her an injection. And then when she felt able to do it herself, then I would still sort of hang around outside the school until I felt that she was safe."
[Mother of a girl aged 15 years; interview no: 23, line 167]

"The school would not give him injections, I mean when he was older, they would watch him taking it but they would never do the injections."
[Mother of a boy aged 19 years; interview no: 20, line171]

Figure 6.3: Management of diabetes at school with injections, as reported by some parents (N=35 out of 38)

Figure 6.4: Management of diabetes at school with injections, as reported by some children and young people (N=29 out of 34)

boluses themselves in the classroom or in the medical office where they also went if the infusion set came out, for re-insertion. They also sometimes called their parents for assistance.

In comparison to the pump, life at school on the injections was considered more difficult. This was because administering injections was not a practice welcomed by many schools. Therefore, parents had to go every lunchtime into the school to administer injections, until children were able to do so themselves. In such cases, children, regardless of age, had to go to the medical office to administer insulin under supervision. In other cases, a private place needed to be found to administer the dose, because children exposed the site where injections were administered. Additionally, food and snacks had to be ingested by the children at fixed times during the day, which did not necessarily correspond with school break times.

From these results, using insulin pumps at school allowed children more independence to undertake management responsibilities compared to injections. Further investigation was undertaken to explain why insulin pumps allowed children more autonomy compared to injections **(Section 6.1.2)**.

6.1.2 Ease of using insulin pumps at school compared to injections

All parents (N=38) and children/young people (N=34) were asked to document how easy or difficult it was to manage diabetes at school with insulin pumps **(Table 6.1)**.

Table 6.1: Ease or difficulty of managing diabetes at school using insulin pumps compared to injections, as reported by parents (N=38) and children/young people (N=34)

Response	Groups based on children's age (years)								
	< 5	5-7		8-12		13-17		Total	
	P N=4*^	P N=2^	C N=2**	P N=21**	C N=20^^	P N=11*	C N=12	P	C
Easy/Easier	2	1	-	17	14	10	10	30	24
More difficult	1	1	-	1	-	-	-	3	-
No difference	-	-	-	1	1	-	2	1	3

P= parents; C= children and young people

* Data are missing from 1 parent
** Data are missing from 2 parents/children
^ Children started school/nursery while on the pump, however, parents gave answers based on their points of view
^^ Data are missing from 5 children

Most parents and children shared the opinion that managing diabetes at school with insulin pumps was either easy or easier than using the injections. Reasons for the easier use of insulin pumps at school compared to injections are shown in **Table 6.2**.

Table 6.2: Reasons for the easier use of insulin pump to manage diabetes at school compared to injections, as reported by parents and children/young people

Reason	P	C
Freeing parents from going to school every lunchtime (school would not give injections and children were too young to give them)	9	5
Allowing flexibility in eating times and patterns	8	10
Achieving more control of diabetes	6	4
Easier to give instructions/rules to follow	4	-
No need to take spares; pump is already worn	3	2
Doses can be administered easier, quicker and without attracting attention	3	6
Children were young on injections and hence could not do them	1	1
Better hypo-awareness, so steps can be taken to avoid hypos	1	-
Pump has a memory and so parent can check how much insulin a child has had given himself/herself	1	-
No needles	-	3
Blood monitoring is easier because of the sensor	-	1
Pump is more accurate	-	1

P= parents; C= children and young people

Insulin pumps have many advantages that made them easier to use than injections. These allowed a more flexible lifestyle, manifested by flexibility in eating times and patterns; easier administration; freedom from needles; easier monitoring/checking (due to facilities with the pump; glucose sensors or memory) and a greater accuracy. Advantages of insulin pumps and their impact on life will be discussed in detail in **Chapter 7**.

In a few cases, using the injections was either thought to be easier or similar to insulin pumps **(Table 6.1)**. The former was reported mainly by parents of very young children (aged 5 years or less), indicating that their child had a short stay at nursery so injections were administered at home, and they did not worry about the pump falling or being damaged:

> *"It is probably be a bit easier* [injections], *because she is only there* [in nursery] *for those morning hours, she does not have her lunch there so they would not have to do the injection. So all then they* [nursery staff] *have to do is a finger prick test that would be just to check if she is alright and also that they would not have to worry about the pump falling in the toilet or in the sand or water tray."*
> [Mother of a girl aged 3 years; interview no: 27, lines 148-149]

Worrying phone calls from school personnel regarding using insulin pumps compared to injections was another reason, as reported by a mother of 8-year old child. Receiving more phone calls from the school personnel when insulin pumps were used compared to injections could be related to the fact that insulin pump therapy was a new technology for managing diabetes, that needs knowledge and skills to deal with which school staff had yet to acquire.

No difference in the ease of use between the two administration techniques was related to the fact that although injections were difficult for the children to administer themselves compared to pumps, school personnel were very cooperative with the families.

6.2 Problems experienced when using insulin pumps at school

All parents (N=38) and children/young people were asked to describe any problems experienced when using insulin pumps at school **(Table 6.3)**.

In many cases, using insulin pumps at school was not associated with problems. Where experienced, the problems were clinical (e.g. hypoglycaemia or hyperglycaemia), technical (e.g. infusion set problems, running out of battery power/insulin and breaking down of pump), or related to the management responsibilities (e.g. forgetting to bolus/test, sensor/ pump bleeping/vibrating at class and running out of supply).

Infusion set-problems were the commonest dilemma associated with using insulin pumps at school. They were usually experienced with young people aged 8-17 years. This could be related to their being more involved in sporty activities compared to younger peers. However, younger children (aged less than 5 years) also faced the issue of the tubing being pulled by other children:

> *"I mean there was one incident where a little boy tried to pull her tubing, they* [nursery staff] *saw it and they just quickly put it away, so it was fine."*
> [Mother of a girl aged 2 years; interview no: 5, line 183]

Table 6.3: Problems experienced by using insulin pumps at schools and ways they were handled, as reported by parents (N=38)* and children/young people (N=34)**

Problems	P N=21	C N=23	Ways they were resolved (if any)
Infusion-set problems	11	10	Either child went home or parent went to school to solve the problem
Hypoglycaemia	4	-	School treated child with hypoglycaemia and parent went and picked up the child
High blood glucose level	-	1	Parent was called
Battery running out	3	5	- Battery was replaced; school had supplies - Parent was called
Lose/breaking pump	3	-	Child found the pump with the help of school teacher
Pump falling during physical activity	-	1	-
Running out of insulin	1	2	- Child came back home to fill insulin - Parent was called
Forgetting to bolus/test for blood sugar	1	1	Parent was called by school to deal with the high blood sugar
Pump alarming in class	1	2	-
Running out of supply (e.g. insulin) from school	-	1	-
Sensor vibrating in class	-	1	-

P= parents; C= children and young people.
Problems were reported by frequencies they were mentioned.

* Data are missing from 3 parents; 17 reported none
** Data are missing from 2 children; 11 reported none

Hypoglycaemia was one of the problems reported only by parents, mainly those of very young children (aged less than 5 years). This also happened for children who had been recently transferred onto the pump and was a result of the need for stabilising blood glucose levels and adjusting insulin doses following the switch from injections:

> *"He did have a fit or he had a hypo at school and fitted and smashed all his face in the playground and obviously an ambulance was called. This was when we only had just gone on the pump, so we were still settling down the blood sugar."*
> [Mother of a boy aged 15 years; interview no: 38, lines 167-171]

In most cases, the parents were called to handle such problems.

6.3 Supporting children using insulin pumps at school

In this section, how children and young people using insulin pumps at school were supported is explored **(Table 6.4)**.

6.3.1 Partnership between home, school and hospital

In this study, it was recognised that the home, the school and the hospital liaised together in order to help children using insulin pumps at school. A form of partnership was identified between the hospital and school. This was manifested from reports by many parents, children and young people that some of school personnel either attended pump training courses with the families at the hospital or received the training in the school, organised by the hospital nurses who visited the school for this purpose. In other cases, parents themselves went into the school (i.e. partnership between home and school) to instruct school nurses and teachers about their child's condition, how to undertake pump management tasks and what to do in emergencies:

> *"So by me going in and talking to the teachers, talking to her friends about diabetes, what it is and how she controls it, and showing them what the equipment is that she uses, and what it is for, and why it is important. Telling them what to do in case of an emergency, on what that might be and demonstrating. My daughter has also talked to her school friends in a formal way, not just chatting, but in a formal way about exactly the same things; about diabetes, what it is and how she controls it, why it is important."*
> [Mother of a girl aged 15 years; interview no: 23, line 156]

This form of education was not only restricted to the beginning of insulin pump therapy, but rather it was an 'ongoing process' of learning, where the parents and the hospital medical staff updated school personnel about the child's condition and insulin pump therapy. For instance, the hospital in addition to providing training to school staff at the initiation of insulin pump therapy, also supported children/young people when they transitioned into a new school:

> *"They went to the first school and then we had changed the school, they went to that one as well, and that was useful, because they sat with the school staff for an hour and half and explained it all, so the school knew exactly what to do."*
> [Mother of a girl aged 10 years; interview no: 8, lines 278-280]

It was believed that when the communication with the school is carried out by the hospital, more attention and care was shown by school personnel than if done by the parents:

Table 6.4: Help and support the school personnel provided to children/young people, and their parents, when using insulin pumps to manage diabetes at school/nursery, as reported by parents (N=38)* and/or children/young people (N=34)**

Parents/children/young people	Help/support
Children aged less than 5 years	▪ Observing child ▪ Testing blood sugar levels ▪ Adding carbohydrate counts given by the parent for snacks ▪ Delivering boluses ▪ Managing hypoglycaemia ▪ Calling parents when needed (e.g. blood sugar readings out of range or not sure how much to bolus)
Children aged 5-7 years	▪ **Testing blood sugar levels** ▪ Recording blood sugar values ▪ Adding carbohydrates (parent gives carbohydrate counts and staff sum up what child eats and enter it into pump) ▪ **Delivering boluses using pump Bolus Wizard®** ▪ Giving correction doses when needed ▪ **Calling parents in emergencies and for queries** ▪ Checking cannula site for infection
Children aged 8-12 years	▪ **Keeping an eye on the child (e.g. in the playground)** ▪ Giving parents the food menu in the school to count carbohydrates required for bolus administration ▪ Adding carbohydrates given by parent and telling child what to put into pump ▪ Delivering boluses ▪ **Reminding, helping and supervising children when administering boluses** ▪ **Reminding, helping and supervising children doing blood sugar testing** ▪ **Keeping notes of blood sugar values before lunch as well as before and after sports** ▪ **Calling parents in emergencies or for queries** ▪ Allowing children to call parents when needed ▪ Making sure that other children are aware of the diabetic child's condition to avoid unnecessary questions, teasing and harassment ▪ **Managing hypoglycaemia** ▪ **Allowing children to eat in class if needed** ▪ **Keeping supplies like insulin and glucose tablets in the medical office** ▪ **Giving children a special card as they have a medical problem which they can show to teachers if they need to leave the class for medical reasons** ▪ **Attending pump training at school or the hospital** ▪ Making sure that if children needed snacks before PE lessons and checking whether children put pump on after PE and did a blood test ▪ Checking cannula site

Table 6.4: Contd.

Children aged 13-17 years	▪ Reminding children to test and bolus ▪ Checking that children did a blood test, before and after PE ▪ Discussing blood sugar readings with the young person ▪ Providing a card for medical problems which young people can use to exclude himself/herself from certain regulations or activities (e.g. wearing school shirts in a different way to hide the pump) ▪ **Calling parents in emergencies** ▪ Reminding young person to eat sweets before PE lessons ▪ Attending pump training at school or the hospital ▪ Allowing young person to leave class and check blood sugar levels if he/she felt unwell ▪ **Keeping supplies like insulin, glucagon, glucose tablets and snacks** ▪ Providing a trained person to accompany young person on school trips to make sure that the management is carried out correctly and to provide help if needed ▪ Prohibiting adolescent from participating in PE lessons if blood sugar values were low or high

PE= physical education
'Bold' text refers to issues addressed by both the parents and the children/young people

* Data are missing from a parent (of children aged 8-12). Two parents (of children aged 8-12) stated that the children had a one-to-one carer and hence did not need help from school staff and another 2 parents (of children aged 8-12) stated that their children received no help from school personnel. A parent (of children aged 13-17) stated that young person did not need help as he/she was confident in doing everything alone

** Data are missing from 2 children (aged 8-12). Two children (aged 8-12) had a one-to-one carer and hence did not need help from school staff. Two young people (13-17) stated they don't receive help at all from school personnel

> *"Actually I think if you spoke to the school, they would be much more positive about their diabetes. They kind of understand the whole business more. When my TA* [teaching assistant] *came to be trained, the thing she said to me 'I had no idea that was all involved with diabetes.' I said: 'but I have talked to you about all of this' and she said 'I know but it did not come across as being a serious condition, as now I came to the hospital and heard nurses speaking to you about it, I can really see this is really a serious thing isn't it.' And I think that is the problem, the whole level of ignorance about it and no matter how many times I as a parent say it, it needs to come from the medical profession into the school to say 'you need some respect of this condition this is a serious one.' "*
> [Mother of diabetic sons aged 9 and 12 years; interview no: 17, line 244]

Other forms of the partnership between home and school was seen when parents, in addition to educating school personnel, calculated carbohydrate counts for the meals cooked in schools **(Table 6.4)**. In this case, the schools gave the parents a list of the food content of the meals they offered, and parents counted the carbohydrate content and sent a daily note to the school of what the child would eat for the day. Subsequently, the school personnel either added up or supervised the child adding up the carbohydrate counts for the ingested food:

> *"We send with her a note in the morning of what she is going to eat. The local Council sent us the school meals with the carb content and the weights and we send a list every morning of what she is going to eat."*
> [Father of a girl aged 10 years; interview no: 13, line 151]

In other cases, children took a packed lunch from home into school, for which the carbohydrate content was already counted and written by the parents in a note for the school staff. Parents also provided schools with backup insulin, batteries for the pump, aids for treating hypoglycaemic episodes (e.g. glucose tablets and dextrose) and snacks. Moreover, there was regular contact between the school and the home, where parents were always on call for emergencies, or if either the child or the school nurse needed to confirm things with parents:

> *"I think it is easier, because when she is in the nurse's office with high or low* [blood glucose level], *then I will just you know speak to her and say 'ok give yourself a correction dose' or I just ask her 'what do you think you should correct by?' and then she tells me and she just does it."*
> [Mother of a girl aged 12 years; interview no: 2, lines 210-212]

In addition to partnerships between school and hospital and school and home (i.e. parents), a third type of partnership was identified as existing between parents and the clinical team at the hospital to support diabetes management at school using insulin

pumps **(Table 6.4)**. For instance, in addition to providing parents with education and training, hospital nurses went themselves with the parents to schools and educated staff members about insulin pump therapy. Also, the hospital staff provided parents with supportive educational guidelines about how to manage diabetes with insulin pumps, which parents gave to the school:

> *"And also recently we had details of the training for schools which I did send to the boys' school even though I'm not sure they need it...particularly because of the age the boys have reached."*
> [Mother of diabetic twin aged 15 years; interview no: 30, lines 331-332]

The support from the hospital was also seen in other situations, by sending staff from the hospital to speak to the school personnel at a parent's request:

> *"I think the hospital nurse did come and talk to somebody at school, at her new school. I think she did come down and that has always been made available if we needed someone at anytime to come and I think that is fabulous."*
> [Mother of a girl aged 15 years; interview no: 23, lines 254-258]

6.3.2 Providing children with medical, educational and psychosocial support

In addition to the partnership between home, school and the hospital, other kinds of support were also apparent from the data, such as medical, educational and psychosocial support. The terminology used in this section: medical, educational and psychosocial support refers to situations where the school personnel: supported children using pumps to manage diabetes and the related problems; provided additional educational support for children with diabetes having difficulties in their learning, or helped children by increasing self-confidence and well-being, respectively **(Table 6.4)**.

In terms of the medical support, in addition to helping or supervising children using insulin pumps, some schools supported the children with diabetes by giving them a 'special card' which they could show to the teacher if they felt unwell and wanted to leave the class to the medical office.

Others allowed children to have their snacks in the classroom if they felt that their blood glucose levels were low, or to check their blood levels:

> *"I'm the only kid who is allowed to eat at the class, and so many times when I was low and I have been having snacks, I had teachers telling me off...and I tell them 'I'm diabetic' then it will be like 'I'm so sorry.' "*
> [A girl aged 12 years; interview no: 42, lines 263-265]

> *"I set his alarm when he has to test, so that reminds him to test and he is allowed to do that in the class."*
> [Mother of a boy aged 15 years; interview no: 38, line 148]

The educational support was shown in the data for a family where the school, in addition to cooperation with parents and the hospital, supported the child with his/her learning:

> *"Interviewer: Does your child receive any help at school?*
> *Mother: Yes she does but some of it is educational as well because she struggles with her learning...she was born early so I think that may be to do with that."*
> [Mother of a girl aged 10 years; interview no: 8, lines 175-177]

School personnel also provided children and young people with psychosocial support, by promoting children's self-confidence, wellbeing and interaction with peers. For instance, in some schools the child was required to talk about his/her condition as a part of their studying, and that in turn showed how the other children were very interested in knowing about the medical condition of the child and how the management was carried out using the pump. As a result, the child became more confident and prepared to talk about the condition:

> *"Once the teacher, because we were working on the human body and I was not there that day, so then I came in the next day and she said 'do you mind talking about it?' and then I was just like 'does anyone want to ask questions?' and about half of the class wanted me to answer their questions, so they really wanted to know about it, it was not just like 'boring.' "*
> [A girl aged 10 years; interview no: 68, lines 198-200]

Another example was shown when a mathematics teacher in one school taught all the students in the class how to do certain mathematical operations using the insulin pump:

> *"Mother: One time her maths teacher taught them how to do ratios with the pump*
> *Child: No, that's not what we were doing...*
> *Mother: What did she teach you then?...Not ratios, decimals?*
> *Child: Just how to find decimals, yes."*
> [Mother of a child aged 10 years; interview no: 36, lines 166-171]

Other forms of psychosocial support were manifested by some schools permitting the children to wear the school uniform in a different way to that outlined in the school rules (e.g. not required to tuck the shirt in the trousers):

> *"He is quite conscious of being a boy wearing a pump. Like in school, they have to have their shirts tucked in and because he does not want the pump to be seen, he would wear his shirt out."*
> [Mother of a boy aged 16 years; interview no: 37, line 151]

Similarly, other schools suspended the rules and made exceptions for diabetic children. This was observed in situations where the children were allowed to have a mobile phone at school, which was prohibited for their peers. One mother explained that the child was using the phone as a kind of protection, to call the parents when they were needed for consultation and for double checking.

Apart from the school and hospital, support was also received from some diabetic organisations. This was illustrated by a 9 year-old girl in the sample, who reported that she was initially very anxious about going to the school with a pump, because she thought that would be focus for bullying. However, a voluntary diabetic organisation (Juvenile Diabetes Research Foundation; JDRF) gave her a diabetic bear wearing a pump on her first day at school. As a result, all children at the school were excited about the pump and she never got bullied about wearing it.

In addition to the above, special concerns were expressed by parents of very young children (aged less than 5) who highlighted the need for assigning one-to-one carers for their children at nursery/school. Those parents expressed their worries about the children starting schools without having a carer authorised by their Local Education Authority (LEA) to care for them at schools:

> *"But I actually think that there is more support needed with the pump than the injections at school, which is why we are trying to get her a Statement for special needs. We did not manage to get that, but what we have got is a guarantee from the Local Authority that they will provide her with specialist support assistant to support her at nursery and reception."*
> [Mother of a girl aged 3 years; interview no: 27, line 126]

Of the sample in this study, 2 children aged 8-12 years had carers at school when they were younger and reported that they did not need help from staff at school, because all the management issues were undertaken by the carers.

Figure 6.5 summarises how children, young people and their parents were being supported at school.

Figure 6.5: Illustration of how children and young people using insulin pumps at schools were supported, based on the data described by parents and their children during the interviews.
LEAs= Local Education Authorities

6.4 Barriers to successful diabetes management in school with insulin pumps

6.4.1 Lack of support/knowledge of school personnel

School personnel played an important role in helping and supporting the children/young people using insulin pumps **(Table 6.4)**. In some cases, however, school personnel lacked the necessary knowledge and competence, or were neither supportive nor responsible.

Some members of the school staff were not confident about their knowledge, although they had received training at the hospital. As a result, concerns about staff capability made parents of very young children, for instance, not leave them for lunchtime at nursery:

> *"I think I will find it harder when I have to let him go for longer. I don't let him stay for lunch because I think it would be too hard for them* [nursery staff] *to deal with the carbs. This is because they cook their own meals, and I just think it would be hard for them to deal with the carb counting and easier for things to go wrong."*
> [Mother of a boy aged 4 years; interview no: 28, line 189]

Moreover, lack of experience of some school staff allowed some children to exploit their diabetes. For instance, 2 teenager boys in the sample used their condition as an excuse to leave classes, or to get more food:

> *"He was actually a bad scholar in that he used diabetes to get out of the classes. He used to spend most of his life with the nurse and then the nurse would call me and then I would take him home. So he knew how to work the system, he would say 'I don't feel well,' and they used to call me."*
> [Mother of a boy aged 19 years; interview no: 20, lines 156-167]

In addition to the lack of knowledge or experience, unhelpful practices by school personnel were manifested by situations where they were not-responsive to the hospital team:

> *"I must admit that the hospital nurse a few months ago ran around trying to chase his teachers for weeks and weeks and she did everything. Another nurse also has been down to the school, they have done their best, do you know what I mean, but the school was just like not cooperative enough."*
> [Mother of a boy aged 11 years; interview no: 32, lines 268-272]

Within this context, some parents highlighted the need for continuous support for the children at the school, even when they move from junior to secondary school:

> *"He used to get help at school, but as he has got older, the school says 'he should be responsible.' But we are trying to say to them 'he is only 11, he still needs some supervision,' especially if he is low* [low blood sugar levels] *and things. I mean if he is low now he just automatically takes dextrose tablets. And then there is a poster* [an information sheet] *to say to him when you are supposed to re-test 15-minutes later. But they don't remind him and he does not remind himself, and so they don't get done."*
> [Mother of a boy aged 11 years; interview no: 32, lines 167-171]

Lack of support from the staff was also manifested in situations where school personnel were reluctant to take on any responsibility for the children:

> *"Well there is one teacher we found; she tried not to have him in class which caused a lot of upset. There was another teacher..., he does not know that, he was rejected from a trip because he had diabetes. It is against the law of course, but she* [the teacher] *was honest enough to say 'I don't want to take him because he has got diabetes' which was unrealistic, and it was not comfortable and it caused few little bit of bad feelings."*
> [Father of a boy aged 9 years; interview no: 7, lines 193-197]

Such reaction of the staff was explained as demonstrating their fear of taking responsibility. Also, many lacked knowledge either about the condition or how to handle management with insulin pumps.

6.4.2 Lack of resources

Lack of resources is one of the barriers that was identified which prevented successful management of diabetes at schools. This manifests as shortage of school nurses; the difficulty of assigning a one-to-one carer and lack of clear guidelines about roles of school staff when caring for children with chronic illness.

The shortage of qualified nurses assigned at each school was one of the issues identified in the interviews. In most cases, only one school nurse was responsible for several schools at the same time. Rather, a first aider was available everyday at each school, who might not be sufficiently trained to care adequately for a child using an insulin pump:

> *"Interviewer: Do you have nurse at school?*
> *Child: No.*
> *Mother: They do* [laughing], *yes they do, all schools have school nurses*
> *Child: I did not know that.*
> *Mother: But the school nurses cover about 5 schools.*
> *Child: I did not know there was one.*
> *Mother: That is terrible really."*
> [A girl aged 9 years; interview no: 62, lines 198-209]

Parents in some families, especially those caring for children aged less than 5, were negotiating with the LEAs in their area, to allocate a one-to-one carer to be present with their children at school/nursery, due to their child's young age. In most cases, the children were staying in nursery for a few hours, and did not go there everyday of the week. However, those parents expressed worries and concerns about when their children would start schools, as they would be there for prolonged periods of time:

> *"It is quite hard at the moment, because there is nobody allocated specifically for my daughter. We are arguing at the moment with the Council, because she started full time last September and she was supposed to have had someone with her in the nursery by the Christmas, but the Council argued with us saying she does not need it. So the nursery nurse or the school nurse has to test my daughter and it is up to nursery teachers to keep an eye on her."*
> [Mother of a girl aged 4 years; interview no: 29, line 167]

Due to these inadequacies of the system, some families chose to pay, in full, for a carer to observe and undertake diabetes management issues for the child at school.

From the examples given by some participants, it was apparent that no clear guidelines were available at some schools to determine the necessary level of involvement of staff members when caring for children with chronic conditions, such as diabetes. Many parents reported that the school staff could, for example, deliver boluses or give injections, however, others stated that the staff could not:

> *"They, I think, are only allowed to use boluses. That day one girl* [a staff member in the nursery] *told me that they legally would not be allowed to calculate anything because that would be prescribing and they are not allowed to do that."*
> [Mother of a girl aged 2 years; interview no: 5, line 162]

Similarly, a mother caring for a 10-year old girl stated that the involvement of school staff was restricted to monitoring and supervision, and that they could not deliver doses. A similar issue was reported by a mother caring for 8-year old boy, who complained that the school would not keep a glucagon injection (for life-threatening hypoglycemic

episodes that could happen to the child at school), because the school's regulations prohibited this. The reason behind such a restriction was not clear:

> *"This is very important because glucagon injection can save my son's life but he cannot keep his glucagon at the school. This is a very serious problem, I don't know why in this country there is a problem with this glucagon. May be if there is a nurse at the school it will be possible, while if it is only a medical room with a person for first aid, he cannot do anything he can only call me or call the emergency services."*
> [Mother of a boy aged 8 years; interview no: 10, line 269]

6.5 Discussion

Children and young people spend almost half of their waking hours (i.e. half of their day time) at school. There is limited evidence on the experiences of children/young people and their parents regarding the use of insulin pumps in comparison to using injections at school. Therefore, addressing diabetes management within schools was a fundamental component of this study.

Self-management is the cornerstone of managing diabetes, together with achieving therapeutic goals. Within this concept, findings from this study showed that managing diabetes with insulin pumps allowed children more autonomy than using injections, and older children undertook more responsibilities than their younger peers. However, they still needed supervision and reminding from school staff. This agrees with the findings of a study by Smith and colleagues (2009) on medication use for chronic illnesses at school, including insulin pumps for diabetes, which showed that not all young people needed help in school, as some were confident about handling management issues fully themselves.

In relation to managing diabetes at school, most parents and children in this study reported insulin pumps were easier to use compared to injections. In many cases, the children and their parents explained that with the injections, parents had to visit the school daily at lunchtime to administer the insulin, as this could not be done by the child, nor were school personnel prepared to give the injection. An insulin pump had many advantages, being a more convenient method for insulin delivery, without children needing to seek a private place or medical office for insulin administration, as was the situation when they had been using injections. Within this context, Newbould and colleagues (2007) reported that young people who used injections to manage their

diabetes at school, needed to seek a private place to administer their injections, which in most cases was either unavailable or inconvenient (e.g. toilets).

Addressing the problems associated with insulin pump use in school is important to find ways to avoid them, and to support the children. This study has identified that in many cases no problems were experienced. However, where experienced, they were various, including: hypoglycaemia, hyperglycaemia, infusion-set problems, pump breaking down and batteries/insulin running out. Other problems such as running out of insulin supply at school, pump/sensor vibrating at class and forgetting to bolus/test were also reported. The most common problems experienced by older children aged 8-17 years were infusion set problems. This could be explained due to older children being more actively involved in sport and physical activities at schools than their younger peers, resulting in problems related to the cannula coming out or tubing breaking down. Similar problems were reported by the nurses in a study which explored nurses' views on caring for children with diabetes using insulin pumps, in which problems were resolved by using resources such as parents and hospitals (Darby, 2006). In this study, problems such as hypoglycaemia were resolved by the school personnel while, other problems, such as dislocation of the infusion set were resolved with the help of parents. This could be related to the fact that changing the infusion set needed skills and continuous practice and hence parents were more capable of doing it. Findings from the current study illustrate that although CSII may make the burden of diabetes easier, dealing with problems that arise at school remains a challenge for medical and/or teaching staff at school. Therefore, it is important to emphasise the need for empowering school staff, by providing them with skills and knowledge to enable them to deal with problems related to managing diabetes at school with insulin pumps.

As shown in **Chapter 5**; within the home, children and young people were usually assisted by their parents to manage diabetes using insulin pumps. However, at school, children/young people had to manage their diabetes and administer insulin doses, whether assistance from school staff was available or not. In this study, varying degrees of involvement of school staff to help the children use their pump at school were reported by the parents and the children/young people **(Table 6.4)**. This is consistent with the views of young people with chronic illnesses in the study by Smith et al (2009), which reported different degrees of help and support received from school staff.

This study explored resources from which school personnel developed their knowledge about insulin pump therapy. It was shown that school personnel, in most cases, either accompanied the families to attend an insulin pump training course run at the hospital, or were taught by hospital staff who went into the school to teach them about diabetes management using insulin pumps. Additionally, parents, in some cases, played a role in educating the school personnel about the child's condition. Similar resources were reported by nurses in a study that explored the nurse' experiences when caring for children receiving CSII at school (Darby, 2006). Some parents and children in this study reported that the staff lacked the knowledge to provide diabetes care at school. These results are consistent with other studies wherein children and/or parents highlighted the need to improve the school staff's knowledge of diabetes (Nabors et al, 2003; Hayes-Bohn et al, 2004; Jacquez et al, 2008). However, the results are inconsistent with a study by Fisher (2006b), in which school nurses reported that they were moderately confident in performing diabetes care and education. Within this context, findings from the current study highlight the need for conducting studies exploring the ways in which school nurses can develop the necessary skills and attitudes to provide adequate diabetes care at school. This is crucial as research has shown that students with diabetes who were cared for by trained personnel at school exhibited better diabetes control than those who interacted with untrained staff (Wagner et al, 2006).

In the UK, the NSF for Children and Young People highlighted the requirement for schools to consider arrangements for the management of children's medication (Department of Health, 2004a). This study has identified the partnership between the home, school and hospital as being crucial in providing children with optimal support at school. Similar issues of support were addressed in other studies, from the school nurses' views (Nabors et al, 2005) and from parents' and children's perceptions (Nabors et al, 2003; Hayes-Bohn et al, 2004). However, this study was unique in exploring other forms of support, which children with diabetes and using insulin pumps in particular might require, including: medical, educational and psychosocial support. In terms of the medical support, children were for example allowed to test blood sugar levels and eat snacks in the classroom, as well as being permitted to go to the medical office upon request. This was consistent with the ADA recommendations (American Diabetes Association, 2003), but is not the case in all schools as a previous study (in the USA) found children were not allowed to do a blood glucose test in the classroom (Jacquez et

al, 2008). In a study by Smith et al (2009), children with chronic illnesses were given permission to leave the class to administer their medications. However, children with chronic illnesses who were taking prescribed medication 'as needed' were not given such permission, unless teachers checked a doctor's note. Supporting children with diabetes at school is important, as Wagner and colleagues (2006) found that children who were allowed to meet their diabetic needs in the classroom had lower HbA1c readings than those who were not allowed to.

In terms of educational support, it was reported by one parent that the school provided the child with educational support because of learning difficulties. The parent explained that educational support was necessary due to the child's premature birth. Within this context, it has been documented in the literature that children with diabetes may have learning difficulties related to their chronic illness, numerous absences from lesson (if the condition was unstable), or because of other conditions accompanying diabetes (Thies, 1999; Strawhacker, 2001). Moreover, Thies (1999) stated that students with chronic illnesses, such as diabetes are at the 'intersection of the health and education systems, which traditionally operate in separate realms with different policies and philosophies' (p. 392). Therefore, highlighting the need for educational support for such students at school, especially those having multiple absences from school due to an unstable condition, is important.

Management of diabetes with CSII requires children and young people to wear a pump which may have consequences due to its visibility. Therefore, psychosocial support may be required for children and young people using insulin pumps at schools. In this study, psychosocial support was defined as empowering children by providing support that promotes their self-confidence and wellbeing when using an insulin pump to manage their diabetes at school. During interviews, some parents and/or children gave examples of the situations where school personnel promoted their confidence and wellbeing. For instance, some schools gave children, especially those aged 13-17 years, special dispensation with regard to wearing of school uniform. Schools permitted them to wear it in a way that allowed the pump to be hidden. With this regard, the psychosocial support for young people with diabetes was highlighted in a review written by Strawhacker (2001) who also suggested the involvement of multidisciplinary team which included, in addition to the parent and adolescent, school nurses and teachers, a

psychologist and a social worker, as this would benefit many young people with diabetes receiving intensive insulin therapy.

