UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES

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Exploration Of The Quality of Life Issues/Benefits Associated With Continuous Subcutaneous Insulin Infusion In Type 1 Diabetes

by

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ABSTRACT

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The prevalence of diabetes is approaching epidemic levels, with reported incidence set to double worldwide by 2035. Both chronic and progressive, diabetes requires individuals to engage in complex self-care regimens to safeguard their long-term health. Achieving optimal quality of life (QoL) in the long-term is an important health outcome in its own right, but treatments that compromise short-term QoL are unlikely to be maintained by the individual, thus threatening long-term biomedical and QoL outcomes. Continuous Subcutaneous Insulin Infusion (CSII) represents the latest technology in insulin delivery and, whilst demanding, arguably provides additional QoL benefits compared to other insulin regimens.

Existing literature provides mixed reports regarding QoL benefits associated with CSII. However, poor methodology, small samples and inappropriate measures may explain this ambiguity. Due to the subjective nature of QoL, quantitative measures alone may be insufficient to capture the impact on QoL.

This thesis supports the conclusion that QoL benefits may be observed in association with CSII therapy. Both qualitative and quantitative studies demonstrate improved QoL (e.g. increased independence, freedom and flexibility, particularly in terms of meal timing and content) for CSII users (measured using a range of generic, health related and diabetes-specific measures). These findings are consistent for children, adolescents and adults using CSII. In addition, Chapters Four and Six report QoL benefits for members of the family as well as the individual with diabetes.

Specific life domains important for QoL cited by children and adolescents are consistent with those in the literature, i.e. 'family', 'friends' and 'school', while parents most frequently cited 'health', 'family' and 'work' as important for their QoL. All domains were rated as better since commencement of CSII therapy.

Future research needs to focus on identifying the factors that predict success using CSII therapy and the individuals who would most be most suited to benefit from using CSII therapy.

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LIST OF DEFINITIONS AND ABBREVIATIONS

ADA	American Diabetes Association
ADDQOL	Audit of Diabetes-Dependent Quality of Life
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
AWI	Average Weighted Impact Score (of the ADDQoL)
BMI	Body Mass Index
BSI	Brief Symptom Inventory
CSII	Continuous Subcutaneous Insulin Infusion
DAFNE	Dose Adjustment For Normal Eating (trial)
DCCT	Diabetes Control and Complications Trial
DCSQ	Diabetes Clinic Satisfaction Questionnaire
DKA	Diabetic Ketoacidosis
DKN	Diabetes Knowledge (scale)
DQOL	Diabetes Quality Of Life
DQOLY	Diabetes Quality of Life Youth Scale
DSN	Diabetes Specialist Nurse
DSQOLS	Diabetes-Specific Quality of Life Scale
DSSQ	Diabetes Social Support Questionnaire
DTSQ	Diabetes Treatment Satisfaction Questionnaire
EQ5D	EuroQol 5D
FDA	Federal Drugs Agency
GHb	Glycated Haemoglobin
HAD	Hospital Anxiety and Depression scale
$HbA_{1(c)}$	Haemoglobin $A_{1(c)}$ - measure of average blood glucose over 6-8 weeks
HRQoL	Health-related quality of life
HFS	Hypoglycaemia Fear Survey
IDDM	Insulin Dependent Diabetes Mellitus

IDSRQ	Insulin Delivery System Rating Questionnaire
ITR-QOL	Insulin Therapy Related Quality of Life
MDI	Multiple Daily Injections
N	Number of respondents/participants
N/A	Not applicable
NICE	National Institute for Clinical Excellence
ns	Non-significant
NSF	National Service Framework
PAID	Problem Areas in Diabetes
PDQOLS	Parent Rated Quality of Life Scale
PeDQL	Pediatric Diabetes Quality of Life
PRO	Patient Reported Outcome
PRPT	Partially Randomised Preference Trial
PSAI	Parenting Stress Index
QoL	Quality of life
RCT	Randomised Controlled Trial
SD	Standard Deviation
SEIQoL	Schedule for the Evaluation of Individualised Quality of Life
SF-36	Medical Outcomes Survey Short-Form 36
STH	St Thomas' Hospital (London)
STTP	Structured Teaching and Treatment Programme
UK	United Kingdom
UKPDS	United Kingdom Prospective Diabetes Study
USA	United States of America
W-BQ	Well-Being Questionnaire (versions include 12, 22 or 28-item)
WHO	World Health Organisation
WHOQOL	World Health Organisation Quality of Life
WHOQOL-BREF	World Health Organisation Quality of Life Abbreviated Measure

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CHAPTER ONE

INTRODUCTION

This thesis provides an exploration of quality of life (QoL) issues/benefits associated with continuous subcutaneous insulin infusion (also known as insulin pump therapy) in the United Kindgom. Chapter One provides a detailed look at the chronic illness of diabetes, its aetiology, prevalence and treatment, whilst Chapter Two explores the issue of QoL in terms of theoretical background, generic QoL assessment measures, health-related measures and diabetes-specific measures. Chapter Three presents a review of existing literature whilst Chapters Four to Seven report on research conducted to explore QoL issues. Finally, Chapter Eight is a discussion of the contribution of research presented in this thesis in relation to previous literature and a conclusion.

BACKGROUND

1.1 DIABETES

Diabetes mellitus is an increasingly common disease for which there is currently no known cure. It is characterised by hyperglycaemia, caused by an absolute insulin deficiency, relative inefficiency in the production and/or action of insulin or insulin resistance [Williams & Pickup, 2000i]. 'Diabetes' is often used to cover a number of distinct disorders that all share the common symptom of raised blood glucose levels, primarily Type 1 diabetes and Type 2 diabetes. Type 1 diabetes is usually diagnosed in childhood and adolescence (although this is not exclusive), whereas Type 2 diabetes has historically been diagnosed later in adulthood [Williams & Pickup, 2000ii]. During recent years, however, things have changed with the diagnosis of Type 2 diabetes occurring much earlier, sometimes even in childhood.

There are several symptoms associated with severe hyperglycaemia including extreme thirst, frequent urination, tiredness, unexplained weight loss and recurrent infections [Williams & Pickup, 2002]. If adequate blood glucose control is not achieved/sustained, these symptoms can recur. Ultimately, acute severe hyperglycaemia may result in severe illness leading to coma and possible death. This life-threatening condition is known as diabetic ketoacidosis (DKA). Less severe hyperglycaemia and long term exposure to asymptomatic raised blood glucose levels causes considerable morbidity and mortality [Department of Health National Standards Framework, 2001]. Long-term complications of diabetes at the micro-vascular level include retinopathy, nephropathy and neuropathy (which increases the risk of foot ulcers and sexual dysfunction). According to the Department of Health (2001, page 2):

"diabetes is the leading cause of blindness in people of working age, the largest single cause of end stage renal failure, and excluding accidents, the biggest cause of lower limb amputation"

Most people will develop microvascular complications after 15-20 years of poorly controlled diabetes [Williams & Pickup, 2002]. Long-term macrovascular complications include cardiovascular disease and stroke. Heart disease is responsible for around half of all diabetes related deaths in developed countries [World Health Organisation, 2002].

1.2 AETIOLOGY OF TYPE 1 DIABETES

Whilst there are several recognised types of diabetes in children and adults, this thesis will focus on Type 1 diabetes. Diabetes was first classified by the World Health Organisation (WHO) in 1980, however, the most recent classification of diabetes by the WHO in 1999 incorporated the increasing knowledge about the disease over the past 20 years.

Table 1.1: WHO (1999) Aetiological Classification of Disorders of Glycaemia

Type	Description
1	Beta-cell destruction, leading to absolute insulin deficiency: - autoimmune - idiopathic
2	Ranges from predominant insulin resistance with relative insulin deficiency to a predominantly secretory defect with or without insulin resistance
Other	Genetic defects of beta-cell function Genetic defects of insulin action Diseases of the exocrine pancreas Endocrinopathies Drug or chemical induced Infections Uncommon forms of immune-mediated diabetes Other genetic syndromes sometimes associated with diabetes
Gestational	Includes the former categories of gestational impaired glucose tolerance and gestational diabetes

[from World Health Organisation (1999) Definition, diagnosis and classification of diabetes mellitus and its complications. Report of a WHO consultation.]

1.2.1 Type 1 Diabetes

Type 1 diabetes (also know as insulin-dependent diabetes mellitus – IDDM) accounts for approximately 15% of all cases of diabetes in England and Wales [Department of Health 2001]. It is mostly recognised because of the need for treatment with insulin therapy and for the common side effect of treatment hypoglycaemia. Type 1 diabetes tends to be rapidly diagnosed and treatment initiated because of the stark onset of illness and severe signs/symptoms. A diagnosis of diabetes is confirmed by at least one fasting blood glucose test showing a raised blood glucose level of >6.7 mmol/L. [National Institute for Clinical Excellence (NICE) guideline, Type 1 diabetes (adults), page 7]

Onset is most common in adolescents. It is generally accepted that the majority of children who develop type 1 diabetes do so as a result of genetic susceptibility, combined with various environmental factors. For the purpose of this thesis, children are defined as aged up to and including 12 years of age, adolescents are defined as

12-19 year olds. This leads to the development of auto-immune disease, directed at the insulin-producing β cells of the pancreatic islets of Langerhans. These cells are progressively destroyed, resulting in impaired glucose tolerance then increasing hyperglycaemia and ketosis. This process continues until all the β cells are destroyed with the individual totally dependent on exogenous insulin [Cunningham & Hanson, 2005].

Insulin deficiency leads to the excessive breakdown of fats and the production of ketones, which are excreted in the urine. It also prevents glucose circulating in the blood being utilised by muscle and adipose tissue as well as prevent storage of glucose in the liver, resulting in hyperglycaemia. As the kidney is unable to reclaim the massive amount of glucose that is filtered out into the urine, there is a subsequent loss of water with the glucose, leading to excessive fluid loss and subsequent thirst. If insufficient fluid is taken, dehydration develops rapidly. The breakdown of adipose tissue leads to weight loss, but if hyperglycaemia continues, ketones cannot be removed from the system quickly enough to prevent blood glucose levels rising. Consequently, this leads to ketoacidosis, manifested by vomiting, dehydration, Kussmaul breathing (air hunger) and finally coma, which can be fatal [Cunningham & Hanson, 2005].

1.3 EPIDEMIOLOGY OF DIABETES

There is clear evidence of rising incidence of Type 1, particularly in developed countries where incidents have doubled over the past 20 years. In the United Kingdom (UK) particularly, the incidence of diabetes has doubled in each of the last two decades from 7.0 to 13.5/100,000/year [Metcalfe & Baum, 1991]. Type 1 diabetes is the third most common chronic condition in the UK after asthma and cerebral palsy. It affects 18-20 per 100,000 children a year in the UK. [Onkamo et al, 1999]

Globally, incidences of Type 2 diabetes are increasing, for example reported incidences in the US are 20.8 million people, representing 7% of the population. This figure is broken down into 14.6 million people diagnosed with diabetes with an estimated further 6.2 million people undiagnosed [National Institute of Health, 2005]. In other parts of the world, Type 1 diabetes is 30 times more prevalent in Scandinavia than it is in Japan [Watkins, 2003]. Wide variations between similar populations (such as Iceland and Norway) or adjacent countries with different lifestyles (such as Estonia and Finland) provide strong support for the role of environmental factors, including lifestyle, as being important agents in the aetiology of IDDM [Lamb 1997]. Intra-country variance also shows substantial variation, for example, in Great Britain rates range from a minimum of 6/100,000 in Southern England to 19.8 in Scotland [Lamb 1997].

1.4 MANAGEMENT OF TYPE 1 DIABETES

Due to the cessation of insulin production necessary to survive, individuals with Type 1 diabetes must assume responsibility for the normally automatic regulation of blood glucose levels. This is achieved by varying schedules of daily subcutaneous insulin administration using either self-administered injections or a continuous subcutaneous insulin infusion system. In addition, it is necessary to co-ordinate dietary intake (i.e. timing, quantity and content of food intake) and energy expenditure (e.g. exercise) with circulating insulin levels. In order to inform self-management decisions (such as calculating insulin doses, food intake and activity levels), capillary blood glucose tests (also known as finger-prick tests) should be undertaken. The aim of such an intensive management regimen is to maintain blood sugar levels as reasonably close as those for people without diabetes, i.e. 4-10 mmol/l [Matthews, 1997].

Whilst finger-pricking provides information on a moment to moment basis, it is of limited value over an extended period. As such, glycated haemoglobin is used as the gold standard for estimating average blood glucose control. This blood test is carried out at intervals of at least 3 months and provides information on the estimated blood glucose levels during that period. Glycated haemoglobin and related measures (GHb and HbA1 or HbA1c) assess average blood glucose by estimating the percentage of haemoglobin that has glucose bound to it over approximately a 6-8 week period. Target levels of HbA1c are below 7 mmol/L.

1.5 ACUTE COMPLICATIONS

Hypoglycaemia and ketoacidosis are the two most common acute complications of Type 1 diabetes. The two most common causes of isolated episodes of hypoglycaemia are unplanned periods of physical activity and delayed/missed meals.

Once identified, hypoglycaemia can be rapidly resolved with ingestion of 10-20g of fast acting carbohydrates (such as lucozade). It is advisable to take a further 10-20g of long-acting carbohydrates following recovery to avoid rebound hypoglycaemia [Fitzgerald et al, 1998].

Diabetes ketoacidosis (DKA) is a serious and life-threatening condition and is the most common cause of mortality in patients under 40 years of age [Laing et al, 1999]. Isolated admissions for DKA can usually be attributed to acute illness or intermittent/non-existent insulin administration [Morris et al, 1997].

1.6 LONG TERM COMPLICATIONS

Chronic microvascular, neuropathic and macrovascular complications account for the majority of morbidity and mortality in Type 1 diabetes. Retinopathy and nephropathy are examples of microvascular complications. Diabetic neuropathy causes primary sensory loss of function affecting the most distal parts of the longest nerves, leading to a range of foot problems such as ulcer and charcot foot. The prevalence of neuropathy increases markedly with age, duration of diabetes and poor blood glucose control [MacLeod & Sonksen, 1996]. Macrovascular complications including large vessel disease contributing to significant reduction in QoL but is also the most likely cause of death.

Current estimates suggest that independent of other risk factors, all types of diabetes post a 2-3 fold increase in risk for coronary heart disease [Shaw, 1997]. Furthermore, diabetes is a very costly disease not only for the affected individual and their family but also for health authorities. In 1997 it was estimated that the cost of treating diabetes in the USA was $44 billion [WHO factsheet 236]. Such costs include medical care, drugs, insulin etc but also the cost of screening and treatment of long term complications and loss of productivity at work. In the UK diabetes costs approximately 5% of the annual National Health Service (NHS) budget [Diabetes UK, 2007]. As such, for the financial year 2005-2006 diabetes cost approximately £5 billion, which breaks down to approximately £100,000 per week or £150 per second.

1.7 CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII)

CSII therapy was introduced into the UK in the late 1970s primarily as a way of achieving and maintaining strict control of blood glucose concentrations in people with Type 1 diabetes. Early problems with DKA [Bradley et al, 1986] and cost of therapy (historically met by the individual) are major contributors to why only a minority of people use CSII therapy.

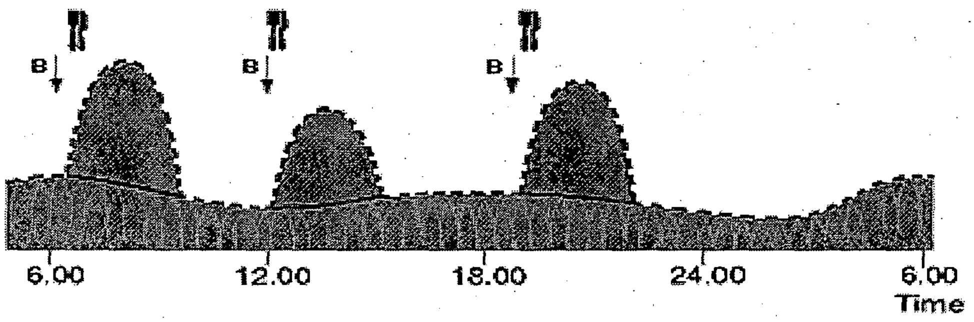
The numbers of individuals using CSII therapy are increasing. In the USA there has been a more than tenfold increase in the number of patients under 20 years old who have been initiated on CSII therapy. [Tamborlane et al, 2001] It is believed that the insulin pump is used in everyday therapy by at least 130,000 people worldwide with more than 80,000 in the United States alone [Pickup, 2001], which suggests that nearly 8% of adults and approximately 6% of children with type 1 diabetes use insulin pumps. In the UK, however, the numbers are tiny, with less than one per cent (approximately 2000 people of the 237,000 people diagnosed with type 1 diabetes using insulin pumps. [Diabetes UK website, 2006]

The National Centre for Clinical Excellence (NICE) estimate the additional cost of pump therapy in comparison to a multiple daily injection regime to be £1,100 to £1,400 per year depending on the life of the pump. There is little information, however, on any associated cost savings in terms of fewer hospital admissions, or long-term diabetes-related complications. NICE do state, however, that ".... the use of CSII therapy would be likely to provide an enhancement in QoL and an improvement of utility score ..." [2003]. They provide no data however to support this assertion either in terms of a systematic literature review or evidenced based research.

1.7.1 How CSII Works

CSII uses a small battery powered insulin pump and short acting insulin (or insulin analogue). The pump is worn 24 hours a day and insulin is delivered via a subcutaneous needle sited in the abdominal wall or thigh. The pump holds sufficient insulin for 2 to 3 days, after which the pump is refilled and the subcutaneous needle re-sited. The pump can be programmed to infuse insulin continuously (basal rate) and the individual is able to administer insulin, via a button on the pump, whenever they eat a meal, so if an individual eats three meals a day then they would administer three boluses of insulin a day via the insulin pump. This system more closely mimics the body's natural insulin production, as can been seen in Figure One.

Figure 1.2
Insulin Delivery Using CSII Therapy



Williams & Pickup, Handbook of Diabetes 2000, page 82]

CSII differs from conventional therapy where insulin is injected 2-3 times a day, generally in the morning and the evening. These injections consist of a combination of long and short acting insulin and individuals must time mealtimes accordingly to avoid episodes of hypoglycaemia. Multiple daily injections (MDI) of insulin simply intensify conventional therapy by dividing the total amount of daily insulin required into basal insulin and bolus injections that are given prior to meals. Basal injections are long acting insulin generally given in morning and night, with bolus injections of fast acting insulin at mealtimes.

1.7.2 Advantages of CSII

There are numerous benefits to using CSII according to published literature. These include improvements in glycaemic control, reductions in glucose fluctuations, prevention of the dawn phenomenon and reduced rates of severe hypoglycaemia. [Rodrigues et al, 2005] Many people have also reported that using CSII has resulted in improvements in their QoL, increased flexibility in meal times and food intake and increased control over insulin levels when exercising. [Linkeschova et al 2002, Chantelau et al 1997, Bruttomesso et al 2002, Hoogma et al 2004] but this is by no means a consistent finding [Kamoi et al 2004, Tsui et al 2001, Weintrob et al 2003].

Other reported benefits of CSII therapy include the apparent lifestyle flexibility and greater independence this system offers to users.

A major advantage of CSII therapy is that it mimics the way that the body naturally produces insulin and so more accurately replicates what happens for people that do not have diabetes. Insulin injection therapy cannot mimic the body in the same way because up to 4 larger doses of insulin are injected daily over periods of up to 12 hours. CSII therapy in comparison provides a continuous drip-feed of insulin in much the same way as the pancreas would normally. The technology was designed specifically for this purpose and when food is eaten, the pump wearer can bolus an additional amount of insulin so as to match the carbohydrate intake they have just eaten, again in the same way the pancreas of a person without diabetes would do.

It is no longer necessary to eat structured meals at structured times to coincide with insulin injections. CSII therapy offers greater flexibility in both the composition and timing of meals with the individual able to adapt the amount of insulin they bolus to their meal preferences. Similarly, CSII is better able to deal with the blood glucose fluctuations produced by increased exercise levels, by allowing individuals to monitor their blood glucose level and immediately adjust their insulin level accordingly. This offers greater flexibility than insulin injections where individuals must calculate their level of exercise and juggle insulin injections and food intake/timing accordingly.

In addition, many insulin pump users report the feeling of a more 'normal' lifestyle. They are able to experience greater freedom not only in meal timings, but also work, school life, sleep and physical activity without the interruptions of insulin injections. This increased freedom is associated with good diabetes control and is thought to contribute to improved QoL. This issue will be explored in this thesis in terms of what constitutes this freedom and what other factors contribute to reported feelings of normality.

1.7.3 Disadvantages of CSII

A major concern with CSII is the increased likelihood of DKA, although good training at the start of pump therapy can help avoid this. Secondly, having to wear the pump continually can interfere with exercise, physical intimacy and choice of clothes. Thirdly, the possibility of marking or scarring where the canula has been placed can be a concern and finally, pump users still need to monitor their blood glucose levels regularly, usually 4 times daily [Fox et al, 2005].

Furthermore, it is extremely difficult to gain access to CSII therapy. The NICE guidelines on its use state that:

> "Continuous subcutaneous insulin infusion (CSII or 'insulin pump therapy') is recommended as an option for people with Type 1 diabetes provided that:
>
> - Multiple doses insulin (MDI) therapy (including, where appropriate, the use of insulin glargine) has failed; and
> - Those receiving the treatment have the commitment and competence to use the therapy effectively.
>
> People for whom MDI has failed are deemed to be those for whom it has been impossible to maintain an HbA1c no greater than 7.5% without disabling hypoglycaemia occurring, despite a high level of self-care of their diabetes" [TA060].

1.8 QUALITY OF LIFE

The concept and assessment of QoL is becoming increasingly important for measuring the impact of illnesses, diseases and their treatments across healthcare generally and for deciding priorities when allocating resources. This is particularly relevant when considering chronic conditions where living with the daily burden of chronic illness is a reality. Diabetes is a demanding disease requiring constant attention. No longer is it enough to simply address the physical and aetiological signs and symptoms of disease, a person's QoL is of growing importance with health professionals now recognising that health consists not only of physical functioning but also of mental and social wellbeing [O'Boyle et al, 1991].

As such, QoL in itself is now recognised as an important outcome for people with diabetes [Wagner et al 2004]. Thus, it is important to consider what QoL actually means and how this impacts on self-care. There is currently no agreed definition of QoL or health related QoL, with several equally valid definitions available in the literature [McGee et al 1991]. For the purpose of this thesis, however, Gill & Feinstein's [1995] definition of QoL as individuals' appraisals of the degree to which their lives contain features that they find satisfying or meaningful has been adopted. Further they state that generally, individuals define QoL in terms of fulfilment or purpose, personal control, interpersonal relationships, participation in pleasant activities, personal and intellectual growth and material possessions.

Diabetes necessitates complex self-care requirements that demand a high commitment from the individual to sustain long-term good health and QoL. Frequent monitoring of blood glucose levels, constant balancing of mealtimes, energy consumption and administration of insulin therapy place a high burden on the individual living with the disease. Such regimen demands do not fit easily with the unpredictable nature of everyday life and there is little perceived short-term gain to be had from such strict management in order to prevent/delay the onset of long-term diabetes related complications.

When people become overwhelmed with the burden of living with diabetes, they sometimes take a 'to hell with it' attitude towards their self-care, doing less than they should to manage their diabetes. [Rubin, 2000] Unfortunately, when this happens it can lead to worsened glycaemic control, increased risk of diabetes-related complications and an even greater sense of overwhelming in both the short and long term. Thus, QoL issues are crucially important not least to avoid deteriorating health status and promote long-term well-being.

Health Related Quality of Life (HRQoL) can be distinguished from generic QoL in that it replaces non-medical factors such as family, economic status and spiritual life with medical factors such as functional status and symptoms [Prutkin & Feinstein, 2002]. Muldoon et al [1998] argued that HRQoL "moves beyond direct manifestations of illness to study the patient's personal morbidity – that is, the various effects that illnesses and treatments have on daily life and life satisfaction". As such, it does not simply reflect biomedical outcomes, rather it incorporates health status factors such as general health, diabetes-specific health, cognitive functioning, psychological and social well-being and reflects the very real burden of chronic illness. In order to investigate QoL associated with insulin pump use, some facet of QoL must be included in the research design. As such, examination of at least one of the factors mentioned above, i.e. health status, well-being, psychological etc must be present.

1.9 PURPOSE OF THESIS

It remains unclear, therefore, whether QoL benefits are associated with CSII therapy and this question requires further investigation. With growing enthusiasm in the UK for CSII therapy, not least on apparent psychosocial issues such as QoL, one must be cautious of such beliefs without a structured investigation as to whether such benefits actually exist.

The main questions posed in this thesis are:

- Are there any QoL benefits associated with CSII?
- If QoL benefits are associated with CSII, what are the specific contributors and effects on QoL?

Initially a pilot study was conducted to establish what issues were relevant to current insulin pump users. The results of this study informed further research to explore further specific domains of QoL and related issues. Both adults and children/adolescents participants were recruited.

Due to the early onset of Type 1 diabetes, it is proposed to investigate both paediatric and adult populations separately in order to identify key issues for each population and any similarities/differences between populations.

CHAPTER TWO

WHAT IS QUALITY OF LIFE AND WHY SHOULD WE MEASURE IT?

2.1 WHAT IS QUALITY OF LIFE?

It would probably be difficult to find somebody today that has not heard of the phrase 'quality of life' or have some idea of what that means to them. It has become a buzzword in modern society that is banded around without any real consensus about meanings. It is likely that if ten people were asked to define 'quality of life', they would come up with ten different definitions, each based on their own unique perspective. Interestingly, if asked to explain what QoL meant in relation to their own lives, there would probably be a number of common themes. Such themes (or life domains) might include issues such as family, work life, financial security and health for example. Such themes, however, would not overlap sufficiently to comprehensively explain the subjective meaning QoL holds for individuals, not least because individuals define life domains in different ways, use different evaluation criteria and place differing emphasis on their overall QoL [Browne et al, 1997]. This raises interesting psychological questions, for example:

- Does the concept of QoL actually exist in reality?
- Is it simply an aspiration about how life could be?
- If QoL does exist, what does it mean?
- How do we measure QoL in any useful way?

It is important to consider, therefore, that the information produced in this chapter is not necessarily the 'right answer' to the question of QoL. It is simply the author's interpretation of theory, previous research and intellectual debate, and is believed to be the most appropriate answer in response to the research questions posed in this thesis i.e., "Exploration of QoL Issues/Benefits Associated With CSII Therapy in Type 1 Diabetes?"

Commonly held beliefs about what constitutes QoL in western culture are centred around good health, a well-functioning family and the possession of material goods or money [Leplege and Hunt, 1997], however this is related to time and place, i.e. Western society in the 21st century. Conversely, poor QoL or health is often associated with sickness, handicap and poverty. However, from this is it unclear which factors are necessarily present to contribute to a good QoL or, indeed, need to be missing or inadequate to justify poor QoL. Spirituality, religion, personal beliefs and societal norms all play a part in defining QoL, however, each individual holds an enormously subjective view of what constitutes their own QoL and how that may or may not be altered. QoL, however, has become increasingly relevant not only in society generally but also in modern healthcare paradigms. Whilst the question of QoL in some form goes back to ancient times with philosophers such as Aristotle arguing that it involves some degree of conflict and challenge, today there are many approaches to the issue [Fayers and Machin, 2000].

The term 'QoL' didn't exist in the Greek language 2000 years ago. It was not until the 20th century that it had taken on a familiarity that no longer required explanation, i.e.:

> *"Life at its noblest leaves more happiness far behind; and indeed cannot endure it ... Happiness is not the object of life: life has no object: it is an end in itself; and courage consists in the readiness to sacrifice happiness for an intenser quality of life."*
>
> [George Bernard Saw, 1900]

Aristotle (384-322BC) provided one of the earliest definitions of QoL in the Nichomachean Ethics stating that "Both the multitude and persons of refinement ... conceive 'the good of life' or 'doing well' to be the same thing as 'being happy' {Fayers and Machin, 2000, p.5]. What constitutes 'happiness' however is disputed both between individuals and within an individual depending on what is happening at the time, a point clearly appreciated by Aristotle. For example, if a person falls sick he thinks health is happiness, when he is poor, that wealth is happiness [Fayers and Machin, 2000]. Furthermore, what does happiness actually mean? Aristotle himself denoted 'happiness' as both a state of feeling and a kind of activity, suggesting internal and external components. Thus, a 'happy' life is not just one lived in a happy state of mind, but one which is objectively happy, one which an impartial judge would regard as fortunate [Ross, 1928]

Alternatively Plato (428-347 BC) considered happiness to be a state of perfection that is hard to comprehend because it is based on metaphysical presuppositions that seem both hazy and out of the realm of ordinary understanding [Frede, 2003]. So in contrast to Aristotle, there is little talk about happiness as a self-sufficient state of the active individual; the emphasis is, rather, on problems and difficulties that need to be solved. Plato's moral ideals certainly appear more austere for example, if "the soul is to remain aloof from the pleasures of the body; communal life demands the subordination of individual wishes and aims" [Frede, 2003]. However, the contrast with Aristotle's views mirror somewhat modern day's debate about what constitute QoL e.g. internal happiness/morality versus external pleasure. These philosophical beginnings have impacted on the way that western society thinks about certain issues, such as QoL.

During the 1930s, psychologists became increasingly interested in the experience of satisfaction, well-being and happiness [Kovac 2004]. This interest developed into the phenomenon of QoL studied by psychologists, sociologists, environmentalists and political scientists today. Emerging as an academic discipline in its own right in the 1970s [Galloway, 2006], the issue of QoL has gained increasing momentum. Its' importance is now such that Government Departments now acknowledge the need to include a wide range of concepts in any evaluation of the QoL of the nation. The American Federal Drugs Agency (FDA) now include QoL as part of the process for evaluating new drugs. Such concepts include economic output, education and pollution. [Eiser and Morse, 2001] These concepts are framed in a specific time and place and may be different for future generations. It is also important to remember that QoL varies across culture and place, e.g. in western culture we take running water, good housing and adequate food for granted. Elsewhere, these are scare commodities and as such, other QoL issues would be considered more relevant.

Firstly, the distinction should be made between QoL and other related concepts. The terms QoL, health status and functional status are often used interchangeably and whilst they are related, they do in fact represent different concepts. Functional status has been defined as an individual's ability to perform normal daily activities that are essential in order to meet basic needs, fulfil usual roles and maintain health and well-being in the physical, psychological, social, and spiritual domains of life [Wilson & Cleary, 1995] An example of which would include being able to perform normal household tasks. Health Status is a broader concept, as a sub-component of functional status, reflecting an individual's relative level of wellness and illness. [Eiser & Morse, 2001]. Heath status takes into account the presence of biological or physiological dysfunction, symptoms and functional impairment, thus functional status is a component of health. In diabetes, for example, the ability to perform normal tasks whilst monitoring blood glucose levels and undertaking behaviours to maintain good blood glucose control. A very low blood sugar or very high blood sugar will generally result in ill-health, thus impacting on an individual's ability to go about their normal routine.

Despite the enormous amount of professional interest, there is still no clear definition of QoL. Rather, there are several equally valid definitions that are applicable dependent upon the perspective of investigation. Functional status, for example, is often confused with QoL, however these are separate concepts. There are several ideas that input into the concept of QoL, one example is the idea that individuals have their own unique perspective that depends on present lifestyle, past experience, hopes for the future, dreams and ambitions. Whilst these concepts are important, they are not QoL per se. Factors such as personality, hardiness, self-esteem, optimism, locus of control and extraversion all play a part in how a person will perceive their own QoL.

Various available QoL definitions include:

> "*A good quality of life can be said to be present when the hopes of an individual are matched and fulfilled by experience. The opposite is also true: a poor quality of life occurs when the hopes do not meet with the experience.*"
>
> [Calman, K.C, 1987]

> "*A multi-faceted construct that encompasses the individual's behavioural and cognitive capacities, emotional well-being and abilities requiring the performance of domestic, vocational and social roles*"
>
> [Tarter et al (1988) quoted in Meebert (1993) p.33

> "*Appraisal of one's current state against some ideal*"
>
> [Cella et al, 1990]

Each of these definitions refers to holistic QoL rather than focusing specifically on health related QoL. Holistic QoL refers to the whole person. i.e. QoL generally, whereas health-related QoL refers to the QoL of a person specifically in terms of their health. As can be seen, they vary in their level of detail. Calman's definition is sufficiently broad that any situation or life experience could be interpreted from the external judgement values of the researcher in terms of what constitutes a good or bad QoL. There is no specification that the individual themselves should determine whether a particular life state equates to a good or bad QoL. Rather, it was deemed that a judgement could be made by an interested third party. This highlights the major flaw with the definition, in that evidence shows that third parties are very poor at accurately reporting an individual's QoL [Uhlmann et al, 1988].

Similarly, Tarter et al's definition infers that an external judgement may be adequate to assess an individual's QoL. Furthermore, there is ambiguity as to what represents the most appropriate definition/criteria for domestic, vocational and social roles. Thus, different researchers could take this definition as a starting point, but end with very different perspectives that could be applied to the same definition, which reinforces the vagueness of determination of QoL.

Thirdly, Cella et al's definition shows how broad and subjective the concept of QoL can be. This definition provides no useful benchmark by which to assess an individual's QoL. Also, one's current state, as in 'now at this moment this is what is happening' could change dramatically within a very short period of time, thus one's definition of their QoL would be constantly changing to incorporate new information.

The rationale for the inclusion of alternative definitions is that it is important to understand that QoL covers more than health, rather it relates to an individual's perspective of their whole life. Also, that there are several ways of assessing QoL, both subjective and externally, bounded by timeframe and definition. However, not all QoL definitions are sufficiently specific or robust to measure, rather they provide a vague enough construct that cannot be disproved. An individual's QoL is important irrespective of health or illness, however health related QoL has justifiably become central to modern health paradigms. A more detailed look at health related QoL is covered later in the chapter.

The QoL definition adopted for the purpose of this thesis has been described as:

> *"individuals' appraisals of the degree to which their lives contain features that they find satisfying or meaningful has been adopted".*

Gill & Feinstein's [1995] Furthermore, they state that

> *"generally, individuals define quality of life in terms of fulfilment or purpose, personal control, interpersonal relationships, participation in pleasant activities, personal and intellectual growth and material possessions".*

This definition has been selected because, whilst it also refers to holistic QoL, it also highlights that there are discrete and specific factors to QoL and including the role of interpersonal relationships, as well as an over-arching general definition. Additionally, the emphasis on personal control is particularly pertinent to the current research. The importance of personal control is central to the thesis question, not least because people with diabetes often describe it in terms of its control of their lives rather than the other way around [Barnard and Skinner, 2007]. It is acknowledged that this is a generic definition, however the component factors hold subjective relevance for all individuals. It should be noted that 'health' is not specifically mentioned in this definition. Health is a component of overall QoL and is not always rated as an important life domain by people with chronic illness [McGee et al, 1991].

It is increasingly recognised that optimal glycaemia control is more likely to be achieved if treatment regimens are tailored to the individual, i.e. convenient and flexible, protecting or even enhancing psychological well-being, than if treatment is inflexible and/or impairs well-being [Glasgow et al, 1999]. Successful biomedical outcomes are more likely to be achieved if they are attained through compromise with the way an individual chooses to live their life.

2.2 WHY IS QUALITY OF LIFE IMPORTANT?

QoL is increasingly recognised as an important health outcome in its own right, representing the ultimate goal of all health interventions. According to the World Health Organization [1992] health is not defined only by the absence of disease and infirmity, but also by the presence of physical, mental, social and spiritual well-being. Whilst historically health care professionals have focussed on the physical and biomedical outcomes of illness, increasingly a person's QoL is considered when making decisions about appropriate treatment.

Illness and its treatment can have a major impact on many aspects that are highly relevant to individual QoL, such as cognitive, emotional and sexual functioning, life satisfaction and the ability to fulfil economic and other social roles [Laborde & Pouers, 1980, Jenkins et al, 1983]. It is widely recognised by healthcare professionals that health consists not only of physical functioning, but also of mental and social wellbeing. Illnesses such as depression have both a biological and psychological cause and treatments targeted at both biological and psychological perspectives are required. Furthermore, depression is more prevalent in chronic conditions than in the general population [Ali et al, 2006]

Depression, for example, plays a huge role in diabetes. A meta-analysis carried out by Ali et al [2006] on the prevalence of co-morbid depression in adults with diabetes resulted with the principal conclusion that diabetes nearly trebles the odds of depression in individuals with diabetes (odds ratio =2.9, 95% CI 1.6-5.5). Depressed adults have a 37% increased risk of developing type 2 diabetes compared with the general population. [Knol et al, 2006] Depression is twice as prevalent in diabetes (10-15%) as in the general population [Anderson et al, 2001] and is more recurrent [Lustman et al, 1997]. Often undiagnosed and treated, depression is associated with poor control and complications [De Groot et al, 2001]. When depression is treated, this treatment is effective in only half of cases [Powers et al, 2004]. This could be because treatment focuses solely on depression, however, depression is often confounded with diabetes burden for those suffering diabetes related complications [Powers et al, 2004]

Furthermore, the 'disability paradox' must be considered when measuring QoL. This paradox lies in the fact that people with chronic or life-threatening conditions may not necessarily rate their own QoL as significantly poorer than people with milder conditions or those who are healthy [Higginson & Carr, 2001]. This is particularly relevant because it can be assumed that people with chronic conditions will experience poorer QoL than the general population, but there is no evidence to support this assertion. Thus reflecting the subjective nature of QoL assessment by individuals. Contrary to expectations, the overall QoL of people with serious illness such as renal disease or cancer may be equivalent to that of the general population [McGee & Bradley, 1994]. It cannot be assumed, therefore, that simply because an individual suffers from a chronic or life-threatening condition, that their self-reported QoL would automatically be worse than that of an individual in the general population without such illness. The disability paradox can indeed present a confounding variable in the definition and measurement of QoL, as indeed could a 'response shift', which may explain why no change in QoL is observed following an intervention. A response shift refers to "a change in the meaning of one's evaluation a construct as a result of a change in one's internal standards of measurement, a change in one's values, or a change in one's definition of the construct" [Sprangers & Schwartz, 1999]. Therefore an individual might give different answers on patient reported outcome measures over time, not only because their QoL has changed, but also because their perception of what QoL means may have changed.

The inability to identify specific elements relevant to an individual's QoL may be more a function of QoL definition and measurement, i.e. whether an external or subjective approach is most appropriate. The choice of assessment measure selected may impact on the subsequent results. As such, it can be difficult to determine the relative value of new treatments, services or interventions using generic measures of QoL, although health related measures may be too narrow because they fail to take account of poor health not always being considered detrimental to QoL by individuals. This is, indeed, a complex issue.

2.3 APPROACHES TO QUALITY OF LIFE

There are a number of approaches to the assessment of QoL. Some of these are outlined below. These approaches reflect QoL per se, rather than the chosen definition of QoL.

2.3.1 Standards Needs Approach

The standards needs approach describes the circumstances of an individual's life. Domains measured by the standards needs approach include:

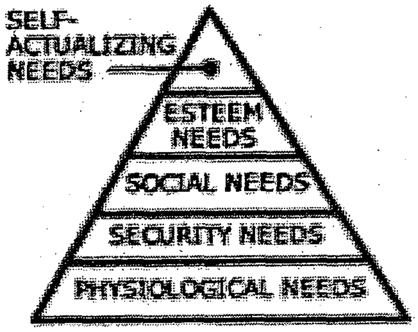
- physical health
- functional ability
- psychological status
- well-being
- social interactions
- economic status

Firstly, the personal circumstances of an individual's life are described in terms of what constitute their QoL. These circumstances are then assigned a numerical value, as determined by the investigator, to indicate an individual's position on a scale assumed to have universal validity [Browne et al, 1997]. The basic premise of the standards needs approach is summarised by Jenkins [1992], i.e. "QoL measures should not be confounded with levels of expectation or personal desire but should refer more clearly and basically to the current situation: physical, psychological and social".

A major flaw with the standard needs approach lies in the assumption that a consensus exists about what constitutes a good or poor QoL and that this can be applied to all individuals. Furthermore, the emphasis on 'needs' rather than 'wants' or 'desires' is misleading because simply because you need something, it does not mean that it will impact on your QoL. The difficulty in explaining QoL in such clear-cut terms is that it ignores the subjectivity of individual perceptions of their own QoL. For example, an individual may not have any specific needs to fill and as such would be considered under the standards needs approach to have a good QoL. Their own perception may be quite different, however, and they may consider their QoL to be very poor because of other important issues not assessed by this method.

This flaw is highlighted in Maslow's hierarchy of needs as outlined in his theory of human motivation (1943). Maslow states that as humans meet 'basic needs' (see Figure 2.1 below), they seek to satisfy successively higher needs as laid out in the hierarchy. The basic concept of the 'pyramid' is that the higher needs only come into focus once all the needs lower down the pyramid are satisfied. Once an individual has moved past a level, those needs will no longer be prioritized. However, if a lower set of needs is continually unmet for an extended period of time, the individual will temporarily re-prioritize those needs - dropping down to that level until those lower needs are reasonably satisfied again. Innate growth forces constantly create upward movement in the hierarchy unless basic needs remain unmet indefinitely.

Figure 2.1
Maslow's Hierarchy of Needs



Maslow's Hierarchy of Needs (1943)

It is perhaps the question of who determines needs that requires further justification. Western culture places greater importance on economic needs, however this is particularly individualist in the west and not necessarily the case for other countries/cultures where different values have greater emphasis.

Evidence suggests that there is often very low consensus about what determines QoL, even in apparently close relationships such as that between patient and physician [Spranger and Aaronson, 1992]. For example, Uhlmann et al [1988] found that physicians rated the QoL of chronically ill elderly patients as significantly lower than the patients' themselves. Indeed, the physicians placed greater emphasis on medical criteria compared to the patients who emphasized non-medical factors such as psychological well-being and socio-economic factors. Throughout medicine generally, results such as these are frequent thus illustrating that low accuracy in third party judgements are not restricted to chronic conditions [Coppola et al, 2001; Hare et al 1992].

2.3.2 Psychological Processes Approach

Approaches focus on the psychological processes involved when individuals evaluate their own QoL. As such, QoL is more than a set of life circumstances alone, rather it is a perception of those circumstances and a judgement about the value individuals place on their own circumstances and personal priorities. There are various psychological processes approaches to QoL measurement:

Content Analysis Methods

"Content analysis is a method for counting particular features of a text or visual image." [Marks & Yardley, 2004] The aim of content analysis is to examine the internal psychological life of the individual concerned by analysing what they say (or write) and how they say (or write) it. [Browne et al, 1997] Thus 'Who says what, to whom, why, to what extent and with what effect? Qualitatively, content analysis can involve any kind of analysis where communication content is categorized and classified. Methods employed attempt to identify recurring themes of spontaneous verbal communication, e.g. most recurring keywords, context and structures of communication [Content analysis, 2007]. "The creation of coding frames is intrinsically related to a creative approach to variables that exert an influence over textual content", thus using politics as an example, political scandals or the impact of polling results would be examined [Content analysis, 2007]. These themes are then categorised and interpreted according to theoretical framework in order to make inferences about antecedents, characteristics and consequences of communications.

Personal Goals Methods

Accordingly to this method, QoL is experienced at an everyday level and cannot be separated from everyday activities. Thus, the personal nature of life goals as perceived by the respondent are fluid in response to existing personal circumstances either facilitating or inhibiting those goals. Measures attempt to capture the dynamic essence of the concept of QoL. Examples of goal attainment measures include the Personal Strivings approach [Emmons, 1986], the QoL Systematic Inventory [Duquette, Dupuis and Perrault, 1994] and the Idiographic Functional Status Assessment [Rapkin, Smith, Dumont, Correa, Palmer and Cohen, 1994].

Repertory Grid Methods

Kelly [1955] developed the repertory grid technique to complement his theory of personal constructs. According to the theory, individuals develop an internal model of the world, based on a hierarchical system of constructs about the elements of the world they encounter in order to successfully adapt to and change their environment. It is a unique system of interconnected meanings defining an individual's perceived relationships to others. This technique attempts to create a representation of personal constructs at the level of the individual. Interestingly, one feature of the repertory grid technique is that it combines aspects of both idiographic assessment and nomothetic research. Thus, the format of the 'repgrid' essentially guides the individual in constructing his or her own questionnaire (by eliciting their own constructs and relevant elements to rate), while allowing comparisons across different people or groups [Neimeyer and Neimeyer, 2002].

A key advantage of the repertory grid method is the use of a well-established technique that directly describes the value structure of the individual. One must be cautious, however when trying to evaluate those value structures. Derivatives from the repertory grid approach do not assign values, rather than are purely descriptive and further analysis is required to evaluate the impact of individuals' value structures on their QoL.

Thus, there are a number of various QoL approaches although not all of these approaches are appropriate in terms of the QoL definition selected as appropriate for this thesis.

2.4 DOES DIABETES AFFECT QUALITY OF LIFE?

Many studies report worse QoL for people with diabetes compared to the general population, especially regarding physical functioning and well-being [Rubin et al, 1999; Peyrot & Rubin, 1997]. There is a 3-fold increase in incidence of depression in Type 2 diabetes compared with the general population [Ali et al, 2006]. A systematic literature review [Chapter Three] showed no similar increase for Type 1 diabetes, although this could be, in part, due to poor methodology in some reported studies. Furthermore, patients suffering from diabetes-related complications tend to report poorer functional status than those without such complications. [Klein et al, 1997]. This is not necessarily related to good or poor blood glucose control. There is a relatively weak association between patients' objective health status and their subjective QoL [Snoek FJ, 2000], therefore good health or glycaemia control do not, in themselves, guarantee better QoL.

The picture is indeed complex and often contradictory. For people with Type 1 diabetes, some studies including those conducted as part of the Diabetes Control and Complications Trial (2003) indicate that treatment intensification has no effect on QoL. Other research suggests that intensification may enhance QoL by reducing the immediate and chronic effects of hyperglycaemia [NICE, 2003]. Yet more research suggests that intensification of treatment may actually worsen a person's QoL because of the highly demanding self-care regimens and increased incidence of hypoglycaemia associated with such intensification. [Hoogma et al 2004] Yet CSII is associated with lower incidence of hypoglycaemia than other intensive insulin regimens [Bode et al, 1996; Rodrigues et al, 2005]. It is clear that further research is required in this area.

2.5 LIVING WITH DIABETES

Whilst the above provides some insight into the enormity of the task, it does not offer any insight into the reality of living with diabetes. Diabetes is a demanding illness that places unreasonable pressures on the person living with it such as frequent blood glucose monitoring, eating when not hungry to avoid hypoglycaemia, not being able to eat when they are hungry so as to avoid hyperglycaemia, balancing medication with food intake and exercises levels and the constant burden of carrying the disease with you for the rest of your life. It requires constant self-management and supreme psychological effort, yet the benefits of this hard work are rarely seen in the short-term. Rather, patients much manage their illness with a view to reducing the risk of long-term complications. This ever-present sword of Damocles co-exists with clinical outcome measures such as HbA1c, blood pressure and cholesterol levels, yet patients must also be able to cope with the psychological burden.

2.6 HOW IS QUALITY OF LIFE MEASURED?

Both generic and disease-specific measures can be useful to help compare the impact of a wide variety of both diseases and treatments on people's lives. This data can then be used to inform appropriate treatment regimen and help direct interventions aimed at reducing the disease burden.

The majority of assessment methods of QoL measurement rely on an external value system on individuals. That is, they are defined based heavily on what researchers believe to be the key factors involved in the make-up of QoL and the best way to measure that, all be it based on aggregated data from their participant pools. Whilst this may identify common issues reported by the majority, it is inadequate to fully understand individual experience. Can a researcher who does not have diabetes, really impose the same external measure of QoL based on the views of others, equally to a teenager with Type 1 diabetes, a working mother of three and a pensioner with Type 2 diabetes?

Diabetes is a chronic condition that demands a high commitment to complex self-care requirements in order to avoid or delay the onset of long-term complications and provide an appropriate QoL. Current goals of treatment in Type 1 diabetes are: to achieve near normal glycaemia, minimise the risk of severe hypoglycaemia, limit excessive weight gain, optimise QoL and delay or prevent late vascular complications [Bode et al, 2002].

It is acknowledged by the American Diabetes Association (ADA) that psychological and social state can impact the patient's ability to carry out diabetes care tasks. As such, the ADA provides specific guidance for psychosocial care alongside biomedical care. Current ADA standards of medical care in diabetes recommendations for psychosocial assessment and care are:

- *Preliminary assessment of psychological and social status should be included as part of the medical management of diabetes.*
- *Psychosocial screening should include but is not limited to attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history.*
- *Screening for psychosocial problems such as depression, eating disorders, and cognitive impairment is needed when adherence to the medical regimen is poor.*
- *It is preferable to incorporate psychological treatment into routine care rather than wait for identification of a specific problem or deterioration in psychological status.*

Standards of Medical Care in Diabetes, ADA 30 (Supplement 1)

The ability to achieve good glucose control, minimise the risk of long-term complications and attend required out-patient visits with the diabetes specialist care team may meet the requirements of good biomedical outcomes. However, when this is viewed in the light of the demanding and unending burden that diabetes places on people suffering from the chronic illness, it is evident that a more holistic approach is required. The partnership between knowledge and management of diabetes along with motivation and self-efficacy is crucial to successful diabetes management. Each of these components is essential and only together can a person manage their illness whilst maximising their ability to live their lives to their desired capacity.

Whilst it is important to acknowledge the importance QoL plays in the treatment of diabetes, as can be seen above, the concept of exactly what QoL entails is hard to measure. Only by finding appropriate measures, however, can we have an understanding of whether a person's QoL has improved or otherwise. There are a number of QoL measures, both generic and health related, which will be outlined below. Other measures are often confused with QoL and used inappropriately. Treatment satisfaction measures for example or measures of health status linking QoL to functional capacity are often misused as measures of QoL.

According to O'Boyle et al, a measure of QoL should quantify the level of functioning of each individual in those areas of life that he or she believes to be most important. [O'Boyle et al, 1992]. This point is reiterated in the chosen QoL definition for this thesis i.e. that "individuals' appraisals of the degree to which their lives contain features that they find satisfying or meaningful" [Gill & Feinstein, 1995]. Thus, individuals identify those areas in their lives that they find satisfying or meaningful. Furthermore, to judge the effect of malfunction, one also needs to know the relative importance attached to a particular area. It must be questioned, however, whether externally determined measures provide a useful assessment of QoL. An externally imposed QoL measure will provide generic and diabetes-specific domains that can be used for larger populations. Whilst some of the rich, subjective nature of an individual's QoL may not be captured by such a measure, there are also many advantages. Large-scale assessments, both generic and disease specific, can provide valuable information in terms of large population samples. Specific items are well-researched and relevant to the majority of participants. Indeed, some externally determined, quantitative measures have the facility for participants to skip questions that are irrelevant to them, yet still provide an overall QoL assessment. Subjective, detailed analysis of individual QoL may give a thorough assessment of an individual, however as QoL changes from individual to individual and even within individuals over time, there must surely be a limit to the usefulness of such measures. Most likely, both quantitative and qualitative measures have their place in QoL assessment.

There is a large body of research demonstrating the importance of measuring psychological processes in the management of diabetes. For many people, the fear of hypoglycaemia is such that they avoid tight blood glucose control, increasing their risk of developing complications [Irvine et al, 1994; Snoek, 2000b]. Alternatively, individuals may be so concerned to avoid long-term complications that they may experience numerous, potentially dangerous hypoglycaemic episodes in an effort to maintain tight glycaemic control.

Below is a critical evaluation of QoL measures, both generic and diabetes-specific.

2.7 MEASUREMENT OF GENERAL QUALITY OF LIFE

Reliability and validity statistics are presented in Chapter Five.

2.7.1 Schedule for the Evaluation of Individual Quality of Life (SEIQoL) Full Version

The SEIQoL is a measure designed to elicit the value system of individual respondents and to quantify QoL using the elicited system [Browne et al, 1997]. Developed almost 20 years ago, the SEIQoL has been used in over a dozen countries in more than 200 studies. [Joyce et al, 2002]. Each individual's QoL is unique. There is no external criteria and as such no 'gold standard' to aspire to.

The SEIQoL was devised from the technique known as judgement analysis to measure patients' level of functioning in five self-nominated facets of life and the relative weight or importance attached to these areas. [O'Boyle et al, 1992]. It is a well-established method of assessing QoL, which incorporates the value system of the individual respondent. There are three stages to the measure: stage one is a semi-structured interview where respondents are asked to nominate five areas (domains) of life they consider most important to the overall quality of their life. Stage two involves respondents rating each life domain on a 0-100mm vertical visual analogue scale anchored at the two extremes by the terms 'best possible' and 'worst possible'. Stage three is designed to quantify the relative importance (or weight) of each domain. The judgements are modelled using multiple regression to produce five relative weights summing to 100. The weights represent the relative importance of each domain to the respondent's overall QoL, and multiplied by the ratings for each domain to produce an overall QoL index score.

A major advantage of using the SEIQoL is its emphasis on individuals choosing/reporting their life domains as opposed to having them imposed externally. Only when individuals have highlighted the areas of life that are important to them can they consider the impact of other factors. Non-medical factors are also extremely important when assessing an individual's QoL. When completing QoL assessments, health is, indeed not always raised as a factor by participants [McGee et al, 1991] and the SEIQoL provides respondents with an opportunity to exclude health if it is not an area of importance for them.

Repeat administration of the SEIQoL enables the assessment of whether there are any QOL changes and if so, whether these are the result of changes in functioning and/or changes in the relative importance or even the nature of the domains used. The 'idiographic' nature of the method is its advantage: the selection of domains can be unique to each individual and even the definition of each domain can be idiosyncratic. [Dijkers, 1999] This increases the relevance of the resulting score to the individual. A disadvantage of the SEIQoL, however, is that a relatively high level of cognitive functioning is required of participants. Furthermore, participants must be willing to spend quite some time during the process, completing semi-structured interviews, sometimes repeated over a period of time.

SEIQoL-DW (Short Version)

The short-form version of the SEIQoL, deriving from the SEIQoL allows respondents to nominate the areas of life that are most important, rate their level of functioning or satisfaction with each, and indicate the relative importance of each to their overall QoL. [Hickey et al, 1996]. It is practical and brief, proving practical for use in clinical situations. As in the full measure, the SEIQoL-DW is administered in a semi-structured interview in three steps. Firstly, cue elicitation i.e. what are the five most important aspects of your life at the moment? Secondly, determining current status on each cue, i.e. how would you rate yourself on each of these areas at the moment? Thirdly, quantification of relative weighting of each cue, i.e. how do the five areas compare in importance to each other? The SEIQoL and the SEIQoL-DW both allow measure of QoL to be completely individualised, but the SEIQoL-DW is perhaps most appropriate in clinical settings where time is limited.

2.7.2 World Health Organisation Quality of Life Abbreviated Scale (WHOQOL-BREF)

Deriving from the WHOQOL-100, the WHOQOL-BREF [Skevington et al, 2004] is reliable and well-validated. It was developed simultaneously in 17 different countries, to be equally valid in each cultural context, which is an important issue, as it resolves some of the issues associated with the translation of measures. It consists of a 26-item questionnaire that provides a broad and comprehensive assessment of QoL. This measure comprises four domains (physical health, psychological, social relationships and environment) plus two items measuring overall QoL and general health. Individuals are required to select one response from five possible responses, ranging from 'very poor' to 'very good' on a likert scale. Questions include 'How much do you enjoy life?' and 'How satisfied are you with your access to health services?'. A particular strength of this measure is that it recognises the multi-dimensional nature of QoL. The WHOQOL-BREF is most useful in studies that require a brief assessment of QoL, for example, in large epidemiological studies and clinical trials where QoL is of interest. In addition, the WHOQOL-BREF is of use to health professionals in the assessment and evaluation of treatment efficacy.

Diabetes specific relevance of the WHOQOL-BREF centres on the impact of diabetes on an individual's own views of their well-being, thus providing a new perspective on disease. For example, that diabetes involves poor body regulation of blood glucose is well understood, but the effect of the illness on the perception that individuals have of their social relationships, working capacity, and financial status has received little systematic attention. [WHO, 1999]. The WHOQOL instruments are tools that facilitate this type of research in that they not only inquire about the functioning of people with diabetes, across a range of areas but also how satisfied the patients are with their functioning and with effects of treatment. Indeed, the WHOQOL-BREF has previously been used to assess QoL in a population with diabetes [Eljedi et al, 2006].

Eljedi et al studied a sample of 197 diabetic patients recruited from three refugee camps in the Gaza strip and 197 age- and sex-matched controls living in the same camps. They used the WHOQOL-BREF, finding all domains were strongly reduced in diabetic patients as compared to controls, with stronger effects in physical health (36.7 vs. 75.9 points of the 0–100 score) and psychological domains (34.8 vs. 70.0) and weaker effects in social relationships (52.4 vs. 71.4) and environment domains (23.4 vs. 36.2). The impact of diabetes on Health Related Quality of Life (HRQoL) was especially severe among females and older subjects (above 50 years). Low socioeconomic status had a strong negative impact on HRQoL in the younger age group (<50 years). Eljedi et al concluded that HRQoL was strongly reduced in diabetic patients living in refugee camps in the Gaza strip with women and older patients being especially affected.

2.8 MEASURES FOCUSING ON FACETS OF QUALITY OF LIFE

There are measures that assess only one facet of QoL such as mental, social or spiritual aspects. Functional status for example, as assessed with the SF36 covers the mental aspect. These measures however do not measure QoL as a whole.

2.8.1 Physical

Medical Outcome Survey Short Form 36 (SF-36)

The SF-36 is a multi-purpose, short-form health survey containing 36 questions. An 8-scale profile of functional health and well-being scores are produced along with psychometrically-based mental health summary measures and a preference-based health utility index. The SF-36 is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. Accordingly, it has proven useful in surveys of general and specific populations, comparing the relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments. [Turner-Bowker, Bartley, & Ware, 2002]

The SF-36 was judged to be the most widely evaluated generic patient assessed health outcome measure in a bibliographic study of the growth of "QoL" measures published in the *British Medical Journal* [Garratt, Schmidt, Mackintosh, & Fitzpatrick, 2002]. Interestingly, the SF-36 does not actually measure QoL, rather it is a measure of health status.

2.9 HEALTH-RELATED QUALITY OF LIFE

The establishment in 1948 of the World Health Organization definition of health was an important milestone in the development of QoL studies within health care. WHO defined health as not only being the *absence* of disease, but the *presence* of physical, mental and social well-being [World Health Organization Handbook, 1952]

HRQoL can be distinguished separately from generic QoL in that it shifts focus to non-medical factors such as family, economic status, spiritual life etc with medical factors such as functional status and symptoms [Prutkin & Feinstein, 2002]. Muldoon et al [1998] argued that HRQoL "moves beyond direct manifestations of illness to study the patient's personal morbidity – that is, the various effects that illnesses and treatments have on daily life and life satisfaction". As such, it does not simply reflect biomedical outcomes, rather it incorporates health status factors such as general health, cognitive functioning, psychological and social well-being and reflects the very real burden of chronic illness. This moves the focus from health related QoL to disease specific QoL.

2.10 MEASUREMENT OF DIABETES-SPECIFIC QUALITY OF LIFE

2.10.1 Diabetes Quality Of Life (DQOL)

The DQOL measure was designed specifically for use in the DCCT because there was no diabetes-specific QoL measure available at the time of the study's inception. [Jacobson & The DCCT Research Group, 1994] The DQOL measure includes 46 core items (assessed on a 5-point Likert scale), forming four subscales (Impact, Worry, Diabetes Satisfaction and Life Satisfaction). Developed from a population of 192 participants aged 13-39 with insulin dependent diabetes, 56 of those participants were aged 13-17 years. Although designed specifically for Type 1 diabetes with intensive insulin treatment, the DQOL has been tested and validated for people with Type 2 diabetes [Jacobson et al, 1994]. There is good evidence for reliability and internal/external construct validity [Garratt et al, 2002].

It was recognised that any impact of insulin intensification on QoL would be significant:

> *"Because intensive treatment would carry additional demands such as extensive re-education, multiple daily injections of insulin or use of the insulin pump, frequent blood glucose monitoring, and greater need for cautious adjustment of food, exercise, and insulin doses, it was anticipated that this might affect the quality of life of patients ... Thus, understanding the effects of the DCCT treatment regimens on quality of life would be potentially useful for clinical application of the trial's findings."*
>
> [Jacobson & The DCCT Research Group, 1994, p65]

Despite the aspects of life measured in the DQOL having been informed by prior research and input from clinicians, a major flaw exists with the questionnaire. There is no scope within the measure for an individual to indicate whether a given aspect of life actually applies to them. For example, items concerning the impact of diabetes on 'family life', 'sex life' and 'ability to drive a car or use machinery' may not be applicable to everyone, thus they are required to provide a response that may not reflect their personal circumstances. Furthermore, responses given to each item in the DQOL are given equal weighting, irrespective of relevance or importance to the individual. Thus, an individual's 'best guess' at an irrelevant, unimportant item would be given the same weighting as a strong 'this absolutely reflects how I feel' type of response. Notwithstanding, the DQOL remains one of the most popular measures of QoL in diabetes.

On careful examination of the individual items there are serious content limitations, for example, many of the items pertain to overall HRQoL issues and are not diabetes-specific ("How satisfied are you with your social relationships and friendships?" "How often do you feel good about yourself?"). Also, many of the items pertaining to treatment satisfaction do not readily fit into the restricted definition of diabetes-specific health related QoL [Polonsky W.H, 2000a]

Further criticism of the DQOL lies in its insensitivity to issues around hypoglycaemia, a point well documented in existing literature [Bradley and Speight, 2002]. This poses a particular problem when attempting to assess the QoL of participants with Type 1 diabetes as hypoglycaemia is a very common concern and this issue is particularly pertinent in this population. A reduction in episodes of hypoglycaemia and blood glucose yo-yo'ing is a contributing factor to outcomes on CSII.

2.10.2 Audit of Diabetes-Dependent Quality of Life (ADDQOL)

A 13-item questionnaire designed to measure individuals' perceptions of the impact of diabetes on their QoL. Each item is scored on a 7-point scale (-3 to +3) and respondents indicate whether the item is very important, important, quite important or not at all important [Bradley et al, 1999]. Items include statements such as "if I didn't have diabetes my employment/career opportunities would be (a great deal better .... a great deal worse)." and "if I didn't have diabetes my motivation to achieve things would be (a great deal better .... a great deal worse)". The advantage of this measure is that respondents are able to indicate if an item is not applicable to them and this item is then dropped from consideration.

The measure is both reliable and well-validated in diabetes populations, with excellent internal validity. It can be used for people with either type 1 or type 2 diabetes and allows the participant to judge the relevance or importance of a given item, such that these items can be discarded before final scoring. This is a specific benefit that sets it aside from the DQOL. Furthermore, no special training is required to administer the questionnaire.

A major concern about this questionnaire is that the logic of the stem question is quite different from all other available instruments [Polonksy, 2000b]. Rather than asking about the degree to which problems associated with diabetes are occurring, this scale asks patients to imagine how life might be different without diabetes. This seems a more complex cognitive task, one step removed from direct questions about diabetes-specific QoL and requiring respondents to think more carefully about their life. It must be questioned, however, whether respondents can accurately represent life without diabetes or whether this representation would be an unrealistic ideal. Furthermore, particularly for individuals with a long duration, or diagnosed in early childhood, it is not clear that such an approach actually allows researchers to accurately assess the impact of diabetes on these broad areas.

Whilst the ADDQOL can be used for people with Type 1 diabetes, herein lies a difficulty. The measures contains items asking participants about life before diabetes, however as many people with Type 1 diabetes are diagnosed at a very early age, it may be inappropriate to ask them questions about life prior to the onset of their diabetes. Notwithstanding, the ADDQOL and the DQOL are the two most predominantly used measures in diabetes currently, however neither measure is appropriate for the purposes of this research.

2.11 DIABETES SPECIFIC MEASURES OF PHYSICAL, SOCIAL AND EMOTIONAL DOMAINS

2.11.1 Physical

The Type 2 Diabetes Symptom Checklist is a 34-item scale designed to evaluate the perceived burden of six categories of symptoms presumed to be associated with diabetes: hyperglycemic, hypoglycemic, cardiac, neuropathic, psychological, and vision-related. [Grootenhuis PA et al, 1994] Respondents indicate on a 5-point Likert scale, their perception of whether a symptom was troublesome or not (i.e. a 1 indicates that the symptom has not occurred or was not perceived as troublesome and a 5 indicates that the symptom was felt to be extremely troublesome). This measure evaluates physical functioning in a broad, comprehensive manner, with the perceived burden of diabetes-specific symptoms being the central aspect of this domain.

The instrument appears to be valid, reliable, and responsive to change although evidence suggests that higher scores are associated with poorer glycemic control, albeit weakly. [Van der Does FE et al, 1996] A difficulty with this approach is that, for many of the symptoms listed, it may be difficult to determine whether the reported symptom distress is actually due to diabetes. Patients may report being symptoms such as "moodiness," "sleepiness or drowsiness," or "deteriorating vision," as extremely troublesome, however this may have little to do with their diabetes.

2.11.2 Social

The Diabetes Social Support Questionnaire (DSSQ) is an example of a social measure. Available in both family and friends versions, the DSSQ examines associations between diabetes-specific family support and adolescents' age, disease duration, gender, emotional support from family and friends, and treatment adherence. Developed by La Greca et al [2002] and tested in a study where 74 adolescents rated 58 DSSQ-Family behaviours on their support, frequency and completed measures of emotional support from family, friends and treatment adherence. After eliminating non-supportive items, the Total DSSQ-Family and five areas of diabetes care (insulin, blood testing, meals, exercise, emotions) were scored for frequency (normative approach) and frequency x support (individualized approach). Results showed that scores from the DSSQ-Family had high internal consistency. Higher frequency and individualized ratings were related to younger adolescent age and to more family emotional support and cohesion, but not to friend support or family conflict. The individualized ratings were significant predictors of adolescents' adherence, even when controlling for age and general levels of family support. The most supportive family behaviours reflected emotional support for diabetes. La Greca et al concluded that the DSSQ-Family was a useful clinical and research tool for measuring adolescents' perceptions of diabetes-specific family support.

The parental involvement scale of the Diabetes Quality of Life for Youth Scale (DQOLY) short-form also provides a diabetes specific social assessment. Although, interestingly, the results from a study using the DQOLY short-form showed that the measure may not reflect issues relevant to adolescents with diabetes. Faro (1999) investigated the effect of diabetes on adolescents' QoL used the DQOLY and compared this with semi-structured open-ended interviews. Faro found that there were issues raised in interviews that were not addressed by the questionnaire.

2.11.3 Emotional

Problem Areas in Diabetes (PAID)

Developed by the Joslin Diabetes Centre, Boston, the validated PAID[Polonsky et al, 1995] scale assesses diabetes-specific emotional distress. This 20-item questionnaire covers a range of emotional problems frequently reported in Type 1 and Type 2 diabetes; issues such as 'feeling scared when you think about living with diabetes' and 'worrying about the future and the possibility of serious complications' amongst others. PAID produces a total score ranging from 0 to 100, where a higher score indicates greater emotional distress. The PAID uses a 5-point item scaling: 'Not a problem' = 0, 'Minor problem = 1', 'Moderate problem = 2', 'Somewhat serious problem = 3', 'Serious problem = 4'. The 0–100 total score is achieved by summing the 0–4 responses given for the 20 PAID items and multiplying this sum by 1.25.

The PAID has been shown to be a statistically significant predictor of glycaemic control, although in cross-sectional studies, the PAID has been found to be weakly correlated with HbA1c and unrelated to duration of diabetes, education, ethnicity and gender when adjusted for age [Welch et al, 1997; Polonsky et al, 1995]. There is also strong support for the measure's sensitivity to change [Welch et al, 2003]. The PAID is currently widely used as a specific measure of emotional distress in the USA, Europe and Asia [Nichols et al, 2000; Snoek et al, 2000, Ishii et al, 1999].

Psychometric reports on the PAID have shown it to have consistently high internal reliability (i.e. a = 0.90); have sound (r = 0.83) 2-month test–retest reliability using a sample of stable patients; to correlate strongly with a wide range of theoretically related constructs such as general emotional distress, depression, diabetes self-care behaviours, diabetes coping, and health beliefs; and to be a statistically significant predictor of glycaemic control in a study that tracked a managed care population control for 1 year [Welch et al. 1997, Polonsky et al. 1995].

Hypoglycaemia Fear Survey (HFS)

The HFS[Cox et al, 1987], is a 27-item validated psychometric tool assessing individuals' fear of hypoglycaemia both overall and in terms of behaviour and worry. The measure provides a total score for each of these domains: how much the individual worries about hypoglycemia, and any subsequent behaviours associated with the fear of hypoglycemia. Questions about worry covered concerns people have with 'having a reaction while alone' and 'making a mistake or having an accident'. Questions about behaviour covered concerns surrounding what people do to avoid low blood sugar, e.g. 'reduce my insulin when I think my sugar is low' and 'keep my sugar high when I will be alone for a while'. Responses range on a 5-point scale from 'never' to 'always'. An Advantage of the HFS is that it may be able to identify individuals who are likely to maintain high blood glucose levels. Thus aiding understanding of potential reasons for poor glycaemic control.

2.12 DISCUSSION

It is clear that QoL has become an integral part of assessments of 'good health'. Now recognised as an important factor in the treatment of diabetes, the focus has shifted to the most appropriate measure of QoL that will most accurately reflect the specific purpose of investigation. Not all QoL measures assess overall QoL, rather several measure specific aspects of QoL. The wide range of measures available provide both externally-judged and subjective perspectives and which represents the most appropriate measure will very much depend on which outcomes are being assessed.

There has been some debate as to whether QOL should/can be measured at all [Wolfensberger, 1994]. Such debate incorporates value judgements such as whether the multidimensional make-up of life can be summarised into very few or even a single judgement without losing essential information. The assumption that people have given thought to their QoL and, upon request, can rate their satisfaction with specific domains of life is not universally shared. Nor is there agreement on whether externally-judged or subjective measures represent the most appropriate direction for QoL assessment. Furthermore, whether a complex, multi-item measure or a single-item assessment is required to provide an evaluation of QoL is questionable.

Debate around QoL dates back to philosophers such as Aristotle and Plato. The focus of what constitutes QoL in terms of internal versus external components was disputed then and still is today. The term 'QoL' only existed in the Greek language as far as 200 years ago and it was not until the 20th century that the term was openly used. With psychological interest increasing in the 1930s and subsequent momentum, many national Governments now include some assessment of the QoL of the nation in Government policy.

When considering health related QoL, the debate often centres around whether generic or disease-specific QoL measures most appropriately reflect individuals' perceptions. As reported above, health is not always considered an important factor when considering individual QoL. Furthermore, it is important to clearly identify exactly what outcomes are being assessed. If functional status is identified as the primary outcome, rather than QoL per se, then a generic measure of functional status such as the SF-36 may be most appropriate. Alternatively, if the primary outcome assesses treatment satisfaction, then the DTSQ may be more appropriate. Also, if investigators wish to find out more about the subjective experience of patients in a given set of circumstances then a tool such as the SEIQoL would provide a valuable insight. Alternatively, if investigators wish to compare large groups of participants on a range of QoL measures, then objective tools such as the WHOQOL-BREF may be more appropriate.

In addition to deciding which QoL measure to use, it is also important to consider the timing of any such measure. The timeframe of questions should be examined to ensure appropriateness for a given population. The ADDQOL asks about life before the onset of diabetes, however for an individual who was diagnosed at a very early age and is now in their 50's for example, it would be inappropriate to ask such questions. When to measure QoL is crucial in evaluating the effectiveness of a given therapy. One cannot know whether a treatment has been effective in terms of improving an individual's QoL if they do not know what an individual's QoL was prior to treatment commencement. Therefore, careful thought needs to be given to timings of QOL assessment, i.e. a minimum of at the beginning and end of any treatment. If treatment is ongoing, an interim QoL assessment may provide useful insight and highlight relevant issues when they arise.

A clear understanding of whether an overall QoL assessment is required, or whether specific areas of life, such as social, physical and mental well-being are to be examined is essential. One must be certain, prior to assessment, that the selected measure will in fact cover the intended area of investigation. Whilst this may seem an obvious point, such errors occur frequently.

This is indeed a complex and sometimes polarised debate, not a million miles away from the quantitative versus qualitative research debate. It could be argued that QoL measures will never be able capture all aspects of life that are important to an individual, and as such, a range of externally-judged and subjective measures are necessary. There is a widely recognised, good quality measure of QoL in diabetes, i.e. the DQoL, however there are more appropriate measures for the purpose of investigation in this study. As such, a combination approach of assessment is appropriate. Difficulties in measuring QoL, however, should not deter us from continuing to strive to use existing methods and develop new methods for such evaluation.

CHAPTER THREE

SYSTEMATIC LITERATURE REVIEW

Quality of Life Associated With Insulin Pump Use in Type 1 Diabetes

3.1 INTRODUCTION

Continuous subcutaneous insulin infusion (CSII) is becoming increasingly popular as a means of insulin delivery for people with Type 1 diabetes in the UK. [NICE, 2002] This is in part due to having been endorsed by NICE, i.e. "…. the use of CSII therapy would be likely to provide an enhancement in QoL and an improvement of utility score …" [NICE 2003] but also because of the apparent lifestyle flexibility, improved blood glucose control and greater independence this system offers to users.

Introduced into the UK in the 1970s primarily as a way of achieving and maintaining strict control of blood glucose concentrations in people with Type 1 diabetes, CSII has provided additional flexibility in meal timing and modifying basal insulin in response to circadian rhythms [Radermaker et al, 2004]. According to Radermecker et al [2004], this greater flexibility is likely to lead to improved 'compliance' and a better QoL for patients using CSII therapy. Furthermore, Bode [2002] reports that CSII using only rapid acting insulin, provides greater flexibility in timing of meals and snacks. Programmable basal rates to optimise overnight glycaemic control can reduce the risk of exercise-induced hypoglycaemia and enhances patients' ability to control their own diabetes. Bode goes on to suggest a final advantage of CSII is that of allowing patients to lead a lifestyle they choose by giving them the capability to control diabetes, instead of allowing diabetes control their lives. It is acknowledged, however, that not everybody's lifestyle is suited to such an intensive therapy as CSII.

Several commentators report that there are numerous benefits to using CSII including improvements in glycaemic control, larger reductions in glucose fluctuations and reduced rates of severe hypoglycaemia. [Rodrigues et al, 2005] A number of patients have also reported that using CSII has resulted in improvements in their QoL but this is by no means a consistent finding [Wilson et al, 2005]. Furthermore, the NICE review indicates that CSII therapy is likely to enhance QoL although they did not carry out a systematic review of existing literature. The purpose of this chapter, therefore, is to systematically review the published literature on the impact of CSII on QoL.

QoL in itself is now recognised as an important outcome for people with diabetes [Wagner et al, 2004; Wagner et al 2004a]. As such, it is important to consider what QoL actually means. There is currently no agreed definition of QoL or health related QoL, with several equally valid definitions available in the literature such as McGee et al [1991]. For the purpose of this review, however, we have adopted Gill & Feinstein's [1995] definition of QoL as individuals' appraisals of the degree to which their lives contain features that they find satisfying or meaningful. Further they state that generally, individuals define QoL in terms of fulfilment or purpose, personal control, interpersonal relationships, participation in pleasant activities, personal and intellectual growth and material possessions.

3.2 RESEARCH DESIGN AND METHODS

3.2.1 Inclusion/Exclusion Criteria

All published studies in which some facet of QoL was measured were included in the study, for example diabetes-specific treatment satisfaction and flexibility. Due to the limited literature available on QoL associated with CSII therapy, the aim of the literature search was to be as inclusive as possible. The inclusion criteria were studies reporting on participants with Type 1 diabetes, regardless of age and gender, good or poor diabetic control.

3.2.2 Search Procedures

MEDLINE, PsychINFO, Cinahl and Embase search engines were individually explored to identify published studies that met the inclusion criteria from date of inception until July 21st 2005. The Diabetes UK website, diabetes journals such as Diabetic Medicine, Practical Diabetes International, Diabetes Care etc and diabetes web-links were also explored along with the Cochrane database, Web of Science and NICE guidelines for citation tracking and highly cited articles. Finally, an electronic investigation of all references of retrieved articles was carried out to ensure that no relevant articles had been missed. The search was conducted using the terms: 'quality of life', 'insulin pump', 'continuous subcutaneous insulin infusion', CSII, 'Type 1 diabetes mellitus', 'Type 1 diabetes', 'drug therapy' and 'patient satisfaction'. Terms were searched both independently and linked to each other term. All synonyms of diabetes, insulin-dependence and insulin infusion systems were also used to identify relevant studies. The search was necessarily broad because this is a vague area to investigate and we wanted to ensure that all relevant articles would be found. As such, diabetes journals not available via the search engines were hand searched to ensure as broad a coverage as possible was achieved.

Members of the Behavioural Science Group of the American Diabetes Association, and the Psycho-Social Aspects of Diabetes group of the European Association of the Study of Diabetes were contacted to request any information they may have about published or unpublished studies with no additional studies identified.

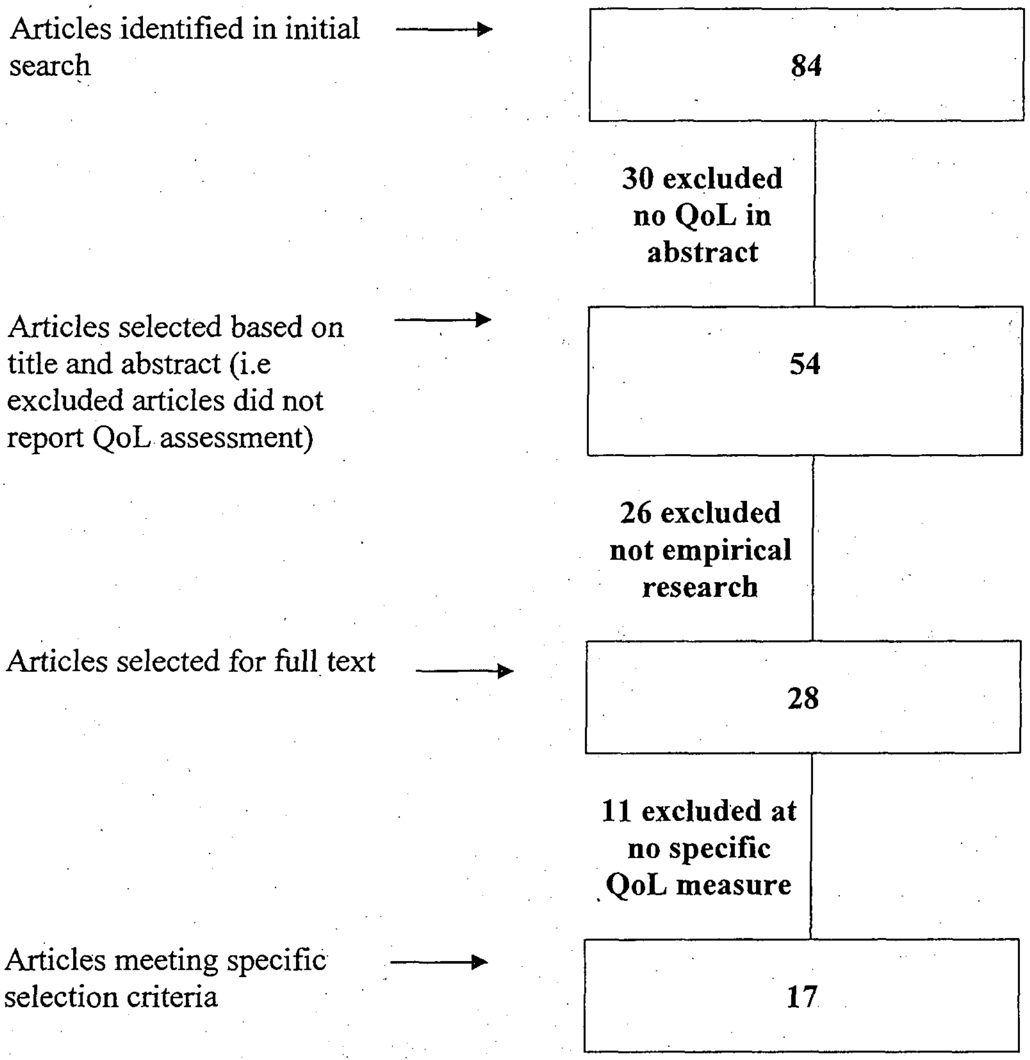
Potentially relevant articles were first identified by examination of information provided in the article title and abstract of articles identified during the electronic search. This information was reviewed for study design, content and patient characteristics with articles not reporting an empirical study or including a specific assessment of QoL were excluded. Retrieval of full text English language articles was then assessed based on the selection criteria detailed above, i.e. articles specifically investigating any facet of QoL in children and adults. All articles that did not meet the selection criteria were discarded at this stage. QoL could be measured independently or alongside biophysical measures. On investigation of the full text articles, those still meeting the selection criteria in entirety were included in this review. All other articles were discarded at this stage. A second reader examined the selection criteria and conducted a brief search of electronic databases (using the same search terms) to ensure no relevant articles had been missed. The selection of studies was a multi-step process. A flow chart of this selection process is attached as Figure One.

3.3 RESULTS

The first identified article was published in 1988. Eighty-four articles were identified in the initial search, of which 54 were selected based on their title and abstract. Where there was absolutely no reference to QoL or QoL related constructs anywhere in the published abstracts, the full text was not retrieved. Of the 54 selected articles, 28 articles were retrieved in full text, of which 17 fulfilled the specific criteria for inclusion. Of the publications identified only 5 reported randomised controlled trials. Details of each study can be found in Tables 1 and 2 later in the text.

FIGURE 3.1

FLOWCHART OF SELECTION PROCESS



3.3.1 Uncontrolled Observational Studies

Seven pre-post studies were identified, with a total of 387 participants across all studies. The main assessment measure was the DQOL with mixed results across the studies.

Adult Studies

Linkeschova et al [2002] carried out an observation study of 100 consecutive patients initiated into the department between October 1995 and April 1999, who were followed for a mean of 2 years. Comparisons were made between glycaemic control, occurrence of acute complications and diabetes-specific QoL (as measured by the Diabetes Specific Quality of Life Survey (DSQOLS) in Type 1 diabetic patients (on intensified conventional insulin treatment) before and after initiation of CSII. All participants were adults (33±11 years) with diabetes duration of 18±9 years. Diabetes-specific QoL showed significant improvement in all parameters during CSII ($p=<0.05$).

In a prospective cohort study, one insulin treatment regimen with low and two treatment regimens with high intensity were studied in two cohorts of individuals with Type 1 diabetes selected from waiting lists who had applied to intensify their insulin therapy by pen or insulin pump. Chantelau et al [1997] investigated the effect of patient-selected intensive insulin therapy on QoL. A total of 132 patients participated in the study, with Cohort A (77 participants) changing from traditional to intensive insulin therapy with pens and Cohort B (55 participants) changing from pen treatment to pump treatment. For comparison of QoL between cohorts, 48 pairs of participants were selected, matched for sex, age, duration of diabetes and education level. The DQOL questionnaire was used, with results showing significant differences between the –1 month versus +3 and +6 months assessments respectively in the subscales 'satisfaction' and 'impact' in cohorts A and B and in the subscale 'diabetes related worries' in cohort A only. CSII significantly improved subscales 'satisfaction' and 'impact' whereas 'social worries' and 'diabetes related worries' remained unchanged. Pump users scored significantly improved QoL with regard to hypoglycaemia, whereas pen users did not ($p=<0.02$). Overall, however, there was very little difference between the two therapy types in terms of improvements in QoL.

Rodrigues et al [2005] studied QoL in relation to differences within pump users rather than compared to any pre-pump participants. All Type 1 diabetic patients on pump therapy were invited to participate. Measures included the DQOL, general health related QoL questionnaire (RAND) and the Hypoglycaemia Fear Scale (HFS).

Results showed that out of the 29 eligible responses, no significant differences on any of the 4 DQOL subscales or total scores were demonstrated between participants with contraindications and those without. HbA1c, insulin dose, blood pressure, weight, height, cholesterol, triglycerides and urine albumin/creatinine ratio and retinopathy were recorded. All participants reported finding their current treatment (i.e. CSII therapy) better compared with their previous treatment, more convenient and more flexible.

Bruttomesso et al [2002] conducted a retrospective study of all diabetic patients treated with CSII excluding those who used it for a few days or irregularly in the Veneto region of Italy: efficacy, acceptability and QoL. The QoL of 98 participants was assessed using the DQOL questionnaire and frequency of hospital admissions and consultations was recorded. Results show that after 7 years of CSII, QoL was rated as good by participants (score 73.0±1.8 on a scale from 0 to 100). Bruttomesso et al concluded that CSII allows a good QoL and decreases out-patient consultations and hospital admissions.

Paediatric/Adolescent Studies

McMahon et al [2005] also conducted a prospective study of patients started on CSII therapy with a view to identifying improvements in key parameters of diabetes management including QoL. Patients were considered for pump therapy if they had recurrent severe hypoglycaemia, poor glycaemic control despite compliance with therapy or erratic lifestyle with regard to sport, food or routine.. A subset of patients (n=43) completed the DQOL questionnaire and self-efficacy for Diabetes Scale (SED). Components of QoL measures showed improvements on pump treatment. There were no significant differences in 'worries about diabetes' and 'satisfaction with life' did not change. Interestingly, however, scores of individuals' self-efficacy with diabetes (as well as those of their parents) increased significantly ($p=<0.05$) and scores for impact of diabetes on the participants fell indicating decreased impact.

Mednick et al [2004] measured satisfaction and QoL in children with Type 1 diabetes following the transition to CSII therapy, as well as that of their parents. Measures included a newly developed measure of CSII therapy satisfaction (IPTSQ). Twenty-two children (mean age 13.59 years, SD 2.59, range 10-18 years) who were transitioning to the insulin pump at an urban children's hospital, and one of each of their parents took part. Prior to the change, all children had been treated on intensive diabetes regimens where average number of blood glucose tests performed each day was 4 and average number of insulin injections completed per day was 3. Results show that children and parents were overwhelmingly satisfied with insulin pump use, with both children and parents reporting greatest satisfaction with flexibility relating to eating and sleeping afforded by pump therapy. Parent-child satisfaction were highly correlated (r=.53) and children's pump satisfaction was significantly positively correlated with diabetes-related QoL (r=.51). DQOLY results also indicated perceived QoL improvements following pump start up, mainly due to greater flexibility with leisure-time activities and with diets. Also interesting is that benefits and changes reported by parents and children were most often related to improved lifestyle or QoL, rather than to metabolic control. Whilst the sample size is small, this finding is important because the focus of research is usually on blood glucose levels, whereas this study shows that QoL can be as important, challenging the assumptions of some members of the medical profession that are (but not always) often held.

Litton et al [2002] analysed the effect of pump therapy in 9 toddlers in whom type 1 diabetes developed between the ages of 10 and 40 months. After a mean of 13.7 months of multiple daily injection (MDI) therapy, patients were treated with insulin pumps for periods ranging from 7 to 19 months (mean 12.7 months). Subjective assessments (not identified) revealed significant improvements in QoL and high levels of satisfaction with pump therapy, although no evidence was provided to support this statement.

3.3.2 Psychometric Studies

Peyrot and Rubin [2005] conducted a comparison study of 197 patients using either CSII (n – 140) or MDI (n – 57). Inclusion criteria were over 18 years, established Type 1 or Type 2 diabetes for at least 1 year, use of CSII or MID and ability to read English. The Insulin Delivery System Rating Questionnaire (IDSRQ) was used. Results showed that CSII users scored lower than MDI users on daily activity interference (p=<0.001), diabetes worry (p=<0.001) and social burden (p=<0.001) but higher on treatment satisfaction (p=<0.001), clinical efficacy (p=<0.001) and psychological well-being (p=0.096).

Lewis et al [1988] conducted a study comparing QoL in 183 individuals who had self-selected either CSII, conventional therapy or intensive conventional therapy. No baseline differences were examined, however, using the diabetes-specific treatment satisfaction scale results showed that people who chose CSII and remained on this treatment for one year reported greater improvements in treatment satisfaction than those choosing either form of conventional therapy.

3.3.3 Controlled studies – Non-Randomised

Three controlled studies were identified, consisting of 231 participants across all trials. Assessment measures were varied across studies, again with mixed results.

Adult Studies

Hoogma et al [2004] compared QoL between CSII and MDI using the DQOL, Diabetes Treatment and Satisfaction Questionnaire (DTSQ) and WHO well-being questionnaires. Two groups of participants (CSII n = 49, MDI n = 79) were matched for duration of diabetes, social class, level of education, marital status, smoking or recent admissions to hospital. All participants were adults (CSII group 41±11.3, MDI group 43.1±14.8), had type 1 diabetes and had been stable for at least one year on CSII therapy. Results showed no statistically significant differences between the two groups with respect to QoL, well-being or satisfaction with treatment.

Kamoi et al [2004] conducted a prospective comparison between multiple daily insulin injections (MDI)(n=16) and continuous subcutaneous insulin infusion (CSII)(n=12). All participants were adult (CSII group mean age and SD 55±13, MDI group mean age and SD 48±17). No inclusion/exclusion criteria defined. A QoL assessment of intensive insulin therapy using insulin lispro switched from short-acting insulin and measured by an un-validated Insulin Therapy Related Quality Of Life (ITR-QOL) questionnaire showed that the QoL of patients treated by CSII was superior to that treated by MDI, i.e. in four subscales of the ITR-QOL, the scores of social and daily activities and of therapy-related feelings in the CSII group were significantly higher (P=0.02) than those in the MDI group respectively. There was no significant difference in the score of physical function between the groups. The means of overall scores of ITR-QOL in the CSII group before and after using insulin lispro were significantly higher than those in the MDI group (p=<0.01).

Paediatric Studies

Boland et al [1999] also conducted a pre-post study examining responses to CSII and multiple daily injections (MDI) in a large group of adolescents with established Type 1 diabetes during a twelve-month period. Adolescents were eligible for inclusion if they were between the ages of 12 and 20 years, had no other health problems except for treated thyroid disease, had been treated with insulin for at least 1 year, had a recent HbA1c level between 7.0% and 14.0%, had no more than 2 severe hypoglycaemic events within the past 6 months and were in a school grade appropriate to their age. One third of 75 youths aged 12-20 chose CSII as their mode of treatment and all participants received intensive treatment and education as described by Diabetes Control and Complications Trial (DCCT) investigators. Self-report questionnaires, i.e. Diabetes Quality of Life: Youth assessment (DQOLY) demonstrated that there was improvement in self-efficacy, depression and QoL in both MDI and CSII treated participants. There were no statistically significant differences between groups. Adolescents using CSII reportedly found coping with diabetes to be less difficult than those adolescents using MDI.

3.3.4 Randomised Controlled Studies

Five randomised controlled trials were identified, consisting of 174 participants in total. Measures were again varied, with results mixed.

Adult Studies

A randomised trial by Tsui et al, [2001] compared CSII with MDI using the DQOL. Adult patients between 18 and 60 years of age with endocrine diagnosis of type 1 diabetes were considered for inclusion if they had been diabetic for more than 2 years, had onset of diabetes on or before the age of 40 years and were able to comply with the treatment regimen. Patients were excluded if they had a history of more than 2 severe hypoglycaemic episodes in the last year, haemoglobinopathy insulin resistance, extreme obesity, severe late complications of diabetes, evidence of significant cardiovascular, hepatic disease, cancer or cerebrovascular or severe peripheral vascular disease, alcohol or drug abuse and/or participation in another clinical trial in the past 4 weeks. Female patients who were pregnant or likely to become pregnant were also excluded. 27 adult participants were randomised to the two groups (13 to CSII and 14 to MDI) with 24 participants completing the DQOL questionnaire at 9 month follow up (11 CSII and 13 MDI). Results show no statistically significant differences between the treatment groups for any of the DQOL subscales used at follow up.

DeVries et al [2002] conducted a randomised trial of CSII and intensive injection therapy in Type 1 diabetes for patients with long-standing poor glycaemic control. Inclusion criteria were type 1 diabetes (diagnosed at or before age 30 years), age between 18 and 70 years, persistent poor control while on 3 or more insulin injections a day. Exclusion criteria were severe active retinopathy, impaired hepatic function, nephropathy, insulin resistance, substance abuse, cardiac disease, uncontrolled hypertension, insulin allergy and past or current psychiatric treatment for schizophrenia, organic mental disorder or bipolar disorder. Women were excluded if they were pregnant or breastfeeding. 79 adult participants from 11 Dutch centers were randomised to 16 weeks of CSII followed by 16 weeks intensive injection therapy, or the reverse order. Changes in health status were assessed using HBA1c, self-reported hypoglycaemia events and blood glucose memory meter read-outs. Changes in quality of health were assessed by self-report questionnaires, i.e. SF-36 administered at baseline and 16 weeks. Results show a high drop out rate (22%) in both groups by the cross-over stage, however of the remaining participants, scores on the short form 36-item subscales of 'general health' and 'mental health' improved in the CSII group compared with stable values in the injection group (+5.9 versus –1.2, P=0.048 and +5.2 versus –0.6, P=0.050 respectively). It was concluded that CSII improves glycaemic control with moderate improvements in general health status and some aspects of health related QoL in patients with a history of long-term poor glycaemic control.