One family in this study reported the support they had received from a voluntary diabetes organisation, which gave the child a diabetes bear on the first day they received pump therapy at school. As a result, other children became attentive and excited about the child's condition, making the child more confident. This suggests that collaboration between school, home and hospital could be extended to include other voluntary or charitable diabetes organisations, such as JDRF which also could help and support children (and staff) using their pumps at school. Moreover, it might be useful to teach diabetic patients, especially, the teenagers, the best ways of hiding the pump under their uniforms, as self-image issues are of great concern to this group of children.

Reducing barriers and improving support for children and young people with T1DM can help to improve regimen adherence and health outcomes (Delamater et al, 1990; Strawhacker, 2001). Therefore, it was essential in this study to address barriers mitigating against using insulin pumps at school. Barriers, such as: unavailability of school nurses present each weekday, children abusing the system, resistance from staff and a lack of knowledgeable staff were addressed in this study from the perspectives of parents and/or their children/young people. Similar issues were previously reported from the perspectives of school nurses (Nabors et al, 2005). From the analysis of transcripts, it was recognised that children faced a lack of support when changing schools, or moving from primary to secondary or high school. Similarly, young people with asthma or diabetes, and/or parents in other studies reported diffused support when transferring between schools (Ayala et al, 2006; Newbould et al, 2007). Accordingly, results in the current study suggest the need for continuous support at school for the children and young people, especially when they change school or transition into a higher educational level.

One barrier that some parents, especially of very young children (aged less than 5 years), addressed was the unwillingness of LEAs to provide a statutory Statement (i.e. a Statement by the LEA if the school cannot provide all the help the child needs) for a one-to-one carer. However in the UK, The Education Act 1996 states that the LEA should provide a statutory Statement of support for children with Special Educational

Needs (SENs), which was defined as 'children having learning difficulties or disabilities that make it harder for them to learn or access education than most children of the same age (Department for Education and Skills, 2001). According to the Education Act, children who have a medical condition, such as diabetes, should receive an adequate level of support to manage their condition at school, so that they can function properly like their peers. Otherwise, their education and health will suffer. The data presented in this study suggest the requirement for conducting studies that explore reasons behind the unwillingness of many LEAs in the UK to assign a one-to-one carer for children with diabetes at school.

It was evident from some participants that there were no clear regulations at schools clarifying the roles of the staff when supporting the children with diabetes at schools. For instance, one parent reported that according to school guidelines, glucagon kits which are vital for managing life-threatening hypoglycemic episodes, where the child might become unconscious and enter a coma, were not made available. In the USA, this would contravene federal laws and ADA recommendations, that promote the right of children and young people to be medically safe while at school, and that a glucagon kit should be made available (Kaufman, 2002; American Diabetes Association, 2003).

In the UK, British Government Policy in relation to supporting children and young people when managing chronic illnesses at school has been limited. The Supporting Pupils with Medical Needs: A Good Practice Guide published in 1996, recommended the implementation of school policies regarding use of medications at school (Department of Education and Employment, 1996). More recently, the NSF for Children, Young people, and Maternity services emphasised the need for schools to consider arrangements for the management of children with chronic illnesses at school, however there was no indication of what was appropriate (Department of Health, 2004a). Therefore, findings presented in this study highlight the need for implementing clear policies and care plans for children with T1DM to support them using insulin pumps in managing their condition at school.

CHAPTER 7 - Impact of using insulin pumps on the lives of children and their families

Chapter 7: Impact of using insulin pumps on the children's and families' lives

In this chapter, the impact of using insulin pumps on family life was explored from the perspectives of the parents and their children/young people. Evidence from the data on benefits and drawbacks associated with using pumps, and how this impacted on families' lives is provided.

7.1 A framework of the impact of using insulin pumps on the lives of the children and their families

Managing T1DM with insulin pump therapy requires families to live with the burden of the associated management tasks which can impact heavily on family life. To meet the aim of this study, a framework was used to identify and assess the impact of using insulin pumps on different aspects of family life.

The framework was designed by adopting the quality of life domains reported by Barnard et al (2008) in a study of children using insulin pumps, and their parents. In Barnard et al's study, the Schedule for the Evaluation of Individualized Quality of Life (SEIQoL), which is an interview technique that has proved to be sensitive to the differences between respondents, was used (McGee et al, 1991; O'Boyle et al, 1992; Hickey et al, 1996). The SEIQoL enables the investigator to assess quality of life from an individual's perspective in healthy and ill individuals. In comparison to other quality of life instruments, such as the generic health instrument (e.g. 36-item short form survey; SF 36) which provides more information on the functional health status and/or disease specific measure (e.g. diabetes quality of life; DQOL) which is more sensitive to lifestyle issues (Jacobson et al, 1994), the SEIQoL has the advantage of allowing the assessment of the level of functioning in, and relative importance of areas of life nominated by the respondents, rather than having predetermined lists of questions that may or may not be relevant to the individual patient (Eiser & Morse, 2001). In addition, the available instruments for measuring quality of life in paediatric patients have the disadvantages of lacking disease specific measures; limited availability of measures for self-completion by the child and having wide variations regarding content of domains of quality of life. For these reasons, adopting Barnard et al's domains of quality of life in this study was considered appropriate.

They identified 5 domains as key components of quality of life and assessed the impact of therapy on each of them: 'health,' 'family' 'school,' 'friends' and 'work.' Parents

prioritised 'health,' 'family' and 'work' as the most important aspects of life for their quality of life, whereas the most frequently reported domains for children and young people were 'family,' 'friends' and 'school' (Barnard et al, 2008).

The current study did not aim to prioritise the domains important for quality of life, but rather sought to explore the impact of pump therapy. Therefore, the domains reported in Barnard et al's study were used as a framework for analysis, which was also modified based on the data obtained from children and their parents. **Figure 7.1** indicates how this framework was operationalised.

The framework for the current study has 3 dimensions: 'domains,' 'issues' and 'family member(s).' 'Domains' represent aspects of life that were examined to identify any impact of insulin pump therapy, while 'issues' illustrate components in each domain that were raised and discussed by the participants during the interviews. The last dimension of the framework 'family member(s)' specifies individuals within the family, upon whom the impact of using the pumps was manifested. Apart from the 5 domains proposed in the study by Barnard et al (2008), the domains 'social life' and 'psychological wellbeing' were added to the framework in this study. Moreover, the domain 'friends' proposed in Barnard et al's study was moved to 'issues' level in the framework under the domain of 'school life.' In undertaking the analysis, some of the issues mentioned were relevant to more than one domain. Also, the impact of insulin pump therapy on these domains could be positive or negative. In the following sections, the definition of each domain and the assessment of the impact of using insulin pumps, as it was explored from perspectives of parents, children and young people, is provided.

7.2 Assessment of the impact of using insulin pumps on different aspects of life, based on the framework

All parents (N=38) and children (N=34) were asked during the interviews to indicate whether using insulin pumps had any impact (positive or negative) on family life. By analysing the interview transcripts, it was revealed that insulin pumps impacted for children and their families on different aspects of life, including: health, home, socialisation, school, parents' employment and psychological wellbeing. In most cases, similar issues were raised by the children and their parents.

Figure 7.1: A framework for assessing the impact of using insulin pumps on the lives of children/young people and their families

7.2.1 Health

In discussing the impact of pumps on health, respondents raised as issues: 'diabetes control,' 'energy,' 'general health' and 'concentration' **(Figure 7.1)**. The issue of 'diabetes control' which is reflected by glycaemic control was addressed in detail in **Chapter 4**: the majority of the parents (N=32) and children (N=30) reporting that using the pumps resulted in improvements in diabetes control, manifested by better blood glucose levels, whereas only a minority of parents (N=6), but none of the children, reported worsened control with pumps compared to injections.

Further observations from parents' and children/young people's interviews, with regard to the impact of using pumps on children's health, were reports on: 'energy,' 'general health' and 'concentration. All the comments pertaining to these issues were positive.

Insulin pumps were reported by 3 parents and one child to improve a child's energy levels:

> *"Energy levels, when they come back home from school, a massive change in their ability* [with using insulin pumps]. *They come in and they used to sit down and read comics or go and play in their rooms* [on injections] *and now when they come in they would come in and want to go out and play again, they just have more energy in their body."*
> [Mother of diabetic sons aged 9 and 12 years; interview no17, line 155]

The improvement in general health was one of the issues raised by parents (N=3). It was manifested by an improved feeling of hunger and relationship with food, better long-term prognosis and less bed-wetting at night:

> *"My son used to find it very hard to get dry during the night* [on the injections] *and in the day as well, because the swings in those blood sugars. His bladder had no*
> *chance to understand what was its normal function and that has been a huge difference* [now on the pump]."
> [Mother of a boy aged 9 years; interview no 17, line 155]

In other instances, the use of insulin pump therapy was associated with 'better concentration' during school lessons:

> *"For instance he stays at his desk longer* [with using an insulin pump], *so he is in class for longer, so his ability increases. I mean you would never find that in a study but that is a massive change for him."*
> [Mother of a boy aged 9 years; interview no: 17, line 155]

> *"Interviewer: Your concentration is better on the pump?*
> *Child: Yes I think it helped."*
> [A boy aged 15 years; interview no: 64, lines 466-467]

7.2.2 Home life

As illustrated in **Figure 7.1**, 'home' was one of the domains impacted by the use of insulin pumps. It refers to life inside the home, by describing the consequences of using insulin pumps on the lives of children with diabetes, siblings and their parents within the home environment. During the interviews, many issues were identified within this domain: 'children's autonomy in performing management tasks,' 'relationship of spouses,' 'leaving child with others,' 'sleeping' and 'siblings' wellbeing.' Some issues, such as spouses' relationships, leaving child with others and sleeping were identified by the analysis of the interview transcripts, while others, e.g. autonomy and effect on siblings' lives were part of the questions, or probes, of the interview schedules. In most families, the impact of using insulin pumps on the home life of the children and their families was positive. However, this was not consistent over all issues described under this domain.

One of the issues in this domain that was affected positively by using the pumps was an increase in children's autonomy or involvement in the management responsibilities associated with insulin pump therapy (see **Chapter 5** for further discussion). This reduced the workload of parents:

> *"Well it makes life easier for my Mum and Dad and my brother. It does not really affect my brother, but my parents have to do a whole lot less."*
> [A boy aged 13 years; interview no: 43, lines 169-170]

By using the pumps, parents were more able to leave children with others, which was not an option with injections (reported by 6 parents). One explanation for this was the fact that the child would not allow people other than parents to deliver the injection. Moreover, insulin pump therapy gave better glycaemic control and more stable blood glucose readings, which consequently made parents more confident to leave the child with others. Additionally, the use of insulin pumps seemed to be more acceptable to others, such as friends or extended family than delivering injections:

> *"I would leave him with a friend, we trained them on the pump, I talk with them through the phone and they can cover the food. On injections, my son was too little to actually inject himself and our family or friends would not take him, because they just could not inject, they did not have the stomach to do it. On the pump, I can drop him off, my sister would know how to operate the pump and I can go for 2 hours or 3 hours shopping and just relaxing or reading a book."*
> [Mother of a boy aged 8 years; interview no: 9, line 178]

As a result, spouses had more time to relax and spend together (reported by 2 parents):

> *"She used to get very upset before with the injections if it was neither myself or my husband doing it. Nobody else would be able to do it to her, because she would completely freak out, so it would not even be an option really to give her to someone else or anything like that. Now on the pump my husband's sister is a nurse and she can take her, and there are my parents so if we wanted to go out at night time or something, they take her then."*
> [Mother of a girl aged 4 years; interview no: 29, lines 144-149]

Other issues were also identified from the interviews where using the pump had positive consequences on 'home life.' An example is 'sleeping.' This issue had two facets: the sleep of the child and the sleep of the parents. In terms of a child's ability to sleep, 4 parents in the sample reported that when using the pump the child had a more relaxed lifestyle with regard to the ability to sleep until late in the morning. Insulin pumps also allowed parents to sleep longer at night. This issue was only mentioned by one child in the sample, who reported that using insulin pumps made life easier at home for their parents:

> *"Well my Mum and Dad feel very happy because I can use a sensor on the pump, so sometimes they get much more sleep at night. So they feel very happy that I got my pump, because sometimes they got much more sleep and because they know it keeps me good."*
> [A boy aged 12 years; interview no: 53, lines 400-401]

The impact of using insulin pump on the lives and wellbeing of siblings was one of the issues investigated during the interviews. The majority of the parents (N=21; out of 32) and children/young people (N=18; out of 21) who commented on the impact on 'home life' agreed that using the pumps did not negatively affect siblings in the family, but rather in some cases they were more supportive and caring of the child with diabetes. Many parents and their children gave similar reasons as to why using pumps did not impact siblings negatively: young age of siblings when the child started insulin pump therapy; those siblings who had medical problems received an equal amount of care; siblings who grew up with the sick child were accustomed to it. Additionally, some

parents reported it was less traumatic for siblings to see a child pressing a few buttons rather than having an injection.

Although the majority of the comments obtained from parents and children on different aspects of 'home life' were positive (especially with regard to 'autonomy,' 'child's sleeping' and 'siblings' wellbeing'), some participants had negative views which were manifested with issues, such as: spouses' relationships; leaving children with others and parental sleeping. This was related to the disadvantages of pumps in terms of workload and complexity (discussed in **Section 7.4)**.

A few parents reported that using the pumps impacted negatively on their relationships with the spouses, especially during the transition period (the very beginning period of the switch from injections to the pump):

> *"At the end of the day it broke up my marriage, the pump, because it was a year from January to when we got it, in September and it was me just focusing on my son. We had lots of appointments and visits to the UCH. I needed to make sure that I could get to grips with this, so obviously my son was my priority and I just concentrated on getting this right. It involved a lot of non-sleeping nights in the beginning as I was up every 2 hours testing and I was also working towards tight control and I was irritable, I can't deny that you know, and obviously my husband had enough with that and left."*
> [Mother of a boy aged 15 years; interview no: 38, lines 125-126]

Caring for children by others was one of the issues raised with regard to the impact of using insulin pumps. Although 6 parents in the sample reported that with using the pumps, it was easier to leave the children with others, another 5 parents reported the opposite. They thought that leaving children with others was more difficult when they were using pumps:

> *"It is difficult for me to leave them with other people, because people don't understand what they are supposed to be doing."*
> [Mother of diabetic sons aged 8 and 12 years; interview no: 15, line 66]

Furthermore, 'sleep deprivation' was one of the bad consequences that impacted on parents. Five parents reported that they lacked sleep at night, especially at start of pump therapy and some were still sleep deprived:

> *"It does affect life because I stay up at night, you know, so we don't go to bed at the same time like a normal husband and wife."*
> [Mother of a girl aged 12 year; interview no: 4, line 251]

The majority of the parents and children who reported an impact of using the pump on 'family life' thought that using the pump did not negatively impact on the siblings, who in some cases became more supportive and caring towards the sick child. However, this was not the case for all the families, as was reported by 6 parents (children did not report similar issues). This was explained by the fact that the healthy sibling was left alone without attention during the time the parent was busy handling management issues for the sick child, in addition, the healthy sibling's life was restricted by the diabetes, as the sibling was "dragged" to clinic appointments and school visits:

> *"She* [the patient's sister] *is left when I'm dealing with my son, when I have to put in a new line and the sensor that in total can may be take half an hour and she has to go and do her own things, so I'm spending more time with him. When he is high he is very manic; not aggressive but very flamboyant, and he cannot go over so that affects her. She has been dragged to the hospital appointments, she has to go to his school because the school do give him the Bolus Wizard, but obviously do not do the new lines* [changing infusion sets] *and they phone me 2-3 times a day everyday, so whatever we do to get calm, quite often we have to go to the school on an emergency."*
> [Mother of a boy aged 5 years; interview no: 11, line 156]

As a result, parents felt that healthy siblings were neglected and not being taken care of (reported by one mother in the sample). In other instance, they had to follow diet restrictions at home, enforced due to the presence of the child with diabetes:

> *"And it does affect the other one* [the patient's brother], *it affects what we do, when we do it, and how we do it, and what we aim for particularly. You know his brother would like for example to sit down and eat a whole chocolate cake, but we could not allow that because that would not be fair for the other* [the child with diabetes] *and it is a constant battle trying to be fair for one and the other and trying to find the middle path."*
> [Father of a boy aged 9 years; interview no: 7, lines 166- 167]

7.2.3 Social life

'Social life' was one of the life domains, upon which using the pumps had an impact (**Figure 7.1**). For the purpose of this study, the term refers to the social interaction of the children using insulin pumps, and their families, with other friends and relatives. Issues identified in this domain were: 'daily activities,' 'social interaction' and 'wearing the pump.' Such issues emerged during the interviews (by 37 parents and 28 children/young people). In most cases, the impact of using the pump on social life was positive, however, in other instances using the pump worsened social life in some families.

With regard to daily activities, insulin pumps allowed children and/or their families greater ability to go out (e.g. restaurants, friends' houses and parties) and to participate in activities (e.g. travelling, camping, attending dancing classes and playing). This was identified from statements by the majority of parents (N=27; out of 38) and children/young people (N=25; out of 34):

> *"I think it is easier for him to go out and be with his friends and to eat some food and put the carbs into his pump than to give himself an injection."*
> [Father of a boy aged 9 years; interview no: 35, lines 168-169]

> *"We had a trip down to one of these sort of farm places and they were having a really nice time and running around. It was a nice day and I would have felt like I needed to rush and get him home for tea half past 5* [if on injections], *but the other day we got back at half past 6 and I was more relaxed about that because of the pump, so that you can do days out more easily and change basal rate. So if I do take him somewhere where he is running around and very active, I can change the basal rate and that helps."*
> [Mother of a boy aged 4 years; interview no: 28, lines 166-167]

Issues under the domains are not restricted to a single domain, but rather they are relevant to more than one. For instance, the improvement in children's social interaction could improve their friendships with peers. The issue 'friendship,' presented in the next section, could also be included in the social life domain.

Only 3 parents and 3 children in the sample reported bad consequences of using insulin pumps on their social lives. This was manifested by children not receiving invitations to people's houses because people were afraid of the responsibility (reported by 2 parents), or by worsened relationship with other families (reported by one parent):

> *"Still it was very difficult* [to start on CSII] *and it* [pump therapy] *had an effect on the whole family, not only our family, but our relationship with others. We had in a way lost a lot of family friends because they did not understand what was going on and they thought we were mad. In a way we did, because the sugar* [i.e. blood glucose] *went mad* [at the beginning of insulin pump therapy] *and we were mad as we were trying to stop the sugar madness. So because of that, we lost a lot of friends."*
> [Father of a girl aged 12 years; interview no: 4, lines 165-168]

'Wearing the pump' and its visibility to others was another issue to be considered in the context of social life. Some children experienced situations where other people questioned them about their pumps. One mother and 2 young people in the sample reported that they did not mind the questions. Although, none of the families faced

issues of bullying or stigmatisation in such scenarios, the mother expressed her 'concerns' about the issues likely to affect her child in the future as he grows older:

> *"He just started swimming lessons and you know in the shower afterwards, it was actually a mother who said 'what is this?' and that made me then think that an insulin pump is more physically obvious that he is diabetic. ...I don't think that anyone has ever been nasty about it but may be as he gets older, the fact that he is wearing the pump will mark him out as 'different,' I don't know, but it has not been a problem, but it does made it just like 'what is this?.' "*
> [Mother of a boy aged 4 years; interview no: 28, lines 182-184]

Along with this, the issue of 'parents' concerns about the future' emerged, which was addressed under the domain of 'psychological wellbeing' **(Section 7.2.6)**.

Using the pumps meant that young children were always accompanied by parents or carers, because they were young to handle management tasks alone, as reported by a 5-year old boy in the sample. However, due to the young age of the child, this would also be the situation if the injections were still used. This example also reflects issue of children's 'autonomy which was addressed earlier in this chapter under the domain of 'home life' **(Section 7.2.2)**.

7.2.4 School life

Using insulin pumps at school in the context of the management of diabetes was discussed in detail in **Chapter 6**. However, the focus in this chapter is on further aspects of school life; regarding the impact of using insulin pumps on the life of children at school. Parents (N=38) and children/young people (N=34) were asked whether using the pump impacted on the life at school with regard to: 'educational performance,' 'friendship and relationship with peers' as well as 'participation in sports and extracurricular activities' (e.g. trips and concerts) **(Table 7.1)**. Moreover, other issues with respect to 'wearing a pump,' such as 'bullying' and 'self-consciousness' emerged from the interviews. To take into consideration, the very young children who went to the nursery, 'school life' in the current study referred to their ability to engage in activities like the other children.

Table 7.1: Impact of using insulin pumps compared to injections on the children's school life, as reported by parents (N=38)* and children/young people (N=34)**

Impact	Aspects of school life impacted by using insulin pumps					
	Education		Friendship		Sports and activities	
	P	C	P	C	P	C
No change	23	17	27	28	35	30
Positive	7	7	6	3	-	-
Negative	1	2	4	-	2	2

P= parents; C= children and young people

* Data are missing from 7 on the 'educational performance;' from 1 on 'relationship to others' and effect on 'sports/activities.'

** Data are missing from 8 on the 'educational performance;' from 3 on 'relationship to others' and from 2 on effect on 'sports/activities.'

In the majority of families, parents and children shared the opinion that using insulin pumps did not have a negative impact on school life compared to using injections. Rather, the impact was positive in some cases.

For instance, in terms of friendships, using insulin pumps did not cause a deterioration in social interaction of the children with their peers, who showed interests in the pump:

> *"All the other kids are quite interested in it* [the insulin pump] *and I am not sort of having anything negative from them."*
> [A boy aged 16 years; interview no: 60, line 161]

Moreover, using the pumps freed children from stigmatisation that was experienced with using injections, as reported by one young person in the sample. This could be related to the fact that using a modern looking device to manage the condition attracted attention of other children in the school in a positive way:

> *"It got me more friends actually* [the insulin pump]. *The first time when I showed them* [peers] *it, they started making little models of it with papers, it is weird. One of my friends, just made a square, just made it like a square, and it is really weird just playing with a bit of square. And one made it into a circle."*
> [A boy aged 11 years; interview no: 48, lines 206-209]

Generally, using insulin pumps at schools did not negatively affect children's participation in sports or any activities at schools (e.g. music concerts and food activities). Rather, it made food-related activities much easier:

> *"It makes activities which involve food much easier. So for instance, if they did a 'Roman day' or a 'French day' and they were going to have a croissant at 10 o'clock in the morning, it was almost impossible to let them join in, because it would be very hard to know how to deal with that* [on the injections]."
> [Mother of diabetic sons; interview no: 17, lines 231-232]

Also, 7 children/young people reported that participating in sport at schools was easier with insulin pumps. Of those, 3 girls reasoned that insulin pumps maintained better glycaemic control and easier correction of insulin doses compared to the injections (discussed in **Section 7.3)**.

The issue of 'going on trips' was raised by 22 parents and some children during the interviews. In most cases, using the pump did not have an impact on children going on trips, as reported by the parents and children. However, a parent or a staff member who knew how to deal with the pump had to accompany younger children. In most cases, it was not a requirement from the school for parents to attend trips. For instance, one boy mentioned that trips were easier with the pump compared to injections, because using injections was disadvantageous in terms of the need to bring extra paraphernalia when going out (e.g. injection, insulin and snacks). The child added that he was checked more regularly when he was on the injections and that disturbed him a lot during trips.

Although using the pump at school, in the majority of cases, did not have a deleterious effect, but rather had a positive impact (manifested by improved educational performance, friendships and participation in sports and trips), for a few families, negative consequences of pump use at school were reported **(Table 7.1)**.

Using the pumps instead of the injections at schools had a negative impact on educational performance for a few children. In such cases, the insulin pump failed to control the child's diabetes, and hence the child had numerous absences from the school:

> *"It* [insulin pump therapy] *has not really had any effect apart from the fact that he does get sick more often because of the ketoacidosis."*
> [Mother of a boy aged 16 years; interview no: 24, lines 215-219]

The fact of 'wearing a pump' also exposed a few children to bullying, as reported by 4 parents in the sample (but none of the children):

> *"He has been bullied. I mean there were other kids who said to him 'you can't play football, because you have got a problem with your body.' So some kids have been quite nasty to him..., but one of his best mates is really good with him and keeps an eye for other things."*
> [Mother of a boy aged 11 years; interview no: 32, lines 161-163]

Two parents and children/young people reported that the pump impacted negatively on the participation of children in sports, activities, or trips. This was either manifested in situations where using the pumps hindered children from participation:

> *"Once when I went swimming with my school, my cannula fell out which means I could not actually go swimming and they did not let me for this reason."*
> [A boy aged 11 years; interview no: 48, lines 170-171]

Or in situations where using the pumps allowed children to participate, but hindered the activity:

> *"In sports, I have to keep on clipping it* [the pump] *off and sometimes if I'm on the climbing frame, I have to, you know, kind of adjust it in a way so that just in case when I'm, you know, swinging about or anything it does not fall off, and if it does I have to somehow get off and put it back on. And that is a bit annoying, just taking it off and putting it back on every time it falls off. So that is why I kind of like keep it in a pocket really."*
> [A girl aged 10 years; interview no: 68, lines 208-209]

On rare occasions, using the pumps negatively affected children's participation in school trips. This was related that to the schools' fear of taking responsibility, which forced parents in some cases to fight with the school and accompany their children on the trips. Others experienced a bad incident during a trip with the pump, which subsequently made the child unwilling to go on further trips:

> *"He does not go on trips with the pump or with the needle though. He would not go because as I say he would feel too scared, because we have had the pump break down before and that now has made him feel like he does not want to do anything like that."*
> [Mother of a boy aged 12 years; interview no: 19, line 202]

7.2.5 Parents' employment

This domain emerged during the interviews with some parents (N=18) and children (N=14) and hence is identified and addressed in this section **(Figure 7.1)**.

During the interviews, 11 parents reported that having their children receiving pump therapy did not affect their jobs in general. Among these, many stated that they had stopped working directly after their children had been diagnosed with diabetes. These scenarios usually related to the mothers in the sample who were the main parent-in-charge of the child with diabetes, while the fathers continued with their jobs:

> *"I already decided to stop working when my daughter was diagnosed, on the injections, so I was actually off work anyway* [when the daughter started pump therapy], *because I wanted to be at home and care for her. So it has stopped me working really, but I would not say that it is the pump that stopped me working, it is just the general diagnosis."*
> [Mother of a girl aged 3 years; interview no: 27, line122]

Similarly, 14 children and young people agreed that using insulin pumps to manage their diabetes did not have any impact on their parents' employment. Some young people reasoned that all management responsibilities were undertaken mostly by them from the beginning, because they were sufficiently grown up. Others related how their parents were working in the medical field, so they knew how to deal with the pump and it did not impact on their jobs:

> *"Well my mother was a nurse so that did not really affect her job. My Dad moved out when I was like 8, so it did not have an effect on him."*
> [A boy aged 19 years; interview no: 56, lines 191-192]

By contrast, a few parents (N=7), but none of the children, stated that using the pumps had a negative impact on parents' jobs. This was related to the days off-work required, especially during the start of insulin pump therapy, to attend clinic appointments and to manage the new situation at home. Moreover, going to school at lunchtime to deliver insulin boluses to their children was one of the burdens for parents until children or school personnel learned to do it. Some parents' work-life was also disturbed by telephone calls from schools, for the purpose of double checking and for emergencies (see **Chapter 6**):

> *"Yes, the beginning of insulin pump therapy was terrible, so we actually did not work for 6 months. We did not do anything, we stopped everything."*
> [Father of a girl aged 12 years; interview no: 4, lines 145-146]

7.2.6 Psychological wellbeing

The last domain in the framework **(Figure 7.1)** is 'psychological wellbeing.' This refers to the effect of using an insulin pump on the wellbeing of the children who have diabetes and wear a pump (e.g. mood, self-confidence, self-consciousness about

wearing the pump and concerns about the future), and the effect on their parents (e.g. stress and concerns about the future). This domain and issues reported within its context were raised during the interviews by some parents (N=18) and children/young people (N=6).

In the majority of those cases, the use of insulin pumps improved the psychological wellbeing of children and/or their parents. In this respect, 7 parents reported that the 'mood' of the children and young people was improved once insulin pump therapy was started:

> *"Psychologically, my son is a completely different child, he is more open, he communicates a lot better and he is not always angry* [as when he was on the injections]."
> [Mother of a boy aged 8 years; interview no: 9, line 180]

'Wearing the pump' was one of the issues that was highlighted under this domain. This issue was not a problem for some children; wearing the pump made them more comfortable and confident about themselves, as stated by 3 parents and 4 children:

> *"My son would hide his diabetes constantly. He did not want his friends to know about it and he certainly did not want his teachers to know when he was low, so he would deal with all of that himself. He would also go and correct himself; he goes out of the class to correct himself using his injection unsupervised. As soon as he got his pump it was a gadget and he had some way of feeling able to interface with his mates, with his diabetes, because gadgets children understand, so it is like showing people your phone, he had showed them his pump."*
> [Mother of a boy aged 12 years; interview no: 17, line155]

> *"I think I'm just more comfortable in being you know diabetic, 'yes I'm diabetic, I have diabetes, this is me'* [laughing] *'what is the problem?.' "*
> [A girl aged 15 years; interview no: 59, lines 155-156]

Improvement in psychological wellbeing was related by some to the fact that insulin pumps did not attract people's attention as the injections did:

> *"Once again you don't feel self-conscious about it, it is a lot easier just to get it out* [compared to injections]."
> [A girl aged 15 years; interview no: 67, line 180]

The positive effect of using the pump was not only restricted to the children's psychological wellbeing, but also involved parents' wellbeing. This was emphasised by the parents themselves (N=4) who stated that having the children on insulin pumps relieved the stress and pressure they had experienced when injections were used. In

agreement with the parents, 2 of the children stated that using insulin pumps relieved parental stress and made them happier. Such effect could be explained by the better control achieved with using insulin pumps compared to the injections.

In contrast to the positive impact of using the pump on psychological wellbeing, using the pumps sometimes had negative consequences. This was manifested with issues, such as: 'wearing the pump,' 'stress' and 'concerns about the future.' Within this context, all the comments were from parents, whereas none were received from children and young people.

In terms of 'wearing the pump,' 4 parents stated that pumps were visible to other people, and that as a result made the children self-conscious about wearing it:

> *"Well he is quite conscious of being a boy wearing a pump, like in school they have to have their shirts tucked in and because he does not want the pump to be seen, he would wear his shirt out."*
> [Mother of a boy aged 16 years; interview no: 37, line 151]

Children were self-conscious about wearing the pump either because they were put on the therapy just before changing schools where they did not have close friends, or because they knew it could be used as an issue for bullying:

> *"He is fine with it; he just does not like it when children stare because he knows that this is a disadvantage for them to bully him."*
> [Mother of a boy aged 9 years; interview no: 17, line 193]

The issue of self-consciousness of wearing the pump was also an issue for very young children (aged less than 5 years), as reported by 2 parents. The children were getting to an age where they realised they were different from their friends, and accordingly asked about wearing the pump:

> *"She's started at an age where it is 'I have this, nobody else has it,' and people are asking her 'what is it?.' I think if it was smaller, she could put it under her school jumper or you know it would not be as obvious."*
> [Mother of a girl aged 4 years; interview no: 29, lines 74-75]

Other negative impacts on the psychological wellbeing of children or parents were related to issues, such as 'concerns about the future.' Parents (N=2) worried about their child being constantly attached to the pump, and how that would impact on their wellbeing, especially at certain ages (e.g. teenage years):

> *"She is not at that teenagers' age, the teenage age is when I wonder whether that would make her more conscious of it."*
> [Mother of a girl aged 10 years; interview no: 34, line 58]

One girl, as reported by her mother, believed at one time that because she was wearing a pump, everyone could see that there is a problem and as a result, she neither would have friends nor get married:

> *"I think it took her a year of having the pump before she started to feel herself. She thought she was going to lose all of her friends, so she thought nobody would like her, because she has diabetes and she was never going to marry anybody, she was never going to have a boyfriend and all this, so I think she was quite depressed."*
> [Mother of a girl aged 15 years; interview no: 33, line 253]

'Parental stress' was one of the issues that emerged as a negative consequence of using the pump to manage children's diabetes (stated by 5 parents). They related their stress to the hard work and continuous thinking associated with pump therapy, or to worries concerning potential pump malfunction (see **Section 7.4**). For instance, a mother stated that she always took spare injections when going out, because she was afraid that the pump might not work.