Paediatric Studies

A two-centre randomised controlled feasibility trial of CSII therapy in young children with diabetes was conducted by Wilson et al [2005], in which CSII was compared to MDI therapy. Toddlers and preschool children less than 6 years old were sought who had had type 1 diabetes for at least 6 months whose families had not requested an insulin infusion pump. Students who would be entering first grade during the 1 year duration of the study were excluded. 19 toddlers and children aged 1-6 years participated, 9 in the CSII group and 10 in the MDI group. Results showed similar metabolic control and similar frequency of hypoglycaemia for both groups and no difference between the groups in QoL when measured using the DQOL completed by the child's parents, designed for parents of toddlers with diabetes that was administered at baseline, 28 weeks and 52 weeks. It is unclear whether the DQOL had been validated for use in this way. The improvement in the CSII group, baseline to the end of the study, was significant (p = 0.03), the difference between the two groups, CSII versus MDI, however was not.

Weintrob et al [2003] conducted a randomised open crossover trial comparing CSII and MDI regimens in children with Type 1 diabetes. Inclusion criteria were type 1 diabetes treated by insulin for at least 2 years, aged 8 to 14 years, deficient C-peptide secretion and ability to cope, together with the parents, with the treatment procedures as judged by the diabetic team. Again, only 23 participants made up the two groups however all participants completed both CSII and MDI phases of the study randomly assigned to either Group A or B. Group A, consisting of 11 participants, started with CSII, whilst Group B, consisting 12 participants, started with MDI. Each intervention lasted for 3.5 months, with a 2-week washout period. Results showed that participants expressed a higher treatment satisfaction from CSII than MDI, a significant difference between treatment groups in patient satisfaction on the DTSQ measure was recorded (p=<.001). There was no significant difference between groups for the DQOLY measure, indicating no difference in QoL between the two modes.

Fox et al [2005] conducted a randomised controlled trial of CSII therapy in young children between the ages of 12 and 72 months with Type 1 diabetes for at least 6 months. 26 children with Type 1 diabetes were randomly assigned to either current therapy or CSII for 6 months. After 6 months, current therapy participants were offered CSII with 11 children from each group completing the trial. At baseline there were no differences in parental QoL, as measured by DQOL and Parent Rated Quality Of Life (PDQOLS) and this remained similar between groups at 6 months.

Table 3.2

Summary of Study Design

Year of Publication	Study	Gender (%fem)	Age (years)	Study Design	No. of Participants Providing QOL Data
1988	Lewis et al	49	16-59	Psychometric	183
1997	Chantelau et al	A –49 B - 49	A – 32 B - 31	Pre/Post	96
1999	Boland et al	60 CSII 56 MDI	13.8±2.1 14.6±2.0	Controlled study	25 CSII/50 MDI
2002	Linkeschova et al	56	33 mean	Pre/Post	50
2002	Litton et al	44	13.7 mths mean	Pre/Post	9
2002	Bruttomesso et al	64	-	Retrospective	98
2004	McMahon et al	59	12.5±3.8	Pre/post	43
2004	Mednick et al	54	13.59 ±2.9	Pre/Post	22
2004	Kamoi et al	66 CSII 62 MDI	55±13 48±17	Controlled study	12 CSII/16 MDI
2004	Hoogma et al	73 CSII 46 MDI	41.4±11.3 43.1±14.8	Controlled study	49 CSII/79 MDI
2005	Rodrigues et al	75	33.2±12.2	Pre/Post	29
2005	Peyrot & Rubin	53	46.4	Psychometric	114
RCTs					
1999	Tsui et al	38 CSII 29 MDI	38 35	Randomised controlled study	13 CSII/14 MDI
2002	DeVries et al	46 CSII 47 MDI	36.2±10.3 37.3±10.6	Randomised controlled study	79
2003	Weintrob et al	57	11.8±1.4	Randomised open crossover trial	23
2005	Fox et al	-	46.3±3.2 months	Randomised controlled study	22
2005	Wilson et al	63	3.6 mean	Randomised open crossover trial	9 CSII/10 MDI
Totals/ Weighted means		61.78	30.07		748

CSII – continuous subcutaneous insulin infusion
MDI – multiple daily injections

Table 3.3
Summary of Methodology & Effect Sizes

Study	Questionnaires & Subscales
Lewis et al	DTSQ
Chantelau et al	DQOL satisfaction, impact, diabetes-related worries
Boland et al	DQOLY – depression, worry, satisfaction, impact (all 6 mth/12 mth)
Linkeschova et al	DSQOLS
Litton et al	subjective
Bruttomesso et al	DQOL
McMahon et al	DQOL impact of diabetes, DQOL – worries about diabetes DQOL – satisfaction with life, Self Efficacy for Diabetes scale
Mednick et al	DQOLY
Kamoi et al	ITR-QOL – overall, ITR-QOL – social activities, ITR-QOL – physical functioning ITR-QOL – daily activities, ITR-QOL – therapy-related feelings
Hoogma et al	DQOL – satisfaction, DQOL – impact, DQOL – diabetic worries Social worries A, Social worries B DQOL A, DQOLB DTSQ – hyper, DTSQ – hypo, DTSQ – satisfaction total WHO5 – well-being, WHO5 – depression, WHO5 – anxiousness WHO5 – energy, WHO5 – positive well-being
Rodrigues et al	DQOL, RAND, HFS
Peyrot & Rubin	IDSRQ
RCTs	
Tsui et al	DQOL
DeVries et al	Medical Outcome study, short form survey (SF-36) – general health, mental health, DTSQ
Weintrob et al	DTSQ, DQOLY – satisfaction, DQOLY – impact, DQOLY - worry
Fox et al	PDQOL, BSI, PSI
Wilson et al	DQOL

Medical Outcome Study 36 item short form survey (SF 36) is a validated generic 36 item instrument that measures health related quality of life, DQOL – diabetes quality of life questionnaire, DQOLY – diabetes youth quality of life questionnaire, DSQOLS – diabetes specific quality of life scale, SED – self-efficacy in diabetes, HFS – hypo fear scale, RAND – measures general health related quality of life, SF-36 - , DTSQ – diabetes treatment satisfaction questionnaire, PDQOL – paediatric diabetes quality of life scale, BSI - Brief symptom inventory, PSI - Parenting stress index, WHO5 – Who Well-Being Questionnaire, CSII – continuous subcutaneous insulin infusion, MDI – multiple daily injections, ITR-QOL – insulin therapy related quality of life, IDSRQ – insulin delivery system rating questionnaire

A 5-nation randomised, controlled, crossover trial conducted in 11 European countries by Hoogma et al [2005] was identified following completion of this review. It was published after the cut-off date and so not identified during the literature search. Because of its' relevance, however, it has been subsequently added. This study looked at 272 patients who were treated with CSII or MDI during a 2 month run in period followed by a 6 month treatment period respectively. Inclusion criteria were ability to manage intensive insulin therapy, including blood glucose monitoring at least 4 times daily, carbohydrate counting and insulin dose adjustment and the technical aspects of insulin pump usage. Exclusion criteria were hypoglycaemia unawareness, progressive retinopathy, renal insufficiency, acute coronary syndrome or cerebrovascular accident within the last 6 months, uncontrolled hypertension, autonomic neuropathy, planned or existing pregnancy, or other clinically significant concomitant disorders. QoL measures included the DQOL, the SF-12 health survey questionnaire and an additional questionnaire assessing lifestyle and manageability of the disease and the acceptability of the treatment types.

Results showed the overall DQOL score was significantly higher for CSII at the end of treatment compared with MDI (75 vs 71, p=<0.001) indicating a positive impact on QoL. There were significant improvements in treatment satisfaction (p=<0.001), treatment impact (p=<0.001) when using CSII compared with MDI. The SF-12 showed no differences in perception of physical health, but a significant improvement in perception of mental health when using CSII compared with MDI (p=<0.05). The analysis of lifestyle and manageability questionnaire showed that patients perceived significantly more flexibility with regard to eating habits (p=<0.001) and significant improvements in lifestyle flexibility and sleep patterns (p=<0.001) when using CSII compared with MDI. It should be noted that the MDI group did not include a long-acting insulin analogue. Despite being outside the scope of this review, this paper represents the most robust study conducted to date, however it is worth noting that this study does not take into account any disappointment effect for patients who have not received the preferred treatment and withdrawal that may have resulted. This could be addressed using a Partially Randomised Preference Trial (PRPT)[1993] design.

3.4 DISCUSSION

Existing literature on QoL benefits associated with insulin pump use is rather limited, with conflicting, often ambiguous results and many design/methodological flaws. It is very difficult to ascertain, therefore, whether CSII therapy does actually contribute to improvements in a person's QoL. Only five studies report randomised controlled trials (RCT) and it is the data from these that should be further scrutinised as RCTs represent a currently accepted robustness of methodology, although other methods, such as qualitative research, are equally valid for other aspects of research and can provide a useful insight. Of these studies, only one reports QoL benefits associated with CSII but the presentation of the results raises doubts as to the robustness of this result.

3.4.1 Study Design

There was no control group in seven studies [Linkeschova et al, 2002; Chantelau et al, 1997; Rodrigues et al, 2005; Bruttomesso et al, 2002; McMahon et al, 2005; Mednick et al, 2004 and Litton 2002]. In six studies, confounding variables were not accounted for [Linkeschova et al, 2002; Mednick et al, 2004 and Litton 2002; Hoogma et al, 2004; Boland et al 1000 and Wilson et al, 2005] and in a further two studies, comparator groups were not truly comparable [Kamoi et al 2004; Peyrot & Rubin, 2005]. It cannot be assumed that such selection processes did not influence results. Few studies have used adequate control groups such as a group who have been through a structured education programme including training for carbohydrate counting and dosage adjustment etc which is really a pre-requisite for appropriate pump use [Linkeschova et al, 2002; Chantelau et al, 1997]. This is not only to control for education input but also in terms of contact time control and placebo effects that may arise from that extra input which cannot be ruled out.

Poor study design is a factor in some cases, for example studies of a pre-post design where participants have received both educational input and increased contact time with medical professionals were common [Linkeschova et al, 2002; Chantelau et al, 1997; Hoogma et al, 2004]. These factors must be acknowledged not least because any resulting effect on participants' QoL may be due to/influenced by this additional support. Furthermore, with no control group it is not possible to attribute effects to insulin pump use.

In three of the five RCTs all participants were under the age of 18 years. Interestingly, in these three studies two found no QoL benefits to using CSII and one had mixed results suggesting that the measures have been used in populations in which they maybe should not have been used due to lack of validity with identified age groups. This could well be a mechanism of the problematic nature of collecting data (first or second hand) from children and young people and extends to the historical lack of validated measures available for use by children. Qualitative procedures such as interviews and focus groups may well have obtained more detailed data.

Furthermore, it is not clear from the content of the publications, what rationale was accorded to recruitment procedures. Nor do any assessments appear to have been made as to whether an individual should be offered pump therapy. This insulin regimen is not suited to everybody, yet none of the existing literature provides a clear explanation as to their inclusion/exclusion criteria for participants. Also, there is no clear explanation as to the criteria for initiating pump therapy for those participants who are offered it, with no evidence that participants with contraindications show any differential benefits or negative consequences [Rodrigues et al, 2005].

Frequently, QoL is measured alongside other diabetes outcomes such as HbA1c and overall diabetes control. Indeed, it appears secondary to the main aims of many of the studies. Current literature indicates a weak relationship between improvements in HbA1c and QoL, however this was not reflected in the DCCT, which reported a very weak relationship between hypoglycaemia and QoL. Interestingly, for adolescents in the DCCT they showed poorer QoL in the intervention group. There is very little published literature relating specifically to QoL issues surrounding insulin pump use as a primary outcome. This represents a clear lack of research into this specific area, in contrast to the already existing wealth of data available on the biophysical outcomes and medical issues surrounding insulin pump use. The majority of QoL literature available is very recent, suggesting a growing interest in this very important area of diabetes self-management.

3.4.2 Participant Numbers

There were low participant numbers in most of the studies, however of the randomised controlled trials only the DeVries and recent Hoogma studies included more than 30 participants. It is concerning that the combined total number of participants for all randomised controlled trials was only 170, of which 79 participated in the DeVries trial. Thus, it is extremely difficult to draw any useful generalisations from these study populations due to the lack of sensitivity/power in the study design. CSII may only have an effect on QoL for some people or it must be questioned whether measures are questioning the appropriate variables. It should be noted that no study has used a validated questionnaire that specifically targets CSII therapy.

3.4.3 Measurement Issues

The DQOL was a popular choice for assessing QoL, however, this was not uniformly the case making comparisons difficult. Questions must be asked about whether existing measures for assessing QoL are either specific or sufficiently sensitive. Limitations of Jacobson's Diabetes Quality of Life (DQOL) measure were initially raised in the DCCT in terms of hypoglycaemia issues, however, a more detailed critique was made by Speight [2003] in which she states that there is no scope, within the measure for an individual to indicate that a given aspect of life is not applicable to him or her. Furthermore, Speight goes on "the DQOL Satisfaction subscale includes items concerned with treatment satisfaction but also items concerned with satisfaction with other aspects of life which may or may not be affected by diabetes, e.g. social relationships, work, bodily appearance. As each item has equal weight in contributing to the overall satisfaction score, the DQOL Satisfaction subscale is unlikely to be as sensitive to changes in diabetes treatment as the DTSQ. There is evidence for the sensitivity of the DQOL satisfaction subscale to major interventions such as kidney/pancreas transplant versus kidney only transplant [Nathan et al, 1991] but not for less extreme interventions, such as CSII pumps versus multiple daily insulin injections [Tsui et al, 2001] ". The limitations of the DQOL highlight why this is not necessarily the most appropriate tool. A good diabetes-specific QoL or diabetes treatment satisfaction measure should be sensitive enough to show differences between treatment groups and any benefits that pumps may have over other forms of insulin therapy.

Two studies have assessed QoL using the SF-36 questionnaire. This is actually a measure of functional health status and not of QoL, thus is inappropriate in this context in the authors' opinion. Other measures such as the ITR-QOL are un-validated and as such cannot be considered sufficiently robust.

In some studies [Wagner et al, 2004; Linceschova et al 2002; Kamoi et al, 2004], comparisons were made between a multiple daily injection regimen and insulin pump use. For these studies, some participants were taken from their existing insulin regimen and placed on either of these intensive insulin regimes. Such studies do not, however, address the key question posed in this review i.e. are QoL benefits associated with insulin pump use? Key issues and methodological weaknesses make it impossible to answer this. In the Peyrot and Rubin study specifically, the aim of the investigation was to assess the reliability of the IDSRQ measurement tool rather than to provide a generalisable comparison between CSII and MDI. As such, the authors rightly acknowledge the limitations regarding non-representative sampling and possible positive predisposition of CSII users to their insulin delivery system.

It is unclear what measurements were used to identify people who started on CSII but subsequently discontinued its use. There appears to be no assessment of those people who don't continue despite the evidence that some people choose not to stay on an insulin pump [Kamoi et al, 2004]. Nor is there any analysis on the total number of participants that started each study, therefore it is impossible to take into account the data relating to those people who started and either find no improvements in QoL or are negatively affected and drop out during the study period. The only study to address this was the Weintrob study where 7 out of the 23 participants preferred to continue with MDI following completion of the study. Of these, 5 had started with CSII and then switched to MDI, stating reasons including deteriorating glycaemic control, fear of overeating and weight gain, scars at infusion site, fear of infusion-set insertion, desire to keep diabetes a secret and the shame of wearing a pump, pain in catheter site and finally frequent self-measurements of blood glucose. Such lack of data on participant continuation is an important issue that is currently under researched.

Another important issue to consider is the timing of any QoL assessment. When considering whether a link exists between improved HbA1c and improved QoL, perhaps achieving better blood sugar levels and the resulting impact of that on QoL could be measured longitudinally, as a confounding variable to any QoL benefits of CSII. Improvements in HbA1c may result in improvement perceptions of QoL, however, the benefits in glucose control and reduction in hypoglycaemia have to occur before this will result in perceived QoL benefits. The timing of any measurement, therefore, is important when considering such an issue.

CSII therapy cannot be regarded as a cure for diabetes and can indeed pose it's own difficulties for those choosing this as their preferred insulin regimen. Insulin pumps require programming; they require continual reliance on an external device, with the need to change insulin cartridges and infusion sets. Pumps are not waterproof so cannot be worn when swimming or bathing, thus requiring removal and reinsertion afterwards. They can also be difficult to conceal depending on clothing, which can cause a problem for some users[Fox et al, 2005]. A good understanding of how diabetes, food and insulin interact is required although it could be argued that this is knowledge that all people with diabetes should have. The biggest disadvantage appears to have been the cost implication. Pumps are more expensive than alternative intensive insulin regimens. It could be argued, however, that cost savings are made in the longer term by fewer diabetes related complications etc.

The literature suggests that people motivated to take better control of their diabetes through the use of CSII therapy should, indeed, have access to it [Hoogma et al, 2005]. Insulin pump use is not suited to everybody and simply the desire to transfer to CSII therapy should not be reason enough, unless the patient shows sufficient understanding of what is entailed and psychological assessment shows the patient may well be better suited to pump therapy than any other kind. Transition should be on the basis of informed personal choice made with a clear understanding of the benefits of all insulin regimens available to them.

It is clear from the existing literature that a large-scale multi-centre patient preference controlled trial is required to focus specifically on QoL issues surrounding CSII therapy. From this, it would be possible to identify more clearly how CSII therapy affects QoL (both positively and negatively) and to evaluate the benefits of this approach for specific individuals. It is important to be clear about what QoL means, i.e. increased independence, greater freedom, greater flexibility, easier management of diabetes, better control etc. Only when this issue is clarified could appropriate, sensitive and validated measures be identified (i.e. general measures of health status such as SF-36 and QoL such as SEIQOL compared with diabetes specific measures such as DQOL and ADDQoL) and a randomised controlled trial be feasible.

In conclusion, to date there are no published qualitative studies that attempt to identify QoL issues that may actually be generated by pump use, thus any benefits accrued by insulin pump use may not have been accurately assessed or been missed altogether. It is acknowledged how difficult it is to conduct the 'perfect study', however, if a minimum standard were assumed to be a randomised controlled trial, that controls for increased education and contact time, uses appropriate sensitive measures and recruits large numbers of participants to each group, there are no current published studies that meet this criteria. Thus, the question of whether CSII therapy improves QoL remains unanswered. That is not to say that CSII therapy offers no QoL benefit, far from it. As it currently stands all of the above criticisms should be carefully considered, alongside the fact that there is no clear consistent QoL benefit reported across the results of the controlled studies. Therefore, there may be a strong argument to support QoL benefits associated with CSII therapy, however, the existing literature does not provide strong evidence to support this assertion. This does, however, appear to be more a function of poor methodology and assessment measure of QoL in existing literature than it is of pump therapy not having a benefit. There is certainly no strong evidence either that there is no QoL benefit from CSII therapy. This issue should be investigated more thoroughly.

Systematic Literature Review of Additional Studies

3.5 ADDITIONAL STUDIES - Identified Between July 2005 and May 2007

The initial systematic literature review was conducted in summer of 2005 and as such, it is reasonable to expect that further studies have subsequently been published. As such, a further systematic literature review, using the same search terms and strategy as the initial review was conducted to identify any studies published in the intervening period. Four additional studies were identified, three of which focused on children/adolescent, one investigated parent reported QoL for family members. Each of these studies is reviewed here.

3.5.1 Self Report/Interview Studies

Child/Adolescent Studies

Low et al [2005] interviewed 18 early adolescents (mean age 13.9 years, SD=2.2, 50% female, mean diabetes duration 6.1 years, SD=2.5) and their parents about the experience of using CSII therapy with transcripts were content analysed. Both open and closed ended questions were generated following a review of relevant literature and conversations with providers and educators working with adolescents and diabetes. Results show that interviews lasted between 30 and 90 minutes with teens and parents reporting high levels of satisfaction with CSII therapy and increased adolescent responsibility for the diabetes regimen.

Parent Report Study

Sullivan-Balyai et al [Oct 2005] investigated the transition to CSII therapy in terms of enhanced freedom and QoL for all family members as described by parents. Twenty-one parents (14 mothers and 7 fathers) of 16 children aged below 12 years of age (mean age 7 years; 14 boys) with Type 1 diabetes using CSII therapy. Parents were interviewed (interview duration 90-230 minutes) and questioned on the daily management of diabetes before and after CSII therapy. Analysis was based on verbatim transcripts of interview audiotapes and field notes. Results show that five themes were identified from these interviews: introduction to the pump; transition from MDI to CSII; day-to-day diabetes management with CSII; QoL with CSII. Parents worried less about overall care, hypoglycaemia and mealtimes. Children were said to be in a “better mood” and have better concentration at school. Benefits were described in terms of freedom in choice/timing of meals, ability to participate in school activities and increased spontaneity in family life.

3.5.2 Controlled Studies – Non-Randomized

Children/Paediatric Studies

Valenzuela et al [2006] compared the QoL of children and adolescents using CSII with those using MDI. Participants were recruited from two sites i.e. a university based outpatient clinic and a community-based outpatient clinic. 160 children and adolescents with Type 1 diabetes participated (54% female; aged 5-17, mean 10.86 years SD=3.65). Inclusion criteria were disease duration of at least 9 months, fluency in English and at least 3 months on present prescribed regimen. The exclusion criteria was the presence of another serious concurrent condition that could affect HRQoL. Assessment included parent interview, medical chart review and HRQoL as assessed by the PedQL. This measure is divided into Generic Core (23 items) and disease-specific (28 items) modules, with children and parents asked to respond to how much of a problem each item has been for the child in the past month. Results show that there were no significant differences between CSII or MDI cohorts for either child reported or parent reported generic or diabetes specific QoL. Valenzuela et al conclude that CSII therapy does not have negative implications for HRQoL.

Battaglia et al [2006] conducted a cross-sectional study into disordered eating and psychosocial factors in adolescent females with Type 1 diabetes. The inclusion criteria were aged 12-18 years, diagnosed with Type 1 diabetes for at least 18 months and using CSII or MDI for 6 months or longer. Exclusion criteria were previous rejection of CSII use, diagnosis of any other medical problems and/or illness or visual and/or auditory impairments that may interfere with diabetic treatment or participation with the study. Twenty-two adolescent females using CSII (mean age 14.09, SD=1.85, mean disease duration 6.82 years, SD=3.37) and 47 adolescent females using MDI (mean age 14.49 years, SD=1.74, mean disease duration 7.48 years, SD=3.66) completed standardized questionnaires measuring disordered eating, QoL and self-efficacy. QoL was assessed using the DQOL. Results show that participants using CSII therapy reported significantly better QoL than MDI users (p=<.05). Battaglia et al conclude that CSII therapy may provide a means for improving QoL in adolescent females with Type 1 diabetes.

3.5.3 Discussion

There is a paucity of published research into QoL and CSII therapy in the intervening period since conducting the first systematic literature review up to July 2005. Only four relevant studies were identified, none of which were RCTs. Of the two controlled studies, similar methodological problems to those identified in the initial review were found i.e. in the Battaglia et al study [2006] there was a small sample size, self-report data was used without cross informant data, thus subject to bias and use of the DQoL assessment tool which has been widely criticised for its lack of sensitivity to issues relevant in CSII. For the Valenzuela et al study [2006], the control group was not comparable to the CSII group i.e. there were significant differences between cohorts in terms of disease duration (p=.002), caregiver education (p=.003) and ethnicity (p=.014). Furthermore, there were many more participants in the conventional insulin injection cohort than the CSII cohort (n=118 compared to n=42).

The self report study by Low et al [2005] gives no indication about what questions the parents were asked. A long list of 25 open questions for adolescents is provided in the article as an appendix, however no such list is provided for parent questions. Furthermore, the interview questions were piloted on only two adolescents and parents prior to the beginning of the study with subsequent minor changes made to content and wording. There is no indication that the revised questions were again piloted for suitability.

More positively, the qualitative parent report study by Sullivan-Balyai et al [2005] delves deeply into the subjective meaning of life with CSII therapy as perceived by parents of children using that therapy, although a list of questions is not provided. This study focuses on the experiences of a small number of parents, so it is not possible to generalise the results to the wider CSII population, however, it provides an insight into the issues perceived as important to parents and the impact of CSII on the lives of their families. This is something that could not easily be identified through a quantitative design, not least because of difficulties identifying appropriate measures. QoL is a subjective concept, thus qualitative research such as this provides an extremely useful insight into individual experiences of the transition to CSII therapy from a family perspective.

Thus, in quantitative terms there has been little substance added to the existing literature on QoL and CSII therapy. The qualitative study by Sullivan-Baylai et al [2005] does, however, provide a useful insight into the subjective understanding and experiences of individuals living with CSII therapy and the impact of that therapy on other family members. Given the subjective nature of QoL generally, this insight contributes to our understanding, however, further research is required to extrapolate those findings to the wider CSII population.

CHAPTER FOUR

PILOT STUDY

4.1 INTRODUCTION

Previous research into QoL issues associated with CSII therapy in people with Type 1 diabetes has assumed that a quantitative measure of QoL will pick up issues relevant to people moving to CSII therapy. However, this does not appear to be the case. The most widely used measure, the DQOL [Jacobson et al 1998], was developed for the Diabetes Control and Complications Trial (DCCT) [1994], where it appeared to lack sensitivity regarding issues surrounding hypoglycaemia. Yet fear of hypoglycaemia is known to be a major concern for people with type 1 diabetes. Also, DQOL is not sensitive enough to pick up differences when comparing interventions, such as pump therapy versus multiple daily insulin injections [Speight 2003]. Some studies used measures like SF36. This is actually a measure of functional health status, not of QoL. Other studies have used non-validated measures, such as the ITR-QOL, giving unreliable results. Thus, the key question is how to appropriately assess QoL in people using a pump to manage their diabetes. Mixed results for the impact of pump therapy on QoL seem to be due to poorly chosen or inappropriate measures. That no-one has yet investigated what issues are relevant to CSII users may be a contributing factor to the repeated use of inappropriate methodology. The two qualitative studies identified in the second systematic literature search, however, identify some issues that may be important to CSII users, although it is not known to what extent this information can be generalised.

To address this shortfall, we need to know what issues are relevant and important to pump users. Qualitative studies into the QoL issues associated with CSII therapy in type 1 diabetes are sparse. This pilot study attempts to plug this gap, not least with a view to aiding the design and selection of appropriate measures for future studies on pump use. It is intended to interview participants and elicit their subjective responses regarding any benefits, downsides or QoL impact they have felt about their use of CSII therapy. Further, participants will be asked whether there are any other unidentified issues they can share with the research team.

4.2 METHOD

Following receipt of University of Southampton ethics committee approval, we conducted an exploratory qualitative study to explore patient experiences of life on a pump. Brief telephone interviews were conducted with current pump users, based on the following key questions:

- What are the benefits you have experienced from using the insulin pump?
- Specifically, how do you think it has affected your QoL?
- Are there any down sides that you have experienced from using the pump?
- Are there any other issues these questions have raised for you?

4.3 PARTICIPANTS

Eighty participants were recruited to take part in brief interviews regarding their experience of living with an insulin pump. All participants were current insulin pump users. Roche Diagnostics wrote to all of its CSII customers and asked them if they would be willing participate in research into QoL issues associated with CSII therapy. In accordance with ethics approval, only those who gave written consent were invited to be interviewed. Subsequently, each time a customer phoned Roche Diagnostics' CSII Customer Services Help Line, interviews were conducted after completing the main purpose of the call. As such the method of sampling used was opportunity sampling, rather than random.

4.4 PROCEDURE

All eligible participants on the insulin pump users database (n = 950) were sent a letter outlining the study and asking potential participants for written consent to be approached. Of these, 255 returned signed consent forms. Subsequently, people contacting the customer services help line, between 12th September 2005 and 12th December 2005, who had returned consent forms, were invited to participate.

To ensure consistency, interviewers were trained on how to conduct the interviews. This training included which questions to ask, how to ask them, how to address any responses and, where appropriate, to explore answers. Additionally, the interviewers were provided with a written guide about how to conduct the interviews. If participants gave closed answers to questions, such as a simple ‘yes’ or ‘no’, interviewers were encouraged to prompt them a little further. Participants were given opportunities to raise any issues of their own. Interviewers generated empathy with participants; they avoided guiding responses towards any particular answer.

All individuals who were invited to participate agreed to do so. Interviewers subsequently put questions to them by telephone, digitally recording each call. Transcription and analysis then took place.

4.5 ANALYSIS

Transcripts were read repeatedly and recordings listened to a number of times to ensure familiarity with the data. A process of thematic analysis and coding was conducted. Responses were coded according to the topic area (e.g. flexibility, independence, cost, visibility etc). Each response was allocated a provisional code (e.g.flexibility at work, flexibility in social life, flexibility in household tasks, and then these three categories were merged to form an overarching theme of flexibility). See Appendix B for details. A second researcher coded 10% of transcripts separately and inter-coder reliability assessed. Final positive and negative themes were agreed between researchers.

Thematic analysis was considered most appropriate in order to identify common themes amongst participants, thus each interview was analysed separately, with concepts or themes evident identified and noted. To reduce the analysis down to a meaningful number of constructs, once all interviews were analysed, this initial list of themes was then examined and grouped where there was evident similarity. This was an iterative process with two researchers reaching consensus on themes, before final allocation of participants’ response to the identified key themes. Themes were separated into positive and negative to gauge overall satisfaction. Reliability in analysis and interpretation were gained by the data being independently coded by two researchers and analyses/interpretations compared and agreed between researchers.

4.6 RESULTS

Interviews generally took between 2 and 10 minutes, but occasionally lasted up to 15 minutes. All participants (n = 80) reported experiencing benefits of CSII therapy and that this therapy had positively affected their QoL.

4.6.1 Key Positive Themes

Control versus controlled (n = 45), flexibility (n = 33), and freedom (n = 28) were the most cited benefits, followed by convenience (n = 7) and independence (n = 5).

Table 4.1

Key Positive Themes

Participants (*n*)	% Total Participants	Theme	Quotes from Participants
45	56.25	Control vs Controlled	"well I suppose very much improved diabetic control" "better control of blood sugar levels, very few hypos these days"
33	41.25	Flexibility	".. I don't have to stick to so much of a routine you know with eating and insulin, because before it was very regimental". "flexibility really with what I eat and flexibility erm in general…"
28	35	Freedom	"you don't have to be tied down by time, it gives you more freedom in life …" "well basically fits around the lifestyle a lot better, you're able to do more, not so restricted"
7	8.75	Family Effects	"it's given her quality of life and also myself as well" "there are benefits to the family and friends …."
7	8.75	Convenience	"greater convenience in so far as it's much easier if you're sitting at a restaurant just to press a couple of buttons than taking out a pen" "It's a lot more convenient, fits my life a lot better"
5	6.25	Independence	"It's just sort of made me more independent … I don't have to rely on my husband to give me injections or anything"

Control –vs- Controlled

Regaining control over their diabetes had a major impact for over half of participants (n = 45). Feeling that they were in control of their diabetes, rather than being controlled by it was not only perceived to be a QoL benefit in itself, but also impacted on other issues such as freedom, independence and flexibility. For example, one participant said:

> "*My blood glucose control has improved no end, erm I just, just completely different person. It's made my life … I feel freer than I have for years.*" (1073)

Freedom

Twenty-eight participants cited increased freedom as a benefit. Freedom represented the removal of ties and limitations, instead offering participants the opportunity for greater choice in living their lives the way they wanted. Participants had often felt regulated by time constraints when using their previous insulin regimes. Whereas pump therapy had relaxed these constraints:

> "*You don't have to be tied down by time; it gives you more freedom in life and better quality and control*" (1039)

Independence

Experiencing greater independence, not only for oneself but also for other family members, had positively affected the QoL of 5 participants directly. A further 7 reported positive effects on family members. Having to rely on another person can steal an individual's independence, the effects of which can build cumulatively.

> *"... so I don't have to rely on my husband to give me injections or anything ... It is just wonderful, it really is". (1015)*

One participant commented that pump therapy had improved his wife's QoL:

> *"My wife wouldn't go away and leave me to fend for myself due to the fact I used to have hypos at night. It's totally stopped that and now I can control it and am aware when hypos are oncoming. It's given her quality of life and also myself as well".* (1052)

Flexibility

Increased flexibility was the second most frequent response. Again, this shows that participants found the lack of restrictions was important:

> "*I don't have to stick to so much of a routine you know, with eating and insulin, because before it was very regimental*" (1073)

The data analysis identified a number of key themes. Participants often mentioned the themes together. Thus, pump therapy improved QoL through a number of inter-related benefits in combination.

Benefits

Specifically, in response to a question about the benefits experienced whilst on an insulin pump, individual participants' responses were varied with a number of participants reporting very high satisfaction with their insulin regime, for example quoting one participant

> *"It's the most wonderful thing that has ever happened to me." (1015)*

A second participant said:

> *"unspeakable really, marvellous"* (1020)

with other participants' quotes including

> *"It's given me my life back really"*, (1024)
> *"It's completely revolutionised my life"*, (1029)
> *"It has changed my life completely"*, (1036)
> *"more freedom mainly, better control, more confidence"* (1032) and
> *"It's given me freedom."* (1089)

Reduction in Hypoglycaemia Episodes/Severity

A number of participants highlighted a reduction in episodes or severity of hypoglycaemia as a benefit to CSII therapy. One participant reported:

> *"very few hypos these days, I used to have them quite frequently, especially during the night." Another said: "I still get hypos, but they are less severe." (1041)*

Associated with this was a reported reduction in day-to-day blood glucose fluctuations by five participants. It can be very difficult to maintain good blood glucose control, particularly when levels are fluctuating wildly throughout the day. The removal of such erratic fluctuations was cited as providing a QoL benefit, e.g.

> *"I'm better because I was having really bad hypos and my blood sugar was flying up, it was really, really erratic and all that's gone."* (1045)

Another participant said:

> *"I used to yo-yo from very high to very low, which definitely had an effect on how I felt, in that way now it's much more controlled..."* (1013)

Comparison with Previous Insulin Regime

A number of participants compared using the pump to their previous insulin therapy in an effort to highlight the improvements their new regime offered, for example one such comparison related to CSII therapy having removed the necessity to carry insulin and needles around with them.

> *"I can go out and only carry my testing kit, without all the other paraphernalia."* (1043)

Effects on Quality of Life

When asked about how being on a pump had specifically affected their QoL, there was also variation in responses. Whilst all participants reported improvements in their QoL, some were more enthusiastic than others. Responses ranged from

> *"erm, improved it"* (1007) to
> *"If somebody tried to take it off me I'd fight them and I would go back to paying for it."* (1028)

Some of the in-between responses included:

> *"... you are very free to live. You don't have certain times to eat, wake up and things like that,"* (1031)
> *"It's changed my life really, it's totally back to ... normal"* (1032) and

"I didn't have a life before. Now I can work. I can have a social life ..." (1029)

4.6.2 Key Negative Themes

58.75% of participants (n = 47) reported having experienced down sides to using the insulin pump. Topping the negative themes was visibility - device (n = 25), followed by breakdown (n = 17), visibility - skin (n = 5) and cost (n = 3).

Table 4.2

Key Negative Themes

Participants (*n*)	% Total Participants	Theme	Quotes from Participants
25	31.25	Visibility - Device	"it's not very easy to wear ... it's quite heavy and quite bulky" "you have to find somewhere to hide it"
17	21.25	Breakdown	"times when I've had some technical problems with the pump ... went into DKA" "when it goes wrong it goes disastrously wrong"
5	6.25	Visibility - Skin	"I get bruising and bleeding and build up of fatty tissue" "it's the marks on your stomach where you put your insulin"
3	3.75	Cost	"well obviously the down side is still paying for things" "apart from the costing, I don't get funding whatsoever"

Interestingly, when asked whether they had experienced any downsides to CSII therapy, less than half (i.e. 40%) of participants reported having experienced no downsides at all.

Visibility - device

Of the almost 60% of participants that had experienced downsides the majority reported difficulties with the visibility of the pump and its concealment. Within this key theme, responses varied greatly and were particularly individual to participants. Such responses included:

> *"the size of the pump, the weight of it"*, (1004)
> *"you can't really hide it in a bikini and you've got to make sure you've got the right underwear on when you're wearing a dress"* (1028) and
> *"I think it's very uncomfortable and very intrusive"*. (1072)

Pump sizes vary. More modern models are smaller. So issues regarding size and concealment cannot be generalised across participants, not least because participants' particular models of pump were not known. Also, what may seem trivial to one person may have very serious implications for another. Thus it is impossible to make judgements on the severity of issues without further exploration into their deeper meaning with participants.

Healthcare Professional Advice and Breakdown

Other downsides included the perceived lack of appropriate health care advice or availability of sufficient trained professionals, as well as what happens if the pump breaks down. This reflected a certain level of frustration by participants that they knew more about the technology and therapy than their first point of contact when they needed assistance. For example, participants' comments included:

> *"I think when you need some specialist advice"*, (1016) another said
> *"There aren't enough health care professionals that know about it or how to deal with people on pumps"*. (1044)

'When things go wrong' was an issue raised by seventeen participants, reflecting the rapid nature problems arising when the insulin pump breaks down. Short acting insulin is used in insulin pumps, necessitating the availability of back-up insulin in case of emergency. It can be an extremely difficult experience, as these comments show:

> *"When it goes wrong, it goes disastrously wrong"* (1034),
> *"The times when I've had some technical problems with the pump, erm, there was one time I got, I think it was my canula was badly sited and I went into DKA"* (1007) and
> *"Yes, I have bubbles in the pump and then that caused ulcers ..."* (1031).

Cost

Cost was still perceived as a downside by three participants. Even though CSII therapy is becoming increasingly available on the NHS, many people are still bearing the costs of their treatment. Comments included:

> "*Well obviously the downside is still paying for things*" (1006) and "*... I don't get funding whatsoever*" (1052).

4.7 DISCUSSION

Participants did not regard CSII therapy as a miracle cure. Rather, they reported that the therapy offered a chance to live as normal a life as possible. For example, one participant commented:

> "*It's changed my life really. It's totally back to, I don't know, totally back to normal.*" (1032).

Improvements in QoL meant different things to different people. For some, it involved the freedom to undertake new activities previously restricted under their old insulin regime. For others, it represented the removal of something unpleasant, such as fear. The comments of one participant highlight this, when asked how pump therapy had affected his or her QoL:

> "*Oh it's far better. It's far better because I've got rid of those ups and downs all the time. It was really making me feel ill before. To be honest, erm, I was on my own and I was frightened because I wasn't waking up in the mornings. You know, because I'd gone so bad into a hypo first thing in a morning that I just wasn't waking up. It's made a big difference to me.*" (1045)

Not only had CSII therapy helped with the blood glucose level fluctuations, it also helped to reduce the fear this participant was experiencing living alone with hypoglycaemia. It would be difficult to capture the essence of this statement in a quantitative measure.

How living with diabetes affects the wider family can sometimes be overlooked. Yet it is tied in with the greater independence that participants reported. A number of participants highlighted the benefits of CSII use in the wider context of how their diabetes affected the whole family and how their reduced reliance had knock-on QoL benefits for other family members. One lady explained:

> *"I was completely reliant on my family, now I'm living with my partner, I've a job, I have a life."* (1029).

Several participants emphasised the positive effects of CSII therapy on family members (n=7). One participant reported:

> *"I think people just don't worry about you quite as much as well. I mean my great story is that my mum doesn't go into meltdown when we go to a family wedding any more..."* (1028)

Other participants reported that other family members believed CSII therapy had had a positive effect. For example:

> "*family think it's improved my life*" (1024),
> "*for the family it's so much easier*" (1026) and
> "*There are benefits to the family and friends as well; it does touch every aspect really in a positive way*" (1056).

The main purpose of this study was to gain a meaningful insight into how CSII therapy affected the lives of people with type 1 diabetes. Until now, it has been very difficult to determine what CSII therapy really means to people (in terms of qualitative experience). Previous QoL assessment has concentrated on quantitative methods, which are unable to capture the essence of subjective experience. Perhaps one of the key strengths of this study is that has drawn out people's real life experiences alongside identifying and raising new issues such as QoL benefits of family members. A traditional RCT simply could not convey the richness of such data or identify such issues.

A new and unexpected finding was the positive effect that pump therapy appears to have had on other family members, with participants reporting improvements in their partners' QoL. This is an issue that requires further research. It is rarely addressed in the literature, because family and partner studies tend to focus on how the partner or wider family influences the QoL of those with diabetes. Clearly this is an area that needs more attention.

This study is not without its limitations. It is recognised that this is a specific target group that was accessed through a Roche Diagnostics' customer services helpline. As Roche Diagnostics supply the insulin pumps to participants, it must be acknowledged that participants may have felt some obligation to answer questions more favourably than if they had been asked by an independent third party. In answer to this, it is contended that it is unlikely that participants had any reason to be influenced by a relatively unthreatening team member within the structure of such a large organisation. Furthermore, regular contact had established a rapport between customer services staff and participants before the start of this study.

The ordering of questions may have had an effect on the responses given by participants, for example, whilst only four questions were asked, the first of these was framed positively i.e. "What are the benefits you have experienced from using the insulin pump?" This may have encouraged participants to think more positively about their CSII therapy than had the questions been ordered differently, for example asking the question "Are there any down sides that you have experienced from using the pump?" first. It cannot be ruled out that had the questions been reordered in this way, a less positive response may have been forthcoming. The fact that all participants reported having experienced benefits and QoL improvements as a result of CSII therapy, however, goes some way to allaying these concerns.

Finally, it must be acknowledged that funding was provided for this study by Roche Diagnostics Ltd. Whilst this did not affect the integrity and independence of the researchers, it may have had an underlying effect on how participants responded to questions. Whilst almost two thirds of participant did highlight downsides to CSII therapy, it is acknowledged that this number may have been different had the research been funded differently or the interviews conducted by an independent member of the research team. Unfortunately, however, due to difficulties gaining access to participants, cost and time constraints, this was not feasible. Thus, it must be acknowledged that different funding sources and focus may have affected the results of this pilot study.

The current study reflects the enthusiasm of participants for CSII therapy. This is not surprising of course, as all participants were current insulin pump users and that they had had to work hard to get access to a pump in the UK. The fact that they choose to remain on a pump reflects their satisfaction with the treatment. A large number of participants did report a wide range of downsides, which may go some way to explaining why a small percentage of pump users return to their previous insulin regime. One must be cautious when making such an inference, because other issues not identified in this study may influence a person's decision to cease pump therapy. Little is known about this population, therefore, further research into this area would be extremely useful and a natural progression to provide a clearer all-round picture of QoL issues related to CSII therapy.

In conclusion, for this highly motivated and enthusiastic population, CSII therapy has provided important improvements in their QoL. Further research is required to establish the long-term benefits and the effects on family members' QoL. Key issues that researchers should investigate further include any long-term benefits associated with CSII therapy, what it is about CSII therapy that provides most QoL improvements or whether it is a combination of a cumulative benefit across a range of issues associated with QoL. Appropriate measures might include the IDSRQ (insulin delivery system rating questionnaire) and a generic QoL measure to determine general versus insulin delivery system specific issues. This pilot study has been useful in identifying issues relevant to current CSII users and has informed the choice of appropriate measures for a large cross-sectional study to examine QoL benefits in a quantitative way in a larger sample. It is intended to take these issues further and conduct a larger scale cross-sectional study using the themes raised in this pilot study as a guide for appropriate question selection.

CHAPTER FIVE

CROSS-SECTIONAL STUDY INTO QUALITY OF LIFE ISSUES SURROUNDING CSII THERAPY USE BY ADULTS IN TYPE 1 DIABETES

5.1 INTRODUCTION

Whilst some people report QoL benefits, others view CSII therapy as a complex and demanding daily regimen, placing a high burden of responsibility on the individual (in terms of insulin administration, blood glucose monitoring, diet, exercise and clinic attendance) [Hoogma et al, 2004]. As such, the potential impact of CSII therapy on QoL (both positive and negative) requires investigation. Historically in the UK, many CSII users have had to pay for their treatment, therefore socio-economic status must be acknowledged as contributory factors when considering QoL.

Some authors have suggested that CSII use is associated with decreased distress from hypoglycaemia, increased acceptance of diabetes, greater flexibility in timing of meals and snacks, ultimately reducing the negative impact that diabetes can have on an individual's everyday life [Chantelau, 1997; Bode et al, 2002].

A critical review of this literature, however, suggested that these claims for enhanced QoL for CSII users couldn't be substantiated by the published empirical literature [Chapter 3]. Although some studies do show QoL benefits such as increased satisfaction, decreased impact of diabetes and increased flexibility and convenience [Linkeschova et al, 2002; Bruttomesso et al, 2002; Boland et al, 1999] other studies fail to do so [Hoogma et al, 2004; Tsui et al, 2001; Weintrob et al, 2003].

This study seeks, therefore, to test the hypothesis that individuals using CSII report better QoL and experience better diabetes-specific psychosocial outcomes than individuals using injections to administer their insulin. Furthermore, to establish the long-term and real-life effectiveness of CSII use in the UK, using an observational study.

5.2 METHOD

5.2.1 Research Design and Method

This was a large scale, cross-sectional, matched group survey, designed to explore whether individuals using CSII in the UK reported better QoL than individuals using injection regimens to manage their diabetes. To control for the differences between the level of self-care and motivation required to use CSII, compared to other insulin regimens, CSII users were compared to a group who were matched for age, gender and frequency of blood glucose testing identified from the blood glucose test strip user database.

5.2.2 Procedure

Following receipt of University of Southampton ethics approval, two groups of participants were recruited. Introductory letters and questionnaire booklets were sent to individuals with type 1 diabetes currently using a CSII device, who were registered on the Roche Diagnostics UK database and had previously given consent to be approached for research purposes [the process was the same as that reported in Chapter 4]. Participants were asked to complete the questionnaires and return them in the pre-paid envelope provided. After allowing 7 weeks for individuals to return their questionnaires, a matched cohort of individuals registered on the Roche Diagnostics UK data base of blood glucose monitor users were sent the same introductory letter and questionnaire booklet. Prior written consent had also been obtained from these participants prior to introductory letters being sent. The matched cohort consisted of all individuals on the blood-testing database who were of the same gender, type of diabetes, age and frequency of self-reported blood glucose testing. The latter established from information held on the Roche Diagnostics UK database. This resulted in a minimum of four matches for every CSII user, with up to six matches identified for some users, thus 225 CSII users and 1449 other insulin regimen users were invited to participate.