Findings presented in this chapter indicate that the use of insulin pumps was associated with multiple improvements in family life. Therefore, in the following section, evidence will be provided by demonstrating, based on the interviews of parents and their children, the benefits of pumps compared to injections, and how that consequently improved the quality of life for children and parents.

7.3 Evidence supporting the positive impact of insulin pumps

Analysis of the data revealed that in most cases, the positive impact of insulin pumps was related to the advantages they had over injections with regard to glycaemic control **(Chapter 4)** and flexibility in lifestyle. The latter was attributed to the increased flexibility of eating patterns and the use of the advanced technology.

The effectiveness of insulin pumps in achieving and maintaining glycaemic control was attributed to easier achievement of target glucose values **(Table 7.2).** Where parents and/or children reported more difficult control, this was mostly due to the involvement

of other factors: difficult to control patient; inaccuracy in counting carbohydrates; puberty and the need to adjust basal rates (see **Chapter 4**).

Table 7.2: Ease of achieving target blood glucose levels by insulin pumps compared to injections, as reported by parents (N=38)* and children/young people (N=34)*

Ease versus difficulty	Parents	Children/young people
Easy/easier	34	32**
Hard/more difficult	3	1^

* Data are missing from 1 parent caring for a child aged 8-12 years (could not give an answer) and from 1 child aged 5-7 years
** Three children could not remember time on injections, but reported easy control on pump
^ Control was hard on pump, but could not compare it to injections.

Good glycaemic control impacted positively on different aspects of family life (e.g. health, school and socialisation) and psychological wellbeing, because it led to improvement in children's general health, concentration in class and mood:

> *"Well with the injections, I had the worst levels* [blood glucose]. *So, that could have made a difference because when you are like low or high, your school performance is not as great."*
> [A boy aged 9 years; interview no: 52, line 156]

> *"Well he has got better glucose levels, you know, which means he is not as miserable...The fact that he has got better sugar levels means he is a better person, so maybe he is getting on with other people better."*
> [Mother of a boy aged 12 years; interview no: 19, lines 177-178]

> *"In her contentment with herself it made a difference, because when the blood sugar is changing rapidly, it causes your mood to change as well...She is growing and you don't control yourself better, but if the control of the blood sugar is better, it will make things easier anyway."*
> [Mother of a girl aged 12 years; interview no: 12, line 156]

In addition to improved glycaemic control, the majority of the parents (N=33; out of 38) and their children (N=23; out of 34) reported that insulin pumps allowed a more 'normal' attitude to food, compared to the injections where fixed eating regimens were necessarily followed:

> *"Meal times are much more relaxed and we are not having to stick to certain times, and also if she decides she does not want to eat, or if she is not feeling well and she skips a meal, no problem. Whereas before with the injections, she would have to eat, she would have to have morning and afternoon snacks regardless of whether she was hungry or not. So here* [with a pump] *I feel for her, it is a lot more freedom."*
> [Mother of a girl aged 10 years; interview no: 34, line 52]

The flexibility in eating patterns was manifested by eating variable portions/variety of food, eating at more relaxed time intervals, or both **(Table 7.3)**.

Table 7.3: Flexibility in eating pattern by using insulin pumps compared to injections, as reported by parents (N=33) and children/young people (N=23)

Eating pattern	Parents	Children/young people
Food type/amount and timing	13	9
Food type/amount	10	10
Timing	10	4

As a result, using the pump impacted positively on the lives of the children and that of the entire family (e.g. home life, social life and school life) **(Section 7.2)**:

> *"She can lie in, in the morning, so I can just, you know, turn her basal down...I still have to wake her up because she is running at one program, but I wake her up and say 'turn the pump down.' Late nights; we can have late nights* [now on the pump], *she can go dancing and we can turn her pump down, she does not have to keep eating all the time."*
> [Mother of a girl aged 15 years; interview no: 33, lines 223-226]

> *"It gives him flexibility just things like going to a party. We went to a party on the weekend, and they had chocolates coming out and then they had sandwiches, and then they were running around to get them, then the birthday cake came out and it was all kinds of foods and drinks, but as he ate I could bolus...so it just meant that I did not have to say 'no' to any of the food, I think it makes that a bit easier."*
> [Mother of a boy aged 4 years; interview no: 28, line 78]

> *"She can eat whenever she wants* [using an insulin pump] *to fit in with everyone else* [at school], *she does not have to eat at specific time, she does not have to be so tight to a meal time* [as it was with injections] *which means that she can lead a normal life."*
> [Mother of a girl aged 15 years, interview no: 59, line 49]

Other advantages of the pumps were related to the 'use of the device.' 'Pump usage' in this section refers to the ease (or otherwise) of using insulin pumps as devices compared to the injections, and how the development in the technology (e.g. pump memory, Bolus Wizard® and basal modification) impacted on life **(Table 7.4)**.

Table 7.4: Ease of using insulin pumps to manage diabetes compared to injections, as reported by parents (N=38)* and children/young people (N=34)

Use	Parents	Children/young people
Easy	32	33
Children found it easy, not parents	3	-
Managing diabetes was not easy, but pump helps	2	-
Child still does not know how to use a pump	-	1**

* Data are missing from 1 parent
** A statement by a 5-year old child

Insulin pumps represented an easier and more straightforward method of delivering insulin compared to injections. In a few cases, children seemed to be more able to cope with the technology than their parents:

> *"Again my daughter is getting much more adapted to the technology. She now understands very very quickly, you know typical parents at this age are a little bit slower in understanding."*
> [Father of a girl aged 14 years; interview no: 2, line 120]

The analysis of the interview transcripts revealed that the easier use of the pump resulted from developments in technology that made them user-friendly and easy to use, even by the young children. For instance, many parents and/or children/young people during the interviews acknowledged the advances in recent pumps, such as having a memory to capture blood glucose readings over days; having a CGMS or a sensor that measures the blood glucose levels every few minutes within the day; having the pump's Bolus Wizard® software integrated into the insulin pump to calculate insulin doses for each meal, based on the carbohydrate content of the meal and the latest blood glucose value; ability to adjust bolus and basal insulin levels (background insulin) to match the activity of the day (i.e. dual wave/square wave bolus vs. temporary basal).

The advantages that insulin pumps had over the injection with regard to use and facilities contributed to the positive impact on family life. For instance, in the context of children's and young people's health, better glycaemic control on the pump resulted from: easier adjustments (parents N=12; children N=8); modification of basal and bolus insulin to fit the activities of the day (parents N=10; children N=2); they were more precise as small insulin increments could be delivered with the pumps, but not the injections (parents N=6; children 6); provided body with a continuous supply of insulin (parents N=2; children N=3):

> *"Before I was on the pump I got quite a few* [hypos] *because corrections being very inflexible, I would often go high and go low again, but now I can correct very easily so I have less* [hypos]."
> [A boy aged 12 years; interview no: 53, line 468]

> *"With the insulin pump we can more closely tie the basal rate to how her body works, and we can change how much insulin she is getting as a basal rate if she is doing sports for example. So if she is getting low* [after sports], *she does not have to keep eating."*
> [Mother of a girl aged 15 years; interview no: 23, line 49]

> *"The accuracy in delivery because in insulin injections you could deliver a unit, half a unit so there was a big error rate, whereas here I can deliver 0.025 units."*
> [Mother of a girl aged 12 years; interview no: 4, line 55]

The use of insulin pumps only involves pressing a few buttons and inserting a catheter every 2-3 days. Consequently, many parents (N=15) and children (N=20) acknowledged the benefit the pumps had over the injections by freeing them from the painful injections. This reflected positively on the children's psychological wellbeing, with some parents reporting that with the use of insulin pumps, their child's mood had improved dramatically, compared to the injections where they were usually irritable and angry. This advantage of the pump was emphasised by more than half of the children in the sample, which illustrate the importance of this issue to them.

7.4 Justifications for the negative impact of insulin pumps on family life

This section explores why insulin pumps had, in some cases, a negative impact on the lives of the children and their families (e.g. relationship between spouses, leaving children with others, sleeping, wearing pump, stress and concerns).

When parents (N=38) and children/young people (N=34) were asked during the interviews to report any drawbacks of pump use compared to the injections, several issues were revealed **(Table 7.5)**.

Table 7.5: Drawbacks of using insulin pumps compared to injections, as reported by parents (N=38)* and children/young people (N=34)**

Disadvantage	Parents (frequency)	Children/young people (frequency)
Use		
Effort/time: hard/continuous work	24	2
Complexity	10	9
Wearing the pump	15	11
Sports/activities	11	14

* One mother reported that there was nothing that she did not like about the pump
** Data are missing from 2 children. One child reported that there was nothing did not like about pumps

Of the main drawbacks, the extensive work and effort associated with the pump (e.g. frequent blood glucose monitoring) and the complexity of some management tasks associated with the pump were highlighted:

> *"That is one of the downs, I feel I'm constantly having to work things out even with his basals, so in that way it is more on me now than before."*
> [Mother of a boy aged 12 years; interview no: 19, line 125]

Such hard work experienced using the device explains the stress and tension that affected parents' wellbeing, and which in some families had led to a strain in the relationships between the partners. The frequent blood glucose testing, including at night time, was one of the issues which affected parents' sleep. However, this issue was mostly problematic at the start of pump therapy, where children had to be closely monitored and doses needed to be adjusted. Moreover, the use of CGMS associated with recent insulin pumps was an acknowledged bonus, as it freed children from frequent finger pricking and parents from doing the task at night.

Although most of the children and their parents reported insulin pumps as being easier devices to use than injections **(Section 7.3)**, the management tasks associated with the

pump therapy were not easy. Ten parents and 9 children/young people reported that many tasks (e.g. carbohydrate counting, dose calculation, infusion-set changing and basal adjustments) associated with insulin pump therapy were complex and required skills as well as knowledge:

> *"Interviewer: How easy or difficult do you find it to use your pump?*
> *Child: Sometimes it is a bit difficult, like when I do sports and stuff it is a bit difficult to sort of adjust the basal levels and stuff like that, but apart from that no, not any major problems."*
> [A girl aged 15 years; interview no: 67, lines 97-99]

This complexity explains why several families thought that 'leaving children with others' was more difficult with the pump.

Drawbacks of using the pumps included issues related to 'wearing the pump.' Fifteen parents and 11 children/young people expressed their views within this context: pumps were clearly visible for other people to see; it was difficult to wear dresses (for the girls) and left only one pocket free (for the boys). Moreover, parents of very young children (<5 years) thought that the pumps were relatively large and hence hard too disguise/conceal:

> *"And that is quite big, that is not very discrete for her now, she's started at an age where it is 'I have this nobody else has it,' and people are asking her 'what is it?.' I think if it was smaller, she could put it under her school jumper or you know it would not be as obvious."*
> [Mother of a girl aged 4 years; interview no: 29, lines 74-75]

Issues related to wearing the pump created some concerns for the children and their parents about the future of the child. Moreover, 'bullying' was one of the issues mentioned as an impact of insulin pump use, which was raised by 4 parents in the sample who stated that their children had situations of stigmatisation, because of the fact that the pumps were obvious to others and labelled them as 'different.' However, the extent to which such an issue impacted lives was not sufficiently clear in the data of the current study.

To avoid such issue, ideas to conceal the pump were generated by some families:

> *"It is difficult to wear a dress but it is not bad now because she puts it on her thigh, she wears it on a garter. I went to 'Ann Summers' and I asked for a garter for my 14-year old daughter, they looked to me as if I was very very strange."*
> [Mother of a girl aged 15 years; interview no: 33, lines 229-231]

Although participation in sports and activities was one of the issues reported as not being affected by using the pumps, some disadvantages were identified in this area. Eleven parents and 14 children/young people reported difficulties when doing sports, due to the tendency of the pump to fall, get in the way and/or make children heavier:

> *"But sometimes when I'm riding my bike the pump just drops off, so I have to brake it suddenly, so like may be more fasteners or something may be in the cases because usually when I'm ridding, it just falls off and then I have to keep on stopping and putting it back on."*
> [A girl aged 10 years; interview no: 68, line 139]

Water activities, such as swimming or going to the beach were regarded by some participants as 'difficult-to-do activities' with insulin pump therapy when compared to the injections. Many participants explained that the children had to be disconnected from the pump prior to such activities, closely monitored and reconnected afterwards, which was troublesome compared to the situation with injections. In addition, many parents stated that their child's pump was not waterproof, and therefore should be kept away from water:

> *"Beach holidays are problematic because, you know, toddlers like to be rolling in the sand, they'd be wanting to go in and out of the sea, so I think on beach holidays we might go back to injections just for a week because she is constantly having to take it* [insulin pump] *on and off, and her levels will be a bit high. And she keeps it on for most exercises, she does ballet and gymnastics and she keeps it for that, but just sand and water is a problem with the pump."*
> [Mother of a girl aged 3 years; interview no: 27, lines 129-133]

> *"Well it bothers me when I go on a holiday. Like I can only be in the pool for 2 hours, that is probably the only reason why I prefer the injections because I can go as long as I like, but it is easier and more efficient with the pump."*
> [A boy aged 11 years; interview no: 66, lines 67-68]

Regardless of the hard and continuous work, all parents (N=37; except one with whom the interview was not competed) and the majority of children/young people (N=29) stated that they preferred using the pump rather than injections due to the advantages of pumps in terms of lifestyle and metabolic control.

In summary, the use of insulin pumps impacted on family life in different ways. The framework for the analysis was adapted from the work of Barnard et al (2008), which informed the development of a model for this study, enabling representation, organisation and validation of data. It enabled a multidimensional model to be produced

to provide a complete picture of the impact of insulin pumps on family life. The value of the model was encountered in considering both parents' and children's self-reports; being detailed so as to outline aspects of life at macro and micro levels, and it was applicable for all children and young people of different ages. The use of the framework could be expanded to include issues, such as 'coping' and 'financial strain' or to involve impact on other caregivers (e.g. nannies and grandparents), friends, or school teachers. The applicability of the framework for children with other chronic conditions or technology-dependent children should be tested.

7.5 Discussion

Managing T1DM with insulin pump therapy requires children/young people and their parents living with the burden of the management tasks associated with the disease, which can impact heavily on the quality of their lives, and that of the entire family. There is an increasing body of literature examining the impact of using insulin pumps on the life of children and young people. However, most of these studies are quantitative, using different instruments to measure quality of life (Barnard et al, 2007). Many evaluative studies have been conducted to assess instruments used to measure paediatric quality of life, which concluded that there is: diversity in the conceptualisation and hence lack in the precision regarding the content of quality of life domains; limited measures for self-completion by children and discrepancies between child and parent ratings (Eiser & Morse, 2001; Davis et al, 2006). In addition, the majority of the existing instruments focus primarily on physical, mental and social health, and there is a shortage of instruments that explore perceptions or feelings of the child/young person. Results from RCTs on the quality of life impact of using insulin pumps to manage T1DM in children and young people have given inconsistent results (Devries et al, 2002; Weintrob et al, 2003; Fox et al, 2005; Wilson et al, 2005). This is counter to the limited amount of qualitative research, where parents and/or children/young people reported benefits to users' lives of using CSII to manage the condition (Litton et al, 2002; Sullivan-Bolyai et al, 2004; Olinder et al, 2007; Barnard et al, 2008; Wilson 2008).

Given the paucity of qualitative research concerning the impact of pump therapy on the lives of children and young people, together with the diversity of the frameworks underlying the current paediatric quality of life instruments, the current study aimed to explore the impact of insulin pumps in the lives of children and their parents.

Understanding specific aspects of family life, upon which insulin pump therapy impacts is important for improving health outcomes and maximising life benefits.

To meet the aim of the study, a framework was used for the analysis by adopting the domains of life proposed by Barnard et al (2008) likely to be impacted by using insulin pumps to manage T1DM of children and young people. The research presented in this thesis furthers the work done by Barnard et al (2008) as it was conducted using a larger sample size (38 parents and 34 children/young people; versus 17 parents and 15 children in their study) and studied children and young people of wider age-ranges (5-17 years; versus 9-17 years). Building on Barnard et al's study, further domains were proposed as being affected by using insulin pumps (e.g. psychological wellbeing and social life) and further elaboration on issues within each domain was undertaken. For example, the framework proposed for the current study included the impact of pump therapy on siblings, which was not included by Barnard and colleagues (2008). As the SEIQoL was used as a tool in the study performed by Barnard et al, and is known to be a sensitive instrument, using their domains as an initial framework for validating the data in this study was appropriate. Moreover, the use of semi-structured interviews in the current study allowed elaboration of the impact of pump therapy on the different aspects of life.

By assessing the use of insulin pumps on children's lives, this study has demonstrated that the impact is multifaceted and complex, involving not only the sick child, but also parents and siblings. The findings suggest that in most cases, the use of insulin pumps did not impact negatively on the quality of children's lives or that of their families, but rather in some instances they improved it. Such impact of the pumps was manifested in the current study on different aspects of life: health, home, school, socialisation, employment and psychological wellbeing.

The positive impact of using insulin pumps on the different aspects of life were attributed, as reported by the majority of the children, young people and parents, to the improvement in glycaemic control and the flexibility in lifestyle, offered by flexible eating patterns and the advancements in the technology that made them user-friendly, even for the children and young people. This is in agreement with findings of other qualitative studies where children using the pumps, and/or their parents, reported better

glycaemic control, more flexible lifestyle and eating patterns as benefits of pumps compared to injections (Sullivan-Bolyai et al, 2004; Low et al, 2005; Olinder et al, 2007; Wilson, 2008).

The majority of the children/young people and their parents in this study shared the opinion that the diabetes control, reflected by blood glucose values, was better controlled on an insulin pump than on injections. Many parents and children/young people related the better control on insulin pumps to easier dose adjustments, improved accuracy and the ability to adjust basal and bolus doses to match the activity of the day. As a result, parents reported that the general health and mood of their children was improved, compared to injections, where the children were irritable much of the time. Such an effect of insulin pump therapy on improvement in the mood of the children has been reported previously (Knight et al, 2009). Moreover, some parents and children attributed improved educational performance of the children at school, to the better concentration and reduced incidence of class absences due to uncontrolled diabetes. Similarly, parents in the study of Barnard and colleagues (2008) associated the heath benefits of insulin pumps with improved blood glucose control.

Autonomy, although absent from Barnard et al's study (2008), was one of the issues raised in the context of home life by both children and parents in this study. Findings presented in this research suggested insulin pumps improved children's independence from their parents when undertaking management responsibilities **(Chapter 5)**. This was attributed by the majority of the participants with the ease of use of pumps, in addition to the technical advancements in pumps design. The advantages of facilities associated with insulin pumps (e.g. Bolus Wizard®) were acknowledged by participants in the current study. They enabled children more independence and freed them from the tedious manual calculations of insulin doses, especially if their age did not permit performance of mathematical calculations. Insulin doses calculated with a Bolus Wizard facility have been reported as effective in improving glycaemic control and are associated with high treatment satisfaction in paediatric patients (Shashaj et al, 2008) and adult users (Gross et al, 2003).

The positive impact of using pumps was also seen in the context of social life. Insulin pumps seemed to facilitate families' social interaction and children's involvement in

daily activities, such as going out. Such flexibility was attributed to the advantages of insulin pumps in terms of allowing more flexible diet patterns and easier use, that freed families from scheduling their days around food and insulin dose (as was the case with the injections) and allowed children to have more independence to undertake management responsibilities themselves. On the other hand, worsened socialisation with others was reported in a limited number of families, which was believed to be because insulin pump therapy was associated with hard and continuous work, which stressed the parents, with a resultant strain on their relationship with each other and with others. This in turn highlights the need to support the families of children using insulin pumps, to relieve the stress and its consequences on their lives. Moreover, the visibility of the pump and its tendency to trigger questions by others was one of the issues reported by some in the context of social life. Although the children did not mind the questions, parents of young children expressed concerns about this issue for their child's future.

As reported by the majority of children and their parents, neither change nor negative impact was identified with using insulin pumps at school compared to injections. Improvements in school performance were explained by many participants as being due to improved metabolic control, and hence fewer absences and better concentration by students whilst at school. This was inconsistent with a study by Smith et al (2009) where using medications to manage chronic illnesses, including diabetes, of young people at school affected the school performance of some. Such a discrepancy may be because in the study by Smith et al (2009), students had other chronic conditions (e.g. respiratory, rheumatologic or gastroenterological problems) where the side effects of the medications used for disease management (e.g. nausea or drowsiness) adversely affected children's ability to concentrate in school lessons. In contrast, the use of insulin does not have such side effects, and an adverse impact on school performance was only reported in this study in situations where insulin pumps failed to achieve or maintain glycaemic control. The improvement in the friendships in the current study was attributed to allowing children to live a more normal life at school. This was manifested by more flexible meal times, rather than having them at fixed times and in the nurse's office (as with injections), which were not necessarily the times when other students had their meals. Insulin pumps resembled a mobile phone or other electronic gadgets which made some children more comfortable using them in public compared to injections, where they had to administer them in the medical room or in a private place.

Being a gadget, insulin pumps attracted the attention of other peers prompting them to ask questions, which in many cases was reported not to bother the children. In contrast, young people (especially those aged 13 and older), had concerns about their overall body shape and figure when wearing the pump, as it was difficult to conceal.

Incidents of bullying and stigmatisation of wearing the pumps were only reported by the parents in the sample. This might be related to children being more reserved in the interviews and not open to discussing such issues with the researcher. Similarly, in another study about using medications to manage chronic illnesses at school, most young people reported that they did not experience negative attitudes from their peers, but rather their peers showed an interest about the use of some medications, especially insulin, and asked questions to which young people were happy to answer. Few children experienced negative attitudes from their peers (Smith et al, 2009).

From these findings, the importance of informing and educating peers at the school about a child's condition in order to avoid cases of bullying and to improve children's psychosocial well-being at school should be considered. Also educating children's friends and school mates about diabetes and how to provide help in emergencies is fundamental, as it has been shown that such education improves quality of life of students with diabetes at school (Wagner et al, 2006).

Using insulin pumps did not have a negative impact on parents' employment, as reported by many children and parents. This could be related to the fact that in many families, the mothers had already given up their jobs after their child was diagnosed with diabetes, and hence became free to take care for the child. However, a few parents (N=7) in the sample reported that they had taken days of off-work, or disturbed working patterns due to their child using insulin pumps. This was explained in relation to: the need to attend many training courses at the hospital and to manage the new situation at home (especially at the start of CSII); going to school every lunchtime to deliver boluses to the child until the child or school personnel became able to do so; calls received from school to check out issues relating to pumps. This is inconsistent with the results reported by the parents in the study of Barnard et al (2008), that more disturbing phone calls at work were received when the children were using injections at schools rather than pumps. None of the children reported a negative impact on their parents'

employment due to their using the pump. They believed this was due to their own greater independence in performing management tasks with pumps compared to injections, with the result that there was less impact on the parents.

Although this study has demonstrated that using pump therapy in most cases did not adversely affect many aspects of the life of families, but rather improved them in some cases, the impact of insulin pumps on the family life was questioned in a few cases. This was apparent with some issues where inconsistent views of parents and/or children/young people were evident (e.g. spouses' relationships, leaving children with others, sleeping, bullying and psychological wellbeing). The data obtained with regard to those issues were simply statements from the interviews, so they were not sufficient to allow drawing of any conclusions, and further investigation with this regards is highly recommended.

Research presented in this thesis is valuable in demonstrating that that use of insulin pumps had in most cases a positive (or at least not negative) impact on different aspects of life. By indentifying how insulin pumps affected different aspects of family life, these findings may be of great use for healthcare providers to find ways to support children and their families, and by minimising the impact of the management burden on their lives, along with achieving target blood glucose levels. For instance, they can provide patients and their families with appropriate educational and psychological support that prepares them to handle management efficiently, and to deal with all social and psychological outcomes that may arise within the context of using insulin pumps (e.g. visibility of pumps and ways to hide them under clothes). Along with this, the NSF in the UK aims to reduce burden of diabetes and its impact on children's and families' lives, by setting standards that involves providing children/young people with diabetes, and their parents, with high-quality care and support to optimise glycaemic control and physical, psychological, intellectual, educational and social development (Department of Health, 2001).

Insulin pumps have developed dramatically over the years (Alsaleh et al, 2010). Findings presented in this chapter have revealed that the developments in pump technology played a role in the positive impact on the lives of the children and young people receiving pump therapy. A number of insulin pumps are currently available on

the market, which makes decisions very difficult for the purchasers and consumers. Healthcare providers should support and guide families to choose the best option that suits their child's condition and usage. Also, communication between families and different insulin pump manufacturers should be arranged and encouraged by the hospital, in order to update families about the pump market and to help them take the correct decision when selecting the ideal pump for their children. In the UK, the NHS has recently published an insulin pump buyer guide to help inform purchasing decisions (Skryabina et al, 2008).

CHAPTER 8 - Insulin pump therapy services at University College Hospital (UCH)

Chapter 8: Insulin pump therapy services at University College Hospital (UCH)

Chapter 8 reports perspectives of children/young people and their parents on the services and support they received at UCH on initiation of insulin pump therapy, and during ongoing therapy. It opens with an introductory section **(Section 8.1)** that describes the development of the insulin pump therapy programme for children and young people in UCH; based on a published paper by one of the diabetes nurses at the hospital.

8.1 The development of insulin pump therapy service at UCH

In the UK, a grant was received in 2004 to develop a multidisciplinary, structured education pump pathway for paediatric patients with diabetes at UCH, London (Thompson, 2008). The programme which aims to encourage motivation, flexible self-management and successful transition to CSII, was adopted following observation of services in other leading centers of excellence in insulin pump therapy, such as: Yale, Connecticut (USA) and Uddevalla (Sweden). This was integrated with an extensive systematic review of the literature (Thompson, 2005). The pump pathway uses a series of pre-defined competencies, together with an innovative psycho-educational programme (Pump School) **(Figure 8.1)**. The latter was developed at the hospital in partnership with families to enable children and young people to manage their diabetes to the best of their abilities.

For successful use of insulin pumps, parents must acquire skills and knowledge, which require beyond learning how to insert, disconnect, suspend and program the pump, the ability to understand and successfully count carbohydrates, correct blood glucose levels outside the target range, handle sick-days management issues and adjust dosing for exercise and changes in activity patterns. Therefore, prior to taking the first steps in the pump pathway, a comprehensive multidisciplinary assessment is usually undertaken for families with CSII candidates, which focuses on achieving a defined level of competency (not less than 5) prior to commencing insulin pump therapy, using eight Competency Scale Levels described by Kaufman et al (2001) **(Table 8.1)**.

In addition, patients' attitudes towards injections are assessed as needle fearfulness has been recognised as an indicator for poor glycaemic control in children and young people (Maniatis et al, 2001b). Regardless of age, all children are made to wear a

Figure 8.1: A schematic presentation of the multidisciplinary structured education pump pathway provided for children/young people, and their families, at UCH, London

Table 8.1: Competency Level Scale used with families of CSII candidates prior to commencing insulin pump therapy (Kaufman et al, 2001)

Competency	Characteristics	Level
Safety	Initial information, injections, blood testing, treatment for hypoglycaemia	1
Basics	Blood glucose targets, actions for levels out of target, glucagons, action of different types of insulin, diet and carbohydrate intake	2
Carbohydrate management	Determine the quantity of carbohydrates in food, use of plan for carbohydrate intake	3
Correction	How to correct blood glucose out of target	4
Daily changes	Decision-making about changes in daily routine, adjusting insulin and carbohydrate intake	5
Base dose adjustment	Making base dose adjustments, review blood glucose values to observe overall effects of treatments	6
Advanced diabetes management	Understand hormone pathways and food absorption; know about strategies to reduce complications	7
Maximized control, basal and bolus therapy	Independence in MDIs/CSII to maximise control, flexibility and freedom	8

demonstration insulin pump filled with saline to enable evaluation of how they cope with the 24-hour attachment to the device, and to observe them regarding the anxiety they might have with cannula insertion. If necessary, a psychological intervention and play therapy for younger children are offered. In some cases, parents also wear a saline pump to see how it feels to be attached to the device. During this stage of pre-pump education, school personnel are invited to attend the 2-day Pump School training course and DSNs visit schools to provide education and hands-on training, necessary for school staff to support and take care of the children. Also a medical management plan containing written instructions and flow charts are given to the school personnel.

On achieving the targets identified in level 5 of the Competency Scale, 2 or 3 families of age-matched children are invited to attend a 2-day Pump School course at the hospital. Beforehand, a written programme is given to the families to encourage their participation in the training. In the first day of Pump School, training in the basic skills of using insulin pumps is undertaken, which comprises education on: differences between insulin delivery via MDIs and CSII; relation of glycaemic control to the development of long-term complications; calculation of insulin requirements; selection of catheters; rewinding and filling reservoirs; monitoring of blood glucose levels; suspending/disconnecting the pump and the pumps' basic functions. Subsequently, a

more advanced educational day is undertaken, where families are trained on: recognition and treatment of hypo/hyperglycaemia; when to give subcutaneous insulin via a pen device; illness management and ketones; advanced functions of the insulin pump as well as alarms and troubleshooting. During this training day, insulin pump therapy is actually initiated.

On the commencement of the therapy, close monitoring of blood glucose levels and basal adjustments are carried out. Families and children are also instructed on how frequently they should check blood glucose levels and 24-hour nursing/medical telephone cover is provided during this period. Families are contacted at least once daily in the first 2 weeks to give them a period of settling down and consolidating their knowledge. During the ongoing period of the therapy, families are allowed to contact the medical team by phone or the email system. In addition, 3-monthly regular clinic visits are arranged for face-to-face evaluation and follow-up. An annual review and open days are also organised, where many families gather and additional information, education and support are provided.

8.2 Introduction to pump therapy and reasons for the switch to pumps

Families were introduced to insulin pump therapy by formal (e.g. local clinics) and informal sources (friends, internet, pump-manufacturer representatives, or diabetes camps), as reported by 9 parents. Parents (especially mothers) were the main source seeking insulin pumps for their children, as reported by 3 children/young people.

Of the informal sources, the diabetes support groups on the web were acknowledged to be important for providing families with answers about pump therapy based on users' experiences, rather than a professional opinion:

> *"There is a few internet based Support Groups and information soon gets around. This is what is the best for families, because the medical professionals will not necessarily provide what is best, often you have to go and seek out and get what is the best for your family and for your child."*
> *Father of a boy aged 9 years; interview no: 7, lines 148-149*

Reasons for switching from injections to insulin pumps were identified and are presented in **Table 8.2**.

Table 8.2: Reasons for switching from injections to insulin pumps, as reported by some parents (N=13) and children/young people (N=5)

Reasons	Parents (frequency)	Children (frequency)
To achieve better control (e.g. less hypos, better sugar values)	9	1
Interested to try something new	6	1
To gain more flexibility in lifestyle (food-wise)	4	1
Injections were non-convenient (limited site for injections, painful, hated them, needle fear)	2	1
Parent's decision (mothers)	-	2

The most frequently mentioned reason for the switch was the pursuit of better blood glucose control, especially if the child was insulin sensitive, and where there is an interest in trying a new method of therapy. The latter induced some families (those which started CSII outside the UK) assign their children to pump therapy, although their diabetes was controlled with the injections:

> *"Interviewer: Ok, in that case why did you decide to go onto pump therapy if the blood sugars were controlled on the injections?*
> *Mother: Because in the States, the insurance companies will always pay for it."*
> [Mother of a diabetic twin aged 15 years; interview no: 30, lines 254-156]

The aim of achieving a more flexible lifestyle was another reason for starting on pumps:

> *"It was difficult on the needles in terms of she had to eat at certain times and things were very restricted, and so we thought with the pump we will have more freedom."*
> [Mother of a girl aged 14 years; interview no: 2, line 45]

In a few families, the decision for the switch to insulin pumps was clearly the parents', rather than child's (reported by 2 young people):

> *"Interviewer: In that case why did you decide to go on a pump therapy?*
> *Child: It was not my decision.*
> *Interviewer: Whose was it?*
> *Child: My Mum."*
> [A boy aged 11 years; interview no: 48, lines 84-88]

8.3 Initial worries and concerns regarding using insulin pumps

In **Chapter 7**, the impact of using insulin pumps (e.g. psychological wellbeing, such as stress and concerns about future) was reported. However, in this section, the initial worries of families before the actual use of insulin pumps are considered **(Table 8.3)**.

Table 8.3: Initial worries families had about commencing insulin pump therapy and ways the hospital responded, as reported by some parents (N=10) and children/young people (N=3)

Worries/concerns	P	C	Response of UCH staff
Cannula in body all the time	4	1	Giving parents a demonstration pump to wear for a few days to see how it felt having a cannula inserted into the body
Fear of using pump	4	-	-
Insertion procedure (i.e. painful)	-	2	Giving children a demonstration dummy to practice on infusion-set insertion and using distraction therapy*
Trusting a machine (looks like a gadget)	2	-	Suggesting books for reading about insulin pump therapy
Interference with child's activities (bath, swimming, going to beach)	2	-	-
Pump size and weight	2	-	Meeting with another child at hospital using an insulin pump to see the actual size of pump
Pump damage	1	-	-

P= parents; C= children and young people.
Numbers refer to the frequency the issues were mentioned.

* A way to help the child cope with painful procedures, e.g. cannula insertion by using methods, such as: talking to the child during the procedure, listening to music, reading books, playing games or solving puzzles

The most worrisome issues that bothered parents were mainly having a cannula inserted inside their child's body all the time, and fear of using the device. Such fears arose from worries of understanding the technology or of making mistakes (e.g. pressing the wrong buttons):

> *"Again in the beginning it is like being diagnosed for the first time, you do become quite panicked again, because this is equipment that just seems so advanced and you think you are never going to get the hang of it."*
> [Mother of a boy aged 15 years; interview no: 38, line 66]

Trusting a 'machine' was another issue which bothered parents at the start of insulin pump therapy, with associated fears of the pump's reliability.

Other parents had worries that the pump might interfere with the child's daily activities or annoy the child with its cumbersome weight and size (these were concerns particularly of parents of younger children):

> *"But I was still concerned about how she would manage this generally you know. She is still in nappies, nappy changing...mess you know, so sitting down even going to the beach, swimming, bath, everything that you would expect and what can be done concerned us actually."*
> [Mother of a girl aged 2 years; interview no: 5, line 51]

On the other hand, all the children's worries were focused on the insertion of the cannula. The diabetes clinical team used different strategies to support families and reduce their stress before the actual start of the therapy **(Table 8.3)**.

8.4 Perspectives on the services provided at the hospital

All parents (N=38) and children/young people (N=34) were asked during the interviews to express their views regarding the services provided at UCH: telephone contact, school contact, and a 2-day Pump School training course at the hospital (joint-training session). In addition, other services were explored from the analysis of the transcripts and hence are addressed in this section.

8.4.1 Telephone contact

The telephone contact service is provided to families for 24-hours a day at the onset of pump initiation, after which the service becomes restricted to working hours (everyday from 9:00 AM to 5:00 PM; except weekends). The telephone service comprises a landline helpline or a nursing mobile phone, through which the families can contact the diabetes medical team directly or leave a message to which they will reply **(Table 8.4)**.

The majority of parents, with the agreement of many children, reported that the service was helpful, especially at the beginning of insulin pump therapy where the contact was 24-hour/day, including night-times:

> *"We could phone them during the night* [in the beginning of pump therapy]. *The nurse took a mobile phone home and she just said 'I don't care what time, even at the early hours of the morning phone me' and we had once called at 11:00 o'clock and I just asked a question. I did not want to do it but I thought I cannot go to bed unless I know, so it was fantastic."*
> [Mother of a boy aged 15 years; interview no: 38, line 282]

Table 8.4: Views on telephone-contact service provided at UCH at the start of CSII and as on-going service, as reported by parents (N=38)* and/or children/young people (N=34)**

Parents	Positive views (N=33)	Negative views (N=3)
	▪ Useful; excellent; very good; brilliant; great service ▪ Always accessible; 24-hour call support (especially at the start of CSII) ▪ At start of CSII, contact with medical team was extensive and also included weekends and out-of-working hours ▪ Reponses to phones were immediate and quick (within the same day) ▪ Medical staff were competent in answering questions and queries ▪ It is the most useful/helpful service ▪ Good but depends on the nurse who picked up the phone (some of them were more knowledgeable and experienced than the others) ▪ It was reassuring and calming for parents to know that there was someone to help when there were problems and to check out things (i.e. made them feel safe) ▪ Useful for advice on blood glucose monitoring, dose adjustments, set change and food ▪ Calling nurses is more useful than regular visits	▪ Not 24-hour contact, only from 9:00AM to 5:00PM, after which a registrar will answer who is not as knowledgeable as nurses ▪ Almost impossible to speak to someone at the weekends ▪ Once, nurses were short-staffed and did not respond to calls or messages ▪ Sometimes parents needed nurses urgently, but they did not always answer the phone or reply to the messages straightaway ▪ Not always helpful, because they sometimes were not able to answer the questions
Children/young people	**Positive views (N=9)**	**Negative views (N=0)**
	▪ Good; useful; helpful ▪ At the beginning, several hotlines were given to the families to call at anytime ▪ Good, although sometimes the staff were busy ▪ They were always there if the family wanted to check out things ▪ It was reassuring that the families were doing fine ▪ It was good that the young people could contact nurses by text messages ▪ It was helpful to give families and patient information and solve problems ▪ Hospital staff were always accessible and replied back to calls or messages	-

* Data are missing from 2 parents.

** Data are missing from 9 children/young people; 13 children/young people did not know about the service or whether their parents were using it; 3 children/young people reported that the service had never been used.

This communication between families and medical nurses was effective in resolving some of the problems over the phone. Moreover, it was crucial in providing parents with support and instilling calmness:

> *"I phone the hospital when I have a problem and I still do occasionally and say 'this is happening, what would you do?' I really need someone else to pat me just on the shoulder and go 'yes I would do the same,' I don't need them to do much more than that now. So that contact is the safety net and they always get back the same day."*
> [Mother of diabetic sons aged 9 and 12 years; interview no: 17, line 369]

> *"He had a stage where I just could not get his target score and he had an infection at the time, so his sugars were really high and I could not get them down. That was the time when I phoned them up and that was when I was literally broken down and they were very good, I mean I really had 2 hours on the phone with them crying, it is emotional really, it is a scary thing and I found that the support from the nurses was the best."*
> [Mother of a boy aged 11 years; interview no: 18, lines 278-281]

The use of the telephone service decreased with time, as reported by many parents, as their confidence and experience in dealing with situations improved.

Although the majority of comments were positive, negative views were also reported by a few parents (but none of the children). The main issue raised by parents was that the routine service was not provided by the diabetes team over 24-hour/day (i.e. only from 9:00AM to 5:00PM), or at weekends:

> *"That is a bit iffy really; if it is an emergency you can't always get hold of the diabetic team on the phone. I would like to have a mobile number that if I ring I know that someone is going to be there. But you know, I think it is possibly unrealistic to expect that of the team. However, I have had an experience where I needed to speak to a pediatric endocrinologist on call and there was no paediatric endocrinologist, just a paediatric registrar who actually knew nothing about diabetes. So that is not very useful."*
> [Mother of a girl aged 15 years; interview no: 23, lines 252-253]

> *"It is almost impossible to speak to someone when is Saturday or Sunday, it is horrible."*
> [Mother of a boy aged 8 years; interview no: 10, line 445]

Other issues were that the diabetes nurses took time to reply to calls/messages, which would not be suitable for emergencies and urgent situations, or they were sometimes unable to answer questions or queries:

> *"But as I say they have not been always helpful, because they have not been always able to answer the questions, but they are happy to do it."*
> [Mother of a girl aged 2 years; interview no: 5, line 253]

When the service was never used, as reported by 3 children, this related to the lack of confidence with the medical team, as reported by one. This was when the child, who was insulin sensitive, received an overdose, due to an incorrect dose of basal insulin at initiation of insulin pump therapy:

> *"Never would* [call the service] *after the first incident with my basal rates."*
> [A girl aged 12 years; interview no: 42, line 625]

8.4.2 School contact

This service comprises the diabetes team inviting the child's school personnel to attend 2-day joint training sessions (Pump School) at the hospital before the start of pump therapy, and/or by the hospital nurses going into schools to educate school staff members on how to care for the children. Additional training documents and management protocols are also given to the schools **(Table 8.5)**.

The majority of parents and their children/young people shared the opinion that this service was excellent. This was because of school personnel were able to deal with emergencies, once they had received the training from diabetes team:

> *"I think the nurse came in* [to the school] *once and talked to the school staff about it, which was quite helpful, because now I know there are staff out there that know what to do if I have any problems."*
> [A girl aged 15 years; interview no: 67, lines 343-344]

In some families, the contact between the hospital and school personnel was not restricted only to the beginning of insulin pump therapy, rather it was a 'continuous service.' This became apparent when children changed schools:

> *"Again yes it was useful, and the hospital nurse came down and she spoke to the school, and even when my son changed schools when he was in year 1, she came down again and spoke to them* [school personnel]."
> [Mother of a boy aged 8 years; interview no: 22, lines 333-334]

Also, the hospital medical nurses provided school personnel with occasional supplementary training courses:

> *"They are good, they do classes and they offer day-courses for someone from the school to go and attend to gain more information about pump therapy."*
> [Mother of a girl aged 10 years; interview no: 34, line 227]

Table 8.5: Views on school-contact service provided at UCH at the start of CSII and as on-going service, as reported by parents (N=38)* and children/young people (N=34)**

Parents	Positive views (N=25)	Negative views (N=5)
	▪ Useful; very good; brilliant; very helpful; perfect; excellent ▪ Hospital nurses went to school and spoke with the staff at the beginning of pump therapy and when child changed schools ▪ The hospital nurse went to the school and was always available if the family needed her to communicate with the school ▪ Hospital gave schools medical documents and protocols to follow ▪ The school would not be alright without the hospital contact ▪ If the parents were not satisfied with the school, they asked hospital nurses to contact the schools and they did ▪ Supplementary educational and training courses were arranged for school personnel ▪ The contact and training was not restricted to school nurses, but also included teachers, teaching assistants and first aiders	▪ The service was not helpful, because the school personnel were not cooperative, although the hospital nurses had contacted them ▪ The contact was restricted to the beginning of insulin pump therapy, while there were no contacts later on or when changing schools ▪ Too much and unnecessary detailed information was given by the hospital nurses to the nurseries ▪ School personnel although they received training, still lacked confidence ▪ The hospital instructed schools to give correction doses (insulin) if the blood sugar readings were 10 mmol/l or more, which the parents thought was too high
Children/young people	**Positive views (N=11)**	**Negative views (N=3)**
	▪ Useful; helpful; good ▪ Hospital nurses went to the school and spoke with the staff at CSII initiation and school personnel attended the training course at the hospital ▪ It was helpful to educate the school personnel to know what to do in emergencies ▪ Hospital nurses explained everything for the school personnel ▪ It was easier that the explanation was done by the hospital nurses, because they can explain things more easily than the young person could	▪ The contact was restricted to the beginning of insulin pump therapy, while there was not much contact later on ▪ The service was not helpful, because the school personnel were not cooperative, although the hospital nurses had contacted them ▪ The service was not helpful and it did not make any difference at school, because the hospital nurse repeated everything that the young person already knew

* Data are missing from 4 parents; 4 parents reported that the service was not done.
** Data are missing from 11 children/young people; 9 children/young people either stated that the service was not done, or they did not know if it was done.

Other justifications for the positive views on the school contact service are provided in **Table 8.5.**

In a few cases, negative views regarding the school contact service were reported. Some parents and children felt that the contact was restricted to the beginning of pump therapy (i.e. there was no contact when changing schools), or the hospital nurses did their best to contact the school personnel who were uncooperative, and this resulted in the service not being as helpful as it might have been:

> *"I mean I must admit, the hospital nurses a few months ago ran around trying to chase his teachers for weeks and weeks, and the nurse did everything, so they did their best. But the school was just like not cooperative enough you know."*
> [Mother of a boy aged 11 years; interview no: 32, lines 268-271]

> *"My kids have not had as much contact. The DSN came up from the UCH, from London to do the training for the school of my elder son, because he had gone from junior school to high school after going onto the pump. He started pump therapy in March and so all the care was placed in the junior school and then in September, he went to a new high school."*
> [Mother of diabetic sons aged 9 and 12 years; interview no: 17, lines 371-374]

Some thought that school personnel still lacked confidence in their knowledge, although training had been received.

In a family, parents thought that the information provided to school personnel was excessive:

> *"I felt that they explained too much, it was too much detail and what I used to tell the nursery staff to do is 5 steps ' do this, do this, do this' and they followed that. However, there was something like a 7-page document which the hospital presented to them which was great, but the fact is that my daughter is only at the nursery twice a week, and she is only there for about 3-hours a day, so it was not really that relevant. Obviously in terms what nursery needs to know about my daughter really, they needed to know the way to check her, how to give a bolus, carbohydrates, the steps of giving the bolus and how we lock the pump again, you know that is really it, and that is all what the nursery staff need to know."*
> [Mother of a girl aged 2 years; interview no: 5, line 255]

In some families, contact with school personnel occurred either after the child had already started treatment with insulin pumps, or was not done at all (reported by 4 families). The latter was explained by: children started insulin pumps at secondary school where they were expected to undertake management responsibilities themselves;

other students had diabetes and were using insulin pumps, so the training by DSNs was expected to be received or the family was still waiting a reply from the local Council about assigning a one-to-one carer.

8.4.3 Two-day Pump School

Pump School is a 2-day training course conducted at the hospital by the diabetes team at the onset of pump use. Two or 3 families are invited to attend the course to learn how to use an insulin pump to manage T1DM of their children and young people **(Table 8.6)**.

Most of the parents and almost half of the children/young people thought the service was good and helpful, as they were taught how to use the pump and to practice:

> *"In the Pump School, every problem which we could have in the future was discussed, so this was very good and yes I was very happy about the Pump School. They also spoke about how to change the set and how to do everything, so this was very good."*
> [Mother of a boy aged 8 years; interview no: 10, lines 393-394]

Wearing a demonstration pump was found to be useful for the parents, to discover how it feels to wear a pump:

> *"I think it was couple of days we had to go up, I hardly remember that now, I think it was 2 days, and having to wear the pump, as well. Both my husband and I had to wear the pump and that was really helpful to see what it was like."*
> [Mother of a boy aged 8 years; interview no: 22, lines 312-313]

Other positive views with regard to the Pump School are shown in **Table 8.6.**

Negative views regarding the Pump School service were also articulated by a few participants. Parents who had negative views were those of children who were pioneers in receiving the service at UCH. They explained their views either in relation to not bonding well with the other family which attended the training with them, or due to the diabetes team focusing on unnecessary issues during the session (rather than focusing on theoretical aspects of the therapy):

> *"And all of it, the training and everything, was ridiculous, you know, it was like an hour spent 'press this button, press that button.' Everyone knows how to press buttons and the person who has a television has a remote control, and knows how to press a button. For example, we asked about dual wave or square wave boluses and they were like 'we don't know, you have to do an experiment.' "*
> [Mother of a girl aged 12 years; interview no: 4, lines 649-652]

Table 8.6: Views on Pump School Training provided at UCH at the start of CSII, as reported by parents (N=38)* and children/young people (N=34)**

Parents	**Positive views (N=29)**	**Negative views (N=2)**
	▪ Fine; adequate; useful; brilliant; very helpful; great; good ▪ In the course, the family had all information and were shown how to use the pump and how it worked ▪ It was useful because all problems that the family might face were discussed and families were taught how to change the infusion set ▪ Families were taught about the pump, practiced, and that was good ▪ Other people, such as child's nanny and school personnel attended the course, which was a relaxed environment to ask questions ▪ Everything was more than adequately explained ▪ Doing course with another family made the session more useful, informative and allowed families to share experiences. Also families became friends and supported each other. If more than two families were there, it would be too much and there would be so many different questions without enough time to answer them ▪ It was good for the child to meet other children of the same age and with the same problem, so the child would not feel that he/she had it alone	▪ The parent did not bond well with the other family ▪ Training was poor and the dietician was not knowledgeable enough ▪ Hospital staff spent an hour teaching families about pressing pump buttons and everyone knows how to press buttons
Children/young people	**Positive views (N=16)**	**Negative views (N=2)**
	▪ Useful; helpful; fine; good; ▪ Without it the child would not know how to use the pump ▪ It was useful, because it taught the families everything they needed to know about the pump and carbohydrate counting ▪ It was good, because the medical team explained everything to the child ▪ The session was relaxed as if it was at home ▪ Doing the session with other children made them become friends and families compared their experience with others	▪ The training and the talking was all directed to the parents only, not to the children, so they put it in parents language which made it harder for children to understand ▪ The dietician lacked knowledge ▪ The other children who attended the same session were not of a similar age to the child, which upset the child

* Data are missing from 5 parents; 2 parents reported that the service was not done.

** Data are missing from 11 children/young people; 5 children/young people were not sure if the service was not done.

The children explained their negative views by referring to the lack of knowledge of some medical staff (e.g. dietician):

> *"And the carb counting lady, she asked 'if this is a potato, how many carbs is it?' Well it depends if it is mashed, sweet, if it is boiled and that, if it is even cooked, and how much it weighs and how big the potato is. And she just looked at us as if we were mad."*
> [A girl aged 12 years; interview no: 42, lines 594-595]

Another reason for negative views by children regarding the Pump School was because all the talking was aimed at parents, and language was used that was comprehensible for the parents, but not for the children:

> *"Mostly they always talk to the parents only, not me. So they all put it in the parents' words which make it a little bit harder."*
> [A girl aged 9 years; interview no: 39, lines 198-199]

Pump School is usually conducted with 2 or 3 families of age-matched children. However, it was apparent from the analysis of the transcripts that this policy was not always followed. Instances where the course was conducted with one family only were experienced. This could be related to the fact that some families had 2 children with diabetes and starting insulin pump therapy, and hence the course was conducted privately:

> *"Yes we had it* [Pump School course] *us alone, because we were both* [his brother and himself] *going on pump at the same time, so there was no other one."*
> [A boy aged 12 years; interview no: 53, lines 524-525]

8.4.3.1 Perspectives on doing the course privately or shared with others

Views on whether having the course privately or with other families were expressed by some parents (N=26) and children/young people (N=14). The majority of those parents (N=24) and children/young people (N=12) acknowledged the importance of doing the course with other families, as this allowed them to support each other, share experiences and allowed children to communicate with peers having a similar experience:

> *"No it was good, because it is always good to chat with other families, with children going through the same thing. Not only because you feel like you are not on your own so much, but also because you can share ideas. And you know we are the ones living with it 24-hours a day and you often get a lot from talking to other parents, sometimes more than talking to, you know, a healthcare professional."*
> [Mother of a girl aged 3 years; interview no: 27, lines 263-265]

> *"I quite liked it with another family, because you sort of feel like you are not the only one that was struggling with that thing, everyone is in the same boat and stuff. So it was quite nice having it with someone else there really."*
> [A girl aged 15 years; interview no: 67, lines 347-348]

Within this context, having too many families attending the course was not recommended (reported by 2 of those parents; out of 24), as that would result in the session not being as useful:

> *"Yes, it was good. There was only one other family and I don't think they could be any larger than that, because you got so many questions that were asked. It was good, because you will get other people's feedback about things. It is nice to see someone else, but I wouldn't want it to be with any more people, because otherwise you will get too many questions and you have not got enough time."*
> [Mother of a boy aged 5 years; interview no: 11, lines 327-330]

Only 2 parents and 2 children/young people had other opinions on whether to do the course alone or with other families. With regard to the parents, a mother stated that it did not matter to her whether they did the session alone or with others, as in all cases it would be the same to her, while another mother who did the session with two further families thought that having the session privately would be better:

> *"A private session would have probably been better. It would have been just easier because I suppose you would have been more able to ask questions and sometimes everybody was programming in and you press the wrong button and about to start and you have to get somebody's attention to come back over and set it for you to get it with the group."*
> [Mother of a boy aged 11 years; interview no: 14, lines 263-267]

An 11-year old boy who had already done the session alone without the presence of other families preferred it this way, while a 10-year old girl stated that she would rather the course was done alone so she would have more privacy to discuss personal issues, but she appreciated that a course done with others would allow experiences to be shared.

8.4.3.2 Sufficiency and clarity of the training in Pump School

All parents (N=38) and children/young people (N=34) were asked during the interviews to express their views about how clear was the training and education they received at the initiation of pump therapy and whether they felt that more education/training was needed or not **(Table 8.7)**.

Table 8.7: Sufficiency and clarity of information received in the educational/training course (Pump School), as reported by parents (N=38)* and children/young people (N=34)**

Information / training	Response					
	Yes		No		Other	
	P	C	P	C	P	C
Sufficiency	27	21	4	2	4	1^
Clarity	29	24	1	3	4^^	-

P= parents; C= children and young people

* Data are missing from 3 parents on the 'sufficiency' and from 4 parents on the 'clarity.'
** Data are missing from 10 children/young people on the 'sufficiency' and from 7children/young people on the 'clarity.'
^ A young girl did not report if information received was sufficient or not; only reported that other resources for information were used.
^^ The response 'other' included statements, such as: 'different people have different levels of understanding.'

The comprehensiveness and clarity of the training and information received at Pump School was confirmed by the majority of parents and their children. However, if more information had been given to families, some felt they would not have been able to embrace it (reported by 3 parents):

> *"Father: It was enough for us.*
> *Mother: Definitely, if you have too much that could become quite confusing."*
> [Parents of a girl aged 9 years; interview no: 1, lines 410-412]

Training was not only given to the parents; the children were also involved:

> *"They really made sure that we understood everything, including the children, so the children did all the mechanical things with their pumps at this training day. So it was not just me being taught about the pump, children also have got taught about the pump."*
> [Mother of diabetic sons aged 9 and 12 years; interview no: 17, lines 349-350]

A few parents and children thought that the information provided in the training course was neither sufficient nor clear. These parents articulated their views with respect to the need for more than 2 days training:

> *"I found the training day good, but I think we could have done with one more, I think probably 2* [2-day Pump School] *was not enough, but again I think that was because of the short time we had to think about it."*
> [Mother of a boy aged 11 years; interview no: 18, line 274]

Children (3 children, aged 8-12 years) indicated that the diabetes team did not explain matters in a simple way, suitable for their age at the time:

> *"No they did not explain it in a way that I could understand."*
> [A girl aged 12 years; interview no: 42, line 581]

> *"It was not really for me, it was Mum and Dad. I did not understand any of it when I was young, I did not understand anything about the insulin."*
> [A boy aged 9 years; interview no: 44, lines 297-298]

Other views on the sufficiency and clarity of training during the Pump School course were reported. For instance, too much information was thought to be given (reported by 4 parents):

> *"It was mind-blowing at the beginning* [laughing] *while you just get your head around it, but actually what they make you do, they like change the cannula and then they make you do it. And then they send you away, and then you just practice and practice and practice."*
> [Mother of a boy aged 8 years; interview no: 22, lines 316-317]

In other instances, information provided in the session was thought to be complicated and hard to understand (reported by 4 parents). However, with the aid of other services, such as telephone contacts and educational materials (mailed to the families' home address before Pump School), families were more able to handle the training.

> *"Interviewer: How easy was it to understand the information you received from the hospital?*
> *Mother: Well as I said at the beginning it was difficult, but we saw the video, we got the book, we got the contact whenever we wanted to call them, so the service was for 24-hours when we started it."*
> [Mother of a boy aged 13 years; interview no: 6, lines 328-330]

8.4.4 Other services

In addition to the services described previously, the diabetes medical team at the hospital also provided the families with other services, such as 3-monthly clinic visits, email contact and other educational sessions or services.

8.4.4.1 Regular 3-monthly clinic visits

All families were assigned to see the diabetes consultants every 3-months for follow-up, monitoring and support (reported by several parents; N=14 and children/young people; N=14). Some parents and children/young people had positive views regarding this service. Parents felt that: the hospital team knew how to communicate with the children,

especially teenagers; gave families enough time during the appointment to discuss issues; made families feel relaxed and part of the team:

> *"That is good, they listen to us and they work with us rather than without us really. They know that parents are the experts on their child and they know their stuff that is the main thing. You know, they know their stuff, while other hospitals have not got a clue."*
> [Mother of a girl aged 9 years; interview no: 26, lines 309-310]

Regarding the 3-monthly clinic visits, the children and young people said they liked the play space provided for them and liked talking with the medical staff:

> *"I think the regular visits are helpful, because it tells me about my HbA1c and if I'm doing bad or good."*
> [A boy aged 13 years; interview no: 43, lines 377-378]

On the other hand, negative views were also reported, concerning either the diabetes team or the administrative service.

Many parents thought that the diabetes consultants did not usually focus on the issues that the families wanted to address, or they only focused on the medical problem without considering the emotional issues:

> *"I find conversing with the nurse is easier than with the consultants because they don't...A lot of problems with the pump are not of the pump itself, it is with the emotional side of my son. I don't always find that is taken on board* [by the diabetes consultants]. *That is my only negative about them."*
> [Mother of a boy aged 5 years; interview no: 11, line 342]

Within this context, many parents thought that diabetes nurses were more helpful, easier to talk to and more knowledgeable than the consultants. As a result, some parents would rather call the nurse and discuss their problems over the phone than travel to the hospital:

> *"I don't find the appointments very useful, because they are only looking at what was going on this week, and on this week I might not have any problems. It is the week before or the week after...They don't want to look at what I want to talk about you know, they don't want to look at that. I don't find the consultants very helpful,* [a nurse name] *is the only one that helps me, if she was not there, I would not bother going."*
> [Mother of a girl aged 15 years; interview no: 33, lines 402-404 & 495-496]

With regard to the administrative part of the service, some parents and young people (aged 13-17 years) complained about the difficulty in getting an appointment every 3 months, or about the long waiting time to see the consultants:

> *"Sometimes we have had long waiting at the clinic, their administrative side is not always the best."*
> [Mother of a diabetic twin aged 15 years; interview no: 30, lines 340-341]

> *"Sometimes it is a bit of hassle, because they have got a really bad working system, so sometimes we are a bit late, so we have to sit there for a while."*
> [A boy aged 15 years; interview no: 63, lines 285-286]

8.4.4.2 Email contact

Fifteen parents expressed their satisfaction with the email service which enabled them to contact diabetes consultants or nurses directly, for instance to double check things, or to send blood glucose readings for dose monitoring and adjustment. Parents also acknowledged the instant reply of diabetes team members to the emails they send. In addition, establishing one email address for the team, which was done lately, was acknowledged as helpful:

> *"I always used to email them individually and actually it is very helpful being able to contact them by email, for example because I don't necessary need to speak to them, it could be just 'this is happening or that is happening or something.' The diabetes nurses at the UCH have set up one email so you send an email in the hope that somebody will pick it up, that sort of thing."*
> [Mother of a boy aged 16 years; interview no: 24, lines: 327-328]

On the other hand, one parent thought that the nurses sometimes took a long time to reply to emails, which was not considered acceptable if there were urgent matters for consideration:

> *"But what I do find helpful is that I can email, and as I get better at it* [pump therapy], *I need more expert help. So sometimes when I'm in a big trouble, it takes quite a long time for them to sort it out. May be the advice they send in they might look at it and then might show it to the consultant and this consultant might sort it out."*
> [Mother of a girl aged 15 years; interview no: 33, lines 404-406]

Regarding children and young people, only one young girl stated that her mother usually contact the medical team at the hospital by emails, which she used more than the telephone. However, she could not express her opinion on the service, as she was not the one who used it.

8.4.4.3 Other educational sessions/services

Other sessions and services were also identified from what was reported by some parents (N=18) and children (N=6) during the interviews. Some of those were received at the initiation of pump therapy, such as meetings with a dietician, a play therapist and a psychologist, whereas others were received on either an occasional or regular basis (e.g. pump upgrade sessions, pump open days and annual reviews). Where reported, families appreciated these services:

> *"And then we had help from the psychologist and a play therapist to help my son with his cannula changes. The play therapist was fantastic with that* [blood glucose testing]. *My son did not seem to notice that he has it done, she did it better than I did."*
> [Mother of a boy aged 4 years; interview no: 27, lines 281 & 341]

> *"We did go on the 'expert pump users' day' which was very very good, and we went down for the day and we were with families that were all on pumps. That was really good and talking about that was really good. We had to speak because we learned a lot about exercises, it was just a little bit more; more than what we got on the pump day."*
> [Mother of a boy aged 11 years; interview no: 18, lines 290-294]

Some parents (N=9) and children (N=4) identified additional services that the diabetes team also provided, for instance providing the families with educational materials (e.g. booklets, DVDs, or websites), which were sent to their home addresses at the initiation of CSII. Participants thought that this was useful as it enabled them to read about insulin pump therapy before they actually went to the Pump School. In other cases, the diabetes team also recommended books and websites to some families for further information on diabetes and insulin pump therapy.

8.5 Recommendations and suggestions to improve the services

All families were asked to propose suggestions that could help to improve pump services provided at UCH. Fifteen parents and 19 children/young people made no suggestions or recommendations as they generally had high levels of satisfaction. The remaining participants, however, did provide some views **(Table 8.8)**.

Table 8.8: Suggestions/recommendations to improve services provided by medical team at UCH, as reported by parents (N=38)* and children/ young people (N=34)**

Service	Recommendations/suggestions to improve services	General suggestions/recommendations
Telephone contact	▪ More chance to contact the diabetes team during weekends ▪ Staff should be more reachable and accessible for emergencies	▪ Every child with diabetes should be given a pump from diagnosis ▪ There should be a regular support group at the hospital (i.e. regular meeting for families with children using pumps) ▪ More support should be given to families which are new to diabetes and pump therapy than to families who have been dealing with diabetes for longer duration ▪ **Make pharmacy waiting time for drugs shorter** ▪ For families with 2 children with diabetes, it would be easier to start CSII together ▪ **Families would rather the service is provided at local areas, so they wouldn't have to travel to London** ▪ Parents should be more involved in the care plan with the diabetes team ▪ Hospital needs to do more practical sessions rather than lecturing ▪ **Improve blood testing service** (make waiting shorter, staff should acquire skills to deal with the children when withdrawing blood); follow Great Ormond Street Hospital policy ▪ Allowing someone to test for blood in the clinic ▪ Hospital should tell families using injections at UCH about the existence of pump therapy as a treatment option for children and young people
School Contact	▪ Support families when children change/transition schools ▪ Diabetes nurses should assess knowledge and confidence of school nurses/staff ▪ Switch to pump therapy when children are at an age of school transition should not be done ▪ Government should allow one-to-one carers for children at schools	
Pump School course	▪ 2-day Pump School might not be enough, one more day might be needed ▪ Families should prepare themselves before they actually get the pump, so they would not get shocked by the amount of information on the training day ▪ Better if the training was for a few days and then to have a second week for a debrief and revision ▪ The training should be done for families with children of similar ages ▪ Medical team should also explain things to the children, not only to the parents	
Regular 3-monthly clinic visits	▪ **Administrative system for appointments should be improved (e.g. shorten waiting time to see consultants)** ▪ Medical team should be specific to the child's condition when giving advice and should cover issues that parents want to discuss ▪ Preferable if all appointments (psychologist, consultants, or dieticians) are assigned on the same day (so child would have less absence from school) ▪ Would rather appointments are more frequent than every 3 months ▪ Medical staff are always busy, which make parents embarrassed to ask them, therefore more staff should be made available	
Other services (e.g. email contact, psychologist and play therapist)	▪ Improve psychological consultation	

Words in bold refer to issues mentioned by both parents and children. Words in red refer to issues mentioned by children and young people only.

* Data are missing from 2 parents; 15 reported that they don't have any recommendation/suggestion because the services were excellent.
** Data are missing from 8 children/young people; 19 children/young people reported that they don't have any recommendations/suggestions because the services were excellent.

In the context of school contact, some families highlighted the need to assess the level of knowledge and confidence of school nurses/personnel:

> *"I think the only thing where we could have had more useful help, would have been when we changed schools, because the new school is bigger, busier and less able to focus on the child's needs, whereas the previous school had a slightly higher staff to students ratio. I think they* [school nurses/staff] *would have been good if the diabetes nurses here had been kind of assessed their knowledge early, and I think they might have detected that they are not actually generally comfortable with it* [pump therapy]*."*
> [Father of a boy aged 9 years; interview no: 35, lines 280-281& 302]

Within this context, recommendations were raised about not switching children to insulin pumps at the time of moving schools (e.g. from primary to secondary school). This was explained by the lack of support experienced from secondary schools, as their policy was generally to make older children take more responsibility for themselves at school. As a result, the child received neither support nor help from the staff at the school. Other families, especially those of very young children, recommended that a one-to-one carer should be made available at school, because young children cannot handle management issues themselves at school, and need to be watched closely.