5.2.3 Measures

To assess QoL, participants were asked to complete a four-part questionnaire booklet. The systematic literature review and results from Chapter Four (where current CSII users identified benefits, downsides, implications for QoL and other relevant issues) were used to identify key relevant issues and facilitate selection of the most appropriate measures. A number of demographic questions were also asked such as age, gender, duration of diabetes, frequency of blood glucose monitoring and number of daily injections. The purpose of these questions was to be able to match CSII users with an appropriate cohort of injection users. Whilst it is appreciated there are many available measures, those selected provide a broad range of psychosocial measures.

Generic Quality of Life

The first part was the well-validated World Health Organisation Quality of Life Abbreviated questionnaire (WHOQOLBREF) [Skevington et al, 2004]. This is a 26-item questionnaire that provides a broad and comprehensive assessment of generic QoL and has previously been used in diabetes research. It comprises four domains (physical health, psychological, social relationships and environment, e.g. financial and resource availability) plus two items measuring overall QoL and general health. Participants could choose from five possible responses, ranging from 'very poor' to 'very good' on questions such as 'How much do you enjoy life?' and 'How satisfied are you with your access to health services?' Following on from the results presented in Chapter 4, an assessment of generic QoL as well as diabetes-specific QoL was deemed appropriate to assess overall and health-related QoL separately.

Diabetes-Specific Quality of Life

The second section of the questionnaire booklet was the Insulin Delivery System Rating Questionnaire (IDSRQ)[Peyrot & Rubin, 2005]. This assesses treatment related QoL and is a well validated questionnaire that gauges overall treatment preference and assess four sub-domains: Satisfaction (cronbach's alpha .92) questions such as 'How satisfied are you with your current insulin delivery system?' with a lower score reflecting greater satisfaction; Interference (cronbach's alpha .90) questions such as 'How much does your current insulin delivery system interfere with the following ....?' With a higher score reflecting less interference; Worry (cronbach's alpha .86) questions such as 'How often do you worry about the following...?' with a higher score reflecting less worry; and Helpfulness (cronbach's alpha .92) questions including 'How good is your current delivery system in helping you with the following....?', where a lower score reflects greater helpfulness.

Responses range respectively from 'completely satisfied to not at all satisfied', 'a lot' to 'not at all', 'all the time' to 'never' and 'excellent' to 'poor', all on a 5-point scale.

Thirdly, considering the relevant impact of fear of hypoglycaemia on QoL, the Hypoglycaemia Fear Scale (HFS)[Cox et al, 1987] was used. This is a 23-item validated psychometric tool that assessed individuals' fear of hypoglycaemia both overall and in terms of behaviour and worry. Responses range on a 5-point scale from 'never' to 'always'. Questions about worry (cronbach's alpha .70) covered concerns people have with 'having a reaction while alone' and 'making a mistake or having an accident', with a higher score reflecting increased worry. Questions about behaviour (cronbach's alpha .94) covered concerns surrounding what people do to avoid low blood sugar, e.g. 'reduce my insulin when I think my sugar is low' and 'keep my sugar high when I will be alone for a while'. There, a greater number reflects more avoidance behaviours.

Finally, the well-validated Problem Areas In Diabetes (PAID)[Polonsky et al, 1995] scale assessed individuals' problems with diabetes. This 20-item questionnaire explored issues such as 'feeling scared when you think about living with diabetes' and 'worrying about the future and the possibility of serious complications' amongst others and responses range on a 5-point scale from 'not a problem' to 'serious problem', with a higher score representing a perception of greater problems. This measure also has four subscales pertaining to 'treatment related problems', 'support related problems', 'food related problems' and 'emotional problems with diabetes'.

A copy of the full questionnaire can be found in Appendix C.

5.2.4 Statistical Analysis Plan

Preliminary analysis was undertaken comparing pump users with non-pump users using T-tests and Chi-square for differences by participant gender. Also, MDI users were compared with individuals on less intensive regimens, to determine whether these groups should be considered differently. Thereafter comparisons were made between CSII users and injection groups initially using ANCOVA. Therefore subsequent analysis was undertaken controlling for potential confounding variables. Finally, a series of multiple regression analysis were undertaken, using forward stepwise entry method, with demographic and medical variables in the first block and then psychosocial variables in block two, to explore determinants of QoL. All analyses were conducted using SPSS v.14. A 15% double-check of data entry was conducted to ensure accuracy.

5.3 RESULTS

255 questionnaires were distributed to insulin pump users, of which 216 were completed and returned representing a response rate of 84.7%. This compared to 1449 questionnaires distributed to the matched cohort, of which 555 were completed and returned, representing a response rate of 38.3% ($p=<.001$). Furthermore, 23 respondents to the matched cohort questionnaire were actually insulin pump users, not registered on the CSII user list, so their data was transferred to the CSII cohort. Thus there were 228 CSII users and 414 people administering injections in the matched cohort. Within the matched cohort, 332 participants were using multiple daily injections (MDI).

Table 5.1 provides a summary of the demographic and diabetes regimens of the two groups. There were no significant differences between CSII users and those on injection regiments for gender ($t = .362$; $p = 0.475$), age ($t = -1.440$; $p = 0.967$), duration of diabetes ($t = 1.419$; $p = 0.932$), although there was a significant difference for frequency of blood glucose testing ($t = -2.268$; $p = 0.009$).

TABLE 5.1

Participant Demographics

	CSII	MDI	Non-MDI	Overall
n	228	332	82	642
Women (%)	68.8	71.3	68.8	68.9
Age (years)	43.6±13.4	45.4±12.9	46.9±15.9	44.9±13.5
Duration of Diabetes (yrs)	24.4±12.1	23.5±12.3	22.8±13.6	23.8±12.4
Length on current insulin regimen (yrs)	3.5±2.8	10.4±8.9	13.8±13.7	8.3±9.0
Mean lowest bg testing	4.8±2.0	4.1±1.5	3.33±1.7	4.3±1.8
4 or more injections daily	-		80.4%	-
3 injections daily	-		4.2%	-
2 or less injections daily	-		15.4%	-

As 20% of the matched cohort participants were using non-MDI insulin regimens, all analyses were repeated between MDI user and non-MDI users. There were no statistically significant differences between these two groups for any of the measures except for the Hypoglycaemia Fear Scale behaviour scale where p=>.05.

Results indicate that for generic QoL, CSII users report better overall QoL and satisfaction with their health, along with higher scores for the environment domain of the WHOQOL-BREF (see Table 5.2). Analysis was conducted on the two single item questions in the WHOQOL-BREF, i.e. 'How would you rate your quality of life?' and 'How satisfied are you with your health?' Results show that insulin pump users reported a better QoL and were more satisfied with their health than the participants using MDI. Thus, 79.8% of CSII users reported their QoL as good or very good compared with 69.2% of MDI users (significant - p=.008). Similarly, 60.4% of CSII users reported being satisfied or very satisfied with their health compared with 46.8% of MDI users (non-significant - p=.880).

All diabetes specific measures evidenced significant differences between CSII users and individuals on injection regimens. Thus CSII users reported less worry about hypoglycaemia and fewer behaviours undertaken in order to avoid low blood sugar, less diabetes related distress in total and fewer diabetes-related emotional problems, treatment-related problems, food-related and social support-related problems (see Table 2 for details). With regard to their perceptions of their insulin delivery system, CSII users reported greater satisfaction, that their insulin delivery system was more helpful, interfered in their daily life less and that they worried less about blood glucose control.

TABLE 5.2

Mean and Standard Deviation for CSII and Injection Users

Variable	CSII Mean ± SD	MDI Mean ± SD	F Value ANOVA	F Value ANCOVA#
WHOQOLBREF – QOL	4.0±.9.0	3.8±.9.0	7.11**	1.41
WHOQOLBREF - health	3.5±1.1	3.2±1.1	7.80***	1.43
WHOQOLBREF Physical health	25.2 ± 5.9	24.7 ± 6.3	.68	3.00
WHOQOLBREF Psychological	22.1± 4.0	21.4 ± 4.7	3.46	2.51
WHOQOLBREF Social relationships	11.1 ± 2.5	11.0 ± 2.7	0.04	5.27*
WHOQOLBREF Environment	31.7 ± 4.5	29.6 ± 6.2	16.89****	------------
IDSRQ Satisfaction	79.7 ± 15.9	74.5 ± 19.5	11.25****	0.33
IDSRQ Interference	18.4 ± 16.7	31.6 ± 25.3	46.66****	21.98****
IDSRQ Helpfulness	69.2 ± 20.3	50.6 ± 22.8	99.21****	38.41****
IDSRQ Worry	42.0 ± 20.3	50.5 ± 21.7	22.21****	6.26*
PAID	16.9 ± 15.1	22.9 ± 18.4	14.91****	0.76
Diabetes-related emotional problems	11.7±10.0	14.5±11.2	8.35****	0.05
Treatment-related problems	1.7±2.5	2.5±2.9	13.09****	0.37
Food-related problems	1.8±2.2	3.2±3.0	37.03****	9.68***
Social support-related problems	1.1±1.6	1.6±2.1	8.29***	0.04
Hypo fear scale total	33.9 ± 14.5	40.5 ± 16.0	20.27****	4.67*
Behaviour score	18.5 ± 5.1	20.7 ± 6.0	17.67****	12.37****
Worry total	15.1 ± 10.9	20.0 ± 12.5	19.36****	2.89

* = p < .05; ** = p <.01; *** = p < .005; **** = p <.001.

results when comparison repeated controlling for Environmental Quality of Life and Frequency of Blood Glucose Monitoring.

The analysis was repeated controlling for the WHOQOL-BREF Environment domain score and frequency of blood glucose monitoring. From Table 2 it can be seen when controlling for these factors that many of the differences are no longer significant between groups. However, the CSII users continue to report that their delivery system is more helpful, interferes with their life less, and causes them less worry. Furthermore, CSII users also continue to report significantly fewer behaviours undertaken in order to avoid low blood sugar levels, and fewer food-related problems on the PAID.

Next, to explore determinants of QoL, a series of multiple linear regression were conducted with the physical, psychological and social domain scores of WHOQOL-BREF as the dependent variable, predicted from demographic (gender, age, environment domain score), diabetes information (insulin regimen, duration of diabetes, age at diagnosis, frequency of blood glucose monitoring) entered in the first block on step 1 of the model, and then PAID, IDSRQ scales and the Hypoglycaemia Fear Scale scores entered on step 2, see Table 5.3 for a summary of the results.

Table 5.3

Results of Multiple Regression to Predict Quality of Life

DV	Predictors	β	t	Sig.
Physical Domain of WHOQOL BREF				
	WHOQOL BREF Environment	.528	9.977	.000
	Age	-.278	-5.794	.000
	CSII use	.209	4.210	.000
	IDSRQ Worry	-.330	-6.231	.000
	Equation Statistics	F = 61.4; R^2 = .55		
Psychological Domain of WHOQOL BREF				
	WHOQOL BREF Environment	.477	8.275	.000
	Age	-.403	-6.407	.000
	CSII use	.148	2.806	.006
	PAID - Diabetes-related emotional problems	.174	2.867	.005
	PAID - Treatment-related problems	.149	2.418	.016
	Equation Statistics	F = 48.6; R^2 = .54		
Social Relationship Domain of WHOQOL BREF				
	WHOQOL BREF Environment	.504	7.507	.000
	Age	-.207	-3.560	.000
	CSII use	.205	3.447	.001
	PAID - Social support-related problems	-.259	-3.459	.001
	PAID - Treatment-related problems	.201	2.680	.008
	Equation Statistics	F = 21.7; R^2 = .35		

These regressions indicate that for physical, psychological and social aspects of QoL in this sample, the environmental domain score is the strongest predictor. However, after entering this and age into the analysis, CSII use added significant variance to the prediction of all three domains of QoL (see Table 3). In addition diabetes related emotional problems and treatment related problems (as assessed by the PAID) were predictive; with treatment related problems also predictive of the social domain along with the social support related diabetes problems (as assessed by the PAID).

Table 5.4

Participant Preferences

	CSII		MDI	
	%	*n*	%	*n*
How satisfied are you with your current insulin delivery system?				
Completely	48.5	116	21.5	111
Very	44.4	106	43.3	224
Somewhat	7.1	17	31.3	162
Not at all	-	-	3.9	20
Would you like to switch to another insulin delivery system?				
Definitely yes	68.9	164	13.2	67
Probably yes	23.9	57	41.1	209
Probably not	5.9	14	36.0	183
Definitely not	1.3	3	9.6	49
Would you recommend your current insulin delivery system to others?				
Definitely yes	81.9	195	20.9	107
Probably yes	17.6	42	64.0	327
Probably not	0.4	1	12.5	64
Definitely not	-	-	2.5	13
How would you compare your current insulin delivery system to your previous system?				
Current much better	96.2	230	44.3	235
Current a bit better	2.3	5	9.0	48
Both about the same	0.4	1	8.6	46
Previous a bit better	-	-	1.5	8
Previous much better	0.8	2	2.3	12

* Not all participants answered each question, % represent % of answers, not % of total participants

In order to explore people's perceptions of CSII therapy more fully in terms of comparison to their previous insulin regimen, satisfaction with current regimen and any desire to change, participants were asked a number of questions relating to this. This analysis was conducted on participants using CSII therapy and multiple daily injections as both of these therapies represent intensive insulin therapy. The majority of insulin pump participants (71.5%) had switched from using a reusable pen to CSII therapy (*n* = 171). This compared in the matched cohort where 43.8% of matched cohort participants (*n* = 233) had switched from vial & syringe to their current insulin delivery device. For 18.6% of matched cohort participants (*n* = 99) this was their first insulin delivery device.

As can be seen from the result in Table 4, firstly, 92.9% of participants in the insulin pump cohort were either very or completely satisfied with their current insulin delivery system, compared to 52.8% of participants in the matched cohort. Secondly, 92.8% of participants in the insulin pump cohort would either probably not or definitely not switch to another insulin delivery system compared with 54.3% of participants in the matched cohort. Thirdly, 99.5% of participants in the insulin pump cohort would either probably or definitely recommend their current insulin delivery system to others compared with 84.9% of participants in the matched cohort and finally, 99.1% of participants in the insulin pump cohort believed their current insulin delivery system was better than their previous system, compared to 54.7% of participants in the matched cohort.

Thus, from these results it can be seen that people using CSII are more likely to be satisfied with their insulin regime, less likely to want to switch to another regime and are more likely to recommend their insulin regime to another person than those participants using multiple daily injections.

5.4 DISCUSSION

The results of this study provide support for a number of assertions that have been made in the literature and may help to explain some of the contradictory findings from previous studies on QoL and CSII use. Firstly, CSII users reported better QoL on all diabetes specific related assessments as well as generic QoL. Historically in the UK many CSII users have had to pay for their treatment, therefore socio-economic status and demographics must be acknowledged as confounding variables, as indicated by the effects of environmental QoL. However, even when the effects of this marker of socio-economic status is controlled for, CSII users report better QoL on a number of dimensions such as food related issues (such as choice and timing of meals), less worry and fewer treatment related problems. CSII use predicts physical, psychological and social QoL, after demographic effects are controlled for.

As might be expected from the research into the glycaemic effects of CSII use reducing hypoglycaemia, CSII users report less fear of hypoglycaemia, even when controlling for socio-economic status and frequency of testing. Unfortunately, frequency of hypoglycaemic episodes was not measured due to the complexity of definitions of hypoglycaemic episodes and severity of hypoglycaemic episodes when relying on questionnaire responding. Of particular note though, is that the effect is a consequence of a reduction in behaviours designed to avoid hypoglycaemia (i.e. behaviours that keep blood glucose levels elevated). This raises the question as to whether reductions in HbA1c associated with CSII use are a result of the specific mechanism of the physiological administration of insulin more closely replicating the body's normal mechanism, or the changes in individuals' hypoglycaemia avoidance behaviour. However, disentangling these effects will be problematic, as it is likely that these two mechanisms form reciprocal relationships to enhance glycaemic control and improve QoL.

Given that Bradley and Speight [2002] reports that overall people with type 1 diabetes report that 'freedom to eat as I wish' is the aspect of QoL, most adversely affected by diabetes self-management and most important for their QoL (closely followed by 'enjoyment of food'), the benefit reported by CSII users in this area is of particular note. However, with the DAFNE trial [DAFNE Study Group, 2002] reporting that intensive education for people with type 1 diabetes particularly improves this aspect of quality life, it is questionable whether the effects seen in this area are due to the CSII or the additional skills training enabling greater flexibility and dietary freedom people commonly get when starting CSII therapy. Future research could benefit from establishing whether individuals attended a carbohydrate counting/dose-adjustment programme, as this may be more likely for people using CSII therapy.

Individuals' commitment to self-care, as indicated by the frequency of self-reported blood glucose monitoring has been controlled for through two mechanisms. First, by recruiting a control group who were matched for frequency of monitoring, and second by statistically controlling for frequency of monitoring when comparing CSII users with individuals on injection regimens. It is not believed that any previous study has attempted to control for commitment to/demands of self-care, assuming randomisation would take care of this. Given the disappointment effects that may be evident in those who do not get randomised to CSII use, this assumption has not been substantiated in research to date. Furthermore, non-randomised trials do not even make the assumption, but still do not attempt to equalize or control for self-care motivation.

Comparisons between previous insulin regimens and a willingness to recommend current regimens to others clearly show the greater level of satisfaction of insulin pump users than the matched cohort. An overwhelming majority of insulin pump users (92.9%) were either very or completely satisfied with their current insulin delivery system, 99.1% believed their current insulin delivery system was better than their previous system, 92.8% cohort would either probably not or definitely not switch to another insulin delivery system and 99.5% would either probably or definitely recommend their current insulin delivery system to others. This compared with 52.8%, 54.7%, 54.3% and 84.9% respectively in the matched cohort. It must be noted, however, that the matched cohort did not have the same knowledge about insulin pump use as the insulin pump user cohort and so would be unable to make or offer an opinion as to whether they might like to change to such a regimen. It is acknowledged that there are serious limitations to asking participants about their preferences, however, this data has been included in addition to the other analysis in an attempt to add another dimension to the results.

A systematic review by King et al [2005] shows that participants' preferences may be based on insufficient or incorrect information. In addition, decisions about treatment choice may be influenced by clinicians, relatives or friends. King et al conclude that when preferences based on informed expectations or strong ethical objections to an RCT exist, observational methods are a valuable alternative. The only better design than this would be a partially randomised preference trial design [Brewin & Bradley, 1989].

CSII users appear to be a highly motivated population, which could contribute to the very high response rate. The response rate from the matched cohort is more indicative of an expected response to a questionnaire survey. Therefore, one must be cautious when attempting to generalise results from a study where some participants are interested in taking part in research data to the wider population. It must also be noted that there is no evidence that both groups have had similar diabetes-specific education, which is an extraneous variable that should be considered. Also, 20% of injection users were not using multiple daily injections, so even with an intensive education programme they would not have the tools for self-management that the other 20% of that cohort have. Analysis was, therefore, also conducted to compare CSII users with multiple daily injection users.

Whilst this study was not a randomised trial, and did not attempt to recruit a random representative sample of people with type 1 diabetes, this study design is relatively robust. The matched cohort design attempted to recruit an equivalent dataset of two samples, matched on several important factors with the notable exception of insulin regimen. Frequency of insulin injections rather than type of insulin regimen was assessed. Additional statistical analysis allowed for the effects of motivation and socio economic status to be controlled for. The fact that the sample was funded by industry, and recruited from an industry database is partly countered by the fact that information sheets and the questionnaire return envelopes made it very clear that the researchers were independent of Roche Diagnostics. Furthermore, to date this is the largest study designed specifically to explore QoL issues associated with insulin pump use. So, whilst not addressing all of the methodological problems highlighted in previous research, it goes some way to addressing those.

In summary, not all generic QoL measures are likely to be sensitive to differences between treatment groups (as seen with other generic measures such as the EQ5D in the UKPDS for example) [Bradley, 2001], however these data suggest that there are several demonstrable benefits of CSII in terms of diabetes-specific psychosocial outcomes (in areas such as food related problems, hypoglycaemia avoidance behaviour, and interference from treatment) that may also serve to enhance metabolic outcomes and reduce the negative impact of diabetes on QoL.

CHAPTER SIX

PAEDIATRIC/ADOLESCENT STUDY INTO QUALITY OF LIFE ISSUES SURROUNDING INSULIN PUMP USE USING THE SEIQoL INTERVIEW

6.1 INTRODUCTION

Three RCTs [Fox et al, 2005; Wilson et al, 2005; Weintrob et al, 2003] have focused on use of CSII in participants under the age of 18 years. In two of the studies, no QoL benefits using CSII were found and one had mixed results. This could well be a function of:

- the problematic nature of collecting data (directly or indirectly) from children and young people
- lack of sensitivity of the psychological measures used [e.g. DQOLY Bradley, 1994]
- inadequate sample sizes to show anticipated effects
- failure to control for confounding variables (e.g. contact time, education)

The conflicting results from the three RCTs for example perhaps reflect the difficulties in measuring QoL, as outlined in chapters four and five. Weintrob et al [2003] reported higher treatment satisfaction for CSII participants than MDI, and a significant difference between treatment groups in patient satisfaction on the DTSQ measure was recorded ($p=<.001$).. However, there was no significant difference in QoL between groups when assessed using the DQOLY measure. As discussed in Chapter Two, treatment satisfaction and QoL represent different outcomes.

Previous research into the benefits experienced by adults using CSII highlighted that a number of participants report improvements in the QoL of other family members. This issue had not been identified in the published literature, and emphasizes the importance of conducting qualitative studies to inform the design and selection of patient reported outcome (PRO) measures e.g. QoL. This is of even greater importance in paediatric studies, where ethical issues will result in minimal sample sizes, requiring greater accuracy in choice of measures if significant effects are to be found. Furthermore, with children the impact on the family is likely to be greater as they are more involved in the child's diabetes care [Anderson, 2004].

The effects of illness and its treatment can have a major impact on many aspects of life that are highly relevant and/or important to individual's QoL. These may be broad-ranging and include cognitive, emotional and sexual functioning, life satisfaction and the ability to fulfil economic and other social roles. Thus, non-medical factors are extremely important when assessing the impact of a condition and its treatment on an individual's QoL. Indeed, when asked to discuss the issues affecting their QoL, respondents do not always raise health as an issue [McGee et al 1991]. Thus, one cannot assume that health is the major QoL priority for people with Type 1 diabetes using CSII. One must consider that people are concerned about many other issues in their lives besides health. The variety and extent of such QoL contributors is often only identified when individuals are asked to report subjectively and spontaneously the factors that they believe contribute to their QoL.

People define QoL in different ways and place differing emphasis on the importance of each aspect of life for their overall QoL [Browne et al 1997]. It is not appropriate to assume that a third party, for example a spouse, relative or doctor can make accurate judgements about an individual's QoL. As previous research shows, third parties (or proxies) are very poor at accurately rating an individual's QoL [Pearlman & Uhlmann, 1988; Walker and Bradley, 2002]. In assessing QoL, it is crucial for the individual to be given the opportunity to identify those factors that are important to him/her and to indicate the relative importance of each area to his/her overall QoL [McGee et al, 1991]. In contrast to the standard needs-based approach to QoL measurement [Jenkins, 1992], the Schedule for Evaluation of Individualised Quality of Life [SEIQoL] method of assessing QoL incorporates the value system of the individual respondent [McGee et al, 1991]. This well-established method emphasises the needs of an individual in terms of the physical, psychological and social that can be equally applied to all individuals.

Rather than simply replicating the open interview style used in previous research, the SEIQoL tool was deemed most appropriate, as it has a number of advantages over other approaches for this population:

- Issues important to adults using CSII had been identified in previous semi-structured interviews [Chapter Four]. For this study, therefore, a specific aim was to assess whether similar issues were important/relevant for children and adolescents using CSII. More than this, however, a deeper insight was sought into what issues were important and how they were rated against each other for children/adolescents and parents of children using CSII (who assist in their children's diabetes care).
- As younger children were to be included in this study, it was felt that they would need more structure to the interview in order to be able to provide full and thoughtful answers. As the SEIQoL has been successfully used previously in paediatric and adult studies, it was deemed appropriate for consistency purposes to use a measure that was applicable for all cohorts.
- The SEIQoL method is targeted specifically at the identification of aspects of life important for QoL, and how those life domains relate to each other. Using this measure, therefore, provides an ideal opportunity to assess the impact of CSII on those aspects of life that are important for individuals' QoL.

From previous research it appears that QoL benefits may accrue in highly motivated individuals. The SEIQoL will detect improvements in QoL as it look at aspects of life important to the individuals with CSII and those of their parents. As such, the purpose of the study was to explore participants' subjective assessments of:

- which aspects of life are relevant to his/her QoL
- the relative importance of each life domain for his/her QoL
- the impact of CSII on those domains and overall QoL.

The primary outcome measure, therefore, is any change in QoL as measured by the SEIQoL for CSII participants and their parents since the commencement of CSII therapy. The secondary outcome measure is the identification of aspects of life that are important to those participants, the relative importance of each and the overall impact of CSII on QoL on those.

6.2 METHOD

6.2.1 Ethics Approval

Following receipt of University of Southampton Ethics Committee approval, a structured interview study was conducted in order to explore the subjective experiences of children/adolescents using CSII and their parents. In accordance with ethics approval, only those who gave written consent were interviewed. Telephone interviews were conducted with current pump users and their parents separately.

6.2.2 Adaptation of the SEIQoL

It is anticipated that using an adaptation of the SEIQoL interview will provide a rich subjective understanding of the issues affecting the quality of lives of children/adolescents using CSII and their parents. The semi-structured SEIQoL interview was used because it initially clarifies the concept of QoL for participants, and then aims to elicit elements that the participant considers contribute to his/her own QoL. Participants are then asked to rate each of the contributing factors they have mentioned in relation to each other. Furthermore, the SEIQoL then provides an opportunity for researchers to identify a specific variable (CSII in this instance) and ask participants about the impact of that variable on the aspects of life important to their QoL. Thus providing a relative weighting of the impact of CSII on each factor.

Forming the basis for all interviews, the SEIQoL semi-structured interview schedule was adapted:

- to be suitable for each target population i.e. parents, adolescents (age 13-18) and children (aged up to 12 years).
- to be CSII specific. Following elicitation of the five key areas of QoL, participants were asked to identify how CSII use impacts on each area and QoL overall.
- to be suitable for use in a telephone interview. Previous research has shown that it is possible to adapt the short version of the SEIQoL interview for administration by telephone rather than the traditional face-to-face interview [Speight et al 2007].

A copy of the adapted interviews used is attached as Appendix D. In order to ensure that all participants would fully understand the questions, the reading age of the child/adolescent questionnaire was reduced to age 8. Two pilot interviews were conducted prior to the start of the study to ensure participant understanding of the questions and the suitability of administering the interviews over the telephone. The primary researcher (Mrs Barnard) conducted all of the interviews, including the pilot interviews. The interviews were tailored to be CSII specific and responses appropriate/specific to CSII therapy and diabetes.

6.2.3 Participants

Participants were invited to take part in the study if they were:

1. registered on the Roche Diagnostics insulin pump user customer database
2. a current insulin pump user aged ≤18 years (or their parent):
    a. children up to and including 12 years of age
    b. adolescents aged between 13 to 18 years
    c. parents of those children and adolescents.

Thirty-four participants (17 children/adolescents and 17 parents/carers) were recruited to take part in the study. Due to database limitations, it is unclear how many participants met the inclusion criteria (i.e. aged 18 years or younger). It was anticipated that approximately 70 children and adolescents would be identified from the existing database, however this was very much guesswork because the database had been inherited from the takeover of another company and records were inadequate to confirm this figure. Database limitations included not being able to ascertain whether all children/adolescents were still under the age of 18, not all personal details were correct/complete, it was not possible to know whether all registered users were still using CSII therapy. Thus, this population of participants represented an opportunistic sampling selection.

6.2.4 Procedures

All potentially eligible participants on the insulin pump users database (n = 110) were sent a letter outlining the study and asking potential participants for written consent to be approached. Enclosed with the letter was a detailed information sheet about the study as well as a consent form for both children/adolescents and their parents to sign if they were willing to participate. All letters and consent forms are attached as Appendix D.

On receipt of signed consent forms, telephone contact was made with those who were willing to participate, in order to arrange a convenient interview time. Relevant materials (i.e. SEIQoL response sheets, Appendix B) were posted to participants and telephone interviews were conducted accordingly.

6.2.5 Analysis

Statistical analysis was conducted using SPSS version 14 to establish frequencies of domains raised, impact of CSII on those domains and on overall QoL, rankings of domains across participants and separately for the three cohorts i.e. parents/carers, adolescents (aged 13-18) and children (aged up to 12 years). Overall QoL scores were calculated, as well as correlations between child/adolescent and their parent/carer.

Content and thematic analyses were conducted with a view to exploring positive and negative experiences of CSII in young children and adolescents. Content analysis focused on the number/frequency of 'instances', their context, meaning and whether they were common across participants. Thematic analysis concentrated on identifying key themes arising with a view to understanding the experiences of children/adolescents and their parents, exploring connections between themes and building a picture of how CSII affects QoL in ways that are important to the child/adolescent and his/her parent. Coding involved identifying each new response, then similar responses were combined into new codes and appropriate themes were identified. Thus, responses were coded according to the topic area (e.g. friends, family, school etc). Each response was allocated a provisional code (e.g.school – interruption to schoolwork, school – stigma associated with diabetes, school – 'different' i.e. being singled out because of injections, and then these categories were merged to form an overarching theme of school). See Appendix D for details. A second researcher coded 10% of transcripts separately and inter-coder reliability assessed. Final themes were agreed between researchers. Themes were discreet to each cohort i.e. children, adolescents and parents, although similarities and differences were acknowledged across cohorts.

6.3 RESULTS

6.3.1 Completion Rates and Validity

Thirty-four participants were interviewed, although only data from 32 participants contributed to all statistical analysis conducted as the data of 2 children was withdrawn. Of these, 17 interviews were conducted with parents (16 mothers and one father) and 15 with children/adolescents. Both mothers of the two excluded children participated in the study. All participants fully understood the purpose and content of the interview and appeared able to complete the judgement tasks using the adapted SEIQoL interview.

Children's age ranged from 9-17 years, (mean 12.07 years, SD 2.71, n=6 adolescents[1] and n=9 children). Duration of diabetes ranged from 2-12 years, (mean 6.67 years, SD 2.42). Whilst parent interviews, on average, took longer to complete, followed by adolescents and children (see Table 6.1), there was no significant difference between cohorts (p=0.28).

Table 6.1

Duration of Interviews per Cohort

Cohort	Number	Interview Duration		
		Mean	Standard Deviation	Range
Children	9	15.89 mins	3.06	11-20 mins
Adolescents	6	12.83 mins	5.04	9-22 mins
Parents	17	19.64 mins	5.38	12-29 mins

---

[1] Adolescents were defined as being aged between 13-18 years

6.3.2 Numerical Analysis of Impact of CSII on QoL

Every parent reported the impact of his/her child's CSII on their own overall QoL to have been positive (see Table 6.2).

Table 6.2

Impact of CSII Therapy on Overall QoL

Cohort	Number of Participants	% of Participants
Children (8 valid answers)		
Very much better	2	25.0
Much better	5	62.5
Better	1	12.5
No difference	-	-
Worse	-	-
Much Worse	-	-
Very much worse	-	-
Adolescents		
Very much better	2	33.3
Much better	3	50.0
Better	1	16.7
No difference	-	-
Worse	-	-
Much Worse	-	-
Very much worse	-	-
Parents		
Very much better	8	47.1
Much better	6	35.3
Better	3	17.6
No difference	-	-
Worse	-	-
Much Worse	-	-
Very much worse	-	-

For parents, the three most frequently reported aspects of life important for their QoL were "health" (n=16), "family" (n=11) and "work" (n=7) whilst children most frequently reported "family" (n=12), "friends" (n=11) and "school" (n=10) (see Table 6.3). Following the initiation of their child's pump therapy, parents indicated that their own "health" had improved. Whilst health was cited as a life domain by 16 parents, only 6 of those rated it as the most important life domain.

For children "friends", "family" and "school" were most frequently nominated as the aspects of life most important for QoL (see Table 6.3). Only seven children (46%) listed "health" as one of their five life domains, with none rating it as the most important aspect of life for QoL.

Table 6.3

Three Most Frequently Cited Life Domains

Life Domain	No of Participants	% of Participants
Children		
Friends	9	100
Family	8	88.9
School	5	55.6
Adolescents		
Family	6	100.0
School	6	100.0
Friends	5	83.3
Parents		
Health	16	91.1
Family	12	75.0
Work	7	43.8

Table 6.4

Impact of CSII on Most Frequently Cited Life Domains

	Very Much Better	Much Better	Better	No Difference	Worse

Table 6.5

Ranking of Life Domains

Cohort	**Number of Participants**	**% of Participants**
Children		
First cited life domain	4	44.4
Second cited life domain	3	33.3
Third cited life domain	1	11.1
Fourth cited life domain	-	-
Fifth cited life domain	1	11.1
Adolescents		
First cited life domain	5	83.3
Second cited life domain	-	-
Third cited life domain	-	-
Fourth cited life domain	1	16.7
Fifth cited life domain	-	-
Parents		
First cited life domain	12	70.6
Second cited life domain	2	11.8
Third cited life domain	1	5.9
Fourth cited life domain	2	11.8
Fifth cited life domain	-	-

The above table shows that 44.4% (n=4) of children ranked their first reported life domain as most important overall. This figure was 83.3% (n=5) and 70.6% (n=12) for adolescents and parents respectively.

Participants were asked about the impact of CSII on aspects of their own QoL. As such, concordance between cohorts would not necessarily be expected. Concordance between issues did occur, however, between children/adolescents and their parents most frequently for "family" (n=8), "health" (n=7) and "friends" (n=3).

6.3.3 Thematic Analysis of Cohorts

CHILDREN

Between them, the nine participants in the children's cohort cited six main life domains during their interviews. These can be seen in Table 6.6 below. Other life domains were cited each by only one participant. The impact of CSII on these is shown in brackets: music (no difference), toys (no difference), holiday (very much better), treatment (better), money (no difference) and pets (no difference).

Table 6.6

Major Life Domains Cited by Children

Life Domain	Number of Participants	% of Participants
Friends/social life	9	100
Family/home life	8	88.9
School	5	55.6
Leisure/sport/exercise	5	55.6
Health/Diabetes	4	44.4
Religion	2	22.2

Friends/Social Life

All nine participants in this cohort cited friends/social life as a life domain, six of whom reported the impact of CSII to have been positive. The remaining three participants reported that it had made no difference to this aspect of their lives. Of the six participants who reported the impact as positive, further breakdown showed one very much better, two much better and three better. Responses focused on independence and freedom from perceived restrictions such as timing of injections, mealtimes:

> *"when I'm out, I don't have to do an injection, I can just press a button and it's done for you"* [113]
> *"I can go out and not worry about having to come home for injections"* [101]
> *"I can go to friends' houses without my mum following me everywhere"* [111].

One of the participants who reported that it had made no difference did also comment that:

> *"well, half the time you just forget that I've got it"* [117]

Family/Home Life

Eight out of the nine participants in this cohort listed family/home life as one of their life domains. Of these, six reported the impact of CSII to have been positive (one very much better, four much better and one better), one participant reported no difference and one participant reported that it had had a negative impact because:

> *"you've got to watch out for it a lot and make sure I'm OK"* [117]

Of the benefits reported, participants cited:

> *"don't have to have injections before food"* [101]
>
> *"it's just easier than having to do the injections"* [113]
>
> *"more freedom with food"* [108]

Comments such as these reflect the reduced interference and greater freedom that is associated with CSII. None of the participants mentioned family relationships or family interactions, rather it was the effect on everyday life of CSII and the lack of insulin injections that participants focused on.

School

School was raised as a life domain by only five participants with each reporting that the impact of CSII had been positive, i.e. two reported very much better and three reported it had been better. Again, issues of independence and the benefits of not having to inject were raised:

> *"if I'm high, I can just go and phone Mum. Say what I want and she can phone me and I can do it myself, save her coming in. It's a lot better really"* [111]
>
> *"no injections at school any more"* [108]

Increased independence and freedom from parental control are important for children, particularly in relation to combining diabetes with school life. School life represents increasing levels of independence for children, thus being able to enjoy that independence without the constant risk of parents coming into school to take control reinforces rather than undermines that increasing independence.

Health/Diabetes

Four participants cited health/diabetes as a life domain, with the impact of CSII having been positive for all four. One participant reported it to be very much better, two reported it as much better whilst one participant said the impact had been better. Responses reflected both physical and emotional states, i.e.:

> *"I used to get lots of bellyache, that's stopped now"* [101]
>
> *"CSII makes me happier, my blood glucose used to be really high and it used to make me cry"* [104]

As can be seen, benefits here are measured in terms of the cessation of something unpleasant rather than in terms of additional benefits. This perhaps reflects the ever-present burden of diabetes and the lifting of some of that burden with CSII.

Physical Activity

Physical activity (combining leisure, sports, exercise) was cited as a life domain by five participants in this cohort. Of these, one participant reported the impact of CSII to have been very much better, one reported it to have been better whilst one participant reported no difference and two participants said the impact was worse. Positive comments included:

> *"I can just sort it out quickly, just go off the field for a bit and just do it"* [111]
>
> *"it makes it easier because you can disconnect it without going low because of your background insulin"* [113]

Reported downsides associated with CSII in terms of physical activity included having to take extra care because of CSII:

> *"I've got to watch out for my pump a wee bit so I can't be too rough"* [117]
>
> *"with activities like sports, the canula hurts, it can be painful"* [108]

This perhaps reflects that whilst CSII offers increased freedom and independence for participants, it cannot completely negate the need for caution and may reflect the constant reminder of ever-present diabetes in everyday life.

Religion

Two participants raised the subject of religion as a life domain (cited first and third), with both reporting the impact of CSII to have made no difference.

ADOLESCENTS

Between them, the six participants in the adolescent's cohort also cited six main life domains during their interviews, although these did not replicate those cited by children. These can be seen in Table 6.7 below. Other domains cited were 'personal belongings' (n=1, no difference), work (n=1, participant didn't work prior to CSII so could not rate its' impact) and 'future' (n=1, no difference).

Table 6.7

Major Life Domains Cited by Adolescents

Life Domain	Number of Participants	% of Participants
Family	6	100
School	6	100
Friends	5	83.3
Leisure	4	66.6
Health	4	66.6
Happiness	2	33.3

Family

All six adolescents cited family as an important life domain. Here responses to the impact of CSII were more varied (n=1 very much better, n=2 much better, n= 1 better and n=2 no difference). Two participants reported CSII to have had a positive impact on food timing and choices:

> *"it makes cooking and stuff easier and choosing food shopping"* [119]
>
> *"before I had to eat at certain times, now I can eat whenever"* [114]

This is also picked up in the parents' cohort with (n=7) parents reporting that meal timings and food choices were easier. Being able to eat the same meals at the same times as other family members reduces the exclusion of 'being different' and enables the person with diabetes to be treated as a 'normal' family member. Other adolescents described the positive impact of CSII on their domain of family in terms of being able to function as a family without being interrupted by having to have insulin injections:

> *"it just means everything's much easier so we can do stuff that we like together rather than being interrupted by injections"* [118]
>
> *"I'm less narky and stuff with my parents, it's a nice atmosphere"* [114]

One participant who reported the impact of CSII to have made no difference on his family life said:

> *"even if I didn't have it, I would still get on with my family"* [106]

which perhaps reflects the subjective nature of defining QoL and the impact of CSII.

School

All six adolescent participants cited their school life or education as one of their important life domains. One adolescent raised it as the second domain, three as the third and one as the fourth. In response to the impact of CSII, five respondents reported a positive impact (n=2 much better, n=3 better) and one participant reported it had made no difference. Perceived benefits included no longer having to inject as school:

> *"it is a lot easier, I don't have to go to student welfare to do injections"* [107]
>
> *"it's better than injections, a lot easier. You don't have to inject at school"* [106]
>
> *"we had to go to the first aid room when we had to do injections at school and that wasted time really"* [119]

Other benefits cited included:

> *"it's just less stressful so I can concentrate on my school work and stuff"* [118]
>
> *"before I was having quite a few hypos and highs and I was going in and out of lessons quite often. I didn't like doing my insulin and bloods in front of people and stuff, so because I don't do that now, it's made it a lot better and a lot more bearable"* [114]

CSII appears to have reduced the interference of diabetes in school life and the stigma associated with 'being sick'. As can be seen above, participants report being more able to simply focus on school life as a teenager without the stigma of being different. Not having to perform insulin injections at school was considered beneficial both in terms of removing the need to repeatedly leave classes to perform the injections, and being able to focus more on school life without the added stress of diabetes treatment. Furthermore, being able to concentrate on schoolwork throughout lessons may reduce the likelihood of poorer academic achievement that could be associated with reduced access to lessons as a result of frequent absences.

Friends

Five adolescent participants cited friends as an important life domain. Of these, the reported impact of CSII was no different (n=3) and much better (n=2). There was some ambivalence in the responses of the two participants reporting the impact to have been much better:

> *"it didn't really affect it anyway, but it just means if I have anything to eat, I don't have to inject myself any more, I can just get on with it"* [119]
>
> *"before [when] I wasn't on the pump and I couldn't do certain stuff like eat the same foods as them.... But now I can have them (snacks) whenever I want"* [116]

Similarly to school, participants reported a greater ability to fit in with friends rather than being identified as 'different'. Connected to this is the dietary freedom participants report, increasing their ability to eat the same things as their friends, at the same times. 'Fitting in' with the group rather than being 'being different'.

Leisure/Social life

Four participants cited leisure/social life as an important life domain. One participant referred to the impact of CSII in terms of their ability to play snooker and said that it had made no difference. The other three referred more to the increased freedom they felt CSII had provided, for example:

> *"I can now go out and do stuff without having to worry about my sugar levels much and having to have injections at certain times and eating at certain times"* [116]
>
> *"before my parents were very anxious letting me go out in case of having hypos and highs. But now, because I'm more level, they don't have to worry as much"* [114]

Health

All four participants who cited health as an important life domain rated the impact of CSII to have been much better. Three participants referred to their diabetes and blood glucose control:

> *"it's a lot easier to use and control, doing sports and eating"* [106]
>
> *"controlled my blood tests more, my blood sugars"* [119]
>
> *"it's just easier, easier to control my blood results and just easier"* [118]

The fourth participant reported the impact in terms of how they felt in themselves:

> *"I am a lot healthier now in myself, I feel a lot brighter, a lot better"* [107]

Happiness

Two participants cited happiness and rated the impact of CSII to have been positive (n=1 much better, n=1 better). Their reasoning was that:

> *"it makes my blood sugars better so that makes me happy"* [118] and
>
> *"when I was having needles, I wasn't very happy because I was sometimes covered in bruises"* [116].

PARENTS

Between them, the seventeen participants in the parent's cohort cited eight main life domains during their interviews. These can be seen in Table 6.7 below. Other life domains, cited by only one person are covered in more detail at the end of this section.

Table 6.8

Major Life Domains Cited by Parents

Life Domain	**Number of Participants**	**% of Participants**
Health	16	94.1
Family	12	70.6
Work	7	41.2
Finances/financial security	6	35.3
Leisure	4	23.5
Friends/friendship	3	17.6
Security	3	17.6
Happiness	3	17.6

Health

Almost all of the parents' interviewed raised health as a life domain. The reported impact of CSII was positive for all respondents, i.e. very much better (n = 9), much better (n = 3) and better (n = 4). Despite such a positive reported impact, only six (43%) participants rated it as their most important life domain. Of the remaining ten participants, three rated it second, five rated it third and two rated it as their fourth most important life domain.

There were also a variety of definitions associated with the domain 'health', specifically in terms of their own health, their children's health and the health of the family as a whole. The impact of CSII was reported in terms of health benefits, particularly for the child with type 1 diabetes, but also in terms of the impact of CSII on the health of other family members. It was acknowledged by some parents that diabetes had impacted on the health of other family members and this impact had reduced since the commencement of CSII. Most commonly this referred to the reduction of stress levels since the introduction of CSII (n = 5):

> *"it means life on a daily basis is much less stressful than before"* [101a]
>
> *"I'm a lot calmer and less stressed about the condition with the pump"* [112a]
>
> *"the other children were affected, **** was obviously very much affected and it did affect the whole family, the stress and trouble"* [113a]
>
> *"her health is better, but also it has impacted on the rest of the family. It was just the stress"* [107a]
>
> *"stress when he has high sugars, it impacts on mine and my husband's health"* [111a]

Other reported health benefits from CSII included their child's improved blood glucose control (n = 6):

> *"controlling blood sugars more, less hypoglycaemia"* [104a]
>
> *"it stabilises more, stabilises the blood sugars more"* [117a]
>
> *"we have much better control over her HbA1c"* [112a]

> *"improved HbA1c"* [111a]
>
> *"his HbA1c is much better controlled"* [106]
>
> *"her control is better, HbA1c is better, just sort of all aspects of her diabetes"* [105a]

Whilst these quotes relate directly to the health of the child/adolescent, their frequent citation by parents reflects the importance of control over his/her child/adolescent's diabetes as directly relevant to his/her own QoL. Better control is associated with better health, which in turn impacts the QoL of parents in terms of less worry, more confidence about the future, as can be seen below. The long-term health benefits for their children was raised as a benefit by three parent participants:

> *"her long-term health prospects are just looking far more positive than we could have achieved on multiple injection therapy"* [112a]
>
> *"entire family's health is better now and in terms of the long-term health of *****."* [108a]
>
> *"it means less chance of complications"* [117a]

The ability to alter the insulin dose rapidly was raised by two parent participants, in terms of being able to bring blood glucose levels down more quickly than waiting for an insulin injection to be fully effective. The short-acting insulin in the CSII facilitates a rapid response to carbohydrate intake:

> *"you can put it on to have more insulin to bring the sugar levels down whereas before, having to inject, you sort of wait a few hours to do it again"* [116a]
>
> *"the ability to correct his blood sugars"* [111a]

Family

Twelve parent participants reported family as a life domain. All reported the impact of CSII to have been positive i.e. very much better (n= 8), much better (n = 3) and better (n = 1). Seven parents defined their family domain in terms of the increased freedom that CSII had provided, particularly around food related issues. Being able to function more as a family without the interruptions of having to eat was reported as a major benefit:

> *"we're not having to time dinners, feed ***** at certain times, we can go out"* [107a]
>
> *"they're happier, it's given us more freedom" (self and husband)* [118a]
>
> *"before it was difficult to fit in around eating times"* [106a]
>
> *"it has given us considerably more freedom as a family. We're not restricted to mealtimes"* [108a]
>
> *"before we would have to think about her food, what we'd have to take with us, when we would have to stop for food and now we don't have to think about that"* [114a]
>
> *"now we don't have to think about what she eats"* [114a]
>
> *"just feel more in control, everything doesn't revolve around ***** eating times"* [111a]
>
> *"we just feel generally more freedom with where and what to eat"* [111a]
>
> *"you can just let **** have things he couldn't have before"* [111a]
>
> *"she can now spend time with family without me being there"* [105a]

Some parents commented on their children's happiness since the switch to CSII and the subsequent impact that it had had on other family members:

> *"his moods aren't so, sort of volatile ..... because he's on the pump then his levels are generally much more even which means he's a much happier child"* [113a]
>
> *"the control is much better of her diabetes so she is much happier and much more relaxed which makes us all a lot calmer and more relaxed"* [112a]
>
> *"he's happier – it's made us happier"* [106a]

> *"they're much happier dealing with their diabetes than they were before. They're much happier with the things that they can do that they couldn't do before"* [118a]

Work

Whilst seven parents cited work as a life domain, only five felt that the impact of CSII had been beneficial, i.e. very much better (n = 1), much better (n = 1) and better (n = 3) with two parents reporting it had made no difference. The major advantage appears to be fewer interruptions at work. Prior to their child's commencement on CSII, parents reported having frequent interruptions to their working day and often being called away from work to attend school in order to administer insulin injections to their children, or deal with the effects of hypo and hyper glycaemia. All parents who raised this issue, said that these interruptions had stopped since their child had been using CSII. Not having to worry about their child whilst he/she was at school was cited by five parent participants. The knowledge that they are able to bolus their own insulin had relieved some of the stress for parents:

> *"when she's at school I know she can be bolusing for her food and her general health is good, so I don't come to work and worry"* [105a]
>
> *"I just know she can control it herself ... it doesn't sort of have that much worry with it all now, with the diabetes"* [116a]
>
> *"she was in school and I used to get phone calls from school saying she's just had a hypo, she's not feeling well, she's this, she's that and since she's been on it (the insulin pump) we haven't had, touch wood, a single phone call"* [114a]
>
> *"you're not worrying all the time"* [114a]
>
> *"I used to take an awful lot of time off work and I'm not having to do that any more"* [107a]
>
> *"it's better because I don't have phone calls like I used to ... I very, very rarely now get a phone call at work"* [118a]

A health economic analysis in terms of lost days at work for parents caring for their child with diabetes would be useful in order to identify the financial cost of frequent interruptions and any cost saving associated with the switch to CSII.