Other recommendations were with respect to the Pump School training course. Although the training course was usually done with families of age-matched children, this was not always the case:

> *"I don't know, may be meeting more people like in your age, because when I did the training, they were not in my age."*
> [A girl aged 16 years; interview no: 51, lines 335-338]

Many recommendations and suggestions were obtained during the interviews from both parents and children with regard to the clinic visits, such as: improving the administrative system to permit shorter waiting times; making appointments more available and more frequent than every 3 months; scheduling the different medical appointments on the same day to reduce school absences and family travelling (for families living away from the hospital) and to provide more staff in the clinic:

> *"The appointment is after every 3 months and this is lots of time, I think. So it should be sooner than every 3 months. In Poland it is after every month in the beginning, then it is after 2 months. So it will be much more comfortable for me and my son's blood sugar levels to make this appointment a little sooner."*
> [Mother of a boy aged 8 years; interview no: 10, lines 441-444]

> *"And the distraction it provides to the school and things. For example, we have been seeing a psychologist as well, so it would have been so nice for those things to be tied up on the same day rather than 3 or 4 days apart coming backwards and forwards."*
> [Father of a boy aged 9 years; interview no: 35, line 315]

> *"Well I know when we first go there* [to the hospital] *they just had problems with scheduling and everything, because there were just tons of people there and then the appointments, there are problems with the appointments scheduling a little bit. They have changed that; the whole got a lot better, but that is the only thing."*
> [A girl aged 14 years; interview no: 40, line 259]

Moreover, not all of the educational sessions (e.g. with a dietician and a psychologist) were done as the families expected them to be:

> *"The psychologist counseling I thought it was a little too much 'motherhood and apple pie,' I was looking for more tangible help."*
> [Mother of a girl aged 10 years; interview no: 36, lines 250-251]

Some parents also emphasised the need for a regular support group at the hospital where they would have an opportunity to meet other families

> *"They should let there be some support group within the hospital, you know if you have a baby you can read about how to look after a baby, how to change a nappy, or how to feed them, but the real support comes from speaking to other Mums who say 'did you try this?' It is that general personal support, and this is what people get comfort from and they learn from each other. This is what we need to do, we need a greater support group within the hospital."*
> [Mother of a girl aged 12 years; interview no: 4, line 642]

Specific recommendations were made by families who had two children on insulin pump therapy. Out of the three families in the sample, 2 parents highlighted that it would be easier to assign the children to the pump at the same time. This was because insulin pump therapy required hard work and frequent blood glucose testing/monitoring, which was hard to repeat:

> *"It would be much easier if I put them on the pump at the same time, because I had 'x' number of days or weeks being up 24-hours testing the sugars and then I had to do it all again. So if I had done both together, it would be easier."*
> [Mother of diabetic sons aged 8 and 12 years; interview no: 15, lines 152-154]

In other cases, parents emphasised that they should be involved in the management plan of their children. Parents felt that they understood how their children responded to treatment more than the medical team:

> *"I think they should involve the parents more. I think that there has been a concerted effort to keep parents apart."*
> [Mother of a girl aged 12 years; interview no: 4, line 641]

Some parents and children shared the opinion that the blood testing procedure inside the hospital was not as good as it could be. Accordingly, service improvement was highlighted. Within this context, a family who were having appointments at the Great Ormond Street Hospital recommended their policy should be followed when performing a blood withdrawal procedure:

> *"It is hard because I would then compare them with Great Ormond Street which is a children's hospital. There are a lot of things they do in Ormond Street that they could do here. For example, blood testing. You know, they have two people one person to do the blood test and one person to occupy the child with books, bubbles and televisions. When we were at the UCH, we were in a very busy blood room, all adults. No one cared that my son was a child, they were very short tempered with him. They did not care that he was a child."*
> [Mother of a boy aged 5 years; interview no: 11, line 349]

Many families in the sample of the current study were not living close to UCH. Within this context, 12 parents and 3 children commented during the interviews on the long distance (up to 338 mile round trip) they needed to travel to get to the clinic. Accordingly, some families highlighted the need for a similar service in their local areas. Some families did not know about the existence of pump therapy service at UCH, although injection therapy was received there. Therefore, suggestions were made that the medical team should inform parents about insulin pumps as a treatment option for the management of T1DM for children and young people. Other suggestions were also provided, as described in **Table 8.8**.

8.6 Discussion

Managing diabetes for children and young people using insulin pump therapy requires an integrated and coordinated service delivered by a multidisciplinary team to maximise treatment outcomes. To our knowledge, this is the first study that explores the perspectives of children, young people and parents using the insulin pump services provided at a major teaching hospital. Knowing how the services are perceived by the families will help inform healthcare providers seeking to improve the services and will identify gaps in the current service provision, leading to better user satisfaction and optimum treatment outcomes.

In agreement with several qualitative studies in the literature (Maniatis et al, 2001b; Sullivan-Bolyai et al, 2004; Low et al, 2005; Olinder et al, 2007; Wilson, 2008), the source of recommendation for initiating CSII, and the reasons for the switch to pumps were identified from some interviews with parents and children/young people in this study. Many, families were introduced to the idea of using an insulin pump either by their local hospital, or informally following a recommendation from a friend, an internet site, diabetes camps, or a pump-manufacturer representative. Parents, especially mothers, were the main source from which the children learned about the use of insulin pumps to manage T1DM. Although this study did not aim to examine the level of children's participation in the decision-making process, some children in the sample seemed not to be involved in the process. This was referred to by 2 boys (aged 11 and 16 years) who stated that assigning them to insulin pump therapy was solely their mother's decision (one of those mothers worked as a nurse). These findings are contrary to the recommendations of the NSF for children and young people, which clearly states that hospital services should be child-centered and children should be encouraged to be actively involved in the decision-making process with regard to their health and care, and where possible, they should be given the opportunity to exercise choice (Department of Health, 2003). A recent systematic review, carried out to critique the existing literature on children's, parents' and healthcare providers' experiences of children's participation in decision-making at heath service level, concluded that the involvement of children was marginal and recommended further research in this area (Coyne, 2008).

Identifying issues concerning parents and their children at the time that pump therapy commences is crucial to enable healthcare providers to deliver the appropriate support and ease the transition to pumps. In this study, the most critical and worrisome issue for some parents and children with regard to using insulin pumps, was the cannulas. Parents were worried that the cannula would be in place continuously in the child's body, while children were scared about the painful procedure of cannula insertion. Some parents also had concerns with regard to: the complexity of the device; trusting a machine; interference of the pump with the child's physical activities; the size and weight of the device; children breaking the device. Similar worries were also documented by parents in a study conducted by Sullivan-Bolyai et al (2004). In this study, the healthcare providers used strategies that helped families to overcome such fears. For instance,

children and some parents wore a pump containing saline before CSII initiation to see how it would feel wearing it. Moreover, hospital staff supported the children by showing the procedure on a demonstration dummy, of how to insert the cannula, in order to overcome their fears. The findings from the current study suggest the need to conduct further detailed studies investigating issues that worry the users of insulin pumps, and their parents, and find ways to support such families before and at the onset of CSII use.

The services offered at the start of insulin pump therapy at UCH described in **Section 8.1**, were based on a paper published by one of the DSNs at the hospital (Thompson, 2008). This is the first study to explore children's and their parents' perspectives about the insulin pump therapy programme developed at UCH. Most of the feedback from both the children and their parents regarding these services was positive. However, some drawbacks were reported. In many cases, views on different services, especially those delivered at the onset of pump use were not articulated by many children, as they were young at that time, and their parents took care of everything related to the management of their condition.

The hospital provided 24-hour telephone contact, especially for families who were new to using insulin pumps, where they could contact the medical team at any time, including night times and at weekends. With ongoing therapy, families were offered an 'office-hours' service, from 9:00 AM to 5:00 PM, week days only. Most of the parents and many of the children thought that the service was excellent, as it enabled families to double check issues and solve problems experienced on a daily basis, over the phone with the help of the medical nurses or consultants. On the other hand, a few families thought that non-availability of the diabetes team during weekends or out-of-working hours was a major drawback. Some had experienced situations where they desperately needed to contact the medical team, but only a registrar who was not knowledgeable about diabetes was available. A few parents felt that the medical nurses took a long time to reply to their contacts, which was not helpful in urgent situations, while others complained that medical staff were sometimes unable to answer their questions or queries. Many of the parents recommended making the diabetes team available and accessible during weekends and during out-of-working hours times.

In terms of the contact of the hospital with the schools, most parents and many children reported that the medical nurses were excellent at educating the school staff about the children's condition, and how to help with managing their condition at the school. Cases where the school personnel were not cooperative were however reported. Educating and training school personnel is important, as research has shown that children with diabetes who were cared for by trained school personnel had better therapeutic outcomes than those who were cared for by untrained staff (Wagner et al, 2006). The impact that educated school personnel had on the glycaemic control was not an objective in this study, and hence was not investigated. Families believed that the contact between the hospital and school personnel should be continuous (e.g. encompassing changing/moving school), though this was not the experience for all families in the sample, as some children as well as parents stated that the contact was restricted to the start of insulin pump therapy only.

The views of the parents regarding the amount of information provided to the school staff varied in the study. Some parents caring for children at nurseries thought that the information given to the nursery staff by the hospital nurses was extensive and detailed, while other parents, caring for school-aged children, thought that the hospital nurses did not provide sufficient information to the school personnel. This discrepancy in parents' views could be related to the fact that children at nurseries in many cases attended only for a few days a week (e.g. 3 days/week) and for short time (e.g. 3-hours). Accordingly, great detail was not considered necessary; parents believed that nursery staff only needed to know tips about how to care for the child and what to do in emergencies. On the other hand, school-aged children spent most of the day at school and hence parents thought the school staff should know as much as possible about the child's medical condition and how to care for them. Within this context, a recommendation was made for the diabetes medical team to assess the knowledge and skills of school personnel to ensure their competence in caring of children using pumps at schools. Other recommendations were extending the school contact service to include times when children change schools, as this did not happen for all families in the sample. Moreover, many parents, especially those caring for younger children, recommended the need for the Government to provide a one-to-one carer for their children at schools.

From the interviews, it was apparent that that nurses, in most cases, contacted schools before children actually started the therapy with insulin pumps. However, this was not the case for all the families, as in a few instances, children started going to the school with the insulin pump before the hospital could actually contact school personnel and provide them with education and training. This may be related to poor organisation within schools, or due to the fact that the school personnel were in some cases uncooperative with the hospital nurses, as experienced by some families. Accordingly, findings from the current study suggest the need to develop a more interactive system to contact, educate and train school personnel about the burden of diabetes in the paediatric population, and the need for cooperation between health and education institutes to help children, young people and their families address any problems, improve glycaemic control and provide maximum support and care during the school day.

The Pump School training course was one of the services provided by the diabetes medical team at the onset of pump initiation. Two to three families of age-matched children were usually invited to UCH to receive education and training on using insulin pumps (Thompson, 2008). Most of the parents and many of the children agreed that this service was very useful, as families were taught about pump therapy and its applications. However, some negative points of view were expressed with regard to the service. It was noticed that in some cases, more than 3 families or families with non age-matched children brought together for the training. Many parents and children articulated that doing the Pump School session with other families allowed for sharing experiences. However, several parents thought that the involvement of more than 2-3 families would not be appropriate, because medical staff would not be able to satisfy all queries raised during the session, resulting in the session being less useful than was currently the case.

Only 2 families thought the training course was not good, as they believed that some of the medical staff encountered lacked knowledge and skills, and did not appreciate that parents knew a great deal about their children. Both of these families were early receivers of the service at the hospital; the service was newly initiated and improvements and developments (e.g. increasing educational materials and being more comprehensive) have since followed. This was confirmed by those 2 families which

reported that the medical staff must have developed their knowledge and skills by now, compared to the time when they had started on the programme.

With regard to the Pump School service, different recommendations were made by the parents and their children. Parents recommended doing the session with other families, but not exceeding 3, and some suggested extending the training over several days. Children recommended doing the course with families having age-matched children and some emphasised that the medical staff should conduct the education and training using language that was appropriate to promote their understanding. This in turn, highlights the need to enforce the established policy of incorporating 2-3 families having age-matched children in the Pump School course conducted at the hospital. It was not clear during the interviews at what age the children were included in the training course with the parents, as it seemed that in some families, the parents were only the ones who did the training, while the children stayed in the play room. In the future, conducting the training course with families of sex-matched children might be considered, as there may be different issues concerning different sexes. In addition, issues accompanying puberty, such as self-consciousness, differ among girls and boys, which in turn suggest that the different sexes might need different kinds of support.

Many comments were obtained from parents as well as children with regard to the 3-monthly clinic visits at the hospital. Many parents as well as the children/young people agreed that the administrative system (i.e. appointment scheduling and clinic waiting time) needed to be improved. Moreover, travelling to the clinic was an issue that concerned families who lived away from the hospital, or outside London, as many children as well as parents would have preferred a similar service to be provided in their local areas. Parents also felt that scheduling different medical appointments (e.g. eye examination and psychological consultation) on separate occasions was very disruptive to the child's school life, and recommended that all appointments could occur on the same day. Others thought that the medical appointments with diabetes consultants should occur more frequently than 3 months, as many issues could arise in a 3-month period which parents would need to discuss in a face-to-face situation, regardless of the availability of email and telephone contacts.

Other recommendations were that families who had 2 children using insulin pumps would find it easier to start the CSII with the two children at the same time. They justified this with the fact that starting insulin pump therapy requires frequent blood glucose testing and monitoring to adjust basal doses, which included night-time and it would be easier for them to do it at once rather than repeating it for each child separately.

A psychologist was provided for the children and young people receiving insulin pump therapy at the hospital (as reported by some participants). However, many parents highlighted the need for providing psychological support groups at the hospital. In agreement with our findings, an audit was carried out recently by the diabetes team at the hospital to explore parents' views of creating psychological groups as a part of the paediatric service at the hospital (Christie et al, 2008). The audit highlighted that the majority of parents were interested in participating in the psychology group and emphasised the need for service providers to consult with service users when developing such a service.

The importance of integrating the medical care with educational and psycho-educational interventions for children and young people with T1DM has been indicated in a systematic review conducted by Hampson et al (2001). Insulin pump therapy at UCH was initiated and overseen by a multidisciplinary team where an integrated medical, educational, and psychosocial care was provided to the children and their families.

CHAPTER 9 – Overall discussion and conclusion

Chapter 9: Overall discussion and conclusion

This chapter provides an overall review of the findings presented in this research and discusses how they could contribute to health policy in the UK. Implications for clinical practice and future research are also highlighted.

9.1 Overview of the study findings

Conducting this study was vital as there is scarcity of published studies on the users' perspectives, and as the use of insulin pumps is still limited in the UK, regardless of the growing data supporting their safety and efficacy (Nahata, 2006; Jeitler et al, 2008; Pickup & Sutton, 2008; Churchill et al, 2009) **(Chapter 1)**. This study aimed to document the experiences of children and young people, and their parents, using insulin pumps to manage T1DM, and to examine the extent to which switching to insulin pumps from injections enables health policy goals to be achieved. This is vital for revealing benefits and concerns in the context of using insulin pumps, and in informing recommendations for their future use in children and young people.

Results from the study showed that insulin pump therapy provided better therapeutic outcomes, manifested by reduced HbA1c levels compared to injections without increasing risk of infections, allergies, or other problems associated with their use. Children and young people had greater mastery and involvement in diabetes management tasks with insulin pumps than they did with the injections. Such autonomy was reflected not only in their home and social lives, but it was also manifested in the context of school life. Overall, the use of insulin pumps enabled children and their families to have more 'normal' lives compared to the situation when injections were used. This was attributed mostly to easier use, the ability to adopt a more flexible lifestyle and improved therapeutic outcomes.

9.2 Study findings in the light of the current government policies

9.2.1 Government policies regarding the health of children and young people

In 2010, the NHS White Paper: 'Equity and Excellence: Liberating the NHS' was published to illustrate the new Government's vision for delivering health services (Department of Health, 2010a). The White Paper stated that in the past, the NHS did not always put the needs of patients the first, as patients were expected to fit around the services rather than services around the patients. Moreover, the focus on the outcomes

in the system did not necessarily produce benefits for children and young people. The new Government's vision is that patients, including children and young people and their families, are to be considered at the heart of everything. They are expected to share fully in decision-making, to have real choices and to be empowered and enabled to make decisions about their own care. Along with the White Paper in 2010, the Department of Health published a document: 'Achieving Equity and Excellence for Children: How Liberating the NHS will help us Meet the Needs of Children and Young People' to illuminate how the proposed new arrangements for the NHS could improve health services for this group of patients (Department of Health, 2010b). In this document, the importance of hearing the voice of children and young people, and their families, is emphasised by offering them the opportunity to express their views and experiences regarding the therapy and services they receive. Within this context, conducting this study was very timely as it enabled children of different ages and their families to document their experiences of using insulin pumps as a new method of insulin delivery, in the context of their health and lives, and to report their perspectives on the services delivered from a major specialised centre in London; UCH.

Findings from this study provide valuable data indicating that the use of insulin pumps to manage T1DM of children and young people was associated with improved therapeutic outcomes and lifestyle. Children, young people and their families were able to have a more normal life compared to when using injections, manifested in the context of home, school and social lives. This is vital as a fundamental goal of the NSF for children and young people is to promote high quality care that meets the needs of children/young people, and their families, to enable them lead more normal lives (Department of Health, 2007c). Accordingly and with the support of the findings from the current study, considerations should be given for the wider use of insulin pumps for children and young people.

The use of insulin pumps in the UK is still limited (Department of Health, 2007a; Pickup, 2009), even though modern pumps have been available since the 1990s (Alsaleh et al, 2010). After the publication of NICE guidelines in 2003, the number of pump users increased (from 1000 to around 2500), however, it was still forming less than 1% of the total T1DM patients and around 0.1% in children and young people (Hammond, 2005; Department of Health, 2007a). The limitation of pump usage was

attributed to the restrictions proposed in the guidelines, requiring treatment failure on MDIs before the initiation of insulin pump therapy. Recently, NICE has changed its guidelines to allow greater flexibility for therapy initiation, so that children (aged less than 12 years old) no longer need to fail when using MDIs (i.e. CSII can be started if the use of MDIs is considered impractical or inappropriate) (National Institute for Health and Clinical Excellence, 2008a), which in turn should allow greater uptake by patients of this therapy option. Within this context, findings from the current study highlight the desirability of the wider use of insulin pump therapy, allowing children of different ages (0-17 years) better lives and improved glycaemic control compared to the injections. Results from this project have shown that even for patients for whom the target therapeutic outcomes were not achieved, almost all children/young people and their parents preferred their use over injections due to lifestyle advantages. Such advantages made the families willing to continue the therapy, regardless of the hard and continuous work associated with management of diabetes using insulin pumps. Insulin pumps also allowed children of different ages greater autonomy and independence from parents compared to injections, which is a central goal for the NSF in the UK (Department of Health, 2001).

9.2.2 Government policies concerning the use of medications within schools

The education and school setting for children with chronic illnesses, such as diabetes should be considered. Children and young people spend almost half of their waking hours at school, therefore supporting them in this setting is essential. Although Government policy in Britain emphasises the importance of developing integrated services around the home, social and school lives of children and young people, that are responsive to their needs and perspectives, and that of their parents (Department of Health, 2003), the policies relating to support for taking medication at school is still limited. The NSF for Children, Young People and Maternity Services (Department of Health, 2004b) highlighted the importance of schools putting in place arrangements for the management of medications at school. However, this point was not further elaborated upon. The most comprehensive guidance within this context has been the publication of: 'Supporting Pupils with Medical Needs: A Good Practice Guide' (Department of Education and Employment, 1996). In this publication, parents were given the responsibility to supply the school with information regarding the health status and medical needs of their children, and head teachers within the school were

made responsible for the medical needs of those children. However, the extent and nature of this responsibility was neither elaborated upon nor discussed.

In this study, children and young people, and their parents, reported diverse experiences of the support they received at school regarding the use of insulin pumps to manage T1DM. No standardised policies were followed across different schools for the level of school personnel involvement when caring for the children and young people using pumps. Moreover, some difficulties were reported by some participants in obtaining a statutory Statement from the LEAs required for a one-to-one carer for the children at school. This is contrary to the Education Act 1996 that indicates children with SENs should receive all the support that meets their needs at school (Department for Education and Skills, 2001). From the results of this study, clearer policies with regard to supporting children with medical conditions, including those with T1DM, at school is highly recommended. Moreover, the implementation of policies regarding the use of medication at school is also strongly recommended. The reasons behind the unwillingness of some LEAs in the UK to provide a statutory Statement should be further researched and addressed.

Although the results from the current study showed that a form of partnership existed between home, school and hospital to support the children using their pumps at school, the partnership was not consistent across the cases. Within this context, the Department for Education and Department of Health should work together, and with the parents, to find out most appropriate ways for supporting children and young people using their medications at schools, as that will help to maximise educational and therapeutic outcomes. Such partnerships could involve other voluntary organisations (e.g. voluntary diabetes organisations) as found in this study. Further research would be interesting to examine more deeply the differences in the services and support provided to the families across hospital and school settings, in order to identify gaps and hence facilitate collaboration between different settings in order to achieve maximum support and provision of services.

9.3 Considerations for the wider use of insulin pumps in the UK

This study has provided a strong evidence in favour of wider use of insulin pumps for children and young people with T1DM, which go alongside with new NICE guidelines published in 2008 (National Institute for Health and Clinical Excellence, 2008a).

However, some factors should be considered to support such a spread of this challenging therapy.

Although the use of insulin pumps had positive therapeutic and lifestyle outcomes for the majority of families who participated in the study, in a few cases, this was not the case. Many factors could have played a role in families not attaining the benefits from the therapy, such as the level of support they received from hospital or school; variable abilities of families to control situations and the particular circumstances of family/child when insulin pumps were commenced (e.g. puberty, travelling, or transferring between schools). This suggests that different families might need different levels of support. In addition, the timing for initiating pump therapy should be taken into consideration.

This study is valuable in describing experiences of the families at different stages of the therapy (i.e. at the onset of the switch to pumps and during ongoing therapy). Many problems were encountered with regard to glycaemic control and accommodation to therapy responsibilities at the start of insulin pump therapy. This was true for the majority of families participating in the study, regardless of the support they received from the hospital at the time. This raises the question as to whether other kinds of support were required during this critical period; not only from the hospital but also from other sources. For instance, the involvement of other relatives or friends in supporting families might be helpful. Moreover, more extensive support from schools during this period would be important in meeting the educational and/or medical needs of the children. Children, during the switch to pumps, might pass through a period of uncontrolled blood glucose which in turn may affect their school performance. Schools could take that in consideration and make appropriate arrangements for accommodating the educational needs of those children. Moreover, current advances in medical therapy entail the use of technology (e.g. insulin pumps) that require in addition to knowledge about the disease, skills and familiarity about handling devices. Therefore, the care of children at school by school personnel who volunteer to do so, as is the case in many schools, might not be appropriate. Appropriate care for technology-dependent children at school should be undertaken by professionals who have the skills and knowledge to deal with situations (although evidence from this study suggest that young people, aged 13-17 years, were largely responsible of managing the technology themselves).

Therefore, the widespread availability of trained school nurses is crucial and should be considered by the Government.

In the current study, UCH, London was selected as a major centre of excellence in delivering insulin pump services for children and young people. It was recognised that patients from different parts of the country travelled to receive the therapy, as such specialist centres were not available in their local areas. Therefore, one of the recommendations made by some parents and children was to have a similar service available in the local hospitals. NICE estimates that with the recent changes in the guidelines for pump initiation, 8-15% of adults and children over 12 years and 15-50% of children under 12 years will be eligible for starting pump therapy in the next 3 to 5 years (National Institute for Health and Clinical Excellence, 2008b). This means that the number of insulin pump users will increase across the country. There will be a need for more specialised centres offering appropriate service, especially since NICE requires the service to be implemented by a trained specialised team. Diabetes specialist professionals need to be encouraged and supported in establishing local pump services and stakeholders should make the provision for adequate funding. The first step towards achieving this is to address variability in service provision by undertaking a national audit of the use of CSII in paediatric and adult centres in order to identify the gaps. Then funding, cost-effectiveness and other barriers preventing access of patients with T1DM, including children and young people, to this challenging but desirable method of therapy should be adequately addressed and evaluated.

Results from this study showed that insulin pump therapy programme implemented at UCH had great users' satisfaction. By considering the recommendations and suggestions that were given by parents and children/young people, further improvements can be introduced to the package of services provided by the hospital. Within this context, the study findings suggest the applicability of the insulin pump therapy programme (at UCH) as an appropriate model for pump users, and hence for extension of the service to other centres across the country.

9.4 Conclusion

Parents and children using CSII found it easier to lead normal lives compared to when they had used injections, by being able to maintain glycaemic control and accommodate a more flexible lifestyle, which is a central goal of health policy for children and young

people in the UK. As the use of insulin pumps is still limited in the UK (Department of Health 2007a; Pickup, 2009), findings from the current study will inform decisions concerning this method of insulin delivery as a treatment option for families with children diagnosed with T1DM.

9.5 Implications for clinical practice

The current study aimed to provide insight into the experience of using insulin pumps, from users' perspectives, by addressing issues and problems that emerged in the context of their lives at different stages of therapy (transition from injections and during ongoing therapy) and across different environments (e.g. home, school and work), and how these impacted their lives. The main value of this research was that children's and young people's voices and those of their families were heard, so that healthcare providers and policy makers can gain appropriate understanding of their lives. Greater insight and understanding should enable stakeholders to provide children and their families with appropriate support and advice in the provision of health, education and family-centred services, as advocated by British health policy (Department of Health, 2003).

9.6 Study limitations

The current study had the following limitations:

- Interviews were initially planned to be conducted with parents and children separately and at their homes, as they represent a more relaxed setting for expressing views in the context of daily lives. However in practice, some families preferred to undertake interviews at hospital. Where interviews were conducted at the hospital, time limitations and distractions by others were issues that challenged the interviewer. Moreover, conducting interviews with children and their parents separately was not possible in most of these cases.
- Clinical data (HbA1c readings) were collected retrospectively from medical records of the patients. Accordingly, time intervals for collecting blood samples were inconsistent for each patient and across all patients. As a result, several patients (N=6) were excluded from quantitative analysis due to missing data.
- Interpretation from multiple quantitative testing versus time should be undertaken with care, because the sample became smaller as the period of follow-up increased.

- Only 2 children in the sample (aged 5 years old) comprised the group of children aged 5-7 years and hence the perspectives of children in this age group were not widely represented.
- The study had a cross-sectional design. Conducting a follow-up study might be more helpful especially with regard to assessing autonomy and transfer of responsibilities when undertaking management tasks.

9.7 Implications for future research

The following are the implications from this study for future research:

- This study used pre/post-pump values to examine effectiveness of insulin pumps in achieving glycaemic control. There are few RCTs conducted within this context and consequently more are recommended.
- Conducting longitudinal studies would be beneficial in providing a better understanding of the lived experience using insulin pumps, especially with regard to the development of autonomy and mastery of management skills.
- The current study provided reports from parents and children about their lived experience of using insulin pumps. Future studies should also collect data that explore the perceptions of other family members (e.g. siblings) and compare those with the perceptions of parents and children. Exploring perspectives of school nurses/personnel assisting children using insulin pumps will also provide valuable data on the concerns and problems that arise in the school or nursing context. Better understanding of the experiences of school personnel/nurses will enable the appropriate support and guidance to be provided.
- Exploring the perspectives of the parent versus the child in each family is vital. This would give an insight on how the parent-child partnership was operating with respect to undertaking management responsibilities. Also it would allow identification of any conflicts that arise in the context of family life and circumstances. The impact of such conflicts on the children's progress towards autonomy in self-management should also be investigated.
- This study did not aim to consider the sex of patients as a variable for responses, therefore, performing a similar study but examining differences between male and female patients is recommended.
- This study suggested that 3 factors might affect children's progress towards autonomy (age, task complexity and duration of pump therapy). Examining the

effect of other factors, such as: sex, motivation and parental educational level is recommended.

- The modified model of Buford for responsibility transfer **(Chapter 5)** and the framework for impact on family life **(Chapter 7)** could be tested for their applicability to children with other chronic illnesses. This would enable researchers to understand how the unique characteristics of different chronic illnesses might affect sharing responsibilities between parents and their children and how that might impact on family life.
- In general, the impact of using insulin pumps was positive on the different aspects of life, as reported by the majority of participants. However divergent views were obtained with regard to some issues that emerged from the interview (e.g. relationship between spouses; leaving children with others; wearing pump and self-consciousness or bullying; stress and concerns). Accordingly, insufficient data were gained in these areas and further investigation is recommended.
- Further studies are needed to explore the issues worrying candidates of insulin pumps before onset of pump initiation. This will help to provide appropriate support for families and allow easier switch to pumps.

9.8 Insulin pumps and Kuwait

T1DM is a common metabolic disorder of increasing incidence and prevalence among the Kuwaiti population, including children and young people (Shaltout et al, 2002; Moussa et al, 2005). Very recently, insulin pumps have been introduced as a treatment option for children and young people in Kuwait. However, the use of this technology is still in its infancy and there are no available reports on their use or the treatment outcomes among patients with T1DM, including children and young people. Given that the culture and social background of Kuwaiti patients may be different from those in previously published international insulin pump studies, it would be interesting to determine whether the benefits of this new technology are also seen across the Kuwaiti population. Therefore, with the paucity of research concerning this technology in Kuwait, conducting a similar study in Kuwait will be of a great interest.