Finances/Financial Security

Of the six parent participants that cited this as a life domain, four reported the impact of CSII to have made no difference whilst two said it had made things better:

> *"less expensive food choices"* [108a]
>
> *"we don't spend as much money on food as we used to"* [101a]

Leisure

Four parent participants cited leisure as a life domain, three of whom reported the impact of CSII to have been positive (n = 1 very much better, n=1 much better and n = 1 better). The fourth participant reported the impact to have been worse in terms of being able to access leisure facilities. [117a].

Friendship/social life

Four parent participants cited friendship/social life as a life domain, with varying responses to the impact of CSII on that domain. Two participants believed the impact to have been positive (n= 1 very much better, n = 1, better) whilst the other two participants reported it to have made no difference.

> *"all my friends know about ***** having diabetes, they must have noticed I'm happier now he's on the pump"* [101a]

Security

Three parents cited 'security' as a life domain, although they each defined it differently, i.e.:

> *"home life"* [101a]
>
> *"being able to look after each other"* [111a]

"knowing the safety of my children" [114a]

Despite these differing subjective definitions, all three participants reported the impact of CSII to have been positive, i.e. very much better (n = 2) and better (n = 1). Overall contentment and reassurance that life is secure perhaps most closely reflects this life domain, although it is difficult to define subjectively.

Happiness

Two parents cited 'happiness' as a life domain, with one of those parents citing 'happiness of husband' as a separate life domain. The impact of CSII was rated as very much better by both participants, with the impact on husband's happiness rated as better.

Other life domains were cited each by only one participant. These were extremely varied and can be seen in Table 6.8.

Table 6.9

Other Life Domains Cited by Parents

Life Domain	Impact of CSII	Definition
Freedom	v. much better	"to do the things you want to do without limitation" [111a]
Spiritual Welfare	better	"my link with the Lord and keeping that pure" [113a]
Spiritual Welfare of Children	Much better	"their happiness" [113a]
Pets	v. much better	"my animals are very important to me" [101a]
Diabetes	v. much better	"***** copes well with it" [106a]
Child's future	better	"his employment, having good skills" [117a]
Children's welfare	v. much better	"making sure that they're happy at school" [116a]
College	no difference	"doing as much work as I can for that" [116a]
Contentment	v. much better	"when things are going smooth" [114a]
Relationship	no difference	"relationship with partner" [105a]
Children's achievements	better	"school achievements, how diabetes affects their studying and taking part in social life" [104a]
Social life	no difference	"whole family's social life" [104a]

6.3.4 Common Themes Across Cohorts

Out of the top three cited life domains for each cohort, only family represented a common theme across cohorts with 88.9% of children, 100% of adolescents and 75% of parents raising the topic. There was some commonality across cohorts in terms of 'friends' and 'school' for children and adolescents, 'health' and 'leisure' for participants in all cohorts (health – parents n=16 (94.1%), adolescents n=4 (66.6%), children n=4 (44.4%) and leisure – parents n=4 (23.5%), adolescents n=4 (66.6%) and children n=5 (55.6%)). However, in consideration of the wide variety of life domains cited, commonality between cohorts was limited.

6.4 DISCUSSION

All children and their parents reported the impact of pump therapy on their QoL to have been positive. One third of parents reported "health" as most important for QoL but none of the children did so. Consistent with the literature [Bradley & Walker, 2002], children most frequently reported family, friends and school as important for QoL. For parents, the most frequently reported aspects of life important for their QoL were "health" and "family", whilst children most frequently reported "family", "friends" and "school". Following the initiation of their child's pump therapy, parents rated their own "health" as very much better (52.9%), much better (17.6%) and better (23.5%), and rated "family" as very much better (41.2%), much better (17.6%) and better (5.9%). Health was rated as most important by only 6 of the 17 (35.2%) parents.

For children and adolescents, pump therapy had made "family" life very much better (13.3%), much better (26.7%) better (26.7%) or no difference (13.2%). Only seven children (46%) listed "health" as one of their five life domains, with none rating it as the most important aspect of life for QoL. Twelve parents reported the positive impact of CSII on the life domain of 'health'. Several studies have been conducted using the SEIQoL methodology and it has been found frequently that "health" is not suggested as a domain of life (important for QoL) by everyone, nor is it the most frequently mentioned. In the first study of 42 healthy individuals, only 35 (83%) nominated health, attaching weights for importance varying from 3 to 59 out of a possible 100 [McGee et al, 1991]. In a study of 40 patients with gastrointestinal problems, reported in the same paper, only 70% nominated health. McGee and colleagues concluded:

> *"The assumption that health is the only, or indeed the major, QoL priority for patients appears unjustifiable. Patients are as concerned, or more concerned in many instances, about aspects of their lives other than health".*
>
> [McGee et al, 1991, p758]

Not only is health not he major priority for most respondents, but the first area of importance reported by participants is not always the area that they consider to be of most importance when asked to rate the order of importance of all of their important areas. However, adolescents were most likely to rate their first area of importance as the most important.

In terms of health, parents cited improved blood glucose levels and long-term good health of his/her child/adolescent in terms of their own health. The diversity in definitions of 'health' by parents could reflect their desire for the overall well-being of their family, particularly when combined with life domains of 'financial security', 'children's welfare' and 'security'. Furthermore, a number of parents attributed a reduction in their own stress levels to their child's CSII. This is perhaps unsurprising when consideration is given to the amount of time children/adolescents spent at school. Thus, feeling less worried about his/her child/adolescent during these periods of separation has implications for parents' own QoL in terms of the parents' own emotional well-being but also in terms of less interference in their own working lives.

Type 1 diabetes can cause enormous disruption and impacts upon the QoL of the person with the disease [Rubin & Peyrot, 1999; Clark & Asimakopoulou, 2005]. This disruption can have consequences for other family members, particularly the parents of a child with Type 1 diabetes, not least because they are primarily responsible for the care and treatment. It has been reported in previous research [Chapter Four] that the QoL of other family members has been positively affected when the person with Type 1 diabetes has begun CSII. The results of the current study support this finding, not only in terms of the effects on family life, but also the effects on parents' working lives. Five parents reported less disruption to their working life (i.e. fewer telephone interruptions, not having to leave work to attend school and administer insulin injections to their child(ren) or deal with the effects of hypoglycaemia and hyperglycaemia). This ties in with the reduced stress levels reported by parents, who no longer need to juggle frequent school visits with their worklife.

A major advantage of using an adaptation of the SEIQoL interview for telephone use is that it provides participants with the opportunity to identify the areas of their life that they consider important rather than imposing external judgements about what should be considered important. Only when individuals have identified the areas that are important for their own QoL, can they assess the impact of CSII on those areas.

Furthermore, when this is done, participants are able to determine the impact of CSII on their overall QoL.

When asked to identify five aspects of life that are important, participants sometimes found it difficult both to select the five most important areas and to rate them in order of importance. This task requires people to think about issues that they would normally take for granted. It could be argued that having to engage in this thought process provides a better reflection of a person's QoL than simply ticking the boxes on a questionnaire where issues have been externally imposed. Furthermore, having to think about individual aspects of life separately and in the context of overall QoL enables participants to piece together the different areas into one 'bigger picture'. QoL is subjective and could indeed represent a whole that is larger than its constituent parts.

The diverse list of life domains and the subjective descriptions of those domains reported by participants highlights the degree of difference between individuals when asked to define the five most important aspects of their life for their QoL. It is perhaps because of such differences and the subjective nature of QoL that "there is no substitute for asking patients what is important to them, how good these things are in their life and how the elements of their life affect each other and their overall QoL" [Walker and Bradley, 2002, p144]. A number of participants cited the same aspects of life as important for their QoL but their rationale for doing so often differed widely. Although a number of studies have reported on the feasibility of the administration of the SEIQoL instrument, little is known about how patients choose and define these five areas, the so-called 'cues'. This is a moot point, as it could indeed be argued that any attempt to quantify the selection of 'cues' or life domains would in itself impose an external judgement by the researcher. As such, one must question whether the lack of apparent insight into participant choice of life domains is actually a drawback of this measure or whether it does, in fact, provide participants with the opportunity to be open about what matters to them. Alternatively, it could be argued that the process of defining life domains and considering the impact of CSII provides increased insight into subjective aspects of life that would ordinarily be missed using more quantitative measures.

Issues around food, food choices, meal timing and not having to inject prior to eating, were raised frequently by participants in all cohorts. Being able to go out as a family without having to plan for mealtimes or being able engage in 'normal' family activities was perceived as important for a number of participants. This perhaps reflects the opportunity that CSII offers for families to return to 'normal' family life, for example being able to go out for a meal together, with less intrusion from the demands of a traditional insulin injection regimen. This reflects previous research, i.e. results from an adult cross-sectional study which showed all participants reporting QoL benefits associated with CSII [Chapter Five]. More specifically from that study, however, insulin pump users reported improvement in food-related issues, which were associated with significantly improved QoL (compared with a matched cohort of multiple daily injection users). These are recurring themes that have been picked up throughout recent literature and a recent pilot study reports food-related benefits for participants [Chapter Four]. The DAFNE programme has shown that dietary freedom (the most negatively impacted aspect of life for people with diabetes [Bradley & Speight, 2002] is significantly improved following training in flexible, intensive insulin therapy [The DAFNE Study Group, 2002], with QoL benefits fully maintained at four-year follow-up [Speight et al, 2007]. The findings of the current qualitative study suggest that insulin pumps may have benefits for people in addition to those experienced by people using the DAFNE approach.

Perhaps unsurprisingly, there wasn't a great deal of commonality between cohorts. That school was raised as a life domain by only three children and by all of the adolescents possibly reflects a response shift from childhood to adolescence. During adolescence, peers and school life play an increasingly important role as individuals define their place in life. The relatively low frequency of 'health' as a life domain for children and adolescents reflects the notion that health is often not a major contributing factor when assessing a person's QoL. Furthermore, many studies measure HRQoL using measures of health status such as the SF36, which is not a major QoL issue for people. This suggests that health status is not a major motivational factor for individuals in terms of treatment.

This study is not without limitations, including the difficulties in knowing exactly how many potential participants were registered on the database. Perhaps the main limitation, however, is that it could be argued that the sample is atypical (highly motivated, enthusiastic CSII users and their parents). It could be argued that individuals who were less enthusiastic about their CSII therapy simply did not respond to the invitation to participate. Thus, the results of this study cannot be generalised to the wider population of CSII users.

Furthermore, the use of telephone interviews, whilst a benefit in terms of being able to access participants from across wide areas of the country, inevitably limit the depth and richness of data being obtained. A face-to-face interview method would have enabled greater exploration of issues, specifically in terms of non-verbal communication such as body language etc. The cost of this method was prohibitive however as participants lived across the United Kingdom and travelling expenses would have been excessive.

Overall, the results of this study highlight the impact of CSII on the QoL of family members as well as the person with diabetes. The introduction of CSII brought perceived benefits for parents in terms of their own QoL, in addition to the QoL benefits reported by their children using CSII. This finding reflects that in previous research [Chapter Four007] and emphasises the need for the provision of adequate support for significant others as well as the individual with diabetes. Furthermore, the view that health cannot be regarded as the major QoL priority for children using CSII [McGee et al, 1991; Walker and Bradley, 2002] is also supported. Future research is required to explore whether QoL benefits are common for other family members and, if so, how best to tailor family education and support at the onset of CSII to most appropriately address these issues.

A large-scale, multi-national cross-sectional survey of adolescents using CSII compared to other insulin injection regimens (similar to that reported in Chapter Five for adults) is necessary in order to investigate whether QoL issues identified in previous chapters are applicable for this age group across a wide range of Diabetes Centres throughout Europe. Furthermore, whether QoL benefits for other family members, i.e. parents, is common for a much larger cohort.

CHAPTER SEVEN

CROSS-SECTIONAL STUDY INTO QUALITY OF LIFE ISSUES SURROUNDING CSII USE BY ADOLESCENTS WITH TYPE 1 DIABETES

7.1 INTRODUCTION

Previous chapters have investigated quality of life of adults, children and adolescents using CSII therapy, both in terms of quality of life benefits and in comparison to other insulin regimens. There appear to be clear differences in important life domains between each of these groups, as illustrated in the SEIQoL study (Chapter Six). Further to the results of that SEIQoL study into the QoL of children and adolescents using CSII therapy, and the QoL of their parents, it is believed that a large cross-sectional study, concentrating only on adolescents is necessary in order to gain a broader picture of the impact of CSII therapy across a number of centres. Adolescents were chosen because it is during adolescents that insulin regimens are commonly intensified to overcome the poor control seen during this period [Mortensen et al, 2004]. Whilst the results of the SEIQoL study (Chapter Six) were useful in terms of providing data on important life domains (family, friends, school) relevant to children, adolescents and parents and the possible impact of CSII therapy on those areas it does not help address the issue of whether CSII users generally reported better QoL in these areas than adolescents using other insulin regimens.

To address this issue a large scale cross sectional survey was used. In 2005 the Hvidoere Childhood Diabetes Study Group [Hvidore Study Group, 2005] conducted a study to explore the role of psychosocial factors in determining centre differences in diabetes outcomes. To this end, young people with diabetes and their parents in 23 centres across 21 countries were asked to complete a range of psychological questionnaires pertaining to their quality of life. These questionnaires combine general measures from the Health Behaviour in School aged Children (HBSC) project and diabetes specific items from previous work of the Hvidoere study group.

A multi-staged level of analysis will be conducted in order to explore QoL issues between different cohorts. Firstly, CSII users will be compared with all other adolescents using other insulin regimens. This will enable a comparison to be drawn between CSII and all other insulin regimens, as compared with a comparison between intensified insulin regimens. A 10% cut off point will be used to define those centres with higher numbers of CSII users. The rationale behind this is that it is believed likely that if centres have more than 10% of individuals using CSII therapy, they would also have systems and procedures in place to support that particular therapy. This may not be the case where centres only have a very few individuals using CSII therapy. Finally, analysis will be conducted comparing only the intensified insulin regimens, i.e. CSII and MDI. This will extract intensification as a confounding variable contributing to QoL. The primary analysis is the comparison between intensified insulin regimens, with the other two subsets of analysis being secondary.

In addition, physiological measures will be explored because the effects on QoL may be not because of CSII therapy per se, but rather a consequence of improved physiological status, such as reduced frequency of hypoglycaemia. As such, it may be possible to reduce hypoglycaemia by other means. Also, whilst social class was measured in Chapter 5, it is not possible to directly assess social class in this study because of the difference in classification systems across such diverse countries. The indices used were language difficulties as a marker for ethnic minority status (Canada won't let you ask about ethnicity), and the parental employment measures re social economic status. That is all that was possible to ensure it would be consistently interpreted across countries in this study.

It is hypothesised that adolescents using CSII therapy will report QoL benefits over and above participants using all other insulin regimens. Furthermore, building on the results from previous chapters (i.e. Chapters 4 and 5), it is hypothesised that CSII users will report improved QoL than participants using MDI. The purpose of this chapter, therefore, is to explore whether there are QoL differences between CSII users and adolescent participants using other insulin regimens.

7.2 METHOD

Between 15 February 2005 and 18 May 2005 all adolescents in the participating centres, between 11-19 years were asked to fill in a questionnaire when they attended for a regular outpatient appointment. This questionnaire was answered while waiting for their visit to the doctor/unit. Once completed the adolescents sealed the questionnaire in an envelope that was then sent for confidential data-entry.

Each of the participants' parents and or guardians attending the outpatient appointment was also asked to fill out a parent questionnaire. The parents completed their questionnaire at the same time as the adolescent, but independently of them. Once completed, the parents sealed the questionnaire in an envelope that was also sent for confidential data-entry. One of the diabetes team members at the outpatient appointment also completed a short questionnaire providing demographic and diabetes treatment and other basic medical information.

All questionnaires and HBSC data was collated in Denmark, where double data-entry was completed and initial cross checking of data-entry, screening and initial data analysis took place.

7.2.1 Participants

This study was a multicultural cohort study, conducted using 22 centres in 18 countries in Europe, Japan and North America. Type 1 diabetic patients who were born between 1980 and 1987 were invited to participate between March and August 1998 at each study centre. The patients were all aged between 10 and 18 years at the beginning of the study, with informed consent provided by all participants, and parents where appropriate. The average age of patients was 14.3±2.1 years. With informed consent, all adolescents (11-19 yrs) with diabetes mellitus, seen in the different paediatric and adolescent diabetes units involved in the study group were invited to participate in the study. Individuals with type 2 diabetes mellitus, secondary diabetes, pregnant or with a severe learning disability, were excluded from the study.

7.2.2 Measures

Table 7.1 shows the important life domains reported by adolescents in Chapter Six. Relevant measures from the current questionnaire have been matched to those life domains in order to address those relevant issues.

Table 7.1

Adolescent Reported Life Domains and Appropriate Measures

Life Domain	Appropriate Measures
Family	DQOLY, SF parental over involvement scale (items.34-36)
School	DQOLY, SF impact scale, (items.40-44)
Friends	DQOLY, SF impact scale (item 29)
Leisure	DQOLY, SF impact scale, (items 30-32)
Health	Symptom checklist and single health perception item (items .52-53)
Happiness	Well-being scale and single item generic QoL measure (item 54)

Table 7.1a

Coefficient Alpha Reliabilities

Scale Item	Coefficient Alpha
DQOLY – impact scale	.709
DQOLY – parent involvement scale	.716
DQOLY – worry scale	.820
WHO-5	.870
HBSC Well-being scale	.424

In order to protect against Type 1 error, exact bonferroni corrected p values have been reported throughout the results section. Results were only considered statistically significant for analysis comparing centres with more/less than 10% CSII users and that for comparisons between intensified insulin regimens if they reached significance at p=<.001.

In addition, demographic measures of age, gender, duration of diabetes, regimen, BMI, number of hospital visits were recorded. Finally, biomedical outcomes i.e. HbA1c, episodes of hypoglycaemia and episodes of DKA were collated. A capillary blood sample was provided by participants and analyzed at Steno Diabetes Center, Gentofte, Denmark. HbA1c was DCCT aligned (normal range 4.4 – 6.3 %, mean 5.4% and an interassay SD 0.15% *Tosoh method*)

Quality of Life and Social Functioning

QoL was assessed by the DQOLY, adapted form the adult-oriented DQOL. Information is gained specifically regarding diabetes-specific QoL in adolescents. Social functioning was assessed by specific items of the impact and parental over-involvement scales.

Generic and Lifestyle factors

Emotional well-being of the individual was assessed by question 2 (6 items including I like the way things are going for me, my life is going well, I would like to change many things in my life, I wish I had a different kind of life, I have a good life and I feel good about what's happening to me), which is taken from the HBSC survey of 2001 [Currie et al, 2001]. Physical well-being is being assessed by questions 52 and 53 taken from the HBSC survey of 2001, with question 54 providing a single item rating of generic perceived QoL, also from the HBSC survey of 2001.

The family environment is assessed by question 51, which provide some basic information about parental employment. These items are taken from the HBSC survey of 2001. Finally two items are included that provide some generic lifestyle information.

Parent Completed (Appendix II)

Generic and Lifestyle factors

Parents' emotional well-being was assessed by the World Health Organisation's short well-being measures (WHO-5) [World Health Organisation 1998 version].

7.2.3 Analysis

As the study group have previously established that there are substantial centres differences, and this would confound any comparisons for pump users, analysis was conducted in three stages. In the first instance a comparison was made between CSII users and all other participants in centres using CSII therapy. Secondly, analysis was conducted on CSII users and participants from centres using more/less than 10% CSII users and finally between CSII users and participants using basal bolus regimens, i.e. other intensive insulin regimens.

Initial analysis compared all adolescents using CSII therapy with those adolescents using other insulin delivery systems. Further analysis was then conducted only on those centres with more/less than 10% of patients using CSII therapy. All analysis was conducted using SPSS v.14 using ANOVA, ANCOVA, T-test, correlations, frequency and descriptive statistics.

7.3 RESULTS

7.3.1 Analysis Conducted on All Participants

Preliminary analysis was conducted for all participants across centres where CSII therapy was being used. Individual participants are using differing insulin regimens according to the routine medical practice at each participating centre. Therefore, it is important to note that the rationale for CSII therapy prescription is likely to differ between centres as some centres are likely to be more enthusiastic about pump therapy than others. For this reason, additional investigation was conducted into centres with more/less than 10% of participants using CSII therapy because this split is likely to represent similar rationales/processes for CSII therapy i.e. those centres with more CSII users are more likely to have clear processes in place.

Demographic Data

A total of 2268 adolescents participated in the study, of which 575 were excluded because they were in centres that were not using CSII therapy (n=6 centres excluded). Thus, 1413 participants reported using a range of insulin regimens (see table 7.2), whilst 336 participants were using CSII therapy. 519 participants did not state which insulin regimen they were using so for the purpose of analysis it was presumed that they were not using CSII therapy. Insulin regimens of all remaining participants are summarised in Table 7.2.

Table 7.2

Summary of Insulin Regimens in Centres Using CSII

Insulin Regimen	Number of Participants	% of Participants
BD premix	48	2.8
BD freemix	121	7.2
Basal Bolus	669	39.5
CSII	336	19.8
Did not state	519	30.7

There were no significant differences between all insulin regimens for duration of diabetes (p=.084) and BMI (p=.258), although significant differences were identified between insulin regimens for age (p=<.001) and gender (p=<.05) with younger participants and females more likely to be using CSII.

Table 7.3

Demographic Data for All Participants

Regimen	Age (Mean)	Duration of Diabetes (yrs)	Gender (% female)	BMI
CSII therapy	14.46±1.91	6.48±3.4	52.4	21.94±3.67
Other regimens	14.88±2.04	5.98±3.53	48.8	22.31±9.94

There were no significant differences between groups for age, duration of diabetes or BMI.

Table 7.4

Employment Status of Mother and Father

	Yes	**No**	**Don't Know**	**Don't Have/See**
Father				
CSII users	289(90.6%)	16(5.0%)	4(1.3%)	10(3.1%)
Other regimens	1040(76.6%)	55(4.8%)	13(1.1%)	47(4.1%)
Mother				
CSII users	241(75.1%)	77(24.0%)	3(0.9%)	-
Other regimens	882(76.0%)	263(22.7%)	8(0.7%)	8(0.7%)

There were no significant differences between CSII users and participants using other insulin regimens in terms of the employment status of either mothers or fathers.

HbA1c

There was a significant difference between groups in terms of HbA1c results, p=0.046.

TABLE 7.5

Difference in HbA1c Results Between Cohorts

	Range	**Mean**	**SD**
CSII users	5.80-15.40	8.10	1.32
Other insulin regimens	4.70-17.40	8.27	1.45

As can be seen, there is a much tighter range for the CSII users than for people using other insulin regimens, although 80.6% of CSII users had an HbA1c of lower than 9% compared with only 75.1% of participants using other insulin regimens.

Episodes of Hypoglycaemia

TABLE 7.6

Episodes of Hypoglycaemia During the Last Three Months

	N	Mean	SD
CSII users	15	0.6	.266
Other insulin regimens	51	0.6	.401

There was no significant difference between cohorts for episodes of hypoglycaemia during the last three months.

Episodes of Diabetes Keto-Acidosis

TABLE 7.7

Episodes of DKA During the Last Three Months

	N	Mean	SD
CSII users	16	0.6	.298
Other insulin regimens	10	0.3	.269

CSII users were significantly more likely to report episodes of DKA during the last three months than participants using other insulin regimens (p=.002, f=9.51).

Accompanied by Parents to Clinic

There was no significant difference between cohorts for whether or not they were accompanied to their clinic appointment by their parents. 95.0% of CSII users reported being accompanied by a parent, compared to 94.2% of participants using other insulin regimens.

Dedicated hotline?

83.4% of CSII users who answered this question (n= 308, 91.7% of sample) reported having a dedicated hotline, compared to only 66.5% of the 'other insulin regimens' cohort who answered the question (n = 1656, 85.7% of sample). This was statistically significant to p=<.001.

Participants were asked a number of questions regarding their thoughts and feelings during the past few weeks. The results have been presented to reflect the specific life domains identified by adolescents in Chapter Six.

Family

Diabetes Quality of Life Youth Measure

Table 7.8

Diabetes Quality Of Life Youth Impact Scales

	CSII		Other regimens		P Value	F Value
	Mean	SD	Mean	SD		
DQOLY impact scale	2.95	2.61	3.06	2.87	6.294	.012*
DQOLY parents scale	3.98	2.53	4.05	2.63	.485	.486
DQOLY worry scale	5.97	5.55	5.61	4.99	4.755	.029*

* p=<0.05

The above table shows that on the impact and parent scales, CSII users report less impact than participants using other insulin regimens. This is reversed, however, for the worry scale with CSII users reporting more worry than other participants. Statistical significance was reached on the impact scale and the worry scale, one each in the favour of each cohort.

Beliefs About Parents

There were no significant differences between cohorts for any of the items in Table 7.9 below. Thus, CSII users were not significantly more likely to report more/less parental interference than other insulin regimens.

Table 7.9

Adolescents' Beliefs About Parents

	Never		Very Seldom		Sometimes		Often		All The Time		
	CSII %	Other %	CSII %	Other %	CSII %	Other %	CSII %	Other %	CSII %	Other %	P Value
How often are your parents too protective?	27.9	26.4	29.7	22.3	21.4	24.6	11.8	14.6	9.3	12.1	.74
How often do your parents worry too much about your diabetes?	13.1	15.5	27.4	21.5	28.0	25.6	18.7	19.9	12.8	17.5	.122
How often do your parents act like diabetes is their disease, not yours?	37.8	39.0	25.7	19.7	14.2	19.0	14.9	12.8	7.4	9.4	.323

School

The impact and worry scales of the DQOLY contain items relevant to the life domain of school, where results show CSII users report less impact than participants using other insulin regimens (refer to Table 7.8 above for details). There were no significant differences between CSII users and all other insulin regimens users in terms of any school specific items. Please see Table 7.10 below for details.

Table 7.10

Adolescents' Worries About School and the Future

	Never		Very Seldom		Sometimes		Often		All The Time		
	CSII %	Other %	CSII %	Other %	CSII %	Other %	CSII %	Other %	CSII %	Other %	P Value
How often do you miss work, school etc because of your diabetes?	42.7	51.5	40.8	32.4	11.5	12.5	4.7	3.1	0.3	0.5	.250
How often do you worry about whether you will pass out?	49.8	45.6	29.1	32.1	13.9	15.3	4.3	4.6	2.8	2.4	.486
How often do you worry about whether you will be able to complete your education?	61.9	64.8	16.7	16.8	12.4	10.8	7.1	5.5	1.9	2.2	.269

* P=<0.05

Friends

The impact and worry scales of the DQOLY contain items relevant to the life domain of friends, again showing CSII users report less impact than participants using other insulin regimens (refer to Table 7.8 above for details). CSII users reported significantly less limitation in social relationships than participants using other insulin regimens (p=.007).

Leisure

The impact and worry scales of the DQOLY contain items relevant to the life domain of friends. (Refer to Table 7.8 above). In terms of interruptions to leisure time activities and interference with exercise, there were no statistically significant differences between cohorts. CSII users, however, reported less interference in terms of diabetes keeping them from riding a bicycle or using a machine (such as a computer) than participants using other insulin regimens (p=.002).

Health

Results of the health symptom checklist are presented in Table 7.11 below. There were no significant differences between cohorts except for feeling afraid. For this, CSII users reported significantly less afraid than participants using other insulin regimens.

Perception of Health Status

313 (93.2%) CSII users answered this question, of which 83 (26.5%) scored their health as excellent, 167 (53.4%) as good, 51 (16.3%) as fair and 12 (3.8%) as poor. This compared to 1684 (87.2%) responses in the all other insulin regimens cohort where 353 (21.0%) scored their health as excellent, 916 (54.4%) as good, 361 (21.4%) as fair and 54 (3.2%) as poor.

Table 7.11

Health Symptom Checklist

	Every Day		More Than Once a Week		Every Week		Every Month		Rarely/Never		P Value	F Value
	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)		
Headache	16(5.0)	61(5.3)	30(9.4)	115(9.9)	54(16.9)	153(13.2)	72(22.5)	254(21.9)	148(46.3)	576(49.7)	.996	.000
Stomach ache	4(1.3)	23(2.0)	26(8.1)	88(7.6)	34(10.6)	116(10.0)	86(26.9)	325(28.1)	170(53.1)	606(52.3)	.964	.002
Back ache	14(4.4)	53(4.6)	25(7.8)	60(5.2)	30(9.3)	103(8.9)	57(17.8)	195(16.9)	195(60.7)	746(64.5)	.207	1.594
Feeling low	13(4.1)	54(4.7)	43(13.4)	175(15.2)	76(23.8)	227(19.7)	78(24.4)	270(23.4)	110(34.4)	426(37.0)	.234	1.418
Bad temper	26(8.1)	89(7.7)	54(16.9)	212(18.3)	87(27.2)	283(24.4)	89(27.8)	303(26.2)	64(20.0)	271(23.4)	.252	1.313
Nervous	20(6.2)	63(5.5)	44(13.7)	162(14.1)	46(14.3)	202(17.5)	95(29.6)	294(25.5)	116(36.1)	432(37.5)	.696	.153
Diff. sleeping	25(7.8)	87(7.5)	28(8.8)	133(11.5)	37(11.6)	126(10.9)	60(18.8)	199(17.2)	169(53.0)	612(52.9)	.276	1.186
Dizzy	6(1.9)	27(2.3)	15(4.7)	73(6.3)	30(9.3)	99(8.6)	57(17.8)	207(17.9)	213(66.4)	750(64.9)	.175	1.841
Neck pain	10(3.1)	34(2.9)	18(5.6)	66(5.7)	32(10.0)	104(9.0)	51(16.0)	204(17.6)	208(65.2)	750(64.8)	.622	.243
Afraid	9(2.8)	42(3.6)	11(3.4)	66(5.7)	28(8.7)	94(8.1)	47(14.6)	202(17.5)	226(70.4)	752(65.1)	.021*	5.378
Tired	54(16.1)	115(10.0)	36(10.7)	195(16.9)	64(20.1)	235(20.3)	88(27.6)	305(26.4)	77(24.1)	305(26.4)	.130	2.293
Angry	26(8.2)	88(7.6)	52(16.3)	181(15.6)	56(17.6)	248(21.4)	90(28.2)	324(28.0)	95(29.8)	316(27.3)	.373	.794

* p=<.05

Happiness

Life Ladder – 10 = best possible life, 0 = worst possible life

319 (94.9%) CSII users answered this question, of which 81.8% (n = 261) scored their lives at least 7 or above. This compared to 1690 (87.5%) responses in the all other insulin regimens category where 75.2% (n = 1270) of participants scored a 7 or above. Whilst CSII users were more likely to report that their lives more positively, this did not represent a statistically significant difference between cohorts (p=0.150).

Results for individual questions are presented in Table 7.6 below. As can be seen from Table 7.6, there were no statistically significant differences between cohorts on any of these questionnaire items.

Table 7.12

Thoughts and Feelings of Adolescents

	Never		Sometimes		Frequently		Almost Always		P Value
	CSII %	Other %	CSII %	Other %	CSII %	Other %	CSII %	Other %	
I like the way things are going for me	11.6	9.2	17.9	25.5	34.6	34.8	35.8	30.5	.833
My life is going well	10.1	7.6	11.3	14.3	30.8	31.3	47.8	46.8	.441
I would like to change many things in my life	13.8	13.0	50.0	53.9	25.8	23.3	10.4	9.9	.259
I wish I had a different kind of life	34.2	33.1	45.5	45.8	14.1	13.1	6.3	8.0	.928
I have a good life	15.1	10.2	8.5	12.5	26.2	27.8	50.2	49.5	.071
I feel good about what's happening to me	12.3	13.3	17.7	26.6	35.3	32.6	34.7	27.5	.071

7.3.2 Centres with More/Less Than 10% CSII Users

Further to the analysis on the whole dataset, secondary hypothesis analysis was conducted comparing those centres using CSII therapy. Centres were compared based on the numbers of CSII users at each centre i.e. more or less than 10% CSII users. Following this breakdown, later analysis focuses on the primary hypothesis analysis i.e. a comparison between intensified insulin regimens of CSII compared with MDI regimens.

Demographic Data

Analysis was split between those centres with more/less than 10% participants using CSII therapy. Fifteen centres were included in this analysis. Of these, eight centres had more than 10% of their participants using CSII therapy, with seven centres where less than 10% of participants were using CSII therapy. The total participant population across the fifteen centres was 1692 participants. Of these, 956 (56.5%) participants were in centres where more than 10% were CSII users and the remaining 736 (43.5%) participants in centres with less than 10% CSII users.

Table 7.13

Distribution of CSII Users Across Centres

Centre	Total Number of Participants	Number of Participants on CSII Therapy	% of Participants on CSII Therapy
Australia	200	14	7.00
Canada*	100	19	19.00
Denmark	104	4	3.85
Finland*	112	24	21.43
Germany*	191	69	36.13
Holland*	64	26	40.63
Israel*	120	39	32.50
Parma	83	4	4.82
Chietti	125	3	2.40
Japan	27	2	7.41
Luxemborg*	68	24	35.31
Norway*	109	33	30.28
Sweden	93	9	9.68
Leicester	100	2	2.00
USA*	192	64	33.33
TOTALS	1688	336	

* centres where more than 10% of participants are using CSII therapy

TABLE 7.14

Demographic Data for Participants at Centres Where More Than 10% Were CSII Users

Regimen	Age (Mean)	Duration of Diabetes (yrs)	Gender (% female)	BMI
CSII therapy	14.47±1.89	6.44±3.41	52.4	21.76±3.68
Other regimens	14.59±2.01	5.92±3.52	49.7	22.74±16.42

TABLE 7.15

Demographic Data for Participants at Centres Where Less Than 10% Were CSII Users

Regimen	Age (Mean)	Duration of Diabetes (yrs)	Gender (% female)	BMI
CSII therapy	14.43±2.11*	6.83±3.44	66.7	22.83±3.46
Other regimens	14.56±2.16	6.09±3.59	50.2	22.67±4.06

*p=<.001

This data can be broken down further to examine each centre individually as follows:

TABLE 7.16

Detailed Demographic Data for Participants at Each Centre Where More Than 10% Were CSII Users

Centre	Age (mean)	Duration of Diabetes (yrs)	Gender (% female)	BMI
Canada				
CSII users	14.81	6.39	63.2	23.21
Other regimens	14.44	6.94	46.8	23.38
Finland				
CSII users	14.65	6.48	33.3	20.84
Other regimens	14.19	5.43	50.6	20.89
Germany				
CSII users	14.13	6.32	52.2	21.90
Other regimens	14.69	5.86	49.5	26.80
Holland				
CSII users	14.12	7.65	53.8	21.63
Other regimens	14.38	6.53	51.9	20.68
Israel				
CSII users	14.70	5.40	51.3	20.98
Other regimens	14.72	5.41	46.9	20.80
Luxemborg				
CSII users	14.90	6.77	50.0	22.52
Other regimens	15.01	5.98	51.2	22.50
Norway				
CSII users	14.69	5.54	42.4	21.96
Other regimens	15.24	5.66	50.7	22.36
USA				
CSII users	14.38	6.99	54.7	21.67
Other regimens	14.24	5.95	49.5	22.07
Totals				
CSII users	14.47	6.44	52.4	21.76
Other regimens	14.59	5.92	49.7	22.74

TABLE 7.17

Detailed Demographic Data for Participants at Each Centre Where Less Than 10% Were CSII Users

Centre	Age (mean)	Duration of Diabetes (yrs)	Gender (% female)	BMI
Australia				
CSII users	14.96	5.35	42.9	22.16
Other regimens	14.71	6.33	43.6	23.82
Denmark				
CSII users	11.78	6.89	75.0	19.10
Other regimens	14.30	5.79	53.8	21.04
Parma				
CSII users	14.57	5.26	100.0	23.10
Other regimens	14.65	6.10	48.3	21.60
Chietti				
CSII users	15.11	9.55	100.0	28.80
Other regimens	14.80	6.51	53.0	24.01
Japan				
CSII users	12.51	7.00	50.0	19.05
Other regimens	14.15	5.94	68.0	20.90
Sweden				
CSII users	14.68	8.40	77.8	24.26
Other regimens	14.25	5.93	45.8	21.74
Leicester				
CSII users	15.72	7.40	100.0	23.19
Other regimens	14.55	5.63	53.6	22.59
Totals				
CSII users	14.43	6.83	66.7	22.83
Other regimens	14.56	6.09	50.2	22.67

TABLE 7.18

Employment Status of Mother and Father of Participants

Centres with Less than 10% pump users				
-	**Yes**	**No**	**Don't Know**	**Don't Have/See**
Father				
CSII users	32 (97.0%)	1 (3.0%)	-	-
Other regimens	545 (91.0%)	27 (4.5%)	3 (0.5%)	24 (4.0%)
Mother				
CSII users	28 (84.8%)	5 (15.2%)	-	-
Other regimens	462 (76.5%)	139 (23.0%)	-	3 (0.5%)
Centres with More than 10% pump users				
	Yes	**No**	**Don't Know**	**Don't Have/See**
Father				
CSII users	289 (90.6%)	16 (4.8%)	4 (1.3%)	10 (3.1%)
Other regimens	1035 (90.0%)	55 (4.1%)	13 (1.1%)	47 (4.1%)
Mother				
CSII users	241 (75.1%)	77 (24.0%)	3 (0.9%)	-
Other regimens	881 (76.2%)	259 (22.4%)	8 (0.7%)	8 (0.7%)

Significantly more mothers of CSII users were employed compared with mothers of participants using other insulin regimens. This represented a significant difference between cohorts (=-.016). There were no significant differences in levels of employment of fathers or of mothers in the centres with more than 10% CSII users cohort.

Accompanied to Clinic by Parents

78.9% of CSII users were accompanied by parents compared to 95.0% of participants using other insulin regimens. For centres with more than 10% CSII users, however, the reverse was the case with 95.0% of CSII users accompanied by parents compared with (94.2%) of participants using other insulin regimens. This difference was not significant.

Dedicated hotline?

There was a significant difference in reported access to a dedicated hotline. 63.5% of CSII users in centres with less than 10% CSII users reported access, compared with 54.2% of participants using other insulin regimens, representing a significant difference between cohorts (p=.000). Similarly, 83.4% of CSII users in centres with more than 10% CSII users reported having a dedicated hotline, compared to only 60.8% of the participants using other insulin regimens, again statistically significant (p=.000).

HbA1c

587 out of 694 (84.58%) participants using other insulin regimens provided HbA1c results in the less than 10% pump users cohort, compared to 34 out of 38 (89.47%) participants using CSII therapy in the same cohort. There was a significant difference between groups in terms of HbA1c results, p=,0.05).

TABLE 7.19

Difference in HbA1c Results Between Groups In the Less Than 10% Pump User Cohort

	Range	**Mean**	**SD**
CSII users	6.30 – 10.10	7.84	0.82
Other insulin regimens	5.30 – 15.20	8.16	1.31

As can be seen, there is a much tighter range for the CSII users than for people using other insulin regimens, although 94.2% of CSII users had an HbA1c of lower than 9% compared with only 78.1% of people using other insulin regimens.

This analysis was repeated for participants in the more than 10% CSII user cohort as follows. 1154 out of 1352 (85.36%) participants using other insulin regimens provided HbA1c data in the more than 10% pump users cohort, compared to 324 out of 336 (96.43%) participants using CSII therapy in the same cohort. The difference between groups was not significant i.e. p=0.103.

TABLE 7.20

Difference in HbA1c Results Between Groups
In the More Than 10% Pump User Cohort

	Range	**Mean**	**SD**
CSII users	5.80 – 15.40	8.10	1.32
Other insulin regimens	4.70 – 17.40	8.26	1.45

Again, there is much tighter range for the CSII users than for people using other insulin regimens, although this is less marked than for the less than 10% CSII user cohort. Alternatively, however only 80.9% of CSII users had an HbA1c of lower than 9% compared with 89.5% of people using other insulin regimens.

Episodes of Hypoglycaemia

TABLE 7.21

Episodes of Hypoglycaemia During the Last Three Months

	N	**Mean**	**SD**
Less than 10% pump users			
CSII users	35	.03	.169
Other insulin regimens	581	.07	.488
More than 10% pump users			
CSII users	327	.06	.266
Other insulin regimens	1150	.06	.401

Despite participants using other insulin regimens reporting more episodes of hypoglycaemia (in the centres with less than 10% of participants using CSII therapy), there was no significant difference between groups for either groups (centres with less than 10% pump users - f=.832, p=.362, t=.465, df=614)(centres with more than 10% pump users – f=.341, p-.559, t=.285, df=1475).

Episodes of Diabetes Keto-Acidosis

TABLE 7.22

Episodes of DKA During the Last Three Months

	N	Mean	SD
Less than 10% pump users			
CSII users	35	.00	.000
Other insulin regimens	580	.03	.329
More than 10% pump users			
CSII users	326	.06	.298
Other insulin regimens	1151	.03	.270

Less than 10% - f=1.113, p=.292, t=.527, df=613
More than 10% - f=9.364, p=.002, t=-1.586, df=1475

There was a significant difference between CSII users and participants using all other insulin regimens in the more than 10% group. i.e. CSII users are significantly more likely to experience episodes of DKA than adolescents using other insulin delivery systems.

Family

Table 7.23

Diabetes Quality Of Life Youth Impact Scales

	CSII		Other regimens		P Value	F Value
	Mean	SD	Mean	SD		
Centres with More than 10%						
DQOLY impact scale	2.95	2.61	3.12	2.90	.004	8.108
DQOLY parents scale	3.98	2.53	3.93	2.55	.873	.026
DQOLY worry scale	5.97	5.55	5.42	4.83	.004	8.144
Centres with Less than 10%						
DQOLY impact scale	3.21	2.97	2.85	2.58	.099	2.73
DQOLY parents scale	3.89	2.53	4.18	2.67	.448	.58
DQOLY worry scale	5.10	4.60	5.88	6.02	.133	2.26

Table 7.23 shows that CSII users in centres with more than 10% on CSII report less impact than users of other insulin regimens on the DQOLY measure,

however they also report more worry on the DQOLY measure and score more highly on the parent scale, although this fails to reach statistical significance. This compares with centres with less than 10% on CSII where CSII users report less impact than adolescents using other regimens, but more worry and more highly on the parent scale. None of these results are statistically significant.

Analysis of Parents' Responses

Parents of adolescents in the centres with more than 10% CSII users reported more disruption to the family (p=.023), more physical and psychological problems (p=.047) and more school performance impairment (p=.006) however the also report better QoL for their child (p=.013). Thus improved QoL yet more negative experiences for the other areas. Similarly, parents of adolescents in the centres with less than 10% CSII users believed their child suffered significantly more school performance impairment (p=.001) when compared with parents of adolescents using other insulin regimens. There was no significant difference for child's QoL.

In terms of parents' own QoL, results were mixed. In the less than 10% CSII users cohort, there was no significant difference between CSII users and participants using other insulin regimens in response to the statements:

- I have felt cheerful and in good spirits
- I have felt calm and relaxed
- I have felt active and vigorous
- I have woken up feeling fresh and rested

There was a difference for the statement 'My daily life has been filled with things that interest me' i.e. less than half of the time for 36.4% of CSII users compared with 44.6% of parents of adolescents using other insulin regimens (p=.010).

Similarly, for the centres with more than 10% CSII users cohort, there was no significant difference for the statements:

- I have felt calm and relaxed

- I have felt active and vigorous
- I have woken up feeling fresh and rested
- I have felt cheerful and in good spirits
- My daily life has been filled with things that interest me

Thus, parents of CSII users are reporting more positive feelings in terms of their own lives than the parents of adolescents using other insulin regimens. This is consistent with results from Chapter Six.

School

The impact and worry scales of the DQOLY are relevant to the life domain of friends (see table 7.23 for details). There were no significant differences between CSII users and participants using other insulin regimens in the centres with more/less than 10% CSII users for any of the school items

Friends

The impact and worry scales of the DQOLY are relevant to the life domain of friends (Table 7.23). CSII users reported less limitation of social relationships than other insulin regimen users in either centres with more or less than 10% CSII users. (less than 10% cohort - p=.029, more than 10% cohort – p=.004).

Leisure

The impact and worry scales of the DQOLY are relevant to the life domain of friends (Table 7.23). There were no significant differences between CSII users and participants using other insulin regimens in centres with less than 10% CSII users, however in centres with more than 10% CSII users, the only significant difference was that CSII users reported less interference in terms of being able to ride a bicycle or operate a machine (p=.000)

Health

Perception of health status

Over three quarters of all participants perceived their health status to be good. Specifically, in the centres with more than 10% pump users cohort believed their health was good or excellent (79.9% pump users compared with 75.7% other insulin regimens). For the centres with less than 10% pump users 84.5% of

CSII users and 75.9% of participants using other insulin regimens reported good or excellent health status.

Results of the health symptom checklist are presented in Table 7.24 below. There were no significant differences between cohorts for any items on the health symptom checklist for centres with more/less than 10% CSII users.

Table 7.24

Health Symptom Checklist

	Every Day		More Than Once a Week		Every Week		Every Month		Rarely/Never		P Value	F Value
	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)		
CENTRES WITH LESS THAN 10% CSII USERS												
Headache	1(3.0)	33(5.5)	2(6.1)	57(9.5)	5(15.2)	81(13.4)	9(27.3)	133(22.1)	16(48.5)	299(49.6)	.313	1.020
Stomach ache	-	11(1.8)	3(9.1)	46(7.6)	2(6.1)	58(9.6)	10(30.3)	169(28.0)	18(54.5)	319(52.9)	.587	.295
Back ache	3(9.1)	25(4.2)	3(9.1)	31(5.1)	3(9.1)	56(9.3)	6(18.2)	100(16.6)	18(54.5)	390(64.8)	.072	3.239
Feeling low	2(6.1)	36(6.0)	10(30.3)	89(14.9)	3(9.1)	111(17.5)	12(36.4)	141(23.5)	6(18.2)	222(37.1)	.800	.064
Bad temper	3(9.1)	48(8.0)	5(15.2)	117(19.4)	8(21.1)	142(23.6)	13(39.4)	159(26.4)	4(12.1)	136(22.6)	.298	1.086
Nervous	1(3.0)	33(5.5)	6(15.8)	88(14.7)	6(15.8)	98(16.4)	13(39.4)	165(27.5)	7(21.2)	215(35.9)	.328	.957
Diff. sleeping	-	40(6.6)	5(15.2)	70(11.6)	1(3.0)	58(9.6)	8(24.2)	102(16.9)	19(57.6)	332(55.1)	.120	2.419
Dizzy	-	11(1.8)	2(6.1)	36(6.0)	2(6.1)	44(7.3)	3(9.1)	99(16.5)	26(78.8)	411(68.4)	.169	1.893
Neck pain	2(6.1)	16(2.7)	2(6.1)	32(8.0)	4(12.1)	52(16.6)	7(21.2)	106(34.2)	18(54.5)	396(65.8)	.186	1.755
Afraid	-	24(4.0)	1(3.0)	43(7.2)	7(21.2)	64(10.7)	6(18.2)	122(20.3)	19(57.6)	347(57.8)	.339	0.917
Tired	4(12.1)	50(8.3)	4(12.1)	87(14.5)	6(18.2)	123(20.5)	12(36.4)	170(28.3)	7(21.2)	171(28.5)	.980	.001
Angry	2(6.1)	51(8.5)	4(12.1)	96(13.8)	6(18.2)	118(19.6)	15(45.5)	179(29.7)	6(18.2)	158(26:2)	.100	2.714

	Every Day		More Than Once a Week		Every Week		Every Month		Rarely/Never		P Value	F Value
	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)	CSII(%)	Other(%)		
CENTRES WITH MORE THAN 10% CSII USERS												
Headache	15(5.2)	28(5.1)	28(9.8)	58(10.5)	49(17.1)	72(13.1)	63(22.0)	121(22.0)	132(46.0)	272(49.4)	.733	.117
Stomach ache	4(1.4)	12(2.2)	23(8.0)	42(7.6)	32(11.1)	57(10.4)	76(26.5)	155(28.2)	152(53.0)	284(51.6)	.975	.001
Back ache	11(3.8)	28(5.1)	22(7.6)	29(5.2)	27(9.4)	47(8.5)	51(17.7)	95(17.3)	177(61.5)	351(63.8)	.733	.116
Feeling low	11(3.8)	18(3.3)	33(11.5)	85(15.5)	73(25.4)	116(21.2)	66(23.0)	126(23.0)	104(36.2)	203(37.0)	.411	.676
Bad temper	23(8.0)	41(7.4)	49(17.1)	94(17.1)	79(27.5)	139(25.2)	76(26.5)	144(26.1)	60(20.9)	133(24.1)	.528	.399
Nervous	19(6.6)	30(5.5)	38(13.2)	74(13.5)	40(13.9)	104(18.9)	82(28.5)	128(23.3)	109(37.8)	213(38.8)	.737	.113
Diff. sleeping	25(8.7)	47(8.5)	23(8.0)	63(11.5)	36(12.6)	68(12.4)	52(18.2)	95(17.3)	150(52.4)	277(50.4)	.217	1.525
Dizzy	6(2.1)	16(2.9)	13(4.5)	36(6.5)	28(9.7)	55(10.0)	54(18.8)	107(19.5)	187(64.9)	336(61.1)	.062	3.481
Neck pain	8(2.8)	18(3.3)	16(5.6)	34(6.2)	28(9.8)	51(9.3)	44(14.8)	97(17.6)	190(66.4)	351(63.7)	.577	.312
Afraid	9(3.1)	18(3.3)	10(3.5)	22(4.0)	21(7.3)	30(5.4)	41(14.2)	80(14.5)	207(71.9)	401(72.8)	.847	.037
Tired	50(17.5)	65(11.8)	32(11.2)	107(19.5)	58(20.3)	112(20.4)	76(26.6)	131(23.9)	70(24.5)	134(24.4)	.395	.724
Angry	24(8.4)	37(6.7)	48(16.8)	84(15.3)	50(17.5)	129(23.5)	75(26.2)	144(26.2)	89(31.1)	156(28.4)	.114	2.507

Happiness

Life Ladder

Participants were asked to indicate where they felt they best fit onto a 'ladder' scale representing their lives. The scale ranged from 0-10 (0 being the worst possible life for them and 10 being the best possible life).

TABLE 7:25

Life Ladder Scores

	N	Min	Max	Mean	SD
Less than 10% pump users					
CSII users	33	4	10	7.58	1.678
Other insulin regimens	599	0	10	7.33	1.828
More than 10% pump users					
CSII users	319	1	10	7.65	1.685
Other insulin regimens	1146	0	10	7.41	1.794

Further analysis of these results showed that there was no significant difference between CSII users and participants using other insulin regimens across the centres with less than 10% of participants using CSII therapy (f=0.060, p=.806, t-.743, df=630). Nor was there a significant difference between scores of CSII users and participants using other insulin regimens in the centres with more than 10% CSII users (f=2.842, p=.092, t=2.118, df=1463).

Interestingly, the minimum score for CSII users across centres with less than 10% CSII users was '4', whereas the minimum score for participants using other insulin regimens was '0'. There was a much smaller difference for participants from centres with more than 10% CSII users ('1' for CSII users and '0' for participants using other insulin regimens respectively).

Feelings about life questions produced some interesting results. In the less than 10% CSII users cohort, there was no significant difference between CSII users and participants using other insulin regimens for the statements:

- I like the way things are going for me
- My life is going well

- I would like to change many things in my life
- I wish I had a different kind of life
- I have a good life

There was not a significant difference for the statement 'I feel good about what is happening to me' in that 36.4% of CSII users reported feeling good only sometimes compared with 27.6% of participants using other insulin regimens (p=.040).

There was a different picture in the more than 10% pump user cohort however, in that there were significant differences for the following statements:

- My life is going well
- I would like to change many things in my life
- I have a good life

CSII users were less likely to report having a good life (never 15.1% pump users compared with 7.3% other regimens, p=.001); CSII users were less likely to report that their lives were going well (never 10.1% pump users, 5.1% other regimens, p=.041) and were more likely to want to change many things in their lives (almost always/frequently 36.2% pump users compared with 29.0% other regimens, p=.014).

7.3.3 Comparison of QoL for Basal Bolus –v- CSII Users

Having looked at differences between other insulin regimens and CSII, both across all centres using CSII and analyzing those with more/less than 15% CSII use separately, perhaps this is arguably the most relevant analysis. This is because it compares intensified insulin regimens. The rationale for conducting the more general analysis first was to identify any generic issues between cohorts and whether those were consistent for centres with or without specific procedures for CSII therapy. Comparison between intensified insulin regimens is appropriate at this stage, however, whilst structured education should accompany both insulin regimens, it cannot be assumed that both cohorts have actually received similar levels of healthcare support and structured education. Analysis was conducted between intensive insulin regimens in order to identify any significant differences in terms of overall QoL, biomedical and parent-reported outcomes.

Table 7.26

Demographic Data for All Participants

Regimen	Age (Mean)	Duration of Diabetes (yrs)	Gender (% female)	BMI
CSII therapy	14.46±1.91	6.48±3.41	52.4	21.88±3.67
Basal Bolus	14.79±2.09	6.10±3.56	52.8	23.13±15.34

There were no significant differences between participants using CSII therapy and those using a basal bolus regimen in terms of age, gender, duration of diabetes or BMI.

Table 7.27

Employment Status of Mother and Father

	Yes	No	Don't Know	Don't Have/See
Father				
CSII users	289(90.6%)	16(5.0%)	4(1.3%)	10(3.1%)
Basal bolus	762(91.1%)	35(4.2%)	11(1.3%)	28(3.3%)
Mother				
CSII users	241(75.1%)	77(24.0%)	3(0.9%)	-
Basal bolus	650(77.4%)	180(21.4%)	4(0.5%)	6(0.7%)

There were no significant differences between CSII users and participants using basal bolus regimens in terms of the employment status of either mothers or fathers.

HbA1c

There was a significant difference between groups in terms of HbA1c results, p=0.046.

TABLE 7.28

Difference in HbA1c Results Between Cohorts

	Range	Mean	SD
CSII users	5.80-15.40	8.10	1.32
Basal bolus	5.30-17.40	8.25	1.51

There were no significant differences between cohorts in terms of HbA1c. As can be seen, there is still a much tighter range for CSII users than for basal bolus users, where 80.6% of CSII users had an HbA1c of lower than 9% compared with 75.2% of participants using other insulin regimens.

Episodes of Hypoglycaemia

TABLE 7.29

Episodes of Hypoglycaemia During the Last Three Months

	N	Mean	SD
CSII users	15	.06	.301
Basal bolus	25	.06	.266

There was no significant difference between cohorts for episodes of hypoglycaemia during the last three months.

Episodes of Diabetes Keto-Acidosis

TABLE 7.30

Episodes of DKA During the Last Three Months

	N	Mean	SD
CSII users	16	.06	.298
Basal bolus	17	.03	.176

CSII users, however, reported significantly more episodes of DKA than basal bolus users (p=<.001).

Accompanied by Parents to Clinic

CSII users were more likely than basal bolus users to be accompanied by their parents to their out-patient appointment (p=0.000). 77.1% of adolescents in the basal bolus cohort reported that they were accompanied to their out-patient appointment by their mothers, 21.9% by their fathers and the remaining 1% by either a guardian, stepmother or stepfather. This compared to 84.% of CSII users being accompanied by their mother, 15.0% by their father and 0.7% by a guardian, stepmother or stepfather.

Overall Quality of Life and Well-Being

Table 7.31

Quality of Life and Well-Being

	INSULINREG	N	Mean	Std. Deviation	P Value	F Value
Hsbc_well_being	Basal Bolus	867	11.3149	4.19846	0.663	0.190
	pumps	312	11.9071	4.10564		
dqolyimpact	Basal Bolus	881	2.9682	2.76814	0.124	2.367
	pumps	317	2.9527	2.61343		
dqolparents	Basal Bolus	879	3.9204	2.67240	0.334	0.934
	pumps	319	3.9781	2.52836		
dqolworry	Basal Bolus	881	5.6958	4.92910	0.040	4.225
	pumps	319	5.9718	5.54761		

The above table shows that there were no significant differences between CSII users and basal bolus users in terms of well-being or on the scales, although CSII users reported more worry about their diabetes than participants using basal bolus regimens, this was not statistically significant to p=<.001.

Parents' Responses to Questionnaires

Table 7.32

WHO 5 quality of life assessment

	CSII		Basal Bolus		P Value	F Value
	Mean	SD	Mean	SD		
I have felt cheerful and in good spirits	3.57	0.885	3.39	1.027	0.001	10.484
I have felt calm and relaxed	3.33	1.038	3.13	1.129	0.240	1.383
I have felt active and vigorous	3.36	1.047	3.31	1.084	0.325	0.968
I have woken up feeling fresh and rested	3.02	1.237	2.97	1.241	0.706	0.142
My daily life has been filled with things that interest me	3.53	0.987	3.49	1.121	0.014	6.072

Parents of adolescents using CSII therapy reported feeling more cheerful and in good spirits, calm and relaxed, active and vigorous, woken up feeling fresh and rested and that their daily lives had been filled with things that interested them than parents of adolescents using basal bolus regimens, however, the difference was only statistically significant for feeling cheerful and daily life being filled with interesting things.

Table 7.33

Parent Reported Burdens Experienced in Managing Diabetes

	CSII		Basal Bolus		P Value	F Value
	Mean	SD	Mean	SD		
Medical treatment/nursing tasks that you need to perform	1.22	1.029	1.14	0.982	0.203	1.626
Disruption in family routines because of caring for child	1.16	1.055	1.15	0.960	0.012	6.354
Physical or psychological problems in the child requiring extra care	1.45	1.195	1.40	1.083	0.004	8.285
General restriction of your child's social and school activities because of diabetes	1.16	1.102	1.11	1.006	0.088	2.907
Concerns about your child's long term health	2.44	1.132	2.54	1.084	0.266	1.239

Parents of adolescents using CSII therapy report increased burden than parents of adolescents using basal bolus regimens in terms of medical treatment, disruption in family routines, physical/psychological problems and general restrictions of child's social life. This increased burden was statistically significant for disruption and physical/psychological problems requiring extra care. Interestingly, however, parents of adolescents using CSII therapy report less burden in terms of concerns about their child's long term health.

7.4 DISCUSSION

This is a very large dataset, so analysis was necessarily selective. The results from previous chapters, in particular Chapter Six were used to identify key QoL domains and specific measures were identified from this questionnaire with a view to taking forward and developing the results from previous chapters, using a much larger participant population of adolescents with type 1 diabetes across a number of countries and centres. As such, analysis has been narrowed to QoL issues as assessed by the DQOLY and other psychosocial outcomes. Biomedical outcomes of HbA1c, hypoglycaemia and DKA have also been included because of their impact on QoL. Therefore, a three-stage analysis was conducted:

- initial analysis on all centres using CSII therapy
- further analysis on centres with more/less than 10% of participants using CSII therapy
- comparison of intensive insulin regimens i.e. CSII and basal bolus

A 10% cut off point was used because it was believed likely that if centres had more than 10% of individuals using CSII therapy they would also have systems and procedures in place to support that particular therapy. This may not be the case where centres only have a very few individuals using CSII therapy.

On the face of it, adolescents using CSII therapy appear to report QoL benefits in some areas, however these are not consistent among participants or indeed universal QoL benefits for individuals. Furthermore, there are no significant

QoL differences between intensive insulin regimens. Parents of adolescents using CSII therapy report better QoL, however they also report increased disruption and increased burden when compared with parents of adolescents using basal bolus regimens. The ambiguities of living with diabetes are starkly demonstrated by some confounding responses to a number of questions regarding feelings and emotions about diabetes, for example comparing burden and interference. Such complexities are mirrored in the concept of QoL itself i.e. also complicated, subjective and fluid. These issues will be unpicked, interpreted and discussed here with each important life domain cited by adolescents in Chapter Six being discussed separately.

7.4.1 Demographic Data

Total number of CSII users in centres with less than 10% of participants using CSII therapy = 38 compared to 694 participants using other insulin regimens, thus only 5.2% of participants in this cohort were using CSII therapy. This compared to a total number of CSII users in centres with more than 10% of participants using CSII therapy = 298 and 658 participants using other insulin regimens, i.e. 19.9% of participants in this cohort using CSII therapy. Holland had the greatest percentage of CSII users (40.63%) followed by Germany (36.13%) and Luxemborg (35.31%). Leicester had the lowest percentage of pump users (2%) followed by Chietti (2.4%) and Denmark (3.85%).

In centres where less than 10% of participants were using pump therapy, 97.0% of fathers of CSII users were employed compared with 91.0% of fathers of adolescents on other insulin regimens (p=.140). For centres with more than 10% of participants using CSII therapy, 90.6% of fathers of CSII users were employed compared with 90.0% of fathers of adolescents using other insulin regimens. CSII therapy is a more expensive treatment than most other insulin regimens and as such, may be inaccessible to some families on low incomes if funding is not available from the country's health service.

Mothers of adolescents in the centres with less than 10% CSII users cohort were more likely to be employed than the mothers of participants using other insulin regimens (p=<.05). There were no significant differences in employment levels of mothers in the centres with more than 10% CSII users cohort. This may relate to research presented in Chapter 5 where parents of children/adolescents using CSII therapy reported fewer work-related problems after their children had switched to CSII therapy and should be examined further.

For centres where more than 10% of participants were using CSII therapy, CSII users had a mean age of 14.47 years, a mean duration of diabetes of 6.44 years, a mean BMI of 21.76 and 52.4% were female. This compared to a mean age of 14.59, mean duration of diabetes of 5.92 years, mean bmi of 22.74 and 49.7% were female. Only age represented a significant difference between cohorts (p=<.001). For centres where less than 10% of participants were using CSII therapy, pump users had a mean age of 14.43 years, duration of diabetes of 6.83 years, mean BMI of 22.83 and 66.7% were female. This compared with participants using other insulin regimens who had a mean age of 14.56 years, mean duration of diabetes of 6.09 years, mean BMI of 22.67 and 50.2% were female. Again, only age represented a significant difference (p=<.001). Thus participants were similar in terms of duration of diabetes, BMI and gender.

Levels of support across centres also differed in terms of availability of a dedicated hotline for participants. CSII users reported having significantly greater access to a dedicated hotline than participants using all other insulin regimens (p=<.001). This significance remained for centres with more and less than 10% CSII users when analysed separately (both p=<.001). Simply by having access to such support may in itself reduce the level of worry felt by participants, which in turn impacts on their QoL.

7.4.2 Overall QoL

Overall, CSII users reported less impact (p=.012) but increased worry (p=.029) than participants using all other insulin regimens as measured by the DQOLY. This reduced impact is consistent with research presented in previous chapters (Chapters 5 and 6) for both adults and children/adolescents using CSII therapy, however the increased worry is an area that would benefit from further research.

QoL is often measured comparing intensive insulin regimens such as basal bolus and CSII [Kamoi et al 2004, Boland et al 1999]. The rationale for this includes comparing like-for-like the intensity of the regimen; allowing for increased contact time with healthcare professionals for both regimens; expectation that participants are often required to undergo structured education in terms of carbohydrate counting, insulin dose adjustment etc. As such, a further analysis was conducted for participants using these intensive insulin regimens within separately to other participants.

There were no significant differences in QoL between cohorts as assessed by the HSBC well-being and DQOLY measures. CSII users reported significantly more worry than basal bolus users (p=<.05), which may reflect the demands of the therapy and reliance on technological success for good health.

7.4.3 Family

For the parent scale of the DQOLY there were no significant differences between CSII users and other participants (p=.873). Nor were there any significant differences between cohorts for specific items pertaining to parents, e.g. 'how often are your parents too protective?', 'How often do your parents worry too much about your diabetes?'. Generally, participants did not feel that their parents were too intrusive or controlling in their diabetes care that is positive. Results from Chapter Six showed that adolescents reported a benefit of CSII therapy to be greater independence from their parents in terms of less parent involvement in the management of their diabetes e.g. 'not following them round' all the time.

Parents of adolescents using CSII therapy in the more than 10% cohort report better QoL than parents of adolescents using other insulin regimens (p=<.05). They also, however, report more burden than parents of adolescents using other insulin regimens. There were significant differences between cohorts in terms of 'disruption to the family', 'physical and psychological problems' and 'school performance impairment'. Whilst this may seem ambivalent, it is perhaps unsurprising when considering that QoL is influenced by expectations. People using CSII therapy tend to come from a higher socio-economic background and possibly have higher expectations about what they expect from a therapy. It could be, therefore, that those parents are reporting more burden of diabetes because CSII therapy has failed to meet those high and perhaps unrealistic expectations. Unfortunately, there is no indication from the questionnaire response choices about parents' expectations of burden and whether or not their child's insulin regimen had lived up to, or otherwise, those expectations. Further research into this is required to explore the matter in more detail.

The results showing that parents of CSII users are reporting more positive feelings in terms of some aspects of their own lives than the parents of adolescents who were using other insulin regimens supports research in previous chapters showing QoL benefits for other family members as well as the person with diabetes. It could be that with a more appropriate, possibly qualitative investigation of these issues that greater detail could be gleaned in terms of the specific nature of these differences in order to try and narrow the gap between CSII users and other regimens.

Parents of adolescents using CSII therapy reported significantly better QoL as measured by the WHO5 than parents of basal bolus users, specifically in terms of 'feeling cheerful and good spirits' and 'life has been filled with things that interest me' (both p=<.05). This is again consistent with research presented in previous chapters (Chapters Four and Five) where QoL benefits have been reported for other family members.

7.4.2 School

CSII users reported less interference in school activities than participants using other insulin regimens. For centres with more than 10% CSII users, the CSII users were significantly less likely to report that their insulin regimen prevented participation in school activities, although the difference for centres with less than 10% CSII users was not significant. Furthermore, the majority of all participants reported either never or very seldom having to miss work, school etc because of diabetes over 80% of the time (CSII users 83.5%, other insulin regimen users 83.9%, p=.250). This again supports findings from Chapter Six where adolescents report less interruption to school life since starting CSII therapy. They report being able to concentrate more and to miss fewer lessons as a consequence of having to go the medical room to administer injections.

7.4.3 Friends

CSII users reported significantly less diabetes interference in terms of limiting social relationships than other insulin regimen users. (less than 10% CSII user cohort, p=.029; more than 10% cohort, p=.023). Reported benefits of CSII therapy include greater freedom and independence, specifically associated with food related issues. Limiting social relationships being reported as less of a problem for CSII users may reflect this greater freedom because CSII users report being able to interact more 'normally' in social situations (Chapters Four and Six). Reported benefits include being able to eat the same things at the same time as others, not having to take time out to administer insulin injections etc.

7.4.4 Leisure

CSII users were again significantly less likely to report that diabetes 'kept them from riding a bike' than other participants (p=<.001). Whilst this response is specific to one leisure-time activity, i.e. bicycle riding, it is perhaps indicative of wider leisure activities such as participating in sports generally. Being able to make rapid insulin adjustments via the CSII provides greater flexibility when participating in sporting activities, resulting in fewer diabetes-related restrictions.

7.4.5 Health

Over three quarters of all participants perceived their overall health status to be good or excellent and there are no significant differences between CSII users and participants using other insulin regimens in terms of the majority of burden of diabetes questions. Results from the health symptom checklist showed no significant differences between CSII users and other insulin regimens at all stages of analysis. The only exception to this was 'afraid' where CSII users reported feeling less afraid at the first level of analysis. Where difference did occur, CSII users report less burden than participants using other insulin regimens. Health is not always a primary factor in QoL with perception of health status extremely subjective. This result is not unexpected and is consistent with results presented in Chapter Six.

7.4.6 Biomedical Outcomes

For all centres using CSII therapy, there was not a significant difference in episodes of hypoglycaemia between adolescents using CSII therapy and those using other insulin regimens (p=.370). Similarly, there was not a significant difference in HbA1c between those cohorts (p=.086). When the data is examined further, however, analysing only those centres that have CSII user participants, there was a significant difference between CSII users and adolescents using other insulin regimens in terms of HbA1c results across all centres with CSII user participants (CSII user HbA1c was lower, p=<.05).

For centres with less than 10% pump users, the mean HbA1c of CSII users was 7.84 (range 6.30-10.10, SD=0.82) and for adolescents using other insulin regimens, the mean was 8.16 (range 5.30-15.20, SD 1.31). There was a similar picture for centres with more than 10% pump users, i.e. CSII users mean HbA1c was 8.10 (range 5.80-15.40, SD 1.32), other insulin regimens mean 8.26 (range 4.70-17.40, SD 1.45). CSII users in both cohorts had a tighter range for HbA1c and, whilst HbA1c targets vary across centres, overall they had a lower HbA1c than adolescents using other insulin regimens.

There were no significant differences in reported episodes of hypoglycaemia, either for all centres using CSII therapy or for either of the cohorts with more/less than 10% CSII users. A reported benefit of CSII therapy is that there are fewer episodes of hypoglycaemia for users, however this assertion is not supported by the results presented in this Chapter.

There was, however, a significant difference in reported episodes of DKA between cohorts (p=.001) i.e. adolescents using CSII therapy reported significantly more episodes of DKA across the whole data-file. In respect of reported episodes of DKA for participants in centres with CSII user participants, there was a significant difference between CSII users and participants using other insulin regimens in the centres with more than 10% cohort. i.e. CSII users were significantly more likely to experience episodes of DKA than adolescents using other insulin delivery systems. This reflects the results from all centres using CSII therapy, however differs to results from the centres with less than 10% pump users cohort where there was no significant difference between groups.

There were no significant differences between cohorts in terms of age, gender, reported episodes of hypoglycaemia or HbA1c. CSII users still reported more episodes of DKA than basal bolus users (p=<.001). Similarities in HbA1c and episodes of hypoglycaemia may reflect the intensity of both regimens providing successful results. The significant difference in reported episodes of DKA, however, indicates that this is a problem specific to CSII users rather than a consequence of intensification of insulin regimen. Further investigation is required to establish when such DKA episodes are occurring, for whom and how best to reduce such episodes.

This is particularly interesting because the current trend of thinking is that increased episodes of DKA for CSII users has been associated with older, less reliable technology, poorer training etc and that today's CSII users are not at any increased risk of DKA than people using other insulin regimens. The results of this study, however, do not support this assertion and further research is required in this area. Furthermore, the data on episodes of DKA refer to the previous 12 months, so it is not possible to determine whether participants experienced a reduction in the frequency of episodes of

7.4.7 Happiness

Analyses of all centres using CSII therapy showed that CSII users were more likely to 'like the way things are going for them' (70.4% reporting almost all of the time or frequently compared to 65.3% of adolescents using other insulin regimens) and 'felt good about what is happening to them' (70.0% compared to 60.1%). There was little difference in response to 'my life is going well', 'I would like to change many things in my life', 'I wish I had a different kind of life' and 'I have a good life'.

Almost a quarter of all participants (23.5%, n=75 CSII users, 22.7%, n=384 other insulin regimens) reported that they never, or only sometimes, had 'a good life'. This is certainly concerning and warrants further investigation from the clinical teams at participating centres.

Life ladder – all centres using CSII therapy - despite 81.8% of CSII users compared to 75.2% of other insulin regimen users scoring 7 or above on the life ladder scale (0=worst possible life, 10=best possible life), this difference was not significant. The majority of participants were positive about their lives and this is reflected in the results presented in this section. A minority of participants were less positive, however, although it is not possible to identify the cause of their unhappiness from this study.

7.5 CONCLUSION

CSII users report improved QoL on some subscales than adolescents using other insulin regimens, although this is not consistent throughout all QoL measures and CSII users are more likely to experience episodes of DKA. Parents report better QoL and some aspects of feelings/emotions more positively than parents of other insulin regimens, although they also report more burden of diabetes. The question is whether subjectively the reported QoL benefits are sufficient to outweigh the increased burden. This question can only be answered by the individual concerned depending on their current situation. Such mixed results perhaps reflect the very subjective nature of individual experiences associated with living with diabetes.

Cultural differences and peer pressure across different participating centres will undoubtedly have influenced the results, as would have the differences in the way care is delivered and the attitudes of health care professionals between centres. Such care and attitudes affect the approach to diabetes management that is taken by adolescents with diabetes and their parents. If parents and adolescents are satisfied with the care they receive and clearly understand their roles and responsibilities in terms of diabetes care, it follows that they are more likely to do better at diabetes self-care.

The argument that CSII therapy provides QoL benefits is by no means clear-cut from the results presented in this chapter. There is certainly some evidence of QoL benefits by some participants in some areas, however these are combined with reported increased burden and interference associated with CSII therapy. Furthermore, the DQOLY has been widely criticised [Speight 2003] for its lack of sensitivity to issues related to hypoglycaemia and CSII therapy. As such, a more appropriate measure may have produced different results.

All three levels of analyses have shown that QoL benefits may be associated with CSII use for motivated individuals. Some aspects of QoL benefits have also been identified for some parents have also been identified, however these are confounded by increased burden and are not consistent. Perhaps unsurprisingly, the difference when comparing intensive insulin regimens was not significant between cohorts as it could be argued that it is the intensification of insulin regimen rather than CSII therapy that provides benefits. Furthermore, particular to this chapter are the confounding results of increased burden and interference associated with CSII therapy. This could possibly be associated with adolescence, which is notoriously a period of change and turmoil [Strachan and Jones, 1982]. A longitudinal study is recommended to be able to determine whether such ambivalence is indeed indicative of adolescence or whether it changes over time. As CSII therapy and MDI are the two intensified insulin delivery regimens, a randomised controlled trial focusing on these therapies, both in terms of insulin delivery and additional healthcare support is recommended.

CHAPTER EIGHT

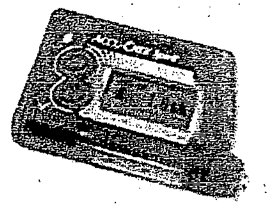
DISCUSSION AND CONCLUSION

There is an increasing argument that CSII therapy is associated with QoL benefits with a number of research studies reporting such benefits [Bode et al, 2002; Wilson et al, 2005]. However, results reported in existing literature are inconsistent in supporting this argument (Hoogma et al, 2004; Fox et al, 2005;Tsui et al, 2001]. This thesis has explored whether there are any QoL benefits associated with CSII therapy and if so, what are the contributory factors of such benefits and the specific areas affected by CSII use. Results from Chapters Four to Six all support the view that QoL benefits may be observed in association with CSII therapy, and that there appear to be specific themes contributing to those QoL benefits. These results are discussed in view of existing literature and suggestions for future research.

The cessation of insulin production, necessary for survival, in people with Type 1 diabetes dictates that those individuals must assume responsibility for the normally automatic regulation of blood glucose levels. To achieve optimum blood glucose regulation, individuals must co-ordinate dietary intake and energy expenditure with circulating insulin levels and making appropriate adjustments of injected insulin. Such intensive management aims to maintain blood glucose levels reasonably close to those for people without diabetes i.e. 4-10mmol/l. The demands of this management, in combination with the chronic nature of the disease place an extreme burden on individuals with Type 1 diabetes. Furthermore, there is also the threat of long-term complications for those people who (for whatever reason) are unable to achieve good metabolic control.

There is little doubt that Type 1 diabetes is a demanding disease, perhaps the most demanding chronic disease, requiring significant effort on the part of the individual to manage it. The all-consuming nature of diabetes means that it impacts on many areas of an individual's life, including physical health, lifestyle, diet, exercise levels and social interaction. This burden may be further exacerbated by the danger of hypoglycaemia if blood glucose levels drop too low (as a result of too much circulating insulin) or ketoacidosis if too high (most commonly a consequence of missed/omitted insulin injections). Fear of hypoglycaemia has been demonstrated in numerous studies, resulting in overcompensation, avoidance behaviours and subsequent hyperglycaemia and the potential for long-term complications [Cox et al, 1987]. Long-term complications associated with Type 1 diabetes include chronic microvascular, neuropathic and macrovascular complications such as retinopathy, neuropathy and nephropathy (see Chapter 1 for further detail). Diabetes also increases the risk of other illnesses such as coronary heart disease and stroke. [Shaw, 1997] It is perhaps unsurprising therefore that "quality of life" has become an increasingly important area of health care for people with diabetes as they strive to balance quality of life with the pressures to maintain optimal glycaemic control over a lifetime.

There are a range of insulin delivery systems available to maintain required blood glucose levels using a combination of long or short acting insulin, which the individual mixes, or comes in pre-mixed rations. Individuals can take subcutaneous insulin injections (normally one or two injections a day depending on treatment regimen) or via intensive management combining multiple daily insulin (MDI) injections (four or more a day) adjusting dosage in association with carbohydrate counting and exercise levels. Self-management programmes for MDI (e.g. DAFNE) have been established to educate patients in correctly titrating their insulin to account for carbohydrate intake. An alternative regimen involves the use of continuous subcutaneous insulin infusion (CSII) whereby an insulin pump is attached to the body via a catheter that is inserted subcutaneously. Insulin delivery is administered via the pump that is programmed by the individual to match circadian rhythms, with additional bolusing of insulin with carbohydrate intake.



This thesis addresses the question as to whether there are any QoL benefits associated with CSII and what factors contribute to any such QoL benefits for people with Type 1 diabetes in the UK, as outlined in the NICE guidance (currently under review).

8.1 CONTINUOUS SUBCUTANEOUS INSULIN INFUSION

CSII therapy is a popular first-line therapy for Type 1 diabetes in the USA (80,000 in 2000) [Pickup, 2001] and is becoming an increasingly popular method of Type 1 diabetes management in the UK. However, its use remains controversial. CSII therapy works by attempting to closely imitate the body's own insulin production system. i.e. provide a basal level of insulin and then deliver bolus doses of insulin after meals. To achieve this, an insulin pump must be worn for 24-hours a day and pre-defined doses of basal insulin are administered via a subcutaneous needle sited in the abdominal wall or thigh. The individual is able to administer bolus insulin whenever required. There is debate around whether CSII provides sufficient specific biomedical benefits in terms of extra cost and effort, compared with other intensive insulin regimens such as multiple daily injections [Bode, 2002; Rodrigues et al, 2005;Wilson et al, 2005] and long-term comparisons are as yet unavailable because of the relatively short period of time that the therapy has been available in the UK.

Notwithstanding, the use of CSII therapy in the UK had increased to approximately 2,000 users in 2005 [Diabetes UK, 2006]. Whilst the NICE guidelines for the prescription of CSII are currently under review in the UK, it is likely that this figure will steadily increase. Yet, despite the increasingly popularity of CSII therapy, relatively little is known about its impact on individual's QoL.

Advocates of CSII therapy report good glycaemic control, reduced episodes of hypoglycaemia, reduced severity of hypoglycaemia, increased freedom surrounding food related issues such as timing and content of meals and "quality of life" benefits (using varying definitions and measurement techniques) for users. Critics report increased episodes of DKA, the requirement for increased blood glucose testing and the increased demands of the therapy as negatives of CSII.

Whilst there is a plethora of published research on the biomedical outcomes associated with insulin pump therapy, there is a dearth of studies into quality of life associated with insulin pump therapy use in Type 1 diabetes.

8.2 QUALITY OF LIFE

Quality of life is a subjective and individualised concept. It can therefore only be reliably measured through patient self-reports (Spranger and Aaronson, 1992). Furthermore, there remains no consensus on a single definition of "quality of life". Although often considered as a modern health paradigm (a phrase that healthcare professionals believe should be used but are unsure as to the definition, purpose or measurement of it). Long-term commitment to self-care requirements for individuals with Type 1 diabetes, in order to sustain both good health and QoL, dictate more than ever the need to accept an adequate definition of QoL and how it can be optimised. Evidence presented in Chapter Two argues for the conceptualisation of QoL to incorporate a broader spectrum than health outcomes and should include physical, psychological and social domains. QoL is becoming increasingly important for measuring the impact of illnesses, diseases and their treatments across healthcare as a secondary outcome, and for deciding priorities when allocating resources. Furthermore, QoL is now recognised in itself as an important outcome with health professionals' recognition that health consists of mental and social wellbeing alongside physical functioning [International Diabetes Federation, 2005]. However, due to the lack of clarity re definitions and its measurement, QoL has been evaluated with little consistency across different studies (see Chapter Three).

So, does the concept of QoL actually exist or is it simply an elusive aspiration about how life could be? If the former, how do we conceptualise it for the purpose of reliable measurement? Since the ancient times of philosophers such as Aristotle and Plato, QoL has formed the centre of debate. Optimal QoL is relative to the environment and culture in which one lives [Eiser and Morse, 2001]. Poor QoL is often associated with sickness, handicap and poverty. Whilst the two sides of the 'QoL' coin, (i.e. good versus poor) seem straightforward, they offer nothing to aid identification of specific factors contributing to good QoL. What constitutes one's own QoL is so subjective that it is perhaps not surprising there is little consensus for one overarching definition. When we consider that individuals are shaped by their environment and relationships, and are steeped in cultural history and social norms, it is difficult to see how the concept of QoL could not be a subjective one.

Thus the acknowledgement that each individual's QoL is unique with no external criteria or gold standard to aspire to, and the subjective importance of specific aspects of life, has resulted in a number of different approaches to its examination. The standards needs approach [Chapter Two, page 21] focuses on domains including physical health, functional ability, psychological status, well-being, social interactions and economic status. Expectation and personal desire are missing from this approach, which assumes that a consensus exists about what constitutes a good or poor quality of life. Herein lies the major flaw, not least because it assumes that once consensus has been found, it is equally applicable to all individuals. Psychological processes approaches [Chapter Two, page 23] focus on the process involved when individuals evaluate their own quality of life. As such, far from being merely a set of circumstances, it is a perception and judgement about the value the individual places on those circumstances and personal priorities. Decision-making methods, such as the SEIQoL are designed to elicit the value system of individuals and to quantify quality of life using the elicited system.

But why does it matter? Why does QoL remain a topic for theoretical debate in academic institutions across the world? Perhaps surprisingly, whilst made fashionable today by media exposure, political jostling and calls for a better work/life balance, the concept of QoL as applied to healthcare, has been relevant since the 1950s. According to the World Health Organisation definition in 1952 health is defined not only by the absence of disease or infirmity, but also by the presence of physical, mental and social well-being. For the purposes of health, it is and has been, recognised as an important health outcome in its own right for a long time, representing the ultimate goal of all health interventions.

By understanding the impact that different conditions have on people's daily lives, taking into account emotional and social functioning as well as physical functioning, can appropriate treatment regimens and interventions be directed towards reducing the disease burden. Numerous measures exist to assess QoL; both generic and disease/treatment-specific. Generic measures allow for comparisons between people with different conditions but are generally less specific and sensitive than those designed specifically for a disease or treatment. However, disease-specific or treatment-specific measures do not allow for comparisons of diabetes with other conditions such as asthma (e.g. you could not suggest that diabetes has a greater impact on QoL than asthma). A combination of both generic and disease-specific measures is required to gain a deeper understanding of the impact of illness and treatment on individuals QoL.

8.3 SYSTEMATIC LITERATURE REVIEW CHAPTER

A systematic search of existing literature was conducted using electronic search engines MEDLINE, PsychINFO, Cinahl and Embase (see Chapter Three for detail on search criteria, limiters and results). Of the seventeen studies meeting the specific selection criteria, only five reported randomised controlled trials. No studies reported qualitative work. Mixed results were reported through the literature, with no clear indication either way about whether CSII therapy is associated with QoL benefits. This is perhaps more likely a consequence of poor methodology such as lack of control groups, small sample sizes and/or reporting, and inconsistent (and inappropriate) use of QoL assessment measures than it is of CSII therapy not having a benefit.

Table 8.1

Inappropriate Measures Used In Previous Research to Assess QoL

Date	Authors	Measure Used	Why Inappropriate
1988	Lewis et al	DTSQ	This is a measure of diabetes treatment satisfaction, not QoL
2002	DeVries et al	Medical Outcome study, short form survey (SF-36) – general health, mental health, DTSQ	SF-36 is a measure of functional health status, not QoL. DTSQ is a measure of diabetes treatment satisfaction, not QoL
2004	Kamoi et al	ITR-QoL	This is an unvalidated measure

All other studies report results using the DQOL, which may not be the most appropriate measure of QoL for participants using CSII therapy, as detailed in Chapter Two.

A recent update (April 2007) of the literature review (originally conducted in 2005) identified a further four published research articles using the same search criteria. Only one of these articles identified new issues associated with CSII therapy, i.e. a qualitative study by Sullivan-Bolyai et al [2005] provided some insight into issues raised by parents of children using CSII. This interview study identified some key themes: introduction to the pump; transition from MDI to CSII; day-to-day Type 1 diabetes management with CSII; and QoL with CSII. Consistent with data presented in Chapter Six of this thesis, parents worried less about overall care, hypoglycaemia and mealtimes. Similarly, Children were reported to be in a "better mood" and have better concentration at school. Adolescent participants from Chapter Six similarly reported increased concentration at school. Other benefits were described in terms of freedom in choice/timing of meals, ability to participate in school activities and increased spontaneity in family life, all of which have been raised by participants throughout this thesis. It is believed that this is the first such qualitative study published in the literature.

8.4 PILOT and SEIQoL STUDIES

Patient input into identifying domains of importance to a diabetes-specific population is vital in measuring QoL. It cannot be assumed that an externally imposed judgement about what should contribute to an individual's QoL will be appropriate. How do we know whether an instrument sufficiently captures the subjective nature of individual QoL if we don't know how relevant, comprehensive (or understandable) it is to patients? The pilot and SEIQoL studies, therefore, were designed to elicit views from current CSII users (adults n=80; children/adolescents n=15; parents n=17) about benefits, QoL effects, disadvantages (pilot study only) and any other relevant issues associated with the therapy. The aim was to gain an insight into the impact of CSII therapy on every day QoL. To this end, the pilot study focused on four key questions (benefits, disadvantages, QoL impact and any other issues that participants wanted to raise). As with the SEIQoL study, a semi-structured interview design was utilised (further detail in Chapters Four and Six, interview schedules attached in Appendices B and D). Detailed thematic analysis and coding was conducted to identify common themes, both positive and negative.

Key positive pilot study themes reported by participants included:

- being in control of diabetes rather than being controlled by it (56.25%);
- flexibility (specifically in term of meal timings and food choices) (41.25%);
- freedom (35.0%);
- family benefits (8.75%);
- convenience (8.75%) and
- independence (6.25%).

These themes (with the exception of family benefits) were recurrent throughout the research presented in this thesis and are consistent with the benefits previously reported in the literature [Rodrigues et al, 2005; Mednick et al, 2004]. This suggests that they are indeed contributory factors that combine (to a greater or lesser degree) to produce an overall perception of improvement in

QoL. These themes most effectively represent the 'normality' that is reported with CSII therapy, i.e.the day not being dictated by timing of insulin injections; being able to fit in with other family members at mealtimes, and for children/adolescents in particular to fit in with friends and peers by being able to eat what they eat, when they want to eat it rather than being singled out as different. This ties in with the theme of having 'control over diabetes' rather than being controlled by it. Furthermore, this 'normality' was repeatedly reflected in comments by participants in the SEIQoL study (Chapter Six) in terms of their important life domains and the impact CSII therapy had on those domains.

Overwhelmingly, all participants across both studies reported benefits and improved QoL associated with CSII therapy. Whilst this had been hypothesised, the strength of feeling (not identified/captured from the literature review in Chapter Three) was unexpected. QoL benefits for other family members identified in the pilot study were reinforced by the parent interviews in the SEIQoL study, with every parent reporting QoL benefits resulting from their child's commencement on CSII therapy.

Pilot study responses including "it has given me my life back" and "if you tried to take it away, I'd fight you for it" in terms of their own QoL, as well as comments such as "my wife isn't afraid to leave the house...", "my mum doesn't go into meltdown..." similarly reflect the strength of feeling participants reported in terms of QoL benefits for others. Impact on loved ones (self-reported or otherwise) is not currently captured in existing measures of QoL (see Chapters Two and Three). For example, whilst the DQOLY for children does have some family items, it has not yet been used in separate analysis in any published literature to date [Skinner et al 2006].

It could be argued that QoL should be defined as "what the patient says it is" rather than what the researcher decides to measure. The SEIQoL semi-structured interview method, developed to assess QoL from the individual's perspective, does just this. Whilst results from the SEIQoL study reflected some of those from the pilot study, it was more focused in terms of identifying important life domains. Furthermore, it assessed participant reported impact of CSII on those life domains and on QoL generally. This was different to the pilot study, where positive and negative aspects of CSII therapy were explored in the first instance to identify whether key themes would emerge. A major advantage of the SEIQoL is individuals' ability to identify life domains rather than external judgements imposed by researchers or other third parties. Furthermore, the ability to rate those important life domains against each other and then to assign them a value, provides a comprehensive assessment of individuals' priorities in terms of their own QoL.

As with the pilot study, all SEIQoL participants reported the impact of CSII therapy on their QoL to have been positive. One third of parents reported 'health' as most important for QoL but none of the children did so. Consistent with the literature [Walker and Bradley, 2002], children and adolescents most frequently reported family, friends and school as important for their QoL. Following initiation of their child's CSII therapy, parents rated their own health as very much better (52.9%), much better (17.6%) and better (23.5%), whilst 'family' was rated as very much better (41.2%), much better (17.6%) and better (5.9%). This again re-emphasises the results from the pilot study in terms of QoL benefits for other family members. That parents are reporting a range of QoL benefits for their own lives resulting from their children's CSII therapy reflects the encompassing nature of diabetes into many aspects of life such as family life.

The diversity of life domains and subjective descriptions reported by participants highlights the degree of difference between individuals when asked to define the five most important aspects of their life for their QoL. This is further exemplified in the range of responses received in terms of the impact of CSII on each domain. Despite being rated most frequently by 16 of the 17 parents, 'health' was rated as most important for QoL only by 6 (35%). Only seven children/adolescents (46%) listed 'health' as one of their five domains, with none rating it as the most important aspect of life for QoL. Again, this finding is consistent with the literature, which suggests that 'health' is not the major QoL priority for everyone [Speight and Shaw, in press] and should not necessarily be the focus when evaluating the benefits of new treatments (i.e. the assessment of QoL not HRQoL).

Interestingly, the first important life domain reported by participants was not always the area that they considered to be of most importance when rating the relative importance of each domain. Adolescents, however, were most likely to rate the first nominated domain as the most important. In terms of 'health', parents cited improved blood glucose levels and long-term good health of his/her child/adolescent in terms of their own health. The diversity in meaning of 'health' by parents perhaps reflected their concern for the overall family well-being, particularly when combined with domains of 'finances', 'children's welfare' and 'security'. Furthermore, a number of parents attributed a reduction in their own stress levels to their child's CSII. This is, perhaps, unsurprising when we consider the amount of time children/adolescents spend at school. Thus, feeling less worried about one's child/adolescent during these periods of separation had implications for parents' own emotional well-being plus less interference in their own working lives and any consequential financial implications.