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Appendices

APPENDIX 1: Literature review of studies of using insulin pumps in children and young people

Literature review of insulin pump studies performed in children and young people

Study	Description	N/Age (years)	Design	Measured outcomes
Tamborlane et al (1979)	Assessed efficacy and safety of CSII in brittle juvenile diabetics	N = 7 Age: 12-17	Prospective study	Mean plasma glucose concentration and fluctuations, hypoglycaemia
Rudolf et al (1982)	Evaluated efficacy and psychosocial impact of CSII compared to MDIs in teenagers	N = 7 Age: N.A	Prospective study for 6 months	HbA1c, psychosocial impact (depression, self-esteem, diabetic adjustment, social adjustment)
Bougnères et al (1984)	Compared efficacy of CSII versus CIT in children with unstable metabolic control	N=6 Age: 1.4 -4.4	Prospective study for 6 months	HbA1c, hypoglycaemia, psychological wellbeing
Flores et al (1984)	Evaluated efficacy of CSII compared to MDIs in newly diagnosed children	N = 15 Age: N.A	Randomised study, follow-up for 1 year	BG, insulin requirements
Schiffrin et al (1984)	Evaluated efficacy of CSII compared to MDIs and combined CSII-MDIs in adolescents	N = 20 Age: N.A	Prospective, controlled study for 1 year	HbA1c, patients' acceptability
Knight et al (1985)	Tested safety of CSII compared with CIT in adolescents and adults	N = 65 Age: 16-59	Feasibility study for 3 years	DKA
Brink and Stewart (1986)	Examined efficacy and safety of CSII in children, adolescents and young adults	N=24 Age: 8-26	N.A	HbA1c, DKA, electro-mechanical problems, patients' errors, local skin irritation
Knight et al (1986)	Evaluated efficacy and discontinuation rate of CSII in adolescents compared to adults	N= 45 Age: N.A	Feasibility study for 1 year	Glycaemic control, discontinuation rate
Bak et al (1987)	Assessed efficacy of CSII (pump) compared to MDIs (pen) in young patients	N = 20 Age: N.A	Prospective crossover study for 6 months	Metabolic control, insulin requirements, patients' acceptability
Connis et al (1989)	Assessed changes in cognitive and social functioning in different age groups (children and adults) of pump therapy compared to CIT	N = 30 Age: 10-47	Controlled study for 6 months	Physical, cognitive, psychosocial , and social health functioning

De Beaufort et al (1989)	Evaluated efficacy and safety of CSII compared to CIT in newly diagnosed diabetic children	**N:** CSII = 15 CIT = 15 **Age (mean ± SD):** CSII group: 9.5 ± 4.2 CIT group: 7±3.6	Randomised prospective study, follow-up for 2 years	HbA1c, SH, DKA, discontinuation rate
Slijper et al (1990)	Evaluated psychosocial impact of CSII compared to CIT in newly diagnosed diabetic children	**N:** CSII= 15 CIT=13 **Age (mean ± SD):** CSII: 12±4 CIT: 10±4	Randomised study for 2 years	Psychosocial parameters (for children and their parents): Junior-dutch personality test, WISC-R intelligence test, family relation test, family interaction scale, acceptance assessment scale, diabetes questionnaire
Steindel et al (1995)	Assessed efficacy and cost-effectiveness of before and after use of CSII in children and adolescents with chronic poorly controlled T1DM	**N:** Group A: non-adherent to diabetes regimen = 4 Group B: children with brittle diabetes =2 **Age:** Group A: 12-16.5 Group B: 8.5-10	Non-randomised retrospective study	HbA1c, insulin requirements, hypoglycaemia, DKA, number of hospital admissions, costs
American Diabetes Association (1996)	Compared quality of life with CSII and MDIs with CIT in both adults and children	N = 1,441 Age: 13-39	RCT	Quality of life
Boland et al (1999)	Evaluated efficacy, safety, and psychosocial impact of CSII compared with MDIs in adolescents	N = 75 Age: 12-20	Prospective study for 1 year	HbA1c, hypoglycaemia, psychosocial parameters: quality of life, depression, self-efficacy, coping
Maniatis et al (2001a)	Evaluated efficacy and safety before and after use of CSII in children and adolescents	N = 56 Age: 7-23	Feasibility study	HbA1c, hypoglycaemia, BMI

Ahern et al (2002)	Examined efficacy and safety of CSII compared to MDIs in large group of paediatrics	**N:** preschoolers (< 7 yr)= 26 School ages (7-11) = 76 Adolescents (12-18)= 59 **Age:** 1½-18	Prospective study for 1 year	HbA1c, insulin requirements, SH
Litton et al (2002)	Evaluated efficacy and safety of CSII compared to MDIs in toddlers and pre-school children	N = 9 Age: 0.8-3.3	Retrospective study for 1 year	HbA1c, hypoglycaemia, BMI
Saha et al (2002)	Evaluated efficacy and safety of CSII compared to CIT in children and adolescents with poor glycaemic control	N = 16 Age: N.A	Retrospective study	HbA1c, hypoglycaemia, DKA, treatment satisfaction
Hathout et al (2003)	Assessed efficacy and safety pre and post-CSII in children and young people	N = 36 Age: 10-20.5	Retrospective study for 1 year	HbA1c, hypoglycaemia, DKA, insulin requirements, BMI
Rami et al (2003)	Compared efficacy and safety of CSII with CIT in toddlers	**N:** CSII = 6 CIT=6 **Age:** less than 3	Case control feasibility study for 1 year	HbA1c, DKA, SH
Plotnick et al (2003)	Evaluated efficacy and safety pre and post-pump in children and adolescents	N = 95 Age: 4-18	Retrospective chart review, then follow-up for 2.3 years	HbA1c, DKA, emergency department visits
Pozzilli et al (2003)	Evaluated metabolic effects of using CSII at diagnosis compared to MDIs in young people and adults	N=19 Age: 12-35	Pilot, randomised study for 2 years	HbA1c, insulin requirements, C-peptide secretion
Sulli and Shashaj (2003)	Evaluated efficacy and safety pre and post-CSII in children and adolescents	N = 40 Age: 4-25	Prospective study for 6 months	HbA1c, hypoglycaemia, insulin requirements, DKA, BMI
Weintrob et al (2003)	Compared efficacy, safety, treatment satisfaction, and quality of life of CSII compared to MDIs	N = 23 Age: 9.4-13.9	Randomised open crossover feasibility study	HbA1c, DKA, hypoglycaemia, BMI, quality of life, treatment satisfaction

Weissberg-Benchell et al (2003)	Compare efficacy, safety, psychosocial impact of CSII with MDIs and CIT in adults, adolescents and children	N = 1,547 Age: N.A	Meta-analysis (52 studies)	HbA1c. hypoglycaemia, DKA, pump malfunction, local skin infection
Willi et al (2003)	Examined the effect on parameters affecting long-outcome of T1DM pre and post-CSII	**N**=51 **Age (mean±SD):** 10.7±3.1yr	Prospective study for 1 year	HbA1c, BG, BMI,
Alemzadeh et al (2004)	Evaluated effects of CSII compared to flexible MDIs	**N:** CSII = 40 MDIs = 40 **Age:** CSII= 10.1-17.8 MDIs: 10.3-17.3	Case-control study for 1 year, matched by age and sex	HbA1c, insulin requirements, hypoglycaemia, BMI
Battelino et al (2004)	Evaluated efficacy and safety of CSII in children and adolescents	N=186 Age: N.A	Prospective, observational study	HbA1c, SH, DKA
Colquitt et al (2004)	Examined clinical and cost-effectiveness of CSII versus MDIs in children and adults	N: N.A Age: N.A	Systematic review of RCT and randomised and non-randomised crossover trials	HbA1c, insulin requirements, BMI, patient's preference, quality of life, adverse effects, cost-effectiveness
DiMeglio et al (2004)	Compared efficacy, safety, and treatment satisfaction of CSII with MDIs in diabetic preschool children	**N:** CSII = 21 N MDIs =21 **Age:** 1.8-4.7	Prospective; RCT for 6 months	HbA1c, blood glucose variation, hypoglycaemia, BMI, treatment satisfaction
Doyle et al (2004)	Compared efficacy of CSII with MDIs in youth	N= 32 Age: 8-21	Randomised prospective trial (short-term study; 16 wreaks)	HbA1c, insulin requirements
Shehadeh et al (2004)	Tested efficacy, safety, quality of life, and treatment satisfaction of CSII compared to MDIs in children	N = 15 Age: 1-6	Multicentre, prospective feasibility study for 1 year	HbA1c, quality of life, insulin requirements, hypoglycaemia
Weintrob et al (2004b)	Compared glycaemic patterns of CSII versus MDIs, using CGMS in children and adolescents	N=23 Age: 8-14	Open randomised crossover study for 3½ months	HbA1c, BG
Weinzimer et al (2004)	Assessed efficacy and safety of CSII in very young children	N = 65 Age: less than 7	Follow-up study for 4 years	HbA1c, SH, DKA, treatment satisfaction

Alemzadeh et al (2005)	Compared CSII and MDIs in terms of glucose excursions in paediatrics	**N:** CSII = 14 MDIs = 14 **Age:** 3.9-16.8	Matched-pair comparison study	HbA1c, hypoglycaemia, BMI
Bin-Abbas et al (2005)	Assessed efficacy and safety of CSII compared with CIT in children	N = 14 Age: 4-18	Follow-up study for 10 months	HbA1c, insulin requirements, hypoglycaemia, DKA
Fox et al (2005)	Evaluated efficacy and quality of life of CSII compared with 2-3 injections in young children	N = 26 Age: 1-6	Prospective; RCT for 6 months	HbA1c, DKA, hypoglycaemia, quality of life
Jeha et al (2005)	Assessed psychosocial impact of pre and post- CSII in pre-school children	N = 10 Age: Under 6	Prospective; uncontrolled trial for 6 months	HbA1c, hypoglycaemia, parental anxiety
Mac-Fogg et al (2005)	Investigated efficacy and safety of CSII in toddlers and children	N = 70 Age: 2-12	Retrospective study	HbA1c, SH, DKA, BMI
McMahon et al (2005)	Evaluated efficacy, safety, and quality of life pre and post-pump in children and adolescents	N = 100 Age: 3.9-19.6	Prospective follow-up study for 4 years	HbA1c, hypoglycaemia, quality of life
Schiaffini et al (2005)	Examined efficacy of CSII compared to MDIs	N= 36 **Age (mean ± SD):** 14.3 ± 6.4	Observational retrospective study for 1 year	HbA1c, insulin requirements, BMI, hypoglycaemia
Wilson et al (2005)	Compared efficacy, safety, and quality of life of CSII with 2-3 injections in pre-school children	**N:** CSII = 9 MDIs = 10 Age: 1.7-6.1	Prospective; RCT, multi-centre study for 1 year	HbA1c, hypoglycaemia, quality of life
Berhe et al (2006)	Assessed efficacy and safety of CSII compared to CIT in young children	N = 33 Age: 2-7	Retrospective feasibility study	HbA1c, BMI, SH,DKA, number of sick day calls
Hanas and Adolfsson (2006)	Evaluated efficacy and safety of CSII compared to MDIs in paediatrics	**N:** CSII= 27 MDIs= 62 **Age:** 7-21	1-year cross-sectional evaluation study, follow- up for 5 years	HbA1c, SH, DKA

Juliusson et al (2006)	Evaluated impact of CSII compared to pre-pump on quality of life in children and adolescents with poorly regulated T1DM	N = 31 Age: 9.7 – 17.1	All parameters were recorded 15 months prior and 15 months after CSII therapy	Quality of life
Kordonouri et al (2006)	Compared efficacy and safety of CSII with MDIs in paediatric patients	**N:** CSII= 59 MDIs= 52 **Age (mean ± SD):** 6.72±3.42	Follow-up study for 1 year	HbA1c, SH, BMI, DKA,
Liberatore and Damiani (2006)	Reviewed current experience with CSII in children and adolescents in order to guide paediatricians	N.A	Systematic review	Metabolic control, quality of life, complications, cost
Nimri et al (2006)	Evaluated efficacy and safety of CSII compared to MDIs in children of different ages	**N = 279:** Pre-pubertal = 23 Adolescents= 127 Young adults= 129 **Age:** Pre-pubertal group: 1.6-8.6 Adolescents group: 9-17 Young adults: 17-40	Retrospective paired study	HbA1c, hypoglycaemia, DKA, BMI
Nahata (2006)	Compared efficacy, safety, psychosocial impact of CSII with MDIs in children and adolescents	N.A	Systematic review	HbA1c, insulin requirements, BMI, psychosocial impact
Ramchandani et al (2006)	Evaluated efficacy of CSII in newly diagnosed children	**N** = 28 **Age (mean ± SD):** 12.1±6.2	Feasibility study, then follow-up for 3 years	HbA1c, insulin requirements, BMI
Sulli and Shashaj (2006)	Evaluated efficacy and safety of CSII compared to MDIs in children	N = 42 Age: 4.5-17	Follow-up study for 4 years	HbA1c, insulin requirements, BMI, hypoglycaemia, DKA
Valenzuela et al (2006)	Compared quality of life of injection with CSII in children and adolescents	N = 160 Age: 5-16	N.A	Quality of life

Alemzadeh et al (2007)	Evaluated efficacy, safety and quality of life of CSII compared to MDIs in pre-school children	N = 14 Age: 2.2-5.5	Prospective study for 1 year	HbA1c, glyceamic variation, hypoglycaemia, DKA, quality of life
Barnard et al (2007)	Assessed quality of life with CSII therapy in children and adults	N=N.A Age: N.A	Systematic review (17studies)	Quality of life
Garcia-Garcia et al (2007)	Compared long-term efficacy and safety of CSII with MDIs in paediatrics	**N:** CSII = 8 MDIs = 24 **Age (mean ± SD):** 12.5 ± 2.5	N.A	HbA1c, BMI, insulin requirements, DKA, hypoglycaemia
Kapellen et al (2007)	Investigated glycaemic control and safety of CSII compared to MDIs in children and adolescents	N=1,567 Mean age: 12.4	Longitudinal study	HbA1c, SH, BMI
Opipari-Arrigan et al (2007)	Compared medical, nutritional and psychosocial parameters of CSII versus MDIs in preschool children	N=16 Age: 3.1-5.3	RCT for 6 months	HbA1c, glucose variation, quality of life, adverse effects, nutritional information
Pankowska et al (2007)	Evaluated efficacy and safety of pre and post-pump in pre-school children	N = 110 **Age (mean):** 0.9-7	Retrospective study	HbA1c, SH, DKA, BMI
Rabbone et al (2007)	Evaluated age-related differences of efficacy of pre versus post-CSII in pre-pubertal and pubertal children	**N:** Group A: pre-pubertal =20 Group B: pubertal group N=27 **Age (mean ± SD):** Group A: (7.43.1± 3.19) Group B: (14.47 ± 1.91)	N.A	HbA1c, insulin requirements, BMI, hypoglycaemia, insulin requirements
Reda et al (2007)	Evaluated efficacy and safety of CSII compared to MDIs in adults and adolescents	N = 105	Retrospective audit	HbA1c, hypoglycaemia, DKA

Berghaeuser et al (2008)	Assessed efficacy of CSII compared to MDIs started at time of diagnosis in very young children	**N:** CSII= 104 MDIs=145 Age: less than 5	Multicentre retrospective aged matched comparative study for 1 year	HbA1c, insulin requirements, SH, DKA
Jakisch et al (2008)	Compared glycaemic control and adverse events of CSII versus MDIs in paediatrics	**N:** CSII: 434 MDIs: 434 **Mean age:** CSII: 10.9 MDIs10.9	Multicentre matched pair study, then follow-up for 3 years	HbA1c, insulin requirements, BMI, hypoglycaemia, DKA
Jeitler et al (2008)	Compared safety and efficacy of CSII versus MDIs in adults and children with T1DM or T2DM	N =33 Age: N.A	Meta-analysis and systematic reviews (22 open, label studies)	HbA1c, insulin requirements, hypoglycaemia
Nuboer et al (2008)	Compared effects of CSII versus MDIs in terms of quality of life and impact of T1DM	N=38 Age: 4-16	Prospective; open, parallel RCT for 14 months	HbA1c, hypoglycaemia, quality of life
Pickup and Sutton (2008)	Compared efficacy and safety of CSII versus MDIs in children, adolescents and adults	N =1414 Age: N.A	Meta-analysis (22 RCTs and pre versus post-pump studies)	HbA1c, SH
Skogsberg et al (2008)	Compared efficacy, safety and treatment satisfaction of CSII versus MDIs started at onset of diagnosis	**N:** CSII= 34 MDIs= 38 **Age:** 7-17	Multicentre, open randomised parallel study, followed for 24 months	HbA1c, insulin requirements, BMI, treatment satisfaction, hyper/hypoglycaemia, DKA
Abaci et al (2009)	Compared long-term outcomes of CSII with clinical and metabolic parameters of MDIs in adolescents	**N**= 17 **Age (mean ± SD):** 15.53±1.8	N.A	HbA1c, Insulin requirements, BMI, hypoglycaemia
Churchill et al (2009)	Evaluated efficacy and safety of CSII compared to MDIs in young children	N total=176 Age 6 or less	Systematic review (7 studies; 3 RCTs and 4 quasi-experimental)	HbA1c, hypoglycaemia, quality of life, parental satisfaction
Fatourechi et al (2009)	Compared CSII versus MDIs in terms of hypoglycaemia in children and adults	N total = 669 Age: N.A	Meta-analysis and systematic reviews (15 RCTs)	Hypoglycaemia

Minkina-Pedras et al (2009)	Assessed efficacy and safety of CSII compared to MDIs in children	**N:** CSII=40 MDIs=36 **Age (mean ± SD):** CSII: 6.5±02.1 MDIs: 7.1±1.8	Follow-up aged matched study for 3.5 years	HbA1c, insulin requirements, BMI, hypoglycaemia, DKA
Nabhan et al (2009)	Compared metabolic control and other parameters in preschool children randomised to either CSII or MDIs	**N:** CSII=21 MDIs=21 **Age:** less than 5	Randomised prospective study	HbA1c, BMI, neuro-cognitive function, parental stress
Pankowska et al (2009)	Investigated effects of CSII compared to MDIs in children	N=165	Meta-analysis and systematic reviews of RCT (6 RCTs)	HbA1c, SH, DKA
Rabbone et al (2009)	Assessed efficacy and safety of CSII compared to MDIs in very young children	N=46 Age: less than 6	Observational study	HbA1c, insulin requirements, BMI, SH, DKA
Bergenstal et al (2010)	Compared efficacy of sensor-augmented pump with that of MDIs in children and adults	**N:** Adults= 329 Children=156	Multicentre RCT for 1 year	HbA1c, BMI, SH
Cummins et al (2010)	Evaluated clinical and cost-effectiveness of CSII versus MDIs in T1DM and T2DM of children and adults	N=N.A Age: N.A	Systematic reviews (74 studies; 16 RCTs, 48 observational , 6 of pregnancy, 4 systematic reviews)	HbA1c, SH, quality of life, cost-effectiveness
Misso et al (2010)	Assessed effects of CSII compared to MDIs in children and adults with T1DM	N =97 Age: N.A	Systematic review (23 randomised studies; 7 in children under 18 yr and 16 in adults)	HbA1c, BMI, SH, quality of life, cost

T1DM, Type 1 diabetes mellitus; T2DM, Type 2 diabetes mellitus; SD, standard deviation; N.A, information was not available; CSII, continuous subcutaneous insulin infusion; MDIs, multiple daily injection(s); CIT, conventional insulin therapy; HbA1c, glycated haemoglobin A1c; BG, blood glucose; DKA, diabetic ketoacidosis; SH, severe hypoglycaemia; BMI, body mass index; RCTs, randomised controlled trials

APPENDIX 2: Invitation letters for participants

The School of Pharmacy
University of London

Mezzanine Floor, BMA House
Tavistock Square
London WC1H 9JP

T 020 7874 1270
F 020 7378 5693

www.pharmacy.ac.uk

Parents of children aged 5 yrs and older

Dear Parent,

INSULIN PUMPS - VIEWS OF CHILDREN / YOUNG PEOPLE AND THEIR PARENTS

We are carrying out a study to find out more about the views and experiences of parents and children/young people with type 1 diabetes mellitus who have been switched from insulin injections to insulin pump therapy. There is very little research and information and we believe this study will help to plan future services.

This project is being run independently by researchers from School of Pharmacy, University of London in collaboration with your clinic at University College Hospital (UCH).

I would like to invite you and your son/daughter to be part of this research. Taking part in this research involves an interview with you and your son/daughter about experiences and views of using an insulin pump in managing diabetes. If you are happy, I would like to arrange a convenient time to come and talk with you and your son/daughter at your home or, if you prefer, at your next clinic appointment. I would expect the interviews to take up to 30-45 minutes.

Enclosed with this letter you will find two information leaflets which will tell you more about the study. The green leaflet is for you, while the blue leaflet is for your son/daughter. You may want to read this with them and decide together if you would like to take part in this research. All information will be kept strictly confidential.

Whether you are willing to take part or feel unable to do so, I would be most grateful if you would complete the reply slip attached to this letter and return it to me in the pre-paid envelope provided.

If you would like to discuss taking part in the research further before you complete the slip, then please feel free to contact me by telephone on **020 7874 1290**.

I look forward to hearing from you.

Yours sincerely

Miss Fatemah Alsaleh

Department of Practice and Policy,
School of Pharmacy, University of London
Tel: 020 7874 1290
Email: fatemah.alsaleh@pharmacy.ac.uk

REPLY SLIP

Name of parent (please print)……..

Name of child/young person (please print) ……

Age of the child/young person……..

Sex of the child/young person (please tick): □ Male □ Female

Number of years since young person was diagnosed with type 1 diabetes……..

Number of days/months/years on an insulin pump……

I am willing / I am not willing * to take part in the research study 'Insulin pumps: Views of children/young people and their parents'.
*- Please delete as appropriate

If you are willing to take part in the research please complete the following section so that I can contact you to arrange suitable time for the interviews and answer any questions you may have.

Your tel. no……..
Your address…….....……...…….
……
……
……

Please return this slip in the pre-paid envelope provide (no stamp required)

Thank you very much for your time

The School of Pharmacy
University of London

Mezzanine Floor, BMA House
Tavistock Square
London WC1H 9JP

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F 020 7378 5693

www.pharmacy.ac.uk

Parents of Children aged less than 5 yrs

Dear Parent,

INSULIN PUMPS - VIEWS OF CHILDREN / YOUNG PEOPLE AND THEIR PARENTS

We are carrying out a study to find out more about the views and experiences of parents and children/young people with type 1 diabetes mellitus who have been switched from insulin injections to insulin pump therapy. There is very little research and information and we believe this study will help to plan future services.

This project is being run independently by researchers from School of Pharmacy, University of London in collaboration with your clinic at University College Hospital (UCH).

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Enclosed with this letter you will find an information leaflet which will tell you more about the study. All information will be kept strictly confidential.

Whether you are willing to take part or feel unable to do so, I would be most grateful if you would complete the reply slip attached to this letter and return it to me in the pre-paid envelope provided.

If you would like to discuss taking part in the research further before you complete the slip, then please feel free to contact me by telephone on **020 7874 1290**.

I look forward to hearing from you.

Yours sincerely

Miss Fatemah Alsaleh

Student, Department of Practice and Policy,
School of Pharmacy, University of London
Tel: 020 7874 1290
Email: fatemah.alsaleh@pharmacy.ac.uk

REPLY SLIP

Name of parent (please print)……..

Name of child/young person (please print) ……

Age of the child/young person……..

Sex of the child/young person (please tick): □ Male □ Female

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Number of days/months/years on an insulin pump……

I am willing / I am not willing * to take part in the research study 'Insulin pumps: Views of children/young people and their parents'.
*- Please delete as appropriate

If you are willing to take part in the research please complete the following section so that I can contact you to arrange suitable time for the interviews and answer any questions you may have.

Your tel. no……..
Your address…….....……...…….
……..……
……..……
……..……

Please return this slip in the pre-paid envelope provide (no stamp required)

Thank you very much for your time

APPENDIX 3: Information leaflets for participants

University College London Hospitals NHS
NHS Foundation Trust

Contact for further information

If you would like to talk to someone about any aspects of the study, then please do not hesitate to contact:

Miss Fatemah Alsaleh
PhD student at Department of Practice and Policy,
School of Pharmacy, University of London,
BMA House (Entrance A), Mezzanine,
Tavistock Square, London, WC1H 9JP
Tel: 020 7874 1290
Email: fatemah.alsaleh@pharmacy.ac.uk

Or

Prof. Felicity Smith
Professor of Pharmacy Practice,
School of Pharmacy, University of London,
Tel: 020 7874 1288,
Email: felicity.smith@pharmacy.ac.uk

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

Insulin Pumps: Views of Children/ Young People and Their Parents

Information form for parents of children aged 5 years and older

You and your son/daughter are being invited to take part in a research study. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your son/daughter and others if you wish. Please contact us if there is anything that is not clear or if you would like more information.

THANK YOU FOR TAKING THE TIME TO READ THIS

What is the purpose of this study?

We would like to find out more about the views and experiences of parents and children/young people with type 1 diabetes mellitus who have been switched from insulin injections to insulin pump therapy. Several studies have been carried out on insulin pumps in the UK. Currently very limited information is available on children/young people's and their parents' views and experiences on pump therapy. We believe that the study will give us important information about the experiences of the children/young people and their parents in the switch from injection therapy to pump therapy, which could be valuable in informing future health policy and service provision.

Why have I been chosen?

Children and young people with type 1 diabetes mellitus attending selected clinics at University College Hospital (UCH), and their parents, will be invited to take part in the study.

What will happen if I take part?

At your convenience, a researcher will visit you at home on one occasion to interview you and your son/daughter, or if prefer in a clinic visit. The researcher will come and ask you and your son/daughter about the experiences and views of using an insulin pump in managing diabetes and the services you receive.

We would like to audio-record the interview. However, if you don't wish the interview to be audio-recorded we would still like you to take part.

We expect the interviews to take about 30-45 minutes

We would also like to record from your son/daughter's medical notes HbA1c measures from 6 months prior to, and following commencement of insulin pump therapy.

Is the study confidential?

Yes. All information collected will be kept strictly confidential and will be made anonymous so that you and your son/daughter cannot be recognised from it.

Who is organising this study?

The research is being carried out by the School of Pharmacy, University of London. We are an independent establishment involved in education and research; we are not a commercial organisation.

The study has been independently approved by the (insert local ethics research committee/hospital approval) local research ethics committee (insert reference number of ethics committee approval).

Do I have to take part?

No. Your participation is entirely voluntary and you are free to withdraw from the study at anytime without the care of your son/daughter or yourself being affected.

Thank you for taking the time to read this. Please contact us if you would like any more information.

University College London Hospitals NHS
NHS Foundation Trust

Contact for further information

If you would like to talk to someone about any aspects of the study, then please do not hesitate to contact:

Miss Fatemah Alsaleh
PhD student at Department of Practice and Policy
School of Pharmacy, University of London,
BMA House (Entrance A), Mezzanine,
Tavistock Square, London, WC1H 9JP
Tel: 020 7874 1290
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THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

Insulin Pumps: Views of Children/ Young People and Their Parents

Information form for parents and children aged less than 5 years

You are being invited to take part in a research study. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information.

THANK YOU FOR TAKING THE TIME TO READ THIS

What is the purpose of this study?

We would like to find out more about the views and experiences of parents and children/young people with type 1 diabetes mellitus who have been switched from insulin injections to insulin pump therapy. Several studies have been carried out on insulin pumps in the UK. Currently very limited information is available on the views and experiences of children/young people and their parents on pump therapy. We believe that the study will give us important information about the experiences of the children/young people and their parents in the switch from injection therapy to pump therapy, which could be valuable in informing future health policy and service provision.

Why have I been chosen?

Children and young people with type 1 diabetes mellitus attending selected clinics at University College Hospital (UCH), and their parents, will be invited to take part in the study.

What will happen if I take part?

At your convenience, a researcher will visit you at home on one occasion to interview you, or if prefer in a clinic visit. The researcher will come and ask you about your experiences and views of using an insulin pump in managing your son/daughter's diabetes and the services you receive.

We would like to audio-record the interview. However, if you don't wish the interview to be audio-recorded we would still like you to take part.

We expect the interview to take about 30 minutes.

We would also like to record from your son/daughter's medical notes HbA1c measures from 6 months prior to, and following commencement of insulin pump therapy

Is the study confidential?

Yes. All information collected will be kept strictly confidential and will be made anonymous so that neither you nor your son/daughter can be recognised.

Who is organising this study?

The research is being carried out by the School of Pharmacy, University of London. We are an independent establishment involved in education and research; we are not a commercial organisation.

The study has been independently approved by the (insert local ethics research committee/hospital approval) local research ethics committee (insert reference number of ethics committee approval).

Do I have to take part?

No. Your participation is entirely voluntary and you are free to withdraw from the study at anytime without the care of your son/daughter or yourself being affected.

Thank you for taking the time to read this. Please contact us if you would like any more information.

University College London Hospitals NHS
NHS Foundation Trust

Contact for further information

If you or your Mum/Dad would like to talk about any aspects of the study, then please do not hesitate to contact:

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PhD student at Department of Practice and Policy
School of Pharmacy, University of London,
BMA House (Entrance A), Mezzanine,
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THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

Insulin Pumps: Views of Children/ Young People and Their Parents

Information form for children aged 5-7 years

You and your Mum/Dad are being invited to take part in a research project. Research is when we try to find out more about something. Read this sheet carefully with your Mum/Dad and choose together if you want to take part.

Thank you for taking the time to read this

What is the purpose of this study?

We would like to find out more about what it is like for you when your medicine is given to you by an insulin pump instead of insulin injections. We believe that the study will give us important information on how children with diabetes and their families feel about using pumps which will help to improve the services for them.

Why have I been chosen?

Children with diabetes like yours who visit the same hospital as you will be asked if they want to take part.

What will happen if I take part?

If you agree, a time will be arranged so someone can visit you at home or at the clinic. She would like to come and ask you and your Mum or Dad about experience in using your insulin pump.

We would like to audio-record the interview. However, even if you don't want to be audio-recorded we would still like you to take part.

We expect the time we will take to talk to you and your Mum or Dad to be about 30-45 minutes.

Will people be told what I say?

No. No one except the research team will know what you have said. All names will be removed from the papers, so no one will know it is you.

Who is organising this study?

The research is being carried out by the School of Pharmacy, University of London.

Do I have to take part?

No. It is up to you if you want to take part, nobody will be upset if you do not. You are free to withdraw from the study at any time without having to explain. If you have any questions ask your Mum or Dad. If they don't know the answers ask them to telephone us.

University College London Hospitals NHS
NHS Foundation Trust

Contact for further information

If you or your Mum/Dad would like to talk about any aspects of the study, then please do not hesitate to contact:

Miss Fatemah Alsaleh
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THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

Insulin Pumps: Views of Children/ Young People and Their Parents

Information form for children aged 8-12 years

You and your Mum/Dad are being invited to take part in a research project. Please read the following information carefully with your Mum or Dad and decide together if you would like to take part. Please contact us if there is anything that you do not understand or if you have any questions.

Thank you for taking the time to read this

What is the purpose of this study?

We would like to find out about yours and your Mum's or Dad's views and experiences in using insulin pumps instead of injections in the management of your diabetes. We are interested in what you think. We believe that the study will give us important information about the views and experiences of children and young people on insulin pump therapy at the University College Hospital (UCH) and help us to improve services provided.

Why have I been chosen?

Children with condition like yours who go to the same hospital will be asked if they want to take part.

What will happen if I take part?

If you are happy, a time will be arranged so a researcher can visit you at home or at the clinic. She would like to come and ask you and your Mum or Dad about experience in using an insulin pump and the services you receive.

We would like to audio-record the interview. However, even if you don't want to be audio-recorded we would still like you to take part.

We expect the interview with you and your Mum or Dad to take 30-45 minutes.

Will people be told what I say?

No. No one except the research team will have access to the data. All names will be removed from the data, so you cannot be recognised from it.

Who is organising this study?

The research is being carried out by the School of Pharmacy, University of London. We are involved in education and research on health and medicines. We are not a money-making organisation.

Do I have to take part?

No, it is up to you to decide if you want to take part in the study or not. You are free to withdraw from the study at any time without having to give a reason.

Thank you for taking the time to read this. Please contact us if you would like any more information.

University College London Hospitals NHS
NHS Foundation Trust

Contact for further information

If you would like to talk about any aspects of the study, then please do not hesitate to contact:

Miss Fatemah Alsaleh
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School of Pharmacy, University of London,
BMA House (Entrance A), Mezzanine,
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Tel: 020 7874 1288,
Email: felicity.smith@pharmacy.ac.uk

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

Insulin Pumps: Views of Children/ Young People and Their Parents

Information form for young people aged 13-17 years

You and your parents are being invited to take part in a research study. Before you decide if you want to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and, if you want, to talk to your parents, friends, and relatives about it. Please contact us if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this

What is the purpose of this study?

We would like to find out about yours and your parents' views and experiences when using an insulin pump instead of insulin injections. Adults often talk about what is best for young people, we want to know what you think. We believe that the study will give us important information about the views and experiences of children/young people and their parents on insulin pump therapy at the University College Hospital (UCH) and may help us to improve services provided.

Why have I been chosen?

Young people with diabetes who go to the same hospital as you will be invited to take part in the study.

What will happen if I take part?

If you agree, a time will be arranged so a researcher can visit you at home or at the clinic. She would like to come and ask you and your parents about experiences and views of using an insulin pump and the services you receive.

We would like to audio-record the interview. However, even if you don't want to be audio-recorded we would still like you to take part.

We expect the interview with you and your parent to take 30-45 minutes.

We would also like to record from your medical notes your HbA1c measures from 6 months prior to, and following commencement of insulin pump therapy.

Will people be told what I say?

No. No one except the research team will have access to the data. All names will be removed from the data, so you cannot be recognised from it.

Who is organising this study?

The research is being carried out by the School of Pharmacy, University of London. We are an independent establishment involved in education and research; we are not a commercial organisation.

The study has been independently approved by the (insert local ethics research committee/hospital approval) local research ethics committee (insert reference number of ethics committee approval).

Do I have to take part?

No. Your participation is entirely voluntary and you are free to withdraw from the study at any time without having to give a reason.

Thank you for taking the time to read this. Please contact us if you would like any more information.

APPENDIX 4: Consent forms for participants

University College London Hospitals NHS
NHS Foundation Trust

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

INSULIN PUMPS - VIEWS OF CHILDREN/YOUNG PEOPLE AND THEIR PARENTS

CONSENT FORM FOR PARENTS OF CHILDREN AGED 5 YEARS AND OLDER

Principal investigator: Fatemah Alsaleh

Please tick box

1.	I confirm that I have read and understood the information sheet for the study, and have had the opportunity to ask questions.	
2.	I understand that I and my son/daughter will be invited to take part in an interview.	
3.	I understand that my participation, and that of my son/daughter, is voluntary. I understand that I am free to withdraw at any time without giving any reasons, without my or my son/daughter's medical care, pharmacy services or legal rights being affected.	
4.	I understand that a request will be made to audio-record the interview, but that this is not a requirement to take part. I know that some things I say may be used to illustrate the results of the study, but that I will not be identified.	
5.	I give permission for the researcher to record from my son/daughter's medical notes HbA1c measures prior to and following commencement of insulin pump therapy.	
6.	I agree that I, and my son/daughter, will take part in the study.	

Name of participant	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Name of researcher	Date	Signature

Comments or concerns during the study

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top of this consent form.