The SEIQoL tool had been previously used in paediatric and adult studies, so it was possible to achieve consistency across interviews of both children/adolescent and parent cohorts. Thus, the study's progression from the results presented in the pilot study was the attachment of relative weighting to life domains and prioritising those domains against each other. It must be acknowledge, however, that the strengths of the pilot and SEIQoL studies in terms of the individualisation of QoL limits the potential to generalise results to the wider population of people with Type 1 diabetes. Whilst key themes were identified, it cannot be assumed that these themes are appropriate for everyone. Indeed, the very point that QoL is such a subjective concept would argue against this.

8.5 CROSS-SECTIONAL STUDIES

The themes identified by participants in the pilot study therefore and the critique of QoL measures from Chapters Two and the systematic literature review

(Chapter Three) were used to inform questionnaire selection for the adult cross-sectional study presented in Chapter Five which aimed to establish the long-term and real-life effectiveness of CSII therapy in terms of QoL benefits comparing CSII participants with a cohort of other insulin regimen users. Consequently, in full consideration, the following measures were selected to provide a broad assessment of QoL and specific issues relating to insulin dependent diabetes: the World Health Organisation Quality of Life Abbreviated Measure (WHOQoLBREF), the Insulin Delivery Systems Rating Questionnaire (IDSRQ), the Hypoglycaemia Fear Scale (HFS) and the Problem Areas in Diabetes (PAID) scale. Additionally, questions about patient preference and their willingness to recommend CSII therapy to others were included to reflect individual's satisfaction with the therapy irrespective of QoL (see Appendix Three). The study design supported the identification of satisfaction scores irrespective of QoL.

CSII users reported better overall QoL (as assessed by the WHOQoLBREF) and satisfaction with their health (as assessed by the IDSRQ), along with higher scores for the environmental domain of the WHOQOLBREF. All diabetes specific measures evidenced significant differences between CSII users and individuals on other insulin regimens (with the exception of WHOQOLBREF physical, psychological and social relationships domains). Thus, CSII users reported less worry about hypoglycaemia and undertook fewer behaviours to avoid low blood sugar, less diabetes related distress and fewer diabetes related emotional problems, treatment related problems, food related and social support related problems. CSII users also reported greater satisfaction with their insulin delivery system, greater helpfulness, less interference with daily life and less worry about blood glucose control.

The adolescent study reported in Chapter Seven utilised a range of additional well-being (WHO-5), functional status (SF) and QoL measures, including the DQOLY. Whilst it is acknowledged that this measure has been criticised for its lack of sensitivity on issues surrounding hypoglycaemia [Speight, 2003], it does provide detailed impact, parent and worry scales that are extremely useful in assessing issues relevant for adolescents, identified from the SEIQoL study.

Participants were asked a number of biomedical and psychosocial questions to explore the roles of psychological and personal well-being, lifestyle, social background and diabetes care. Existing literature is consistent in documenting that adolescents with diabetes have elevated levels of psychopathology and lower emotional well-being than 'healthy' adolescents. It is unclear, however whether these differences persist when comparing treatment arms of trials involving regimens e.g. CSII versus MDI. This study aimed to identify any QoL differences between those two groups.

Adolescent CSII users reported a better QoL (as assessed by the DQOLY) than adolescents using other insulin regimens, although they also reported having experienced more episodes of DKA, even when compared with MDI, the other intensive insulin regimen. Similarly to Chapters Four and Six, parents of adolescent CSII users reported better QoL and some aspects of feelings/emotions more positively, although they also reported more burden of diabetes. Does this improved QoL outweigh the burdens? Unfortunately, this question cannot be answered from the results presented in this study. Based on previous criticisms of the DQOLY, it could be argued that it was perhaps not the most appropriate measure to address this question. It is unlikely, however, that this is sufficient to explain all of the results.

Cultural differences and peer pressure across different participating centres (n = 15) will undoubtedly have influenced the results, as would have the differences in the way care is delivered and the attitudes of health care professionals between centres. Such care and attitudes affect the approach to diabetes management that is taken by adolescents with Type 1 diabetes and their parents and may be influenced by a wide range of factors. If parents and adolescents are satisfied with the care they receive and clearly understand their roles and responsibilities in terms of diabetes care, it follows that they are more likely to do better at diabetes self-care.

Three levels of analyses were conducted (centres using CSII therapy and finally, a comparison between intensive insulin regimens) and QoL benefits associated with CSII use were observed throughout. QoL benefits for parents of CSII users have also been identified. Both of these results are consistent with previous research presented in this thesis. Particular to Chapter Seven, however, are the confounding results of increased burden and interference associated with CSII therapy. This may be associated with adolescence, which is notoriously a period of adaptation, experimentation and change. Only a longitudinal study would be able to determine whether such ambivalence remains or changes over time.

Biomedical benefits associated with CSII therapy were reflected in Chapter Seven with CSII participants reporting a tighter HbA1c range and reduced episodes of hypoglycaemia. These participants were significantly more likely to have access to a dedicated hotline whereby they could received advice about managing their diabetes. It could be argued that if the participants using other insulin regimens had access to such a hotline, this may have influenced these biomedical results. Furthermore, participants using CSII therapy reported significantly increased incidence of DKA than other participants and this is an area that certainly requires further investigation. Parents of adolescents were significantly more likely to be employed than parents of adolescents using other insulin regimens. This may reflect the higher socio-economic status associated with CSII therapy, particularly in the UK.

Bradley and Speight [2002] suggest that 'freedom to eat as I wish' is the aspect of quality of life most adversely affected by diabetes self-management and most important for their quality of life (closely followed by 'enjoyment of food') in people with Type 1 diabetes. The benefit reported by CSII users in this area is of particular note. The success of the DAFNE trial [2002] (intensive education for people with diabetes) to improve this aspect of quality life could confound this finding as patients are now required to undergo training prior to CSII commencement[1], which may not be the case for MDI, and as such it could be questioned whether the effects seen in this area are due to the CSII or the additional skills training enabling greater flexibility and dietary freedom. This

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[1] People who express a desire for CSII therapy are now required to attend structured education prior to commencement on that therapy. This training covers carbohydrate counting, when to test blood glucose levels and how to use that information, the impact of illness, exercise etc on blood glucose levels.

point is critical in understanding the problems regarding the benefits of CSII use as the relevant of structured diabetes education cannot be underestimated.

The key themes identified in the existing literature and the pilot study, were supported by the results of both cross-sectional studies. The results of the IDSRQ where adult CSII users report significantly greater satisfaction, helpfulness and less interference and worry, support the themes of increased freedom, flexibility and control. This is supported by the results of the adolescent study where both adolescents and their parents report improved QoL. Furthermore, the food related considerations evaluated by the PAID reflect flexibility with food and cross-validate with the IDSRQ. Other cross-validated domains include social relationships (PAID and WHOQOLBREF) and psychological issues (IDSRQ, PAID and HFS). Adolescents also report fewer limitations to social situations than participants using other insulin regimens. Being able to eat the same things at the same time as friends was identified in Chapter Six and this is linked to removing some of those limitations.

The results of both the cross-sectional studies provide support for a number of assertions that have been made in previous literature in terms of QoL benefits and may help to explain some of the contradictory findings from previous studies on QoL and CSII use. CSII users report better QoL on all diabetes specific related assessments, generic QoL and satisfaction with health. Such demographic effects must be controlled for because historically in the UK many CSII users have had to pay for their treatment and so only those who can afford the treatment have easy access to it. Thus, socio-economic status must be acknowledged as a confounding variable. In fact, in the pilot study results show that cost was still perceived as a downside of CSII therapy by some participants, not least because of the monthly cost of medical supplies required, indicating some people still bear the financial burden of their CSII therapy.

8.6 COMPARISON BETWEEN INTERVIEW AND CROSS-SECTIONAL STUDIES

QoL benefits associated with CSII therapy were consistent across research chapters. The interview studies provided a rich understanding of the subjective meaning attached to living with Type 1 diabetes and the impact of CSII therapy on their lives. Also, participants' beliefs about the main contributors to their improved QoL painted a complex picture. Alternatively, the cross-sectional studies were able to assess both generic and specific components of QoL for much larger numbers of participants. They also provided a comparison between CSII users and participants using other insulin regimens.

The identification of key themes (such as freedom, independence, control) facilitated the selection of measures for quantitative analysis, thus both interview and cross-sectional studies were equally valuable in the exploration of this topic.

8.7 WHY CSII MAY PROVIDE QoL BENEFITS

CSII therapy represents the most advanced technology currently available. It most closely mimics the body's own insulin production in terms of meal times and insulin production. It is also demanding, requiring individuals to calculate insulin doses in association with exercise levels and food intake, whilst frequently monitoring their blood glucose levels. The rapid biomedical improvement in terms of blood glucose levels, fewer episodes of hypoglycaemia and reduced blood glucose fluctuations, in conjunction with individual motivation to manage the therapy combined, lead to the reported improvements in QoL. Improved blood glucose control, greater independence, freedom from injections and food related benefits are all contributory factors enabling individuals to engage in activities that had been restricted by Type 1 diabetes. These contributory factors appear to redress the balance between controlling Type 1 diabetes and being controlled by it.

People could be willing to live with the downsides of CSII therapy because of the returning 'normality', i.e. the life they remember before they became burnt out by Type 1 diabetes. Thus, Type 1 diabetes becomes inconvenient rather than unmanageable. In the UK, patients are likely to have had Type 1 diabetes for a long time prior to commencement of pump therapy (as it is considered a 'last-resort' by NICE). This may go some way to explaining why people report such dramatic improvements in QoL. After having 'failed' at other treatment regimens, it could be expected that people's QoL would be poor prior to commencement of CSII. Also, combine this with poor general health resulting from poor blood glucose levels/control and the potential result is an overwhelming sense of the burden of Type 1 diabetes. As stated in Chapter Two, ill-health and feelings of lack of control over Type 1 diabetes are contributory factors to QoL.

Furthermore, there are several demonstrable benefits of CSII in terms of diabetes-specific psychosocial outcomes (in areas such as food related problems, hypoglycaemia avoidance behaviour, and interference from treatment) that may also serve to enhance metabolic outcomes and reduce the negative impact of Type 1 diabetes on QoL, as shown in Chapter Five.

There appears to be no elusive benefits that CSII therapy offers over MDI. Rather, it is the overwhelming sense that CSII gives people the opportunity for their lives to return to as close to 'normal' as they currently can be. The discreetness of the therapy generally and the freedom, independence, specifically food related appears to remove the 'burden' of Type 1 diabetes over and above the alternative intensive insulin regimen (MDI). Not having to carry injections, administer injections in public or 'feed' the previous insulin injection were all cited as benefits of CSII over MDI.

8.8 CONCLUSIONS

The aim of this thesis research was to explore QoL issues/benefits associated with CSII therapy. It is believed that the combination of both quantitative self-report and interview data for adults and children/adolescents using CSII therapy presented in the research chapters provides a broad understanding (and novel evaluation) of relevant issues associated with QoL, in terms of what and how to measure it.

Diabetes is undoubtedly a growing concern for today's healthcare providers around the world. As perhaps one of the most demanding chronic conditions, QoL is increasingly recognised as an important health outcome. Difficulties identifying appropriate definition and assessment for QoL, however, complicate matters adding confusion to evaluating an already burdensome disease. As we embrace new technologies and offer people with diabetes, particularly Type 1 diabetes, an increasing range of insulin delivery options we are best placed to optimise both biomedical and psychosocial outcomes. QoL should be considered when deciding on the most appropriate therapy for individuals, alongside optimal biomedical outcomes and personal choice.

While previous research has indicated that the effectiveness and flexibility of CSII therapy may compensate for problems caused by the pump [Kamoi et al, 2004], the National Institute for Health and Clinical Excellence (NICE) estimates the additional cost of pump therapy in comparison to an MDI regimen to be £1,100-£1,400 per year. As a result, NICE has recommended CSII therapy as a treatment option only where MDI therapy has failed and the patient demonstrates both the commitment to and competence in using the therapy effectively (though it is unclear how this should be assessed). Very little information exists concerning associated long-term cost savings (e.g. fewer hospital admissions or reduced risk of developing diabetes-related complications), although Scuffham & Carr [2003] identified a gain of 0.48 quality adjusted life years (QALYs) over the eight-year life cycle of a pump[10] when compared with MDI.

For the populations reported in this thesis (adults, children, adolescents), CSII therapy is associated with QoL benefits for this highly motivated, enthusiastic population, specifically in terms of QoL, with some commonly reported disadvantages. This is a key overarching finding of the thesis and should not be lost in the detail reported in each study. Each research chapter highlights the positive QoL benefits of CSII therapy, and whilst the statistical significance may be lost when controlling for socio-economic environment and frequency of blood glucose testing (as in Chapter Five), this could still be a mechanism of failure to identify the most appropriate measures available, or that to date, there are no such measures available to target such a specific outcome.

Whilst the research presented in this thesis provides support for the argument that CSII therapy is associated with QoL benefits, it is apparent that there are specific issues within this that require further investigation. There are potential QoL benefits reported in each of the research chapters for CSII users, with Chapters Four and Six also reporting QoL benefits for other family members. There are, however, confounding variables within the adolescent cross-sectional study (Chapter Seven), which add a level of ambiguity to the results, for example the mixed QoL benefits (participants reported both positive and negative impacts of CSII on different aspects of their QoL) and the reported increases in episodes of DKA that require further examination in future research. The mixed QoL results could indeed be a function of using the DQOLY measure, and possibly differing expectation levels of parents, or could simply reflect the complexity. QoL is an extremely diverse concept and as such an individual may indeed report benefits to one aspect of QoL, however, disadvantages to another. As stated previously, socio-economic status is highly relevant to whether an individual can gain access to CSII therapy through self-funding. As such, it could potentially be argued that those individuals from a higher socio-economic background may have higher expectations of the therapy, not least because they have had to pay for it rather than receive it free of charge from their national health services. Furthermore, the 'last resort' nature of CSII therapy may in itself be confounding, not least because such treatments typically result in large placebo effects. Therefore, it must be questioned whether it is the therapy itself that provides the QoL benefits, or simply an acceptance that there is no other choice so individuals simply 'make the most of it'.

For those people that report CSII benefits, these benefits are reported very enthusiastically and appear to be remarkable benefits and QoL improvements. Indeed, the drop-out rate for people choosing to stop CSII therapy and return to their previous insulin regimen is only 2-3%. The analogy was frequently made by participants that CSII therapy had 'given them their lives back' and 'that they now controlled their diabetes rather than being controlled by it'. It must be noted, however, that CSII therapy is neither appropriate nor suitable for all patients with Type 1 diabetes. Furthermore, as long as CSII therapy is seen as the 'gold standard' of insulin delivery systems, reinforced by the NICE guidance that dictates individuals must have 'failed' at MDI therapy to be considered for CSII therapy, it should be considered what message this gives to those people who decide that CSII therapy is not for them. As stated previously, diabetes is an extremely burdensome disease that seeps into every aspect of daily life. Intrusive and limiting behaviours must be endured to maintain appropriate blood glucose levels and prevent the likelihood of long term complications, however there can be no guarantees that such complications will indeed be prevented, despite an individual's best efforts. Participants frequently cite the reduction in the number of injections as a major benefit as well as diabetes control, i.e. one canula change every three days compared to four injections a day. It could be argued that with appropriate training and support, individuals may gain greater diabetes control on MDI and with that greater control, the impact of frequent injections may be reduced. This certainly warrants further investigation e.g. a prospective long term study comparing MDI with intensification of education and support compared with CSII.

By considering CSII therapy as simply another tool in the armoury against Type 1 diabetes, it can be used to match the needs of the individual with the most appropriate resource/therapy to manage their diabetes. This tool should fit in with their lifestyle whilst enhancing both biomedical and QoL outcomes, and reducing as much as possible the risk of long-term complications. If CSII therapy is deemed most appropriate, there are QoL benefits to be gained from using it.

Whilst the research presented in this thesis reports on relatively large sample sizes, it is unclear to what extent these results can be generalised to the wider Type 1 population. As stated, The National Institute for Clinical Excellence are currently reviewing their guidelines on CSII therapy and the research presented in this thesis is being considered as part of that review process. At present, there is pressure to limit prescription of CSII therapy to no more than 10% of patients with Type 1 diabetes. Consequently, demand far outweighs supply at a number of Type 1 diabetes centres. The ability to identify groups of patients that would most benefit from CSII would be extremely useful for healthcare professionals faced with the decision to prescribe such an expensive regimen as CSII therapy. This is, however, a suggestion for future research. A randomised controlled trial in this population, in the first instance could establish whether CSII does result in benefits in this group.

8.9 LIMITATIONS OF THESIS RESEARCH

The CSII population in the UK represents a very small percentage of people with Type 1 diabetes. Whilst every attempt was made to recruit as many participants as possible, numbers are still relatively small, making it difficult to generalise results. Furthermore, CSII participants from Chapters Four, Five and Six were recruited via Roche Diagnostics pump users database. It is believed that these participants were a representative sample of individuals using CSII therapy in the UK as Roche provide approximately half of insulin pumps used in the UK. A wider recruitment, perhaps from a number of Diabetes centres or from the other main insulin pump supplier, Medtronic may have reflected a larger, more representative sample.

A number of different methodologies have been used in this thesis, the majority of which were reliable and well-validated. This was not the case for the patient preference questions in Chapter Five, however, due to the subjective nature of QoL, it is believed their inclusion was appropriate. The inclusion of both interview and cross-sectional studies may have reduced the statistical impact of the thesis, however it has provided a wealth of highly personal, rich subjective meaning that adds enormous value to the thesis.

Finally, it must be acknowledged that in Chapter Six, there were six tapes that were corrupted post-interview and pre-transcription. Full transcription was not possible, therefore for these tapes, the researcher's extensive notes were used to code the interview data. Whilst unfortunate, it is not believed that this had a strongly detrimental effect on the results of the study.

8.10 SUGGESTIONS FOR FUTURE RESEARCH

8.10.1 How Can We Best Identify/Assess Individuals for Suitability for CSII therapy?

Should such identification/assessment be based primarily on biomedical outcomes, psychosocial outcomes or a combination of both? If a combination of biological and psychological outcomes is most appropriate, the next question is how to balance those outcomes to maximise health benefits. Furthermore, appropriate measures must be identified/developed to ensure that target outcomes are being assessed e.g. specific QoL measures that are sensitive to issues associated with CSII therapy.

Future research into developing a screening tool to identify those people who would benefit most from CSII therapy is required. The success of that tool should then be tested using a prospective study design. Participants identified as appropriate for initiation on CSII therapy should be assessed and followed-up for a period of not less than six months in order to allow time for adjustment to the therapy, when their progress should be reviewed and assessed against the selection criteria.

8.10.2 Which People Will Be Most Able to Meet The Demands of CSII Therapy?

Are people with certain personality types, demographics and clinical factors most likely to be able to meet the demands of CSII therapy or is a person's level of motivation more important? Both MDI and CSII therapy require an initial period of adjustment during which there is a very steep learning curve and often worsening of biomedical outcomes. CSII therapy requires constant monitoring and adjustment, frequent canula changes and 24-hour attachment to the insulin pump. Do the benefits of insulin pump therapy outweigh the amount of ongoing effort required following the phase of transition? It is questionable whether a study to identify personality types of pump users would provide useful results. There are numerous factors affecting a person's success or otherwise with insulin pump therapy and it would be extremely difficult to extract personality type as uniquely one of those contributing factors.

8.10.3 Why Do People Cease CSII Therapy?

There are a small percentage of people who initiate CSII therapy but subsequently choose to discontinue that therapy. It cannot simply be assumed that they experience more of the downsides already identified and reported by current pump users. Rather, there may be as yet unidentified causes for discontinuation. This issue requires further investigation because it may provide valuable information in terms of whether it is possible to identify individuals in advance for whom CSII therapy may not be appropriate.

8.10.4 Is CSII Therapy The Answer?

Individuals expressing a desire to commence CSII therapy are often required to undergo structured education in terms of carbohydrate counting, insulin adjustment. After such education, many people decide not to continue onto CSII therapy but prefer instead to go onto multiple daily injection therapy. Individuals could be identified when they first express a desire for CSII therapy, followed through a structured intensive education programme and the reasons ascertained as to why some individuals choose MDI at this stage and why others go on to commence CSII therapy. These individuals could then be followed for a further period of 6 months to determine whether CSII therapy has provided the benefits they expected, alongside improved biomedical outcomes. Biomedical and psychosocial data should be collected at baseline, three and six months in order to track progress.

APPENDIX A

Confirmation of University of Southampton Ethics Approvals

Main Identity

From: "Smith K.M." <K.M.Smith@soton.ac.uk>
To: <katharine.barnard@ntlworld.com>
Sent: 10 February 2006 15:18
Subject: Ethics Application

Dear Katharine

Re: Qualitative study into quality of life associated with use of insulin pumps

The above titled application was approved by the School of Psychology Ethics Committee on 26 January 2006.

Should you require any further information, please do not hesitate in contacting me. Please quote reference PG/03/89.

Best wishes,

Kathryn

Miss Kathryn Smith
Secretary to the Ethics Committee
School of Psychology
University of Southampton
Highfield
Southampton SO17 1BJ
Tel: 023 8059 3995 Fax: 023 8059 2606
Email: kms@soton.ac.uk

Main Identity

From: "Smith K.M." <K.M.Smith@soton.ac.uk>
To: "katharine barnard" <katharine.barnard@ntlworld.com>
Sent: 24 May 2006 13:34
Subject: Ethics Application

Dear Katharine

Re: Cross sectional study into quality of life associated with use of insulin pumps

The above titled application was approved by the School of Psychology Ethics Committee on 23 May 2006.

Should you require any further information, please do not hesitate in contacting me. Please quote reference PG/04/06.

Best wishes,

Kathryn

Miss Kathryn Smith
Secretary to the Ethics Committee
School of Psychology
University of Southampton
Highfield
Southampton SO17 1BJ
Tel: 023 8059 3995 Fax: 023 8059 2606
Email: kms@soton.ac.uk

Main Identity

From: "Smith K.M." <K.M.Smith@soton.ac.uk>
To: "katharine barnard" <katharine.barnard@ntlworld.com>
Sent: 31 October 2006 14:23
Subject: Ethics Application

Dear Katharine

Re: Qualitative Study into Quality of Life of Paediatrics Using Insulin Pump Therapy

The above titled application was approved by the School of Psychology Ethics Committee on 25 October 2006.

Should you require any further information, please do not hesitate in contacting me. Please quote reference PG/04/24.

Best wishes,

Kathryn

Miss Kathryn Smith
Secretary to the Ethics Committee
School of Psychology
University of Southampton
Highfield
Southampton SO17 1BJ
Tel: 023 8059 3995 Fax: 023 8059 2606
Email: kms@soton.ac.uk

Main Identity

From: "Smith K.M." <K.M.Smith@soton.ac.uk>
To: "katharine barnard" <katharine.barnard@ntlworld.com>
Sent: 31 October 2006 14:33
Subject: Ethics Application

Dear Katharine

Re: **Explaining Centre Differences in Quality of Life of Adolescents with Diabetes using Continuous Subcutaneous Insulin Infusion (CSII) compared to other insulin regimens - Hvidore study group**

The above titled application was approved by the School of Psychology Ethics Committee on 21 September 2006.

Should you require any further information, please do not hesitate in contacting me. Please quote reference PG/04/23.

Best wishes,

Kathryn

Miss Kathryn Smith
Secretary to the Ethics Committee
School of Psychology
University of Southampton
Highfield
Southampton SO17 1BJ
Tel: 023 8059 3995 Fax: 023 8059 2606
Email: kms@soton.ac.uk

APPPENDIX B

Invitation Letters, Consent Forms, Coding Framework and Instructions for Interviewees for Chapter Four

5 July 2005

Dear Sir/Madam

We (Dr Chas Skinner and Mrs Katharine Barnard) are writing to you to ask for your help with a project we are undertaking in collaboration with Roche Diagnostics (the people who make your insulin pump/blood glucose testing equipment).

This project hopes to gain a detailed insight into the different quality of life benefits of using different regimes to manage Type I diabetes. To this end we are writing to ask you to complete the attached questionnaire, which asks about some of your experiences of living with diabetes, your concerns about living with diabetes, along with your thoughts about your treatment and your overall quality of life. Your help with this project would be greatly appreciated and we hope can be used to inform decisions about the availability of different treatment regimes in the UK.

Therefore, could you please complete all of the questionnaires included in this booklet. Whilst it may look like a lot, please be assured that it should take approximately 20 minutes of your time. All responses will be treated in utmost confidence and there are no identifying marks on any of the questionnaires. Please try and complete the questionnaires as fully as possible. We understand that not every question will be relevant to you, so please ignore the ones that do not apply, as per the instructions on each form. **Please return the forms even if you only manage to complete part of them or none at all.**

If you have any questions about this project, then please contact:

Katharine Barnard, Health Psychologist
email kdb103@soton.ac.uk,
Postal address: School of Psychology
University of Southampton
Highfield Campus
Southampton
SO17 1BJ

Thank you very much for taking the time to read this letter and we hope that you will be able to help us with this project.

Yours faithfully

DR T C SKINNER PhD K D BARNARD MSc, BSc(Hons)

Study Descriptions

Study N° 1: Qualitative Exploration of Pump Benefits

- This study will analyse over a three month period recorded customer support telephone calls.
- 5 minutes will be added to each call asking key questions about insulin pump use and quality of life.
- This research programme will last around 3-6 months. However, you will only be asked to answer the questions once.

Study N° 2: Prospective Quality of Life Benefits from Pump Use

- This study will analyse over a period of six months results from responses received to written questionnaires sent out to participants.
- All new pump users will be sent quality of life questionnaires starting at pre-pump and thereafter one questionnaire at intervals at one month, three months and six months respectively.
- The responses received will be analysed on prospective changes in quality of life.
- This research programme will last around six months and you will receive questionnaires starting at pre-pump and thereafter one questionnaire at intervals at one month, three months and six months respectively.

Study N° 3: Cross Sectional Comparison of Quality of Life

- All pump users and non-users with type 1 diabetes will be sent a quality of life questionnaire.
- The analysis will compare pump with non-pump users.
- This research programme will last 3-6 months. However, you will only receive a questionnaire once.

All three studies are being sponsored by Roche Diagnostics Limited. **Participation in these studies is entirely voluntary.** The University of Southampton and Roche Diagnostics Limited will require your consent to ask questions along the lines of the examples set out below under the heading "Study Procedures". The University of Southampton will use the results to evaluate the effect of pump therapy on quality of life.

Selection Criteria

To take part in the studies you must be over the age of 18 and currently using insulin pump therapy.

Study Procedures

Study N° 1

After having received your consent to take part in the telephone survey, you will be asked a number of questions by Roche's customer support team, for example:

- What are the benefits you have experienced from using the insulin pump?
- Specifically, how do you think it has affected your quality of life?
- Are there any down sides that you have experienced from using the pump?
- Are there any other issues these questions have raised for you?

Study N° 2

After having received your consent to take part in the written survey, you will be sent questionnaires (at the intervals set out above) to complete and return to the Roche Diagnostics in a pre-paid envelope which will be sent to you along with each questionnaire.

Roche Diagnostics Limited will collect all the responses to pass on to Southampton University.

Study N° 3

After having received your consent to take part in the written survey, you will be sent one questionnaire to complete and return to Roche Diagnostics in a pre-paid envelope. This will be sent to you along with the questionnaire.

Roche Diagnostics Limited will collect all the responses to pass on to Southampton University.

Benefits of the Trial

You will not gain any direct benefit from taking part in this study. However, the study will be an important addition to what is known about insulin pump therapy. The weight of knowledge about pump therapy will inform its future use in the UK.

Informed Consent

A copy of the informed consent form for this study is included at the end of this document. You will be asked to sign two copies of this. You should retain one copy of the consent form for your information and the other should be returned to Roche Diagnostics Limited in the enclosed pre-paid envelope. The consent form protects your right to withdraw from the study at any time.

Current and Future Use of Records/Data

Data collected during your participation in Study N° 1 will be recorded by Roche Diagnostics Limited call centre staff and provided only to Southampton University, who are acting on behalf of Roche Diagnostics Limited in analysing the answers to the questions.

Certain statistical tests will be carried out on the data, along with that collected from other volunteers who entered the study. Roche Diagnostics Limited may then forward the results of the study to health authorities worldwide, and the results may also be used in reports of the study or for scientific presentations or publications. Roche Diagnostics Limited may need to re-analyse the data from this study at a later date, or perform further statistical tests on the data. The results of this study may be used for future diagnostic research.

Please note that should you decide to withdraw from the study at any time, information collected from you up until that point will still be provided to Roche Diagnostics Limited.

Confidentiality

As has always been the case, personal information and data is held anonymously. Occasionally, at any time during or after the study, staff from Roche Diagnostics Limited or their designated representatives and health authorities will be granted direct access to the telephone recording or the questionnaires so that they can confirm that the information collected during the studies is accurate. In these circumstances your identity may be disclosed. Representatives of the local Institutional Review Board / Ethical Review Committee may also be granted similar access. However, all these bodies are bound by strict rules of confidentiality.

INFORMED CONSENT FORM

1. Where I am taking part in Study N° 1, I the undersigned, voluntarily agree to take part in this study by agreeing to answer questions and for my telephone conversation with the Roche Diagnostics Limited call centre staff to be recorded and for the recordings relating to my answers only to be sent to the University for analysis.

2. Where I am taking part in Study N° 2 and/or 3, I the undersigned, voluntarily agree to take part in the study/ies by agreeing to complete the questionnaire(s) and for my completed questionnaire(s) to be analysed by the University of Southampton.

3. I have been given, and understand, a detailed explanation of the nature and purpose of the study/ies and what I will be expected to do. I have also read and had explained to me the volunteer information document describing the study/ies.

4. I understand that I am free to withdraw from the study/ies at any time without the need to give any justification for my decision.

5. I have not been placed under any pressure to enter the study/ies and am taking part in it voluntarily.

6. I understand that I will not be referred to by name in any report concerning the study/ies disclosed to any other person. I shall not claim to be entitled to restrict in any way the use to which the result of the clinical study may be put and, in particular, I agree to disclosure of any report of those results to the regulatory authorities for approvals of medical devices in the United Kingdom or elsewhere. I consent to Roche Diagnostics Limited and Southampton University collecting and processing my information, including information about my health and mental wellbeing. I consent to my information being processed by Roche Diagnostics Limited and Southampton University, and passed to other Roche group companies (including Roche group companies who are outside the European Union) or to companies working with Roche Diagnostics Limited, and I understand that my information may be forwarded to other countries worldwide. If I decide to withdraw from the study/ies, I agree that the information collected about me up to the point when I withdraw may continue to be processed. I consent to Roche Diagnostics Limited, or its other group companies, and Southampton University using my information, including information about my health for future research.

7. In the event of my withdrawal, either at the request of the company or at my own request, the company can use the data obtained during my participation or such withdrawal does not invalidate the provision of paragraph 5.

8. If I have further questions regarding any study in which I have agreed to take part, I understand I am able to contact Katharine Barnard at the University of Southampton for further clarity. If, after that time, having already given my consent to take part, I decide to withdraw prior to taking part, I understand that I shall not be placed under any further obligation to take part.

SIGNED: .... DATE: ....
(Volunteer)

NAME: .... DATE OF BIRTH: ....

GUIDING SCRIPT FOR CUSTOMER SERVICES STAFF

This is a guiding script to use when asking customers if they would be willing to participate in the explorative telephone study. Please try to stick to it as closely as possible, however, we recognise it may not always be possible in every circumstance.

When you have finished discussing the main reason for the call, e.g. ordering of supplies etc, could you please:

Firstly, tell the customer that we are conducting research in association with the University of Southampton, into quality of life issues surrounding insulin pump use and ask them if they have received an information letter and consent form.

If they have received and returned their signed consent form, please confirm that they are still happy to participate.

If so, tell them that they will be asked four brief questions about their experience of using an insulin pump. Please, then ask the following four questions:

What are the benefits you have experienced from using the insulin pump?

Specifically, how do you think it has affected your quality of life?

Are there any down sides that you have experienced from using the pump?

Are there any other issues these questions have raised for you?

Please give customers plenty of time to consider their response before they answer and try to encourage them to explore their answers more fully to give as much detail as possible, e.g. 'what do you mean?', 'really?' etc

If they have not received the information letter and consent form, please ask if they would be interested in participating and take their name and address details so that a letter can be sent out. They will then have the opportunity to participate and their response included when signed consent has been received.

K Barnard
19 Aug 05

CODING FRAMEWORK

Chapter Four – Pilot Study

Codes were initially assigned for every new occurrence. As such there was a large number of codes, some with more responses than others. Following initial coding, themes were then developed and key themes identified.

A second coder also coded 10% of responses. These were reviewed by discussion with both coders and inter-coder agreement was reached on final codes/themes.

Initial Codes

- Flexibility at work
- Flexibility in social life
- Flexibility in household tasks
- Family – benefits to others
- Family – flexibility
- Health – blood glucose (HbA1c)
- Health – yo-yo'ing of blood sugars
- Health – fewer episodes of hypoglycaemia
- Health – less severe hypos
- Diabetes – control
- Hypoglycaemia Unawareness
- Hypoglycaemia Nocturnal
- Dawn Phenomenon
- Fluctuating Blood Glucose
- Lower HbA1c
- Pregnancy
- Injecting Site Problems
- Problems with Basal Insulin
- Number of Injections
- Flexibility to fit lifestyle
- Management of Exercise
- Coping
- When things go wrong
- Marks on tummy
- Where to wear it – visibility/colour co-ordination
- Cost – who pays?
- Cost – very expensive
- Lack of HCP knowledge when things go wrong

Final Codes/Themes

Positive

- Control versus controlled
- Flexibility
- Freedom
- Family effects
- Convenience
- Independence

Negative

- Visibility – device
- Visibility – skin
- Breakdown
- Cost

APPENDIX C

Invitation Letters, Consent Forms and Questionnaire for Chapter Five

5 July 2005

Dear Sir/Madam

We (Dr Chas Skinner and Mrs Katharine Barnard) are writing to you to ask for your help with a project we are undertaking in collaboration with Roche Diagnostics (the people who make your insulin pump/blood glucose testing equipment).

This project hopes to gain a detailed insight into the different quality of life benefits of using different regimes to manage Type I diabetes. To this end we are writing to ask you to complete the attached questionnaire, which asks about some of your experiences of living with diabetes, your concerns about living with diabetes, along with your thoughts about your treatment and your overall quality of life. Your help with this project would be greatly appreciated and we hope can be used to inform decisions about the availability of different treatment regimes in the UK.

Therefore, could you please complete all of the questionnaires included in this booklet. Whilst it may look like a lot, please be assured that it should take approximately 20 minutes of your time. All responses will be treated in utmost confidence and there are no identifying marks on any of the questionnaires. Please try and complete the questionnaires as fully as possible. We understand that not every question will be relevant to you, so please ignore the ones that do not apply, as per the instructions on each form. **Please return the forms even if you only manage to complete part of them or none at all.**

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Study N° 2: Prospective Quality of Life Benefits from Pump Use

- This study will analyse over a period of six months results from responses received to written questionnaires sent out to participants.
- All new pump users will be sent quality of life questionnaires starting at pre-pump and thereafter one questionnaire at intervals at one month, three months and six months respectively.
- The responses received will be analysed on prospective changes in quality of life.
- This research programme will last around six months and you will receive questionnaires starting at pre-pump and thereafter one questionnaire at intervals at one month, three months and six months respectively.

Study N° 3: Cross Sectional Comparison of Quality of Life

- All pump users and non-users with type 1 diabetes will be sent a quality of life questionnaire.
- The analysis will compare pump with non-pump users.
- This research programme will last 3-6 months. However, you will only receive a questionnaire once.

All three studies are being sponsored by Roche Diagnostics Limited. **Participation in these studies is entirely voluntary.** The University of Southampton and Roche Diagnostics Limited will require your consent to ask questions along the lines of the examples set out below under the heading "Study Procedures". The University of Southampton will use the results to evaluate the effect of pump therapy on quality of life.

Selection Criteria

To take part in the studies you must be over the age of 18 and currently using insulin pump therapy.

Study Procedures

Study N° 1

After having received your consent to take part in the telephone survey, you will be asked a number of questions by Roche's customer support team, for example:

- What are the benefits you have experienced from using the insulin pump?
- Specifically, how do you think it has affected your quality of life?
- Are there any down sides that you have experienced from using the pump?
- Are there any other issues these questions have raised for you?

Study N° 2

After having received your consent to take part in the written survey, you will be sent questionnaires (at the intervals set out above) to complete and return to the Roche Diagnostics in a pre-paid envelope which will be sent to you along with each questionnaire.

Roche Diagnostics Limited will collect all the responses to pass on to Southampton University.

Study N° 3

After having received your consent to take part in the written survey, you will be sent one questionnaire to complete and return to Roche Diagnostics in a pre-paid envelope. This will be sent to you along with the questionnaire.

Roche Diagnostics Limited will collect all the responses to pass on to Southampton University.

Benefits of the Trial

You will not gain any direct benefit from taking part in this study. However, the study will be an important addition to what is known about insulin pump therapy. The weight of knowledge about pump therapy will inform its future use in the UK.

Informed Consent

A copy of the informed consent form for this study is included at the end of this document. You will be asked to sign two copies of this. You should retain one copy of the consent form for your information and the other should be returned to Roche Diagnostics Limited in the enclosed pre-paid envelope. The consent form protects your right to withdraw from the study at any time.

Current and Future Use of Records/Data

Data collected during your participation in Study N° 1 will be recorded by Roche Diagnostics Limited call centre staff and provided only to Southampton University, who are acting on behalf of Roche Diagnostics Limited in analysing the answers to the questions.

Certain statistical tests will be carried out on the data, along with that collected from other volunteers who entered the study. Roche Diagnostics Limited may then forward the results of the study to health authorities worldwide, and the results may also be used in reports of the study or for scientific presentations or publications. Roche Diagnostics Limited may need to re-analyse the data from this study at a later date, or perform further statistical tests on the data. The results of this study may be used for future diagnostic research.

Please note that should you decide to withdraw from the study at any time, information collected from you up until that point will still be provided to Roche Diagnostics Limited.

Confidentiality

As has always been the case, personal information and data is held anonymously. Occasionally, at any time during or after the study, staff from Roche Diagnostics Limited or their designated representatives and health authorities will be granted direct access to the telephone recording or the questionnaires so that they can confirm that the information collected during the studies is accurate. In these circumstances your identity may be disclosed. Representatives of the local Institutional Review Board / Ethical Review Committee may also be granted similar access. However, all these bodies are bound by strict rules of confidentiality.

INFORMED CONSENT FORM

1. Where I am taking part in Study N° 1, I the undersigned, voluntarily agree to take part in this study by agreeing to answer questions and for my telephone conversation with the Roche Diagnostics Limited call centre staff to be recorded and for the recordings relating to my answers only to be sent to the University for analysis.

2. Where I am taking part in Study N° 2 and/or 3, I the undersigned, voluntarily agree to take part in the study/ies by agreeing to complete the questionnaire(s) and for my completed questionnaire(s) to be analysed by the University of Southampton.

3. I have been given, and understand, a detailed explanation of the nature and purpose of the study/ies and what I will be expected to do. I have also read and had explained to me the volunteer information document describing the study/ies.

4. I understand that I am free to withdraw from the study/ies at any time without the need to give any justification for my decision.

5. I have not been placed under any pressure to enter the study/ies and am taking part in it voluntarily.

6. I understand that I will not be referred to by name in any report concerning the study/ies disclosed to any other person. I shall not claim to be entitled to restrict in any way the use to which the result of the clinical study may be put and, in particular, I agree to disclosure of any report of those results to the regulatory authorities for approvals of medical devices in the United Kingdom or elsewhere. I consent to Roche Diagnostics Limited and Southampton University collecting and processing my information, including information about my health and mental wellbeing. I consent to my information being processed by Roche Diagnostics Limited and Southampton University, and passed to other Roche group companies (including Roche group companies who are outside the European Union) or to companies working with Roche Diagnostics Limited, and I understand that my information may be forwarded to other countries worldwide. If I decide to withdraw from the study/ies, I agree that the information collected about me up to the point when I withdraw may continue to be processed. I consent to Roche Diagnostics Limited, or its other group companies, and Southampton University using my information, including information about my health for future research.

7. In the event of my withdrawal, either at the request of the company or at my own request, the company can use the data obtained during my participation or such withdrawal does not invalidate the provision of paragraph 5.

8. If I have further questions regarding any study in which I have agreed to take part, I understand I am able to contact Katharine Barnard at the University of Southampton for further clarity. If, after that time, having already given my consent to take part, I decide to withdraw prior to taking part, I understand that I shall not be placed under any further obligation to take part.

SIGNED: .... DATE: ....
(Volunteer)

NAME: .... DATE OF BIRTH: ....

Insulin Pump Quality of Life Study

PATIENT CHARACTERISTICS

(Please tick all that apply and write in the space provided where applicable)

Diabetes type: ☐ 1 ☐ 2

Gender: ☐ Male ☐ Female

Age at diagnosis of diabetes: ______________ years

Current age: ______________ years

Age at start of insulin use: ______________ years

FREQUENCY OF BLOOD GLUCOSE MONITORING *(Please tick one box only)*

☐ Never ☐ Rarely ☐ A few times a month ☐ A few times a week

☐ Once daily ☐ Twice daily ☐ Three times daily

If more than three times daily how many? ______________

These questions refer to the insulin delivery system you are *currently* using:

(Please tick all that apply and write in the space provided where applicable)

☐ Vial and syringe ☐ Insulin pump ☐ Reusable pen

☐ Needleless injector ☐ Disposable pen

☐ Other *(please state)* ______________

How long have you been using this insulin delivery system? ______________ years

If you take injections, how many injections do you take per day? *(Please tick one box only)*

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7+

University
of Southampton

HOW TO ANSWER THIS QUESTIONNAIRE

We'd like to ask you how you feel about your quality of life, health and other areas of your life. **Please answer all or as many of the questions as possible.** If you are unsure about which response to give to a question, please choose the **ONE** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks.**

EXAMPLE QUESTIONS

	Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
Do you get the kind of support from others that you need?	1	2	3	4	5

You should **circle** the number that best fits how much support you got from others **over the last two weeks.** So you would circle the number 4 if you got a great deal of support from others as follows:

	Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
Do you get the kind of support from others that you need	1	2	3	[✓ 4]	5

You would circle the number 1 if you did not get any of the support that you needed from others in the last two weeks.

NB: The answer scale is different for each question. Make sure you check and circle the appropriate number.

QUESTIONS FOR YOU TO ANSWER

PART 1

Please read each question, assess your feelings, and circle the number on the scale for each question that *gives* the best answer for *you*.

	Very poor	Poor	Neither poor nor good	Good	Very good
1. How would you rate your quality of life?	1	2	3	4	5

	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
2. How satisfied are you with your health?	1	2	3	4	5

The following questions ask about *how much* you have experienced certain things *in the last two weeks.*

	Not at all	A little	A moderate amount	Very much	An extreme amount
3. How much do you feel that pain prevents you from doing what you need to do?	1	2	3	4	5
4. How much do you need medical treatment to function in your daily life?	1	2	3	4	5
5. How much do you enjoy life?	1	2	3	4	5
6. To what extent do you feel life to be meaningful?	1	2	3	4	5
7. How well are you able to concentrate?	1	2	3	4	5
8. How safe do you feel in your daily life?	1	2	3	4	5
9. How healthy is your physical environment?	1	2	3	4	5

The following questions ask about *how completely* you experience or were able to do certain things *in the last two weeks.*

	Not at all	A little	Moderately	Mostly	Completely
10. Do you have enough energy for everyday life?	1	2	3	4	5
11. Are you able to accept your bodily appearance?	1	2	3	4	5
12. To what extent do you have enough money to meet your needs?	1	2	3	4	5

	Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
13. How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14. To what extent do you have the opportunity for leisure activities?	1	2	3	4	5
15. How well are you able to get around?	1	2	3	4	5

The following questions ask you to say *how good or satisfied* you have felt about various aspects of your life *over the last two weeks.*

	Very dissatisfied	**Dissatisfied**	**Neither satisfied nor disastisfied**	**Satisfied**	**Very satisfied**
16. How satisfied are you with your sleep?	1	2	3	4	5
17. How satisfied are you with your ability to perform daily living activities?	1	2	3	4	5
18. How satisfied are you with your capacity for work?	1	2	3	4	5
19. How satisfied are you with yourself?	1	2	3	4	5
20. How satisfied are you with your personal relationships?	1	2	3	4	5
21. How satisfied are you with your sex life?	1	2	3	4	5
22. How satisfied are you with the support you get from your friends?	1	2	3	4	5
23. How satisfied are you with the conditions of your living place?	1	2	3	4	5
24. How satisfied are you with your access to health services?	1	2	3	4	5
25. How satisfied are you with your transport?	1	2	3	4	5

The following question refers to *how often* you have felt or experienced certain things *in the last two weeks.*

	Never	**Seldom**	**Quite often**	**Very often**	**Always**
26. How often do you have negative feelings, such as a blue mood, despair, anxiety, depression?	1	2	3	4	5

How satisfied are you with your *current* insulin delivery system?

	Completely satisfied	Very satisfied	Somewhat satisfied	Not at all satisfied
27. How much time it takes	1	2	3	4
28. How convenient it is	1	2	3	4
29. How easy it is to take insulin	1	2	3	4
30. How painful it is	1	2	3	4
31. Occurrence of skin infections	1	2	3	4
32. Occurrence of skin irritations/bruises	1	2	3	4
33. Embarrassment when using it	1	2	3	4
34. Embarrassment having it with you	1	2	3	4
35. How easy it is to learn to use it	1	2	3	4
36. How complicated it is to use	1	2	3	4
37. Difficulty in having all your supplies with you	1	2	3	4
38. Difficulty in taking all insulin prescribed	1	2	3	4
39. Difficulty in measuring insulin dosage accurately	1	2	3	4
40. Uncertainty about getting the amount of insulin intended	1	2	3	4
41. How much it costs to use it	1	2	3	4

How much does your *current* insulin delivery system interfere with the following?

	A Lot	Some	A Little	Not at all
42. Wearing the clothes you want to	1	2	3	4
43. Getting a good night's sleep	1	2	3	4
44. Sleeping late when you want to	1	2	3	4
45. Eating late when you want to	1	2	3	4
46. Eating when you want	1	2	3	4
47. Eating what you want	1	2	3	4
48. Exercising when you want	1	2	3	4
49. Exercising as much as you want	1	2	3	4
50. Doing the type of exercise you want	1	2	3	4
51. Engaging in sexual activities	1	2	3	4
52. Taking care of yourself when travelling	1	2	3	4

53. Does your current insulin delivery system require you to monitor your blood glucose more often than you would like? *(Please tick one box)*

☐ Yes, much more often ☐ Yes, somewhat more often ☐ No, not really

How good is your *current* delivery system in helping you with the following?