University College London Hospitals NHS
NHS Foundation Trust

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

INSULIN PUMPS - VIEWS OF CHILDREN/YOUNG PEOPLE AND THEIR PARENTS

CONSENT FORM FOR PARENTS OF CHILDREN AGED LESS THAN 5 YEARS

Principal investigator: Fatemah Alsaleh

Please tick box

1.	I confirm that I have read and understood the information sheet for the study, and have had the opportunity to ask questions.	
2.	I understand that my participation is voluntary. I understand that I am free to withdraw at any time without giving any reasons, without my or my son/daughter's medical care, pharmacy services or legal rights being affected.	
3.	I understand that a request will be made to audio-record the interview, but that this is not a requirement to take part. I know that some things I say may be used to illustrate the results of the study, but that I will not be identified.	
4.	I give permission for the researcher to record from my son/daughter's medical notes HbA1c measures prior to and following commencement of insulin pump therapy.	
5.	I agree to take part in the study.	

Name of participant	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Name of researcher	Date	Signature

Comments or concerns during the study

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top of this consent form.

University College London Hospitals NHS
NHS Foundation Trust

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

INSULIN PUMPS - VIEWS OF CHILDREN / YOUNG PEOPLE AND THEIR PARENTS

ASSENT/CONSENT FORM FOR CHILDREN AGED 5-7 YEARS

Principal investigator: Fatemah Alsaleh

1.	With my Mum or Dad, I have read the blue leaflet.	
2.	I understand that I do not have to take part in the study and that nobody will be upset if I do not.	
3.	I understand that no one, except the researchers, will know what I have said.	
4.	I know that I will be asked if I am happy for the interview to be audio-recorded, but that this is not necessary for me to take part.	
5.	I will take part in the study.	

Please tick box

Name of participant _____ Age _____ Date _____ Signature _____

Name of person taking Consent (if different from researcher) _____ Date _____ Signature _____

Name of researcher _____ Date _____ Signature _____

University College London Hospitals NHS
NHS Foundation Trust

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

INSULIN PUMPS-VIEWS OF CHILDREN/YOUNG PEOPLE AND THEIR PARENTS

ASSENT/CONSENT FORM FOR YOUNG PEOPLE AGED 8-12 YEARS

Principal investigator: Fatemah Alsaleh

		Please tick box
1.	I have read and understood the information sheet for the study and have been able to ask questions.	
2.	I understand that I can choose if I take part in the study or not and that I can stop at anytime without having to give a reason.	
3.	I understand that no one other than the researchers will know what I have said during the interview.	
4.	I understand that I will be asked if the interview can be audio-recorded, but that this is not necessary for me to take part.	
5.	I agree to take part in the study.	

Name of participant _____ Age _____ Date _____ Signature _____

Name of person taking Consent (if different from researcher) _____ Date _____ Signature _____

Name of researcher _____ Date _____ Signature _____

University College London Hospitals NHS
NHS Foundation Trust

THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON

INSULIN PUMPS - VIEWS OF CHILDREN/YOUNG PEOPLE AND THEIR PARENTS

ASSENT/CONSENT FORM FOR YOUNG PEOPLE AGED 13-17 YEARS

Principal investigator: Fatemah Alsaleh

		Please tick box
1.	I have read and understood the information sheet for the study and have been able to ask questions.	
2.	I understand that I can choose if I take part in the study or not and that I can stop at anytime without having to give a reason.	
3.	I understand that no one other than the research team will know what I have said during the interview, and that I will not be recognised in any report.	
4.	I know that a request will be made to audio-record the interview, but that this is not a requirement to take part.	
5.	I understand that the researcher will record my HbA1c measures from my medical notes.	
6.	I agree to take part in the study.	

Name of participant	Age	Date	Signature
Name of person taking Consent (if different from researcher)		Date	Signature
Name of researcher		Date	Signature

Comments or concerns during the study

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top of this consent form.

APPENDIX 5: Interview schedules

INTERVIEW SCHEDULE FOR PARENTS OF CHILDREN AGED 5 YEARS & OLDER

Participant no: _____ Date: _____

Before we start the interview, I'll just remind you briefly what the study is about.

We want to find out about your experiences of switching your son/daughter to an insulin pump for their diabetes. Insulin pumps are one way of managing diabetes and we know very little about young people's and their parents' experiences of using them. We want to know what you like and dislike about them, what you feel are the benefits and disadvantages, any problems that you/your child have had, and how easy or difficult using a pump to manage diabetes.

Ensure respondent has read BOTH information leaflets

Ensure consent form is completed

Obtain consent to audio-record interview

Prompts are small and in italics

General experiences and views

How long have your son/daughter had diabetes?

How old was he/she when it was first diagnosed with T1DM?

Before using an insulin pump, how were you looking after your son/daughter's diabetes?

Describe treatment regimen

Numbers of injections

Monitoring of blood sugar levels

How long has your son/daughter been on an insulin pump?

When did your son/daughter start pump therapy?

Did your son/daughter start insulin therapy at UCH?

If no, how long has he/she using an insulin pump before started treatment at UCH?

How do you feel about using an insulin pump?

What do you like the best about it?

What do you not like about it?

Compare the advantages and disadvantages with injection therapy

How easy or difficult do you find it to use an insulin pump for the management of your son/daughter's diabetes?

(Depending on how long have been using it: when you first started, now you have been using it for some time)

How long did you and/or your child take to feel comfortable and confident in using the pump?

[Record details of current insulin usage, units and timings, type of pump]

Using pump at home

Can you describe to me how do you help your son/daughter to manage pump therapy?

Calculation of doses and need for boluses

Carb counting

Monitoring of blood levels

Changing of catheters

Operating the equipment

Checking the injection sites

Which of these activities does your child manage by him/herself?

Which do you/**other family member** help with?

How does the help your son/daughter has now compare with the help he/she needed with injections and monitoring before having the pump?

What do you feel are the advantages and disadvantages of insulin pump therapy on home life compared with injections/previous therapy he/she had?

Going out

Things he/she can do with the family

Taking part in sport, hobbies and seeing friends

Social life

Impact on the lives of other family members (does you having a pump affect life of other family members, how does it affect, in what ways). Compare that with injection therapy.

Are there things that you feel easier to do now by you or your child, than did before?

What are these? Why are they easier?

Are there things that are more difficult to do with pump?

What are these and what sorts of problems do you and/or your child find?

Using pumps at school/college

When your son/daughter is at school, how easy or difficult do you find it to for him/her to use an insulin pump?

Has he/she had any particular problems? Tell me about these?

How easy or difficult is it for your child to monitor blood levels, snack, or do other things to manage diabetes during school day?

How has having a pump affected your child at school?

Is easier or more difficult for you to manage your child's diabetes with a pump when at school than it was before?

In what ways?

Does your child receive any help at school?

What help?

How does having a pump affect the activities that the child can take part in at school?

Sport
Meals and snacks
Monitoring/maintaining blood glucose levels
Extracurricular activities
Going on school trips
Other

How do you feel about your child using a pump at school?

Pumps and blood sugar levels

How did you find the transition to the pump in terms of blood sugar control?

What sort of blood levels do you aim for?
How easy or difficult do you find it to achieve these?
How has switching to an insulin pump affected the management of your child's diabetes?
blood sugar levels, numbers of hypo attacks

How does this compare with before your son/daughter had the pump?

Has your child had any problems with using an insulin pump?
Problems at the injection site, e.g. allergy, pain, infection
Mechanical problems
Any other?

For all problems: what were these problems, when did they occur and how were solved?

In the last four weeks, has your son/daughter experienced any hypoglycaemic episodes?

Yes / No
On how many occasions?
What happened on each of these occasions?

In the last four weeks, has your son/daughter experienced any problems using the pump?

What were these?

How were they solved?

In general, how easy or difficult do you find it to achieve glycemic control with the pump as compared to injections?

At the Hospital

Could you describe the help you and your child have received from the hospital when switching to an insulin pump?

What have you found most helpful?

What other help you have liked?

How easy was it to understand the information you received?

Would you have like more information?

If so, what?

Have you used any other sources for information or advice on the pump? What are these?

How helpful or useful have you found, or you find:

Telephone contact that is available to you

The contact the hospital has with the school

Joint training sessions at the hospital with other families

What do you like best about the services and advice you receive from the hospital?

What do you like the least?

Have you got any recommendations for how they could be improved?

Final question

Overall, do you feel the pump or injections is better for managing your son/daughter's diabetes?

Some more information

Note sex of the respondent

Male Female

What is your date of birth?

What is your child's date of birth?

What is your relationship to the child/young person?

☐ Mum ☐ Dad ☐ Guardian

In which country was your child born?

What is your child's ethnic group?

White
Mixed
Asian or Asian British
Black or Black British
Chinese
Other (please specify)

Thank you for your participation

COMPLETION FORM (TO BE COMPLETED BY THE INTERVIEWER)

Total interview time:

Parent interview:

Young person interview:

Was anyone else present at this interview?

Parent interview:

Young person interview:

Please make comments regarding their participation in this interview.

Was the interview audio-recorded? Yes / No

If No, state the reason/s:

Any other comments about the interview:

INTERVIEW SCHEDULE FOR PARENTS OF CHILDREN AGED LESS THAN 5 YEARS

Participant no: _____ Date: _____

Before we start the interview, I'll just remind you briefly what the study is about.

We want to find out about your experiences of switching your son/daughter to an insulin pump for their diabetes. Insulin pumps are one way of managing diabetes and we know very little about young people's and their parents' experiences of using them. We want to know what you like and dislike about them, what you feel are the benefits and disadvantages, any problems that you/your child have had, and how easy or difficult using a pump to manage diabetes.

Ensure respondent has read BOTH information leaflets

Ensure consent form is completed

Obtain consent to audio-record interview

Prompts are small and in italics

General experiences and views

How long have your son/daughter had diabetes?

How old was he/she when it was first diagnosed with T1DM?

Before using an insulin pump, how were you looking after your son/daughter's diabetes?

Describe treatment regimen

Numbers of injections

Monitoring of blood sugar levels

How long has your son/daughter been on an insulin pump?

When did your son/daughter start pump therapy?

Did your son/daughter start insulin therapy at UCH?

If no, how long has he/she using an insulin pump before started treatment at UCH?

How do you feel about using an insulin pump?

What do you like the best about it?

What do you not like about it?

Compare the advantages and disadvantages with injection therapy

How easy or difficult do you find it to use an insulin pump for the management of your son/daughter's diabetes?

(Depending on how long have been using it: when you first started, now you have been using it for some time)

How long did you and/or your child take to feel comfortable and confident in using the pump?

[Record details of current insulin usage, units and timings, type of pump]

Using pump at home

Can you describe to me how do you help your son/daughter to manage pump therapy?

Calculation of doses and need for boluses

Carb counting

Monitoring of blood levels

Changing of catheters

Operating the equipment

Checking the injection sites

Which of these activities does your child manage by him/herself?

Which do you/**other family member** help with?

How does the help your son/daughter has now compare with the help he/she needed with injections and monitoring before having the pump?

What do you feel are the advantages and disadvantages of insulin pump therapy on home life compared with injections/previous therapy he/she had?

Going out

Things he/she can do with the family

Taking part in sport, hobbies and seeing friends

Social life

Impact on the lives of other family members? (does it affect the life of other family members, how does it affect, in what ways). Compare that with injection therapy.

Are there things that you feel easier to do now by you or your child, than did before?

What are these? Why are they easier?

Are there things that are more difficult to do with pump?

What are these and what sorts of problems do you and/or your child find?

<u>Using pumps at school/nursery/child care</u>

When your son/daughter is at school, how easy or difficult do you find it to for him/her to use an insulin pump?

Has he/she had any particular problems? Tell me about these?

How easy or difficult is it for your child to monitor blood levels, snack, or do other things to manage diabetes during school day?

How has having a pump affected your child at school?

Is easier or more difficult for you to manage your child's diabetes with a pump when at school than it was before?

In what ways?

Does your child receive any help at school?

What help?

How does having a pump affect the activities that the child can take part in at school?

Sport
Meals and snacks
Monitoring/maintaining blood glucose levels
Extracurricular activities
Going on school trips
Other

How do you feel about your child using a pump at school?

Pumps and blood sugar levels

How did you find the transition to the pump in terms of blood sugar control?

What sort of blood levels do you aim for?
How easy or difficult do you find it to achieve these?
How has switching to an insulin pump affected the management of your child's diabetes?

Blood sugar levels, numbers of hypo attacks

How does this compare with before your son/daughter had the pump?

Has your child had any problems with using an insulin pump?

Problems at the injection site, e.g. allergy, pain, infection
Mechanical problems
Any other?

For all problems: what were these problems, when did they occur and how were solved?

In the last four weeks, has your son/daughter experienced any hypoglycaemic episodes?

Yes / No
On how many occasions?
What happened on each of these occasions?

In the last four weeks, has your son/daughter experienced any problems using the pump?

What were these?

How were they solved?

In general, how easy or difficult do you find it to achieve glycemic control with the pump as compared to injections?

At the Hospital

Could you describe the help you and your child have received from the hospital when switching to an insulin pump?

What have you found most helpful?

What other help you have liked?

How easy was it to understand the information you received?

Would you have like more information?

If so, what?

Have you used any other sources for information or advice on the pump? What are these?

How helpful or useful have you found, or you find:

Telephone contact that is available to you

The contact the hospital has with the school/nursery

Joint training sessions at the hospital with other families

What do you like best about the services and advice you receive from the hospital?

What do you like the least?

Have you got any recommendations for how they could be improved?

Final question

Overall, do you feel the pump or injections is better for managing your son/daughter's diabetes?

Some more information

Note sex of the respondent

☐ Male ☐ Female

What is your date of birth?

What is your child's date of birth?

What is your relationship to the child/young person

☐ Mum ☐ Dad ☐ Guardian

In which country was your child born?

What is your child's ethnic group?

White
Mixed
Asian or Asian British
Black or Black British
Chinese
Other (please specify)

Thank you for your participation

COMPLETION FORM (TO BE COMPLETED BY THE INTERVIEWER)

Total interview time:

Was anyone else present at this interview?

Please make comments regarding their participation in this interview.

Was the interview audio-recorded? Yes / No

If No, state the reason/s:

Any other comments about the interview:

INTERVIEW SCHEDULE FOR CHILDREN AGED 5-7 YEARS

Participant no: _____ Date: _____

We want to find out about how easy or difficult you find it to use your insulin pump. Insulin pumps are one way of looking after diabetes and we know very little about how children and young people who use them feel about using them and the sorts of problems they have. We want to know what you and your Mum and Dad think.

CONSENT FORM

Now before we start, we have to fill out this form, we will read through it together. It says that you are happy to talk with me today, but that anytime if you don't like to continue talking to me then you just have to say so and we will stop the interview and I will go home. Have you got any questions? Are you happy to sign the form?

CONSENT TO AUDIO-RECORD THE INTERVIEW

This part of the form asks if you mind if I audio-record what you say to me today. I am the only one who will listen to what you say. It means that I don't have to write everything down now, but I can listen to you and write out later. Are you happy for me to record what you say?

Ok is there anything else that you would like to ask me before we start?

There are no wrong or right answers. I am interested to hear from you how you feel about using insulin pumps in treating diabetes.

Prompts are small and in italics

General experiences and views

Can you remember how old you were when you first had diabetes?

How long have you been using an insulin pump?

When did you start using it?

Before you had the pump, how were you looking after your diabetes?

Numbers of injections

Monitoring of blood sugar levels

How do you feel about using an insulin pump?

What do you like the best about it?

What do you not like about it?

How easy or difficult do you find it to use?

In what ways is it easy or difficult?

How did you find changing to an insulin pump?

How easy or difficult is to control your blood sugar levels with a pump?

What sort of blood levels do you aim for?

How easy do you find it to achieve these?

How has switching to an insulin pump affected this?

How does this compare with before you had the pump?

Have you had any problems with using your pump?

Problems at the injection site, e.g. allergy, pain, infection

Mechanical problems

Any other?

How does this compare with the injections that you were using before?

Using your pump at home

When you are using your pump at home, what help do you receive from your parents / (other carers)/**other family members**?

Advice about how much insulin, calculation of doses and need for boluses

Carb counting

Monitoring of blood levels

Changing of catheters

Operating the equipment
Checking the injection sites

Which of these activities do you do yourself?
Which do your parents help with?

How does the help you have now compare with the help you needed with injections and monitoring before you had the pump?

How has having the pump affected the sorts of things that you can do?

Such as going out
Seeing friends
Impact on the lives of other family members (does you having a pump affect life of other family members, how does it affect, in what ways). Compare that with injection therapy.

When you go out, what happens?

What help do you need?

<u>Using your pump at school</u>

When you are at school, how easy or difficult do you find it to use your pump?

Have you had any particular problems? Tell me about these?
How easy or difficult is it to monitor blood levels, snack, or do other things to manage your diabetes during school day?

How has having a pump affected you at school?

Is easier or more difficult for you to manage your diabetes with a pump when you are at school?

In what ways?

Do you receive any help at school?

What help do you get?

How does having a pump affect the activities you can take part in at school?

Sport
Meals and snacks
Monitoring/maintaining blood glucose levels
Clubs

Going on school trips

Other

How do you feel about using your pump at school?

At the hospital

What help have had from the hospital in using your pump?

What have you found most helpful?

What other help would you have liked?

How easy was it to understand the information you received?

What do you like best about the services and advice you receive from the hospital?

What do you like the least?

Some information about you

How old are you

Date of birth or birthday

What is your current school year?

Male / Female

We want to find out as much as we can about what children think about using insulin pumps for their diabetes.

Is there anything else that you would like to tell me?

Have you had any problems that we have not talked about?

Are there any other good things about using a pump that are important to you?

Thank you for talking to me.

The information will be helpful to us in planning our services for young people with diabetes in the future.

COMPLETION FORM (TO BE COMPLETED BY THE INTERVIEWER)

Total interview time:

Parent interview:

Young person interview:

Was anyone else present at this interview?

Parent interview:

Young person interview:

Please make comments regarding their participation in this interview.

Was the interview audio-recorded? YES / NO

If NO, state the reason/s:

Any other comments about the interview:

INTERVIEW SCHEDULE FOR YOUNG PEOPLE AGED 8-12 YEARS

Participant no: _____ Date: _____

Before we start the interview, I'll just remind you briefly what the study is about.

We want to find out about your experiences of switching to an insulin pump for your diabetes. Insulin pumps are one way of managing diabetes and we know very little about young people's experiences of using them. We want to know what you like and dislike about them, what you feel are the benefits and disadvantages, any problems that you have had, and how easy or difficult you find using a pump to manage your diabetes.

CONSENT FORM

Now before we start, we have to fill out this form. It says that you are happy to talk with me today, but that at anytime we can stop the interview if you wish. You are completely free to say that you want to stop the interview at anytime. Are you happy to sign the form?

CONSENT TO AUDIO-RECORD THE INTERVIEW

I would like to audio-record this interview today. I am the only one who will listen to what you say. It means that I don't have to write everything down now, but I can listen to you and write out later. But if you don't want me to tape-record, that is still OK. Are you happy for me to record what you say?

Ok is there anything else that you would like to ask me before we start?

There are no wrong or right answers. I am interested to hear from you your experiences and views on using insulin pumps.

Prompts are small and in italics

General experiences and views

How long have you had diabetes?

How old were you when it was first diagnosed?

Before you had the pump, how were you looking after your diabetes?

Describe your treatment regimen

Numbers of injections

Monitoring

How long have you been using an insulin pump?

When did you start using an insulin pump?

Did you start pump therapy at UCH?

If no: how long were you using an insulin pump before you started

treatment at UCH?

How do you feel about using an insulin pump?

What do you like the best about it?

What do you not like about it?

Compare the advantages and disadvantages with injection therapy

How easy or difficult do you find it to use your pump?

(Depending on how long have been using it: when you first started, now you have been using it for some time)

How long you took to feel comfortable and confident in using the pump?

[Record details of current insulin usage, units and timings, type of pump]

Using your pump at home

When you are using your pump at home, what help do you receive from your parents / (other carers)?

Advice about how much insulin, calculation of doses and need for boluses

Carb counting

Monitoring of blood levels

Changing of catheters

Operating the equipment

Checking the injection sites

Which of these activities do you manage by yourself?

Which do your parents/**other family members** help with?

How does the help you have now compare with the help you needed with injections and monitoring before you had the pump?

What do you feel are the advantages and disadvantages of insulin pump therapy on your home life compared with your injections/previous therapy?

Going out

Things you can do with your family

Taking part in sport, hobbies and seeing friends

Social life

Impact on the lives of other family members? (does it affect the life of other family members, how does it affect, in what ways). Compare that with injection therapy.

Are there things that you feel easier to do now, than you did before?

What are these? Why are they easier?

Are there things that are more difficult to do with pump?

What are these and what sorts of problems do you find?

<u>Using your pump at school</u>

When you are at school, how easy or difficult do you find it to use your pump?

Have you had any particular problems? Tell me about these?

How easy or difficult is it to monitor blood levels, snack, or do other things to manage your diabetes during school day?

How has having a pump affected you at school?

Is easier or more difficult for you to manage your diabetes with a pump when at school than it was before?

In what ways?

Do you receive any help at school?

What help?

How does having a pump affect the activities you can take part in at school?

Sport

Meals and snacks

Monitoring/maintaining blood glucose levels

Extracurricular activities

Going on school trips

Other

How do you feel about using your pump at school?

Using the pump and your blood sugar levels

How did you find the transition to the pump in terms of blood sugar control?

What sort of blood levels do you aim for?

How easy or difficult do you find it to achieve these?

How has switching to an insulin pump affected the management of your diabetes?

blood sugar levels, numbers of hypo attacks

How does this compare with before you had the pump?

Have you had any problems with using your pump?

Problems at the injection site, e.g. allergy, pain, infection

Mechanical problems

Any other?

For all problems: what were these problems, when did they occur and how were solved?

In the last four weeks, have you experienced any hypoglycaemic episodes?

Yes / No

On how many occasions?

What happened on each of these occasions?

In the last four weeks, have you experienced any problems using your pump?

What were these?

How were they solved?

In general, how easy or difficult do you find it to achieve glycemic control with the pump as compared to injections?

At the hospital

Could you describe the help you have received from the hospital when switching to an insulin pump?

What have you found most helpful?

What other help you have liked?

How easy was it to understand the information you received?

Would you have like more information?

If so, what?

Have you/your parents used any other sources for information or advice on the pump? What are these?

How helpful or useful have you found, or you find:

Telephone contact that is available to you

The contact the hospital has with the school

Joint training sessions at the hospital with other families

What do you like best about the services and advice you receive from the hospital?

What do you like the least?

Do you have any recommendations for how they could be improved?

Final question

Overall, do you feel the pump or injections is better for you in managing your diabetes?

Some information about you

How old are you

Date of birth or birthday

What year are you in at school?

Male / Female

We want to find out as much as we can about what young people think about using insulin pumps for their diabetes.

Is there anything else that you would like to tell me?

Have you had any concerns or problems that we have not discussed?

Are there any other good things about using a pump that are important to you?

Do you have any questions you would like to ask me?

Thank you for talking to me.

The information will be helpful to us in planning our services for young people with diabetes in the future.

COMPLETION FORM (TO BE COMPLETED BY THE INTERVIEWER)

Total interview time:

Parent interview:

Young person interview:

Was anyone else present at this interview?

Parent interview:

Young person interview:

Please make comments regarding their participation in this interview.

Was the interview audio-recorded? YES / NO

If NO, state the reason/s:

Any other comments about the interview:

INTERVIEW SCHEDULE FOR YOUNG PEOPLE AGED 13-17 YEARS

Participant no: _____ Date: _____

Before we start the interview, I'll just remind you briefly what the study is about.

We want to find out about your experiences of switching to an insulin pump for your diabetes. Insulin pumps are one way of managing diabetes and we know very little about young people's experiences of using them. We want to know what you like and dislike about them, what you feel are the benefits and disadvantages, any problems that you have had, and how easy or difficult you find using a pump to manage your diabetes.

CONSENT FORM

Now before we start, we have to fill out this form. It says that you are happy to talk with me today, but that at anytime we can stop the interview if you wish. You are completely free to say that you want to stop the interview at anytime. Are you happy to sign the form?

CONSENT TO AUDIO-RECORD THE INTERVIEW

I would like to audio-record this interview today. I am the only one who will listen to what you say. It means that I don't have to write everything down now, but I can listen to you and write out later. But if you don't want me to tape-record, that is still OK. Are you happy for me to record what you say?

OK, is there anything else you would like to ask me before we start?

There are no wrong or right answers. I am interested to hear from you your experiences and views on using insulin pumps.

Prompts are small and in italics

General experiences and views

How long have you had diabetes?

How old were you when it was first diagnosed?

Before you had the pump, how were you looking after your diabetes?

Describe your treatment regimen

Numbers of injections

Monitoring

How long have you been using an insulin pump?

When did you start using an insulin pump?

Did you start pump therapy at UCH?

If no: how long were you using an insulin pump before you started treatment at UCH?

How do you feel about using an insulin pump?

What do you like the best about it?

What do you not like about it?

Compare the advantages and disadvantages with injection therapy

How easy or difficult do you find it to use your pump?

(Depending on how long have been using it: when you first started, now you have been using it for some time)

How long did you take to feel comfortable and confident in using the pump?

[Record details of current insulin usage, units and timings, type of pump]

Using your pump at home

When you are using your pump at home, what help do you receive from your parents / (other carers)?

Advice about how much insulin, calculation of doses and need for boluses

Carb counting

Monitoring of blood levels

Changing of catheters

Operating the equipment

Checking the injection sites

Which of these activities do you manage by yourself?

Which do your parents/**other family members** help with?

How does the help you have now compare with the help you needed with injections and monitoring before you had the pump?

What do you feel are the advantages and disadvantages of insulin pump therapy on your home life compared with your injections/previous therapy?

Going out

Things you can do with your family

Taking part in sport, hobbies and seeing friends

Social life

Impact on the lives of other family members? (does it affect the life of other family members, how does it affect, in what ways). Compare that with injection therapy.

Are there things that you feel easier to do now, than you did before?

What are these? Why are they easier?

Are there things that are more difficult to do with pump?

What are these and what sorts of problems do you find?

<u>Using your pump at school/college</u>

When you are at school, how easy or difficult do you find it to use your pump?

Have you had any particular problems? Tell me about these?

How easy or difficult is it to monitor blood levels, snack, or do other things to manage your diabetes during school day?

How has having a pump affected you at school?

Is easier or more difficult for you to manage your diabetes with a pump when at school than it was before?

In what ways?

Do you receive any help at school?

What help?

How does having a pump affect the activities you can take part in at school?

Sport

Meals and snacks

Monitoring/maintaining blood glucose levels

Extracurricular activities

Going on school trips

Other

How do you feel about using your pump at school?

Using the pump and your blood sugar levels

How did you find the transition to the pump in terms of blood sugar control?

What sort of blood levels do you aim for?

How easy or difficult do you find it to achieve these?

How has switching to an insulin pump affected the management of your diabetes?

Blood sugar levels, numbers of hypo attacks

How does this compare with before you had the pump?

Have you had any problems with using your pump?

Problems at the injection site, e.g. allergy, pain, infection

Mechanical problems

Any other?

For all problems: what were these problems, when did they occur and how were solved?

In the last four weeks, have you experienced any hypoglycaemic episodes?

Yes / No

On how many occasions?

What happened on each of these occasions?

In the last four weeks, have you experienced any problems using your pump?

What were these?

How were they solved?

In general, how easy or difficult do you find it to achieve glycemic control with the pump as compared to injections?

At the hospital

Could you describe the help you have received from the hospital when switching to an insulin pump?

What have you found most helpful?

What other help you have liked?

How easy was it to understand the information you received?

Would you have like more information?

If so, what?

Have you/your parents used any other sources for information or advice on the pump? What are these?

How helpful or useful have you found, or you find:

Telephone contact that is available to you

The contact the hospital has with the school

Joint training sessions at the hospital with other families

What do you like best about the services and advice you receive from the hospital?

What do you like the least?

Do you have any recommendations for how they could be improved?

Final question

Overall, do you feel the pump or injections is better for you in managing your diabetes?

Some information about you

How old are you

Date of birth or birthday

What year are you in at school?

Male / Female

We want to find out as much as we can about what young people think about using insulin pumps for their diabetes.

Is there anything else that you would like to tell me?

Have you had any concerns or problems that we have not discussed?

Are there any other good things about using a pump that are important to you?

Do you have any questions you would like to ask me?

Thank you for talking to me.

The information will be helpful to us in planning our services for young people with diabetes in the future.

COMPLETION FORM (TO BE COMPLETED BY THE INTERVIEWER)

Total interview time:

Parent interview:

Young person interview:

Was anyone else present at this interview?

Parent interview:

Young person interview:

Please make comments regarding their participation in this interview.

Was the interview audio-recorded? YES / NO

If NO, state the reason/s:

Any other comments about the interview:

APPENDIX 6: A letter of response from the R & D Unit

University College London Hospitals NHS
NHS Foundation Trust

Joint UCLH/UCL Biomedical Research (R&D) Unit
Professor Ian Jacobs

Office Location:
1st Floor Maple House
149 Tottenham Court Road
London WC1

Postal Address:
Rosenheim Wing, Ground Floor
25 Grafton Way
London, WC1E 5DB

Email: philip.diamond@uclh.nhs.uk Tel: 020 7380 9833 Fax: 020 7380 9937 Web-site: www.uclh.nhs.uk

10 January 2008

Miss F Alsaleh
School of Pharmacy
University of London

COPY

Dear Miss Alsaleh,

Study No: **07/0165** *(Please quote in all correspondence)*
Title: Insulin pumps - views of children/young people and their parents

Thank you for registering the above study with the UCLH/UCL Biomedical Research Unit. I am pleased to give the approval of UCL Hospitals NHS Foundation Trust for the study to proceed.

You will be aware that as principal investigator you have various responsibilities under the Department of Health's *Research Governance Framework for Health and Social Care*. Please note that you are required:

- to comply with the UCLH Information Security Policy (the data protection toolkit "Consent and Security" will help you meet the requirements of the Data Protection Act and is available at http://www.uclh.nhs.uk/services/research/.
- to ensure that any co-investigator who is not an employee of UCLH has in place an up-to-date honorary contract.
- to keep copies of all consent forms with your project documentation. UCLH carries out audits of informed consent and if your project is selected for audit, you will need to provide access to the consent forms.
- To use an investigator file to store all the documentation relating to this research project (the attached list of headings is designed to help you assemble your investigator file).

This approval is conditional upon you having addressed any outstanding issues raised by the research ethics committee (REC) and having full ethical approval in place for the project. You should also be aware that your REC approval requires that you comply with all the requirements of the ethics committee regarding progress reports, notification of protocol amendments and adverse event reporting.

This approval is awarded on the basis of all the project documents you included in your submission to the UCLH/UCL Biomedical Research Unit, including any research agreements or contracts. In the event that the terms of any research contracts or agreements change or a new contract is issued this approval may be invalidated while the terms of the contract are negotiated.

Yours sincerely

pp P O'm

Professor Ian Jacobs
Director of R&D, UCL Hospitals NHS Foundation Trust

Director - Prof Ian Jacobs; Deputy Director - Prof Alan Thompson
Assistant Directors: Dr Nick McNally; Mrs Yvanne Enever; Ms Sue Kerrison; Prof Rosalind Raine

UCL HOSPITALS

UCL Hospitals is an NHS Foundation Trust incorporating the Eastman Dental Hospital, Elizabeth Garrett Anderson & Obstetric Hospital, The Heart Hospital, Hospital for Tropical Diseases, The National Hospital for Neurology & Neurosurgery, The Royal London Homoeopathic Hospital and University College Hospital.

APPENDIX 7: Final letter of response from the Ethics Committee Alpha

NHS

National Research Ethics Service

The Joint UCL/UCLH Committees on the Ethics of Human Research
Committee Alpha
Institute of Child Health
30 Guilford Street
London, WC1N 1EH
Tel: 020 7599 4130
Fax: 020 7599 4138
Email: t.lucas@ich.ucl.ac.uk

Our Ref: 08AL 085
10 March 2008

Miss Fatemah M. A. A. Alsaleh
PhD student at the Department of Practice and Policy
School of Pharmacy,
University of London
BMA House (Entrance A),
Mezzanine, Tavistock Square
WC1H 9JP

Dear Miss Alsaleh

Full title of study: **Using insulin pumps - the views of children/young people and their parents**
REC reference number: **07/H0715/109**

Thank you for your letter of 08 February 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 05 March 2008. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committee to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application		05 December 2007
Investigator CV		03 December 2007
Protocol	1	03 December 2007
Covering Letter		03 December 2007
Letter from Sponsor		07 September 2007
Interview Schedules/Topic Guides		03 December 2007
Participant Information Sheet: Young people 13-17	2	08 February 2008
Participant Information Sheet: Young people 8-12	2	08 February 2008
Participant Information Sheet: Young people 5-7	2	08 February 2008
Participant Information Sheet: Parents of children over 5	2	08 February 2008
Participant Information Sheet: Parents of children under 5	2	08 February 2008
Participant Information Sheet: Young people 5-7	1	03 December 2007
Participant Information Sheet: Young people 8-12	1	03 December 2007
Participant Information Sheet: Young people 13-17	1	03 December 2007
Participant Information Sheet: Parents of children under 5	1	03 December 2007
Participant Information Sheet: Parents of children over 5	1	03 December 2007
Participant Consent Form: Young people 5-7	1	03 December 2007
Participant Consent Form: Young people 8-12	1	03 December 2007
Participant Consent Form: Young people 13-17	1	03 December 2007
Participant Consent Form: Parents of children under 5	1	03 December 2007
Participant Consent Form: Parents of children over 5	1	03 December 2007
Response to Request for Further Information		08 February 2008
Interview schedule for young people 5-7	2	08 February 2008
Interview schedule for young people 8-12	2	08 February 2008
Interview schedule for young people 5-7	1	03 December 2007
Interview schedule for young people 8-12	1	03 December 2007
Interview schedule for young people 13-17	1	03 December 2007
Interview schedule for parents of children under 5	1	03 December 2007
CV Felicity Smith		
Interview schedule for young people 13-17	2	08 February 2008
Interview schedule for Parents of children under 5	2	08 February 2008
Interview schedule for children aged 5 and older	2	08 February 2008
Cover letter Parents of children under 5	2	08 February 2008
Cover letter Parents of children over 5	2	08 February 2008
Letter of invitation parents of children under 5	1	03 December 2007
Insurance details	1	
Letter of invitation parents of children over 5	1	03 December 2007

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from http://www.rdforum.nhs.uk/rdform.htm.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.
b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk .

07/H0715/109	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Mrs Patricia Orwell
Chair

Email: Tom.Lucas@ich.ucl.ac.uk

Copy to: Ms Maureen Boylan
School of Pharmacy, University of London.
29-39 Brunswick square, London,
WC1N 1AX

APPENDIX 8: An example of a coded transcript

Blue font: My explanation and comments
..... Pauses or interruptions
hehehe: Laughs

Patient Name: EK
Recruitment #: 22
Day/Date: Saturday 9/11/2008
Place: Patient's home
Attendants: Mother + Patient
Start time: 4:25 PM
End time: 5:00 PM
Total time: 1 Hour, 6 Minutes

Field notes:

- The interviews were done separately in a private room (the living room) and no one has bothered us in terms of coming into the room or outside noise.
- Before the interviews, the mother gave the young person popcorn to eat and asked him to bolus at certain time. After I finished the interview with young person, the mother asked him whether he took his bolus or not, so he replied 'no' and the mother was mad at him, but he told her that he forgot to bolus.

Notes

- Before each interview, I asked them (mother and young person) to sign the consent forms.
- The interviews were done separately; one with the child and another with the mother. However, the mother attended the last part of the child interview (questions about the hospital services).

Parent's Interview

Interviewer: Can I start doing the interview with you now? (With the mother).
Young person: Am I allowed to go now?
Interviewer: Yaah you are free now, thank you very much. (The boy went outside the room and left me with his mother. The mother at this point asked the her son whether he took his bolus

and he said 'no' as he forgot to do so. The mother became angry on her son and asked him to take the bolus immdeiately).So before we start, I just want to remind you that we want to find out about your experience of switching your son from insulin injections to insulin pump therapy, what you feel, what you like, what you don't like and your experience overall. I will audio-record if you don't mind. I will start by asking you general questions about the experiences and views of using the pump.

General experiences and views:

1. How long have your son/daughter had diabetes?

Interviewer: How long have your son had diabetes?

Duration

Mother: It is (aaaa)…12 years now.

Interviewer: How old was he when it was first diagnosed?

Age at diagnosis

Mother: 13 months

2. Before using an insulin pump, how were you looking after your son/daughter's diabetes?

Interviewer: Before using insulin pump, how were you looking after your son's diabetes?

Mother asking me: How do I??

Interviewer clarifying: Looking after…what you were using…

Mother interrupted: With injections

Interviewer: Ok, can you describe the treatment regimen? The units, how many times?

Insulin type

Mother: He used to have Mixtard 3 times a day. The percentage is different like we tried all of them 30:70, 40:60, 50:50. We tried all those.

Interviewer: How did you monitor his blood glucose level? (On injections)

Injection control

Mother: He was ok, but it was not great, but he was ok. (She did not understand my question)

Interviewer: Ok what did you use to monitor his blood glucose levels?

Blood glucose monitoring

Mother: With glucose monitor at home.

3. How long has your son/daughter been on an insulin pump?

Interviewer: Ok. **How long has your son been on an insulin pump?**

Duration/Date

Mother: This February it is becoming 4 years. He is over 3 years. (She means he is using the pump over 3 years by now).

Interviewer: (aaaa) **When did he start pump therapy?** Do you remember the date?

Duration/Date

Mother: It is February….. I think we went for that school (she means 2-day School Pump training) February 15, I think after that we…

Interviewer interrupted: And that was which year?

Duration/Date

48 **Mother:** .....Aammm I think 2005

49 **Interviewer commented: He said the same thing.**

50 **Mother:** Yaaah

51 **Interviewer: Did your son start pump therapy at UCH or somewhere else?**

Place

52 **Mother:** Yaaah, UCH.

53 **4. How do you feel about using an insulin pump?**

54 **Interviewer: How do you feel about your son using an insulin pump?**

General pump views

55 **Mother:** It is brilliant

56 **Interviewer: What do you like best about it?**

Other advantages
Diet management
Daily activities
Pump control

57 **Mother:** It is freedom. It is has got more freedom, we do not restrict him with food, with sleep, with going out. He is basically he is.....overall we have control of his diabetes.

58 **Interviewer: Ok, what you do not like about using an insulin pump?**

General pump views

59 **Mother:** .....None.

60 **Interviewer: Can you compare these advantages, what you like, with what you dislike with the injections therapy?**

Comparison

61 **Mother:** With the injection (aaaaa) we do not know how much we need to give him, we just guess, and there is another one I have to wake him up at certain times in the morning, I hate that to have his injections, and then he would not allowed to sleep after that because he has to have a breakfast. And another thing is when we go out, I have to carry everything in case of emergency, even food I have to take food everywhere I go, because I don't know....

Injection views

62 **Interviewer continued: Whether he will develop hypo attack**

63 **Mother:** Yaaah, so I that is what I dislike about the injections.

64 **Interviewer: Are there things that you liked about injections?**

Injection views

65 **Mother:** No

66 **5. How easy or difficult do you find it to use an insulin pump for the management of your son/daughter's diabetes?**

67 **Interviewer: How easy or difficult do you find it to use an insulin pump for managing your son's diabetes?**

Ease vs complexity

68 **Mother:** It is not difficult.

69 **Interviewer: Ok, was it easy from the beginning or it became.....**

Ease vs complexity

70 **Mother interrupted:** It was confusing me at the beginning, because we did not know but sometimes I ask him as well just because he is very advanced, so at the beginning I was frustrated even to do small things but now it becomes a part of our life.

71 **Interviewer: Ok roughly, how long did you take to feel confident and comfortable with using the pump?**

Gaining confidence/comfort

72 **Mother:** ……About after 2 months.

73 **6. [Record details of current insulin usage, units and timings, type of pump]**

74 **Interviewer: Ok regarding his current insulin usage, what type of insulinhe is using?**

75 **Mother:** Now?

76 **Interviewer: Yaah**

77 **Mother:** Aaaaaaah

78 **Interviewer: If you remember**

Insulin type

79 **Mother:** Novorapid

80 **Interviewer: Ok the units and timing?**

81 **Mother:** The units……

82 **Interviewer: The basals and the bolus**

83 **Mother:** Well it depends on what he eats

84 **Interviewer: Ok, the timings, how many basals is he using, the frequency, the…**

Units/Frequency

85 **Mother:** I think he has got…….I can't remember how many basals he has got.

86 **Interviewer: That is fine.**

87 **Mother added:** But he has got different basals for different times of the day.

88 **Interviewer:** Ok, **do you know the type of pump he is using now?**

89 **Mother:** Hehehehe (she is laughing because she does not know that as well).

90 **Interviewer smiling: Ok**

Current pump type

91 **Mother:** I don't know it by heart.

92 **Interviewer: Ok it is the Medtronic MiniMed.**

93 **Mother:** MiniMix?

94 **Interviewer: Medtronic MiniMed, it is difficult I know. (I meant it is difficult to pronounce)**

95 **Mother:** Yaaah

96 **Using pump at home**

97 **Interviewer**: I will ask you questions about using the pump at home.

98

99 **7. Can you describe to me how do you help your son/daughter to manage pump therapy?**

100 **Interviewer**: **Can you describe to me how do you help your son in managing his diabetes using the pump?**

Child's indepenency

101 **Mother**: He just does it.

102 **Interviewer**: **Everything? What help you can offer to him?**

Catheter changing
Reasons
Reminding

103 **Mother**: The help I just do for him is when I change his cannula, because he has got in on his bum and it is difficult for him, that is the only thing I do. And then I just always see, always nagging him did you give and just give…

Reminding

104 **Interviewer interrupted: Remind him.**
105 **Mother:** Yaaah just reminding.
106 **Interviewer:** Ok, **what about calculation of doses and the boluses, who does that?**

Calculation of doses/boluses

107 **Mother:** Both of us.
108 **Interviewer:** Ok **monitoring the blood levels, taking the sugar**?

finger pricks

109 **Mother:** He does it. If I have to do it while he is sleep, we do it my husband or myself.

Catheter changing

110 **Interviewer:** Ok, **and changing the catheters?** You do it. (She said that before)
111 **Mother:** I do it.

Equipment operation

112 **Interviewer: Operating the equipment?**
113 **Mother:** Both of us, three of us actually his dad as well.

Site checking

114 **Interviewer: Checking the injection site if there is infection, allergy, swelling?**
115 **Mother:** I do.

Help from other family members

116 **Interviewer: Is there any other family member other than you and your husband helping your son?**
117 **Mother:** His brother.
118 **Interviewer: What type of help he can do for him?**
119 **Mother:** Now he reminds him as well to take his bolus.
120 **Interviewer: He is the older?** (I mean the brother)
121 **Mother:** He is the youngest. We involve them, he is involved as well.

122 **8. How does the help your son/daughter has now compare with the help he/she needed with injections and monitoring before having the pump?**

Partnership on injections

Catheter changing

123 **Interviewer**: **How does the help he has now compare with the help he needed when he was on the injections?**
124 **Mother**: The injections…even the injection he does inject himself since he was 7, yaah 7, but the cannula (aaa) that I have to do it, I have to be here for him.
125 **Interviewer**: **Do you mean on the pump?** (I mean when she said about the cannula in the above answer)

Dependence comparison

126 **Mother**: Yaaah
127 **Interviewer**: **In comparison to the injections, do you feel now that your son needs more help?**
128 **Mother**: No I just involve with that one (pump)as well, sometimes I just check his site. It is…it is more or less it is the same.

129 **9. What do you feel are the advantages and disadvantages of insulin pump therapy on home life compared with injections/previous therapy he/she had?**

130 **Interviewer**: **What do you feel are the advantages and disadvantages of insulin pump therapy on home life compared with injections?** When I say home life I mean

going out, social life you know, doing things.

General pump views

131 **Mother**: It has got advantage, I don't see any disadvantage.

132 **Interviewer**: **Ok can you give me examples of the advantages?**

Family home/social life

Comparison

133 **Mother**: For example if we go out, ammm something to eat, he does not have to go anywhere he just does it there and then, but with injections he had to take his trouser down I have to….

134 **Interviewer interrupted**: **So it is like a process.**

135 **Mother**: Yaaah, but with the pump it is easy.

136 **Interviewer**: **What about taking part in sports or doing you know hobbies, going out, visiting friends, which one is easier to manage?**

137 **Mother**: The pump, because I remember once we went to friends, I put the injections in the fridge, I forgot…

Comparison

Family home/social life

138 **Interviewer interrupted**: **To take it with you.**

139 **Mother continued**: But this one (pump) is always with us, so I do not have to worry.

Diet management

140 **Interviewer**: **What about, you know, eating food outside, which one is more flexible?**

141 **Mother**: I would say the pump again because if he eats more than he should we check, and if we know he is high, we only give him a correction dose and that is easy.

Pump impact

142 **Interviewer**: **Ok, can you describe the impact of using pump therapy on the lives of other family members?** His brother, his sister, you know I mean the pump therapy it needs lots of work ok so do they feel….felt for example ignored or you are paying most of the attention to EK?

143 **Mother**: No

Comparison

Diet management

144 **Interviewer**: **Are there things that you feel easier to do now with your child than before?** I mean in activities in terms of social life or home life?

145 **Mother**: Very easy

146 **Interviewer**: **Can you give me examples?**

147 **Mother**: As I said to you if we have to go out, I have to prepare in advance to take what he is going to eat (on injections), what we are going to do, things like that. Now (on the pump) I don't do that as long as we know what he is going to eat. Even outside I have got the little book, I always carry it with me so I check things there and just…

148 **Interviewer interrupted**: **Calculate that.**

149 **Mother**: Yaaah

150 **Interviewer**: **Are there things that are more difficult to do now with the pump?** In terms of social life?

151 **Mother**: No

152 **Using pumps at school**

153 **10.When your son/daughter is at school, how easy or difficult do you find it to for him/her to use an**

insulin pump?

154 **Interviewer:** Ok. I will ask you questions about using the pump at school. **When your son is at school, how easy or difficult do you find it for him to use the insulin pump?**

Views

155 **Mother:** I think it is the same as at home.

156 **Interviewer: Has he had any particular problems of using the pump at school?**

157 **Mother:** He had once and they (school personnel) called me. The cannula came out, they called me and I went and had it done for him. Once he forgot the pump at school hehehhehe. He came home, he was doing some activities and that was when he was in a junior school, so I phoned them and I went to…

Problems

Solving school problems

158 **Interviewer continued: To pick it (th pump) up.**

159 **Mother:** Yaaah.

160 **Interviewer: How easy or difficult for your child to monitor blood levels or taking snack or do other things while he is on pump at school?**

Pump management

161 **Mother:** ……..It is as far as I know it is smooth.

162 **Interviewer: Ok if we compare his, you know, life at school when he was on injection therapy, what kind…**

163 **Mother interrupted:** Terrible.

164 **Interviewer: Ok, can you give me examples why was that?**

165 **Mother:** Because with the injections, he used to have snack between the meals because then he was very young, they kept forgetting to remind him.

Compl/Diabetes management

166 **Interviewer asking: The school?**

167 **Mother:** The school and then at the end of the day when I went to pick him up, his face was pale, he was very low and things like that it just was a nightmare. The school they kept forgetting to give him his thing. And if I have to go and inject him they would not do it, I have to go and do it myself. But with this one (she means the pump) they phone me (if there is any problem) I give them instructions over the phone and he does it. But with the injections I had to go physically.

Help/Support

168 **11.How has having a pump affected your child at school?**

169 **Interviewer: Ok. How has having a pump affected your child at school**? Like his performance, his relationship with his colleagues?

School peformance

170 **Mother:** It does not affect him at all.

Relationship to other kids/colleagues

171 **Interviewer:** Ok. **Is easier or more difficult for you to manage your child's diabetes with a pump when he is at school than it was before?**

Views

Compl/Diabetes management

172 **Mother:** It is easier with the pump. With the injection, (aaaa) I remember there is one particular teacher she is…..he is her favourite, when he goes high she used to send him to walk around or run around with one of the boys. But now he does not have to do that if he is high just give correction.

173 **Interviewer: Ahhaaa**

174 **Mother added:** That is easier.

175 **Interviewer:** Ehhhm. (aaaa) **Does your child receive any help at school?**

176 **Mother:** He used to.

177 **Interviewer:** He used to. **Ok at that time can you describe the help he used to receive?**

Help/Support

178 **Mother:** Well aammm he had a helper she always remind him to check and give me a call when he is low or high.

179 **Interviewer: Is she a teacher?**

180 **Mother:** No she is……

181 **Interviewer interrupted: TA**

182 **Mother:** She is …..support…..support teacher

183 **Interviewer: Ok, and now he does not need any help**?

184 **Mother:** Now because he is in a high school. When they are in a high school, they are on their own. They do not give them any help but they would…..but they allow him to go and check himself, that is all they do and they kept some of the hypo-stop things like that in the school. That is all the help they give because they think that they are big enough to do things for themselves so we do not get any help.

Help/Support

185

186

12.How does having a pump affect the activities that the child can take part in at school?

187 **Interviewer**: **How does having a pump affect the activities that your child take part in at school?**

188 **Mother**: No it des not affect him.

189 **Interviewer continued**: **Like sports, having snacks?**

Effect of pump on sport

190 **Mother**: He does……..whatever that the activities, he does it as well.

191 **Interviewer**: **Ok when he was on injection therapy, (aaa) using the injection did it restrict him from doing you know sports, doing extracurricular activities, going on trips?**

192 **Mother**: Yaaah, going on trips they would not allow him unless I'm with him. I was always with him.

193 **Interviewer**: **While with the pump?**

194 **Mother**: No with the injections

Comp/Sports and activities

Effect of pump on sport

195 **Interviewer**: **Yaaah while on the pump do they allow him, it is ok for him to go on trips or they restrict him?**

196 **Mother**: No, they do not restrict him. Even with the injections they do not restrict him (this is opposite to what she said before, she said they would not allow him to go on trips unless she is with him)….but I would just go with him because they would forget to remind him to eat and give his injection and so I go with him all the time but with the pump I let him go.

Opposite opinions

197

13.How do you feel about your child using a pump at school?

198 **Interviewer**: **How do you feel about your child using a pump at school in general?**

199 **Mother:** He is good.

Views

200 **Pumps and blood sugar levels**

201 **Interviewer**: Ok I will ask questions about using the pump and blood sugar

202 control achieved by it.

203 **14.How did you find the transition to the pump in terms of blood sugar control?**

204 **Interviewer**: **How did you find the transition or the switch from insulin injection to insulin pump therapy in terms of blood sugar control?**

205 **Mother**: Improved a lot; the control compared to the injections.

206 **Interviewer**: **Ok what sort of blood levels do you aim for?**

207 **Mother**: Aaaaam we aim between 4 and 7.

208 **Interviewer**: **Ok how easy or difficult to achieve that using insulin pump therapy?**

209 **Mother**: It is not easy

210 **Interviewer:** **Can you explain why?**

211 **Mother:** If he eats more than he should, and as you see I keep telling him to take the bolus on time because he is busy he forgets, so it is not simple as that. We have to work hard for that.

212 **Interviewer:** **Ok if we compare the work now with insulin pump therapy with the work needed on injection therapy to the control blood glucose levels. Are you doing more work now compared to the injections to achieve control?**

213 **Mother:** I do more work now with the pump.

214 **Interviewer:** **What about when he was on the injection?**

215 **Mother:** Well with the injections, I would not allow him to eat anything in between, unless he have the injection first, but with the pump he eats and he gives the bolus. Yaaah.

216 **Interviewer:** **How has switching to an insulin pump affected the management of your child's diabetes in terms of blood sugar control?**

217 **Mother:** Good.

218 **Interviewer continued:** **In terms of number of hypo attacks?**

219 **Mother asking:** Hypo?

220 **Interviewer confirmed:** **Hypos yaaah.**

221 **Mother:** ……..He has got hypos (on the pump) but not …dangerously but ammm….

222 **Interviewer:** **Ok, if we compare that to injection therapy did he used to have hypos as well?**

223 **Mother:** Well he blacked out as well on the injections, he blacked out twice since he was diagnosed. With the pump we have not seen that.

224 **Interviewer:** **What about the number of hypos, were there more on the injections or are there more now or the**

Injection comparison
Frequency

225 **same?**
Mother: I can not give you an answer, probably it is the same.

226 **15.How does this compare with before your son/daughter had the pump?**

227 **Interviewer: How does this compare this compare with before when your son was on the pump?** Ok you answered that.

228 **16.Has your child had any problems with using an insulin pump?**

229 **Interviewer: Has your child had any problems with using an insulin pump** in terms of mechanical problems, problems at….

Other problems

230 **Mother interrupted:** He broke it once

231 **Interviewer: Ok**

Pump problem

232 **Mother continued:** I do not know whether if he mentioned that hehehe?

233 **Interviewer: Broke it no, he said once it gave a message that it is not releasing the bolus or something like that**

234 **Mother interrupted:** Yeaah when it is not correctly reboot.

Solving mechanical problems

235 **Interviewer continued: Yaah and you used to fix it.**

236 **Mother:** Yaaah

237 **Interviewer smiled and continued: But he did not tell me that he broke it.**

Other problems

238 **Mother:** Yaah he went to his friend's house which was luckily not far from here, when they played he fell and that pump completely broke.

239 **Interviewer: Ehhm and how did you manage that at that time, what did you do?**

Managing other problems
team/nurse help or support

240 **Mother:** RT (a diabetes specialist nurse at the UCH) helped us, you know RT, RT?

241 **Interviewer: Yaah RT.**

242 **Mother:** When we phoned the UCH they told me to go to Barnet hospital and stay there and I refused to go because I do not trust any hospital except the UCH and finally we phoned RT and she told us what to do, we give manually and the next morning we went and she…

243 **Interviewer interrupted: Replace it?**

244 **Mother:** No we borrowed another one and then they replaced it after 3 days, yaah

245 **Interviewer: Ok what about problems at the injections site such as infection, allergy, swelling, pain?**

Injection problems

246 **Mother:** Yaah swelling he used to have a lot but not infection.

247 **Interviewer: Ehhm, ok any other problems?**

248 **Mother asked:** With the injection?

249 **Interviewer answered: With the pump therapy**

Problem

250 **Mother:** He had once infection, recently.

Injection problems

251 **Interviewer double checking:** Aaah you meant that with the injections he did not have infections?

Injection problems

Problem

Other problems

Managing other problems

252 **Mother confiriming:** No.

253 **Interviewer double checking: He did not have** (I mean infection with the injections).

254 **Mother confirming:** No.

255 **Interviewer: While on pump he had?**

256 **Mother:** Just once on the site yaaah.

257 **Interviewer: Ok, are there other problems with pump therapy that we have not mentioned?**

258 **Mother:** Well I might be wrong but since he started the pump we had… his skin colour changed I do not know whether that is related to the pump.

259 **Interviewer asked: Do you mean at the injection site?**

260 **Mother:** No it is all over… his skin, the colour is changing. They (consultants) do not know why it is changing but as soon as we started the pump, we had got that. I do not know whether there are other children having that. And it is expanding now rapidly.

261 **Interviewer: And in the hospital what did they say about that?**

262 **Mother:** He…we went to Great Ormond Hospital for that, so they took a biopsy and they could not find anything and I do not know what it is.

263 **Interviewer: Ehhm, ok.**

264

265 **17.In the last four weeks, has your son/daughter experienced any hypoglycaemic episodes?**

In the last month

266 **Interviewer: In the last four weeks, has your son experienced any hypo?** In the last month?

267 **Mother:** No

268 **18.In the last four weeks, has your son/daughter experienced any problems using the pump?**

In the last month
In the last month
In the last month

269 **Interviewer: In the month, has your son experienced any problems with using the pump?**

270 **Mother:** No.

271 **Interviewer: Ok**

272 **19.In general, how easy or difficult do you find it to achieve glycemic control with the pump as compared to injections?**

Pump control

273 **Interviewer:** Ok, **in general, how easy or difficult do you find it to achieve glycaemic control with pump therapy?**

274 **Mother**: ……..Is that the HbA1c?

275 **Interviewer clarifying: Yaah the blood control, the HbA1c or the blood glucose control?**

276 **Mother**: Yaah it is good.

277 **Interviewer repeating: It is good.**

278 **Mother confirming**: Yes.

279 **Interviewer: But how easy or difficult do you find it?**

280 **Mother**: To achieve that?

281 **Interviewer confirming: To achieve that.**

Time/Effort

282 **Mother**: Obviously we have to work hard for it (for the blood sugar control). They are just measuring the carbohydrates by (one missing word) ratio.

283 **Interviewer**: **But is it achievable?**

284 **Mother**: Yes, if you work hard yes.

285 **Interviewer:** Ok so I will ask you questions about the services you are receiving or you received from the hospital.

286 **At the hospital**

287 **20.Could you describe the help you and your child have received from the hospital when switching to an insulin pump?**

288 **Interviewer**: **Can you describe the help you and your child have received from the hospital when switching to an insulin pump?**

Possitive views

289 **Mother:** It is fantastic.

290 **Interviewer:** **Ok can you describe what help you had at that time?**

team/nurse help or support
Service at pump initiation
Possitive views

291 **Mother:** Well at the beginning when he started, I used to get a phone call from RT even from the doctor and to see how we are doing. I think we used to check him every two hours and then we had all the support we get.

292 **Interviewer:** **Can you give me examples what support you had receieved or you receieve?**

Service at pump initiation
Phone/positives

293 **Mother:** They were with us all the time when we started with the pump. They were assuring us how to work with the pump. If I phone any of the team they give me the answer all the time I need to know.

294 **Interviewer:** **What have you found most helpful among the telephone contact, the school day….**

Best service liked
Possitive views

295 **Mother interrupted:** The training day, the phone calls..

296 **Interviewer interrupted:** **What about the regular visits?**

297 **Mother:** All, all of them.

298 **Interviewer asking :** **You found them helpful?**

299 **Mother:** Very helpful

300 **Interviewer:** **Is there other help, other than those you liked at that time, other than those I mentioned to you?**

School/Positives

301 **Mother:** We got another help by RT coming to school and just give them….

302 **Interviewer:** **Instructions**

303 **Mother:** Yaah

Clarity
Other materials
Phone/positives
Service at pump initiation
Possitive views

304 **Interviewer:** **How easy was it to understand the information you received from the hospital?**

305 **Mother:** Well as I said at the beginning it was difficult but we just see the video, we got the book, we got the contact whenever we want we call them, even the service it was for 24 hours when we started it.

Sufficiency

306 **Interviewer:** **Ok would you have liked more information**

Sufficiency

or what you received…

307 **Mother interrupted:** No, it was sufficient.

308 **Interviewer:** Ok. **Have you used any source for information other than the hospital service?**

Other materials

Others

309 **Mother:** No, we read a book (aaaaaa)…the book they gave us, that is the information we get and I had a contact with one of the people who had it before us, so I had information from them (the hospital)as well.

310 **21.How helpful or useful have you found, or you find:**

311 **- Telephone contact that is available to you**

312 **- The contact the hospital has with the school**

313 **- Joint training sessions at the hospital with other families**

314 **Interviewer: How helpful or useful you found or you find the telephone contact that is available for you?**

Phone/positives

315 **Mother:** Very useful.

316 **Interviewer: Ok, the contact the hospital has with the school?**

317 **Mother:** Yaah very useful as well

318 **Interviewer: Can you describe that?**

School/Positives

team/nurse help or support

319 **Mother:** Yaaah if I'm just not satisfied with the school, I just tell RT and then they contact the school as well.

Opposite opinions

320 **Interviewer:** Ehhm. **The joint training session at the hospital, have you, you know, gone through that? Because usually in the beginning they do like a session where two families with children having insulin pump therapy sit together and they teach them about you know how to use insulin pumps?**

Opposite opinions

321 **Mother:** Yaah we went I do not know why he said no (She means her son when he said they did not have joint training session), yaaah.

322 **Interviewer: Yaah can you describe that?**

323 **Mother:** You mean when they displayed the food and …

Joined sesion/Positives

324 **Interviewer: Yaah how to calculate carbs**

325 **Mother:** Yes It was very useful, was very useful.

326 **Interviewer: Did you prefer at time to have a separate session or was it ok to sit with other families?**

Opinion on private session

327 **Mother:** No it was ok because you get different opinion from other people, the other parents

328 **22.What do you like best about the services and advice you receive from the hospital?**

329 **Interviewer: Ok what do you like best about the services and advice you receive from the hospital?**

Best service liked

330 **Mother:** Everything, yaaah

331 **Interviewer: Ok, is there thing that you like it the least?**

Least liked service

332 **Mother:** As he mentioned I don't like the pharmacy, you have to wait for very very long time.

333 **Interviewer:** Ok. **Do you have recommendations or**

suggestions for them to improve the services?

Suggestions, recommendations

Visits/Positives

Mother: Make it shorter (smiling) that is all I can say. (I think she means about the pharmacy waiting).

Interviewer: Ok, **what about waiting for the doctors when you go for the regular visits?**

Mother: I do not have any complaint.

Final question:

23. Overall, do you feel the pump or injections is better for managing your son/daughter's diabetes?

Preference

Interviewer: Ok, final question: overall, **do you feel the pump or injections is better for managing your daughter's diabetes**?

Mother: Pump

Some more information

24. Sex of the respondent:

Gender

Mother: Female

25. What is your date of birth?

Parent/Carers' DOB

Mother: 16/02/1964

26. What is you child's of birth?

Child's DOB

27/02/1995

27. What is your relationship to the child/young person?

Relationship to the child

Mum

28. In which country was your child born?

Country of child birth

England

29. What is your child's ethnic group?

Ethnicity

Black British

Interviewer: Thank you very much for your time and your participation and I hop I did not take much of your time.

Mother: No no that is fine. This is important for you and it is important for us.

APPENDIX 9: A list of themes/subthemes in the current study and origins of the major themes

A list of themes/subthemes of the current study and origins of the major themes *

No	Code	Origin
1	**Transition period** -how heard about it -reasons for transition -parents battles to assign children on pumps - initial worries -problems at transition -blood glucose control at transition	Interviews
2	**General experiences and views** -general views on pumps -misconceptions -gaining confidence -general views on injections -preference	Study's aim and objectives
3	**Glycaemic control** -pump control -target glucose -injections control -ease of control -factors affecting control	
4	**Safety** -hypoglycaemic episodes -infection -allergy -mechanical malfunctions -swelling -weight loss -other problems -managing problems on pump -injections problems	
5	**Management of diabetes with pump therapy at schools** -views -problems -pump management -school staff -impact of using pump at school -sport/trips/activities -comparison to injections -other issues	
6	**Hospital services** -services outside UCH -services at pump initiation -now how often used -views: positive, negative -telephone contact -school contact -joint-training sessions -other services (regular visits, email, team help/support, other sessions/services, other materials) -best service liked -least service liked	

	-information: sufficiency/clarity -other educational resources used by parents/children	
7	**Day-to-day management issues at home** -roles in partnership (dose calculation, carbohydrate counting, blood glucose testing....etc) -independency/dependency on parents -responsibility transfer -partnership on injections	Study's aim and objectives as well as literature review
8	**Advantages and disadvantages of pump therapy** -diet management -daily activities -family home/social life -use -other advantages -disadvantages -comparison to injections	
9	**Impact on family life** -diabetes impact -injections impact -pump impact	

* Sub-themes under each major theme were mostly generated from issues raised by the respondents during the interviews

Publications

Journal articles

Accepted and published

Alsaleh, F.M., Smith, F.J., Keady, S. & Taylor, K.M.G. (2010). Insulin pumps: From inception to the present and toward the future. *Journal of Clinical Pharmacy and Therapeutics*, 35(2), 128-138.

Submitted [accepted for publication]

Alsaleh, F.M., Smith, F.J. & Taylor, K.M.G. Experiences of children/young people and their parents, using insulin pump therapy for the management of type 1 diabetes: A qualitative review.

Submitted to *Journal of Clinical Pharmacy and Therapeutics* in May 2010 and accepted for publication in June 2011.

Conference abstracts

International Diabetes Federation (IDF) 20th World Diabetes Congress, Montreal, Canada. 18-22 October 2009.

Alsaleh, F.M., Smith, F.J., Taylor, K.M.G., Thompson, R., Agostini, K. & Potts, L. (2009). Insulin pump therapy for children/young people: Impact on condition management in the context of family lives. *IDF 20th World Diabetes Congress.* p491. [Poster].

The 2nd Kuwait International Pharmaceutical Conference, Kuwait, 1-3 March 2009

Alsaleh, F.M., Smith, F.J. & Taylor, K.M.G. (2008). Using insulin pumps – Experiences and views of children/young people and their parents. *The 2nd Kuwait International Pharmaceutical Conference.* [Poster].