	Excellent	Very Good	Good	Fair	Poor
54. Getting good blood glucose control	1	2	3	4	5
55. Keeping your blood glucose stable	1	2	3	4	5
56. Avoiding low blood glucose without extra snacks	1	2	3	4	5
57. Avoiding low blood glucose at night	1	2	3	4	5
58. Realising when your blood glucose is going low	1	2	3	4	5
59. Avoiding high blood glucose	1	2	3	4	5
60. Avoiding doctor visits for poor control	1	2	3	4	5
61. Avoiding hospital visits for poor control	1	2	3	4	5
62. Avoiding weight gain	1	2	3	4	5

How often do you worry about the following?

	All the Time	Frequently	Sometimes	Rarely	Never
63. Getting complications	1	2	3	4	5
64. High blood glucose	1	2	3	4	5
65. Low blood glucose	1	2	3	4	5
66. Unpredictable blood glucose	1	2	3	4	5
67. Being home alone	1	2	3	4	5
68. Travel away from home	1	2	3	4	5

69. Overall, how satisfied are you with your current insulin delivery system? *(Please tick one box)*

☐ Completely ☐ Very ☐ Somewhat ☐ Not at all

70. Would you like to switch to another insulin delivery system? *(Please tick one box)*

☐ Definitely Yes ☐ Probably Yes ☐ Probably Not ☐ Definitely Not

71. Would you recommend your current insulin delivery system to others? *(Please tick one box)*

☐ Definitely Yes ☐ Probably Yes ☐ Probably Not ☐ Definitely Not

72. The following questions refer to the insulin delivery system you used **right before you switched** to your current system. *(Please tick all boxes that apply)*

☐ Nothing (move to question 74.)

☐ Vial and syringe ☐ Insulin pump ☐ Reusable pen ☐ Needleless injector

☐ Disposable pen Other (please state)________________________________

73. How would you compare your current insulin delivery system to your previous system?

☐ Current much better ☐ Current a bit better ☐ Both about the same

☐ Previous a bit better ☐ Previous much better

74. Do you have any comments you would like to share?
(Please write below and continue onto back page if required)

PART 2

Behaviour:

Below is a list of things people with diabetes do in order to avoid low blood sugar. Please read each item carefully. *Please **circle** one number that best describes what you do during your daily routine to **AVOID** low blood sugar.*

	Never	Rarely	Sometimes	Often	Always
1. Eat large snacks at bedtime	0	1	2	3	4
2. Avoid being alone when my sugar is likely to be low	0	1	2	3	4
3. If test blood glucose, run a little high to be on the safe side	0	1	2	3	4
4. Keep my sugar high when I will be alone for a while	0	1	2	3	4
5. Eat something as soon as I feel the first sign of low blood sugar	0	1	2	3	4
6. Reduce my insulin when I think my sugar is low	0	1	2	3	4
7. Keep my sugar high when I plan to be in a long meeting or at a party	0	1	2	3	4
8. Carry fast-acting sugar with me	0	1	2	3	4
9. Avoid exercise when I think my sugar is low	0	1	2	3	4
10. Check my sugar often when I plan to be in a long meeting or out at a party	0	1	2	3	4

Issues:

Which of the following diabetes issues ***are currently problems*** for you? Please read each item carefully. *Please **circle** one number that best describes how much of an **issue** each item is for you.*

	Not a problem	**Minor problem**	**Moderate problem**	**Somewhat serious problem**	**Serious problem**
24. Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
25. Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
26. Feeling scared when you think about living with diabetes?	0	1	2	3	4
27. Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat)?	0	1	2	3	4
28. Feelings of deprivation regarding food and meals?	0	1	2	3	4
29. Feeling depressed when you think about living with diabetes?	0	1	2	3	4
30. Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
31. Feeling overwhelmed by your diabetes?	0	1	2	3	4
32. Worrying about low blood sugar reactions?	0	1	2	3	4
33. Feeling angry when you think about living with diabetes?	0	1	2	3	4
34. Feeling constantly concerned about food and eating?	0	1	2	3	4
35. Worrying about the future and the possibility of serious complications?	0	1	2	3	4

	Not a problem	**Minor problem**	**Moderate problem**	**Somewhat serious problem**	**Serious problem**
36. Feelings of guilt or anxiety when you get offtrack with your diabetes management?	0	1	2	3	4
37. Not 'accepting' your diabetes?	0	1	2	3	4
38. Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
39. Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
40. Feeling alone with your diabetes?	0	1	2	3	4
41. Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4
42. Coping with complications of diabetes?	0	1	2	3	4
43. Feeling 'burned out' by the constant effort needed to manage diabetes?	0	1	2	3	4

We would like to thank you for taking the time to complete this questionnaire. Please return it to us in the pre-paid reply envelope supplied.

APPENDIX D

Invitation Letters, Consent Forms, Coding Framework and Questionnaires for Chapter Six

Roche
Diagnostics

Name
Address 1
Address 2
Address 3
Address 4
Postcode

Friday, 24 November 2006

Dear Parent/ Guardian,

Roche Diagnostics and Southampton University are working together to research the issues that affect the quality of life of children using insulin pump therapy and their parents. Most research to date has focused on the bio-medical impact of pump therapy telling us very little about the personal experience of using a pump. Thus, this research into quality of life will add an important dimension to what is known about pump therapy. The results of this research will be used to inform local and national NHS organisations as they decide on the future use of insulin pump therapy, so your help will be extremely valuable.

Southampton University will be undertaking the research project. Participation will involve taking part in a 30 minute telephone interview, answering questions about pump therapy and its impact on quality of life. Please note that the interview will include questions both to your son/daughter and to you as the parent/guardian. You will not be referred to by name in any report concerning the study.

In order for the researchers to ask you for your views and opinions, please read carefully the enclosed consent form. If you are happy to be contacted, please sign and return the form in the prepaid envelope provided. Please note that the consent form must be signed by you as the parent/guardian. If you do not wish to take part then there is no need to sign and return the form. A second copy of the form is enclosed, in case you wish to keep a copy for your records.

Once your signed consent has been received, your details will then be passed to the research team at Southampton University and they will contact you directly to answer any questions you may have and make arrangements to conduct the study. Your details will not be used for any other purpose.

Roche Diagnostics Ltd

Roche Place
Charles Avenue
Burgess Hill
West Sussex RH15 9RY
Registered number: 571546

Infusion Systems

Tel: +44(0)1444 256279
Email: julietralph@roche.com

We enclose a brief description of the study and very much hope you will agree to help. However, should you wish to receive any further information or have any further questions before deciding whether to participate, then please do not hesitate to contact Chas Skinner or Katharine Barnard on 02380 594588 or kdb103@soton.ac.uk

Yours faithfully,

JRalph

Juliet Ralph
Assistant – Infusion Systems
Roche Diagnostics

Roche Diagnostics Ltd

Roche Place
Charles Avenue
Burgess Hill
West Sussex RH15 9RY
Registered number: 571546

Infusion Systems

Tel: +44(0)1444 256279
Email: juliet.ralph@roche.com

Study Description

Qualitative interviews will be conducted to gain a rich understanding of what issues affect the quality of life of children using insulin pump therapy and their parents. Previous research has shown that insulin pump therapy affects the quality of life of the person using this therapy, but also the quality of life of their family members. We aim to explore this issue further.

This study is being sponsored by Roche Diagnostics Limited. **Participation in this study is entirely voluntary.** The University of Southampton and Roche Diagnostics Limited will require your consent to ask questions along the lines of the examples set out below under the heading "Study Procedures". The University of Southampton will use the results to evaluate the effect of pump therapy on quality of life.

Selection Criteria

This study is for persons of 18 years and under who are currently using insulin pump therapy and will also include their parent/ guardian.

Study Procedures

After we receive your consent for yourself and your son/daughter to take part in the telephone study, you will be contacted by a member of the research team. At this time you will be asked if you would like any clarification about the study and a time convenient to yourself will be arranged for the research team to ring you to conduct the telephone interview. Interviews are expected to last approximately 30 minutes. An information pack will be sent to you when an interview time has been arranged, which you will need to keep handy for when the researcher calls to interview you.

Benefits of the Trial

You will not gain any direct benefit from taking part in this study. However, the study will be an important addition to what is known about insulin pump therapy. The knowledge we gain about the impact of pump therapy on quality of life may inform its future use in the UK.

Informed Consent

A copy of the informed consent form for this study is included at the end of this document. You (the parent/guardian) will be asked to sign two copies of this. You should retain one copy of the consent form for your information and the other should be returned to Roche Diagnostics Limited in the enclosed pre-paid envelope. The consent form protects your right to withdraw from the study at any time.

Current and Future Use of Records/Data

Data collected during your participation in this study will be recorded by a member of the Southampton University research team. This recording will be transcribed and anonymised. The tapes will be held for the duration of the study and will be destroyed no more than 6 months after analysis has been completed.

Please note that should you decide to withdraw from the study at any time, information collected from you up until that point will still be provided to Roche Diagnostics Limited.

Confidentiality

As has always been the case, personal information and data is held anonymously. Occasionally, at any time during or after the study, staff from Roche Diagnostics Limited or their designated representatives and health authorities will be granted direct access to the telephone recording or the questionnaires so that they can confirm that the information collected during the studies is accurate. In these circumstances your identity may be disclosed. Representatives of the local Institutional Review Board / Ethical Review Committee may also be granted similar access. However, all these bodies are bound by strict rules of confidentiality.

INFORMED CONSENT FORM

1. Where I and my son/daughter are taking part in the study, I the undersigned, voluntarily agree for myself and my son/daughter to take part in this study by agreeing to answer questions and for my/our telephone conversation with the Research team to be recorded and for the recordings relating to my/our answers only to be used by the University for analysis.

2. I have been given, and understand, a detailed explanation of the nature and purpose of the study and what I/we will be expected to do. I have also read and had explained to me the volunteer information document describing the study.

3. I understand that I/we are free to withdraw from the study at any time without the need to give any justification for my decision.

4. I/ we have not been placed under any pressure to enter the study and are taking part in it voluntarily.

5. I understand that I/we will not be referred to by name in any report concerning the study disclosed to any other person. I/we will not claim to be entitled to restrict in any way the use to which the result of the clinical study may be put and, in particular, I agree to disclosure of any report of those results to the regulatory authorities for approvals of medical devices in the United Kingdom or elsewhere. I consent to Roche Diagnostics Limited and Southampton University collecting and processing my/our information, including information about my/our health and mental wellbeing. I consent to my/our information being processed by Roche Diagnostics Limited and Southampton University, and passed to other Roche group companies (including Roche group companies who are outside the European Union) or to companies working with Roche Diagnostics Limited, and I understand that my/our information may be forwarded to other countries worldwide. If I decide to withdraw from the study, I agree that the information collected about me/us up to the point when I withdraw may continue to be processed. I consent to Roche Diagnostics Limited, or its other group companies, and Southampton University using my/our information, including information about my/our health for future research.

6. In the event of my withdrawal, either at the request of the company or at my own request, the company can use the data obtained during my participation or such withdrawal does not invalidate the provision of paragraph 5.

7. If I have further questions regarding any study in which I have agreed to take part, I understand I am able to contact Dr Chas Skinner or Mrs Katharine Barnard at the University of Southampton for further clarity. If, after that time, having already given my consent to take part, I decide to withdraw prior to taking part, I understand that I shall not be placed under any further obligation to take part.

SIGNED: .... DATE: ....
(Must be signed by Parent/Guardian)

NAME: ....

I AM THE PARENT/GUARDIAN OF: ....

WHOSE DATE OF BIRTH IS: ....

Respondent ID: __________

Date: __________

Quality of Life Issues Associated With CSII Use in Type 1 Diabetes

Under 18
Interview Schedule

Part I: Introduction

Thank you for taking part in this study. Before we start, I would like to say again that you can stop at any time. You don't have to answer any questions you don't want to.

Do you have the information we sent in front of you...? That's great, we can start.

We want to find out how using CSII affects your quality of life. I will start by saying what we mean by quality of life.

How happy we feel and how good we think our life is depends on what is important to us. When these things are there or going well, we are quite happy, but when they go away or go badly we feel sad or unhappy. These important parts of life affect the quality of our lives. What's important can change for us all. What is most important to you may not be so important to me or to your parents/friends/teachers (mention one or two of these groups as appropriate)... **and the other way round."**

"I'd like to know what the most important parts of your life are now. Most of us don't normally spend a lot of time thinking about this. Sometimes we only notice that something is important to us if something happens to change it. Sometimes it is easier to say what is important by thinking about things that bother us when they are missing or going badly".

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part II: Eliciting 5 Most Important Aspects of Life (Cues)

a) **What five things are most important to you – the things that make your life happy or sad ...? The things that you feel mean a lot to the quality of your life?**

(If the respondent does not understand what is required the question may be rephrased in the following ways:

"What parts of your life are most important?.../ what things are most important? .../ 'The most important things in my life are...'.")

Elicit areas NOT individuals, e.g. marriage, not wife. Do not give examples.

The meaning of each cue for the respondent must be documented at this stage on the Cue Definitions Record Form. Establish what the respondent means by each quality of life area named as being important. For example, if an individual were to name 'golf' as a cue, this may relate primarily to leisure activity, but equally it may represent social activity, or physical mobility. Similarly, if 'religion' were named as a cue it might relate to the respondent's spiritual life, but might equally relate to being physically able to get to church, or to the social dimension of meeting one's friends at church. This is particularly important for subsequent review of the data, and of obvious relevance when respondents must be re-assessed at some future date in order to ensure that the same cues are being considered.

Having defined what the respondent means by the cue, it is important that the cue, as labelled by the individual, be used by the interviewer and not the interviewer's interpretation of what the respondent is saying.

Should the respondent volunteer cues which resemble 'quality of life' in meaning (e.g. satisfaction, life quality), the interviewer should probe for more specific cues. Cues such as 'happiness', 'attitude to life', 'morale' are acceptable.

If it is absolutely necessary to make some suggestions, then read the following list, excluding any cues already mentioned – **family relationships, health, finances, living conditions, work, social life, leisure activities, religion/spiritual life**. This list is derived from our findings with a range of populations and represents the cues most commonly elicited, in descending order of frequency. It provides for consistency across the interviews where such prompting is absolutely necessary.

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

b) **Please look at the blue piece of paper titled 'The Five Most Important Areas in My Life'. Please tell me the five most important areas you said and I'll read them back to you?** (Read aloud the 5 'cues')

Part III: Impact of CSII on QoL

a) **I am now going to ask you to tell me how CSII affects each of those important areas.**

Please look at the yellow sheet of paper that shows your choices. Can you see it goes from 'very much worse' to 'very much better', and goes through 'much worse' – 'worse' – 'no difference' – 'better' and 'much better'?

i. **So, using these choices, does <u>CSII</u> make your** [State elicited cue]:

Very much worse	Much worse	Worse	No difference	Better	Much better	Very much better

ii. **How does <u>CSII</u> make it** [State chosen rating]

Repeat i. and ii. for each elicited cue

b) **Thinking about your quality of life overall, how do you feel CSII has made a difference?**

Again please look at the yellow piece of paper showing the choices . Does <u>CSII</u> make your overall quality of life:

Very much worse	Much worse	Worse	No difference	Better	Much better	Very much better

---

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part IV: Direct Weighting

Now, I want you to tell me how important the five areas of life you told me about are. Which are more important than others.

Some areas in life are often more important to some people than others. Please look at the blue piece of paper and think about the areas of life you have told me about. Please think about how important it is to have these things in your life. If it helps, you can put a line of coloured counters to show how important each area is. So you could put more counters for the most important and less for the least important. Take your time, there's no hurry.

So which of these is the most important to you?

Thinking about the four that are left, which is most important to you?

Thinking about the three that are left, which is most important to you?

Finally, which is the most important area out of the last two?

Thank you very much.

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part V: Symptoms and Treatments

I would like to find out more about what it's like living with CSII.

a) **How long have you been diagnosed with diabetes? When did your symptoms first appear?**

b) **Do you suffer from any other illnesses as well as diabetes?**

c) **Are there any other factors you feel are important?**

d) **What symptoms of diabetes do you experience?**
   i. **When do they mostly happen?**
   ii. **What time of day do they mostly happen?**
   iii. **How often do they happen?**
   iv. **How serious are they?**
   v. **How much do they bother you?**

Get participants to voluntarily suggest symptoms, which will tell us about their perception of the condition. Afterwards prompt them with symptoms they forget to acknowledge. Symptoms include: extreme thirst, needing to urinate frequently, tiredness and sleep problems.

e) **Do you use any other treatment to control your diabetes?**
   i. **How good is this treatment in reducing your symptoms?** (Repeat for each named in part (e))
   ii. **How easy is it for you to take this treatment?**
   iii. **Does** [named medication] **have any side effects? Make you feel bad at all?**
   iv. **How bad are they?**
   v. **How much do they bother you?**

(Repeat for each medication and previous medications)

f) **Overall how satisfied are you with the treatment(s) that you are taking?**

g) **People can think about being satisfied with treatment in different ways. What is it about your treatment that makes you:**
   i. **satisfied?**
   ii. **dissatisfied?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part VI: Closing

Is there anything else you want to tell me about your diabetes? Is there anything else you want to tell me about CSII?

(Reflect on any issues raised here and consider whether or not they should be included as questions in subsequent interviews.)

Thank you very much for your time today. We are very grateful that you volunteered to take part in our study.

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part II. Five most important areas		Part III. a) Impact of CSII on areas		Part III. b) Impact of CSII on overall QoL	Part IV. Order of importance
Definition	Label	Choice	How		

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

PART V.	
a) Duration of Diabetes	
b) Comorbidity	
c) Other Factors	

Part V.
d) Symptoms

i. Symptoms?	ii. Situations?	iii. Time of Day?	iv. How often?	v. Severity?	vi. Bother?

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part V.					
e) Treatment etc?	**i. Effectiveness?**	**ii. Ease?**	**iii. Side Effects?**	**iv. Severity?**	**v. Bother?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part V.		
F) Overall Satisfaction?	**g) i. Why Satisfied?**	**ii. Why dissatisfied?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Interview Record Form

1. Time taken ________

2. Understanding of method

Not understood ________

Poor/Uncertain
Understanding ________

Understood ________

3. Fatigue/Boredom

None ____/____

Some ____/____

A Lot ____/____

4. Overall validity of information (in light of 2 & 3 above)

Definitely invalid ________

Uncertain ________

Valid ________

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

CSII Interview Study: Demographics Questionnaire

Are you:	☐ Male ☐ Female
How old you are you?	________years
Are you:	☐ Employed ☐ Unemployed ☐ Retired ☐ At School/College ☐ Other: __________________
How long have you had Diabetes?	________years ______months
Has anyone else in your family had Diabetes?	☐ No ☐ Yes: please state: __________________________
Would you say your symptoms are:	☐ Mild ☐ Moderate ☐ Severe
Do your symptoms occur?	☐ Daily ☐ A few times each week ☐ Weekly ☐ Less frequently

Thank you.

Please check that you have answered all the questions.
Please return your responses to: kdb103@soton.ac.uk.

Participant sheet

5 Most Important Areas of Your Life	How Important Are these Areas?

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

RESPONSE CHOICES

Very Much Worse	Much Worse	Worse	No Difference	Better	Much Better	Very Much Better

---

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Respondent ID: __________

Date: __________

Quality of Life Issues Associated With CSII Use in Type 1 Diabetes

Parent/Carer
Interview Schedule

Part I: Introduction

Thank you for taking part in this study. Before we begin, I would like to remind you that you are free to stop or withdraw at any time during this interview. You are also free to refuse to answer any questions.

Do you have the information we sent in front of you…? That's great, then we can begin.

The aim of this interview is for us to understand how CSII use impacts on your quality of life. I'm going to begin by explaining what we mean by quality of life.

So, "for each of us, happiness and satisfaction in life depends on those parts or areas of life which are important to us. When these important areas are present or going well, we are generally happy, but when they are absent or going badly we feel worried or unhappy. In other words, these important areas of life determine the quality of our lives. So what is considered important varies from person to person. What is most important to you may not be so important to me or to your husband/wife/children/parent/friends (mention one or two of these groups as appropriate)… **and vice versa"**

"I am interested in knowing what the most important areas of your life are at the moment. Most of us don't usually spend a lot of time thinking about these things. Indeed, we often only notice that certain things are important when something happens to change them. Sometimes it is easier to identify what is important by thinking about the areas of life that cause us concern when they are missing or going badly".

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part II: Eliciting 5 Most Important Aspects of Life (Cues)

a) **What are the five most important areas of your life at present – the things which make your life a relatively happy or sad one at the moment ...? The things that you feel determine the quality of your life?**

(If the respondent does not understand what is required the question may be rephrased in the following ways:

"What parts of your life are most important?.../ what things are most important? .../ 'The most important things in my life are...'.")

Elicit areas NOT individuals, e.g. marriage, not wife. Do not give examples.

The meaning of each cue for the respondent must be documented at this stage on the Cue Definitions Record Form. Establish what the respondent means by each quality of life area named as being important. For example, if an individual were to name 'golf' as a cue, this may relate primarily to leisure activity, but equally it may represent social activity, or physical mobility. Similarly, if 'religion' were named as a cue it might relate to the respondent's spiritual life, but might equally relate to being physically able to get to church, or to the social dimension of meeting one's friends at church. This is particularly important for subsequent review of the data, and of obvious relevance when respondents must be re-assessed at some future date in order to ensure that the same cues are being considered.

Having defined what the respondent means by the cue, it is important that the cue, as labelled by the individual, be used by the interviewer and not the interviewer's interpretation of what the respondent is saying.

Should the respondent volunteer cues which resemble 'quality of life' in meaning (e.g. satisfaction, life quality), the interviewer should probe for more specific cues. Cues such as 'happiness', 'attitude to life', 'morale' are acceptable.

If it is absolutely necessary to make some suggestions, then read the following list, excluding any cues already mentioned – **family relationships, health, finances, living conditions, work, social life, leisure activities, religion/spiritual life.** This list is derived from our findings with a range of populations and represents the cues most commonly elicited, in descending order of frequency. It provides for consistency across the interviews where such prompting is absolutely necessary.

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

b) Please place the blue sheet of paper titled 'The Five Most Important Areas in My Life' in front of you. Will you please write down the five most important areas you mentioned as I read them back to you? (Read aloud the 5 'cues')

Part III: Impact of CSII on QoL

a) Now that you have named the five most important areas in your life, I am going to ask you to rate how each of those areas are affected by CSII.

Please look at the yellow sheet of paper which shows the response options. You can see the options range from 'very much worse' to 'very much better', and pass through levels such as 'much worse' – 'worse' – 'no difference' – 'better' and 'much better' between the two extremes.

i. **So, using these options, does CSII make your** [State elicited cue]:

Very much worse	Much worse	Worse	No difference	Better	Much better	Very much better

ii. **In what way does CSII make it** [State chosen rating]

Repeat i. and ii. for each elicited cue

b) Thinking about your quality of life as a whole, how would you rate the impact of CSII?

Again I would like to refer you to the yellow sheet of paper which shows the response options. Does CSII make your overall quality of life:

Very much worse	Much worse	Worse	No difference	Better	Much better	Very much better

Part IV: Direct Weighting

Now, I would like you to tell me how important the five areas of life you have mentioned are in relation to each other.

People often value some areas in life as more important than others. Please look at the blue sheet of paper and think about the areas of life you have named. I'd like you to think about how important it is for you to have these things in your life. So which of these is the most important to you?

Thinking about the remaining four, which is most important to you?

Thinking about the remaining three, which is most important to you?

Finally, which is the most important area out of the remaining two?

Thank you very much.

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part V: Symptoms and Treatments

Now, I would like to find out more about your experience of CSII, its symptoms and any treatment/techniques you use whilst managing your CSII.

a) **How long have you been diagnosed with diabetes? When did your symptoms first appear?**

b) **Do you suffer from any other illnesses as well as diabetes?**

c) **Are there any other factors you feel are important?**

d) **What symptoms of diabetes do you experience?**
   i. **In what situations do they mostly occur?**
   ii. **What time of day do they mostly occur?**
   iii. **How often do they occur?**
   iv. **How severe are they?**
   v. **How much do they bother you?**

Get participants to voluntarily suggest symptoms, which will tell us about their perception of the condition. Afterwards prompt them with symptoms they forget to acknowledge. Symptoms include: extreme thirst, needing to urinate frequently, tiredness and sleep problems.

e) **Do you use any other treatment/medication to control your diabetes?**
   i. **How effective is this treatment/medication/technique in reducing your symptoms?** (Repeat for each named in part (e))
   ii. **How easy is it for you to take this treatment?**
   iii. **Does** [named medication] **have any side effects?**
   iv. **How severe are they?**
   v. **How much do they bother you?**

(Repeat for each medication and previous medications)

f) **Overall how satisfied are you with the treatment(s) that you are taking?**

g) **People often think about satisfaction with treatment in different ways. What is it about your treatment that makes you:**
   i. **satisfied?**
   ii. **dissatisfied?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part VI: Closing

Is there anything else you would like to tell me about your diabetes and CSII use that we haven't discussed already?

(Reflect on any issues raised here and consider whether or not they should be included as questions in subsequent interviews.)

Thank you so much for your time today. We really appreciate you volunteering to take part in our study.

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part II. Five most important areas		Part III. a) Impact of CSII on areas		Part III. b) Impact of CSII on overall QoL	Part IV. Order of importance
Definition	Label	Choice	How		

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

PART V.	
a) Duration of Diabetes	
b) Comorbidity	
c) Other Factors	

Part V.
d) Symptoms

i. Symptoms?	**ii. Situations?**	**iii. Time of Day?**	**iv. How often?**	**v. Severity?**	**vi. Bother?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part V.					
e) Treatment etc?	**i. Effectiveness?**	**ii. Ease?**	**iii. Side Effects?**	**iv. Severity?**	**v. Bother?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Part V.		
F) Overall Satisfaction?	**g) i. Why Satisfied?**	**ii. Why dissatisfied?**

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Interview Record Form

1. Time taken __________

2. Understanding of method

Not understood __________

Poor/Uncertain Understanding __________

Understood __________

3. Fatigue/Boredom

None _____/_____

Some _____/_____

A Lot _____/_____

4. Overall validity of information (in light of 2 & 3 above)

Definitely invalid __________

Uncertain __________

Valid __________

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

Participant sheet

5 Most Important Areas of Your Life	How Important Are these Areas?

Parts I-IV adapted form the SEIQoL-DW (© Department of Psychology, Royal College of Surgeons in Ireland, 1993) to be CSII specific and for use in a telephone interview.

RESPONSE CHOICES

Very Much Worse	**Much Worse**	**Worse**	**No Difference**	**Better**	**Much Better**	**Very Much Better**

CSII Interview Study: Demographics Questionnaire

Are you:	☐ Male ☐ Female
How old you are you?	________years
Are you:	☐ Employed ☐ Unemployed ☐ Retired ☐ At School/College ☐ Other: ____________________
How long have you had Diabetes?	________years ______months
Has anyone else in your family had Diabetes?	☐ No ☐ Yes: please state: ____________________________
Would you say your symptoms are:	☐ Mild ☐ Moderate ☐ Severe
Do your symptoms occur?	☐ Daily ☐ A few times each week ☐ Weekly ☐ Less frequently

Thank you.

Please check that you have answered all the questions.
Please return your responses to: kdb103@soton.ac.uk.

CODING FRAMEWORK

Chapter Six – SEIQoL Study

Codes were initially assigned for every new occurrence. As such there was a large number of codes, some with more responses than others. Following initial coding, themes were then developed and key themes identified.

A second coder also coded 10% of responses. These were reviewed by discussion with both coders and inter-coder agreement was reached on final codes/themes.

Initial Codes Assigned – Parents

- Own health
- Children with diabetes' health
- Family health
- Stress
- Dietary restrictions - flexibility
- Family conflict – between husband and wife
- Family conflict – between parents and children
- Blood glucose control
- Diabetes control
- Hypoglycaemia frequency
- Work – interruptions
- Work – worry
- Freedom
- Spiritual welfare
- Pets
- Child's future
- College
- Contentment
- Children's achievements
- Social life
- Leisure time

Final Codes/Themes - Parents

- Health
- Family
- Work
- Finances/financial security
- Leisure
- Friends/friendship
- Security
- Happiness

Initial Codes Assigned – Adolescents

- School - interruption to schoolwork
- School – stigma associated with diabetes
- School – ‘difference’ - being singled out because of injections etc
- Family – flexibility eg food, day trips etc
- Family – relationships (easier/less ‘narky’)
- Friends
- Health – blood sugars
- Sports – playing sports
- Leisure – going out with friends
- Leisure – fewer restrictions
- Personal belongings
- Work
- Future
- Happiness

Final Codes/Themes - Adolescents

- Family
- School
- Friends
- Leisure
- Health
- Happiness

Initial Codes Assigned – Children

- Family – freedom
- Family – impact of injections
- Friends – being with friends
- Friends – not being followed by parents
- Social life – going out and not worrying
- School – injections
- School – stigma
- Health – illnesses
- Health – blood glucose levels
- Health – emotional status e.g. happier
- Health - treatment
- Sports – ability to play sports
- Sports – injections
- Religion
- Music
- Toys
- Holidays
- Money
- Pets

Final Codes/Themes - Children

- Friends/social life
- Family/home life
- School
- Leisure/sport/exercise
- Health/diabetes
- Religion

APPENDIX E

Letters of Invitation, Consent Forms and Questionnaires for Chapter Seven

Dear

We are writing to you and your child to ask for your help.

We know it can be hard to live with diabetes, whether you have it yourself or are the parent of someone with diabetes. So we want to do the best we can to help you. To do this we often talk to doctors and nurses from other hospitals to find out how what they do, to help people and families with diabetes.

As a result we know that there are many ways to control diabetes. But we do not know what things we or other doctors do and say work well and what things do not.

To find what we can do better, we are asking young people with diabetes and their main care giver in many hospitals, how they live with diabetes.

To do this we really need your help as parents or person who looks the child with diabetes most of the time. We would like you to answer some questions about how you feel about diabetes, and life with diabetes. It will only take you about … minutes to complete a short questionnaire.

In addition, to help us see what things are affecting the diabetes control, we would like to do a long term sugar test (Hba1c) which should only mean a finger prick.

So, it would help if you could bring your child to your next visit at the hospital about 30 minutes early. If you can not do this, then we will ask you to answer the questions after you have seen the doctor or nurse.

We hope to see you soon

---------.

Dear

We are writing to you to ask for your help.

We know it can be hard to live with diabetes. So we want to do the best we can to help you. To do this we talk to doctors and nurses from other hospitals to find out how what they do to help people with diabetes.

As a result we know that there are many ways to control diabetes. But we do not know what things we or other doctors do and say work well and what things do not.

To find what we can do better, we are asking young people with diabetes in many hospitals, how they live with their diabetes.

To do this we really need your help. We would like you to answer some questions about how feel about your diabetes, and you live with diabetes. It will only take you about … minutes to complete.

To find out how well we are doing at helping you, we would also like to take a small amount of blood (by pricking your finger).

So, it would be great if you came to your next visit at the hospital about 30 minutes early. If you can not do this, then we will ask you to answer the questions after you have seen the doctor or nurse.

We would also like your parents, or the person who looks after you most of the time, to help. So could you give them the other letter that came with this one so they know what to do as well.

We hope to see you soon.

(Form to be on headed paper)

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: **Optimising metabolic control in children and adolescents with diabetes: Exploring centre differences:**

Name of Researcher:

Please initial box

I confirm that I have read and understand the **Exploring centre differences,** information sheet dated the 1st June 2004 (version 1) for the above study and have had the chance to ask questions of the diabetes staff.

☐

I understand that .... (insert name of child). does not have to participate, and that they are free to change their mind and withdraw from the study at any time. Should he or she decide to withdraw, they do not have to give any reason, and that this will not change the medical care they receive from the diabetes team or their legal rights being in any way.

☐

I am happy for .... , my .... (son / daughter / custodian) to participate in this study and agree to them taking part in the above study.

☐

Your Name	*Date*	*Your Signature*
Researcher	*Date*	*Signature*

(Form to be on headed paper)

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: **Optimising metabolic control in children and adolescents with diabetes: Exploring centre differences:**

Name of Researcher:

Please initial box

I confirm that I have read and understand the **Exploring centre differences,** information sheet dated the 1st June 2004 (version 1) for the above study and have had the chance to ask questions of the diabetes staff.

☐

I understand that I do not have to participate in the study and that I can change my mind and tell people that I do not to participate at any time. If I change my mind, I understand that I do not have to give any reasons for this and this will not change the medical care I receive from the diabetes team or my legal rights being in any way.

☐

I agree to take part in the above study.

☐

Your Name	*Date*	*Your Signature*
Researcher	*Date*	*Signature*

email f [illegible]

Hvidøre Study Group on Childhood Diabetes
Exploring Centre Differences

Centre and patient ID HSG ☐☐ ☐☐☐
Centre Patient

Patient agreed to participate: ☐ yes ☐ no Sex: ☐ Male ☐ Female	Date of Visit: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)
Date of Birth: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	Date of Diagnosis: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)
Height ☐☐☐ cm Weight ☐☐☐.☐ kg	Date of first visit to you center: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)

INJECTION THERAPY: (last week day prior to visit – pump therapy use table below)

Types of insulin	No. of daily inj.	Total dosage (IU/day)	Injection devices used for this type of insulin*
Rapid acting insulin analogue	☐	☐☐	1 2 3 4
Short acting/Regular insulin	☐	☐☐	1 2 3 4
Intermediate/long acting insulin	☐	☐☐	1 2 3 4
Long acting insulin analogue	☐	☐☐	1 2 3 4
Premixed insulin (any ratio)	☐	☐☐	1 2 3 4
Premixed insulin analogue (any ratio)	☐	☐☐	1 2 3 4

*Circle code(s) for injection device: **1**= syringe, **2**=durable pen, **3**=prefilled pen, **4**=other

PUMP THERAPY (only fill in if pump therapy is used last week day prior to visit)

Types of insulin	Basal insulin IU/24 hours	Bolus insulin IU/24 hours	No. of Bolus
Rapid acting insulin analogue	☐☐☐	☐☐☐	☐☐
Short acting/Regular insulin	☐☐☐	☐☐☐	☐☐

Severe hypoglycaemic episodes
Resulting in unconsciousness/seizures within the last 3 months, number: ☐☐

Diabetic Ketoacidotic episodes
Number during the past 12 months: ☐☐

Concomitant pathology: ☐ yes ☐ no (If yes, tick below)		
Celiac disease ☐	Thyroid disease ☐	
Epilepsy ☐	Asthma ☐	Other ☐

Language difficulties causing communication problems? ☐ yes ☐ no (If yes, tick below)		
With the child ☐		With the parent ☐
Demography: Born in this country?		
Child? ☐ yes ☐ no	Father ☐ yes ☐ no	Mother? ☐ yes ☐ no

For Steno Diabetes Centre only: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y)	HbA_{1C}: ☐☐.☐ %

Hvidøre Study Group on Childhood Diabetes

Identification sticker

Questionnaire for parent

Thank you for agreeing to complete this questionnaire, which will take about 15 minutes

Caring for a child or an adolescent with diabetes can be difficult in different ways for parents. This questionnaire asks you about how you are feeling as well as the difficulties or burdens you experience in managing diabetes. There are no right or wrong answers to any of the questions..
We are interested in your feelings and thoughts, so that we can help you look after diabetes better in future.

Please, complete all questions.

1. Who is filling in this questionnaire?

☐ Mother ☐ step mother ☐ Father ☐ step father ☐ Guardian

2. Where are you filling in the questionnaire?

☐ At the clinic ☐ At home

3. Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks.

	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
I have felt cheerful and in good spirits	☐	☐	☐	☐	☐	☐
I have felt calm and relaxed	☐	☐	☐	☐	☐	☐
I have felt active and vigorous	☐	☐	☐	☐	☐	☐
I have woken up feeling fresh and rested	☐	☐	☐	☐	☐	☐
My daily life has been filled with things that interest me	☐	☐	☐	☐	☐	☐

For each of the following parts about diabetes care, tick the box for the answer that best describes the way you handle things at home. If your child takes responsibility and/or reminds you to do things almost all the time tick the **MY CHILD** box. If you and your child share responsibility then tick the **BOTH ME AND MY CHILD** box. If you take responsibility or remind your child to do things almost all the time, tick the **ME** box.

4. Who remembers or decides what to do?	My child	Both me and my child	Me
Telling friends about diabetes	☐	☐	☐
Telling teachers about diabetes	☐	☐	☐
Remembering to take insulin injections	☐	☐	☐
Adjusting insulin according to results of blood sugar tests	☐	☐	☐
Deciding what to eat at meals or snacks	☐	☐	☐
Carrying some sugar in case of low blood sugar	☐	☐	☐
Remembering when blood sugar should be tested	☐	☐	☐
Noticing differences in health such as weight changes or signs of an infection	☐	☐	☐
Rotating or moving around the injection sites	☐	☐	☐
Noticing early signs of low blood sugar	☐	☐	☐

The next questions are about your visit to and your contact with the out-patient clinic

5. Including today's visit, how many times did you have an out-patient visit to the clinic in the last 6 months? Number of visits: ____.

6. As part of the Normal and Emergency-diabetes care how many times have you spoken to the following members of the diabetes-team during the last 6 months including today's clinic visit ?

	Don't know one	0	1	2-4	5 or more
Diabetes doctor	☐	☐	☐	☐	☐
Diabetes nurse/educator	☐	☐	☐	☐	☐
Dietician	☐	☐	☐	☐	☐
Social worker	☐	☐	☐	☐	☐
Psychologist/psychiatrist	☐	☐	☐	☐	☐

7. Have you been given a diabetes dedicated phone-number to call 24 hours a day when you need help about diabetes (for instance if your child is sick)

Yes ☐ No ☐

8. Do you think that the members of the diabetes team talk together to help you with any problems with diabetes in your child?

Yes ☐ No ☐

The next questions are about the long term sugar test, HbA_{1c}.

9. What do you think the ideal result should be?				
Less than 7.0	Between 7.0 and 7.4	Between 7.5 and 8.0	Between 8.1 and 9.0	Don't know
☐	☐	☐	☐	☐

10. What result would you be happy with today?				
Less than 7.0	Between 7.0 and 7.4	Between 7.5 and 8.0	Between 8.1 and 9.0	More than 9.0
☐	☐	☐	☐	☐

Now we want to ask about the difficulties or burdens you experience in managing diabetes.

11. How much burden do you experience because of ...

	Major burden	Large burden	Moderate burden	Small burden	No burden
Medical treatment / nursing tasks that you need to perform	☐	☐	☐	☐	☐
Disruption in family routines because of caring for child	☐	☐	☐	☐	☐
Physical or psychological problems in the child requiring extra care	☐	☐	☐	☐	☐
General restriction of your child's social and school activities because of diabetes	☐	☐	☐	☐	☐
Concerns about your child's long term health	☐	☐	☐	☐	☐

12. Is your child's performance at school impaired as a result of having diabetes?

☐ Yes (impaired) ☐ No (not impaired) ☐ my child is not in school

13. Do you feel that your child's general health at present is

☐ Excellent ☐ Good ☐ Fair ☐ Poor

14. Do you feel that your child's quality of life at present is

☐ Excellent ☐ Good ☐ Fair ☐ Poor

15. Are the child's parents living together?

☐ Yes ☐ No

Finally, we ask you about how you and/or your child manages diabetes

16. How often at a typical school/college week at the following times does your child eat carbohydrate snacks?

	Hardly ever	Almost always
Between breakfast and lunch	☐	☐
Between lunch and dinner	☐	☐
Between dinner and bedtime	☐	☐

17. When the **blood glucose is high,** how often does your child

	Never	Sometimes	Frequently	Almost always
Eat less carbohydrate at next main meal/snack	☐	☐	☐	☐
Take more insulin	☐	☐	☐	☐
Do some exercise	☐	☐	☐	☐

18. How often do you or your child adjust insulin dose based on the blood sugar levels over the past few days?

☐	Never
☐	Sometimes
☐	Frequently
☐	Almost always

19. How often does your child get extra insulin, if he/she has eaten extra snacks?

☐	Never
☐	Sometimes
☐	Frequently
☐	Almost always

20. How often does your child adjust insulin dose based on what he/she is going to eat at the next meal?

☐	Never
☐	Sometimes
☐	Frequently
☐	Almost always

21. If your child has symptoms of a **hypo**, how often do he/she -

		Never	Some-times	Frequently	Almost always
A	Do a blood test before eating	☐	☐	☐	☐
B	Just eat until he/she feels better	☐	☐	☐	☐
C	Eat some food, wait 5-10 min., then test blood to see if more food is needed	☐	☐	☐	☐

Please check that you have answered all the questions

THANK YOU VERY MUCH FOR YOUR HELP!

Identification sticker

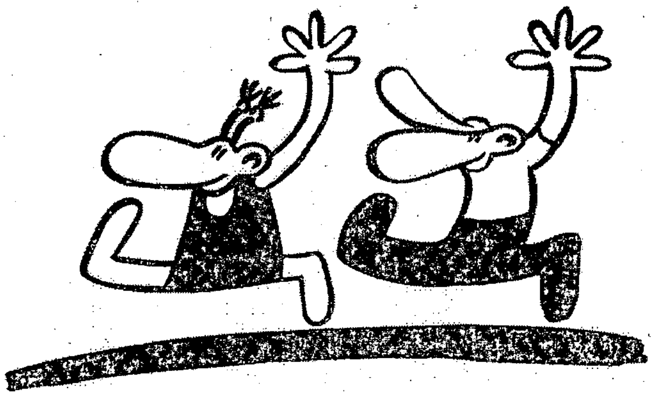
QUESTIONNAIRE FOR ADOLESCENTS

We know it can be hard to live with diabetes, and we want to do the best we can to help you.

Therefore, we would like you to answer some questions about your diabetes, how you feel about your diabetes, and how you live with your diabetes.

To answer the questions just put a tick or mark in the box that is closest to what you do, think or feel. There are no right or wrong answers, so please let us know how *YOU* think and feel about *YOUR* diabetes, and there is no need to check your answers with your parents.

When you have answered all the questions, please place the questionnaire in the envelope. This envelope will then be sent to Denmark where it will be opened. But no-one who knows you, your parents, doctors or nurses, will know what answers you gave.



Thank you for your help.

1. Are you accompanied by your parent(s) at this clinic visit? Yes ☐ No ☐

First of all we would like to know a little about you and how you think and feel most of the time.

2. For each of the statements below, please **tick the box that best describes how often you have felt like this in the past few weeks.**

		Never	Sometimes	Frequently	Almost always
a	I like the way things are going for me	☐	☐	☐	☐
b	My life is going well	☐	☐	☐	☐
c	I would like to change many things in my life	☐	☐	☐	☐
d	I wish I had a different kind of life	☐	☐	☐	☐
e	I have a good life	☐	☐	☐	☐
f	I feel good about what's happening to me	☐	☐	☐	☐

3. How often do you usually have **breakfast** (more than a glass of milk or fruit juice)? **Please tick one box for weekdays and one for weekend**

 **Weekdays**	 **Weekend**
☐ I never have breakfast during weekdays	☐ I never have breakfast during the weekend
☐ One day	☐ I usually have breakfast on only one day of the weekend (Saturday OR Sunday)
☐ Two days	
☐ Three days	☐ I usually have breakfast on both weekend days (Saturday AND Sunday)
☐ Four days	
☐ Five days	

4. How often do you usually have **lunch** (midday meal) (more than a drink or snack)? **Please tick one box for weekdays and one for weekend.**

Lunch **Weekdays**	Lunch **Weekend**
☐ I never have lunch during weekdays	☐ I never have lunch during the weekend
☐ One day	☐ I usually have lunch on only one day of the weekend (Saturday OR Sunday)
☐ Two days	
☐ Three days	☐ I usually have lunch on both weekend days (Saturday AND Sunday)
☐ Four days	
☐ Five days	

5. How often do you usually have **dinner** (evening meal) (more than a drink or a snack)? **Please tick one box for weekdays and one for weekend.**

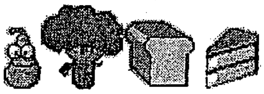
Dinner **Weekdays**	Dinner **Weekend**
☐ I never have dinner during weekdays	☐ I never have dinner during the weekend
☐ One day	☐ I usually have dinner on only one day of the weekend (Saturday OR Sunday)
☐ Two days	
☐ Three days	☐ I usually have dinner on both weekend days (Saturday AND Sunday)
☐ Four days	
☐ Five days	

Now we would like to find out about the sort of things you eat and do each day

6. How often at the following times do you eat carbohydrate snacks?

	Hardly ever	Almost always
Between breakfast and lunch	☐	☐
Between lunch and dinner	☐	☐
Between dinner and bedtime	☐	☐

7. How many times a week do you usually eat or drink ...? **Please tick one box for each line**

	Never	Less than once a week	Once a week	2-4 days a week	5-6 days a week	Once a day, every day	More than once a day, every day
Fruits	☐	☐	☐	☐	☐	☐	☐
Vegetables	☐	☐	☐	☐	☐	☐	☐
Sweets (candy or chocolate)	☐	☐	☐	☐	☐	☐	☐
Coke or other soft drinks that contain sugar	☐	☐	☐	☐	☐	☐	☐
Any alcoholic drink	☐	☐	☐	☐	☐	☐	☐
Diet coke or diet soft drinks	☐	☐	☐	☐	☐	☐	☐
Low fat/semi skimmed milk	☐	☐	☐	☐	☐	☐	☐
Whole fat milk	☐	☐	☐	☐	☐	☐	☐
Cheese	☐	☐	☐	☐	☐	☐	☐
Other milk products (yoghurt, chocolate milk)	☐	☐	☐	☐	☐	☐	☐
Cereals like cornflakes	☐	☐	☐	☐	☐	☐	☐
White bread	☐	☐	☐	☐	☐	☐	☐
Brown bread	☐	☐	☐	☐	☐	☐	☐
Crisps	☐	☐	☐	☐	☐	☐	☐
Cakes or pastries	☐	☐	☐	☐	☐	☐	☐
Chips/fried potatoes	☐	☐	☐	☐	☐	☐	☐

To be continued on next page.

Continued from previous page.

Hamburgers, hot dogs, sausages	☐	☐	☐	☐	☐	☐	☐
Stimulant drinks e.g. red bull, jolt							
A. As a mixer	☐	☐	☐	☐	☐	☐	☐
B. On it's own	☐	☐	☐	☐	☐	☐	☐

8. At present, are you on a diet or doing something else to lose weight?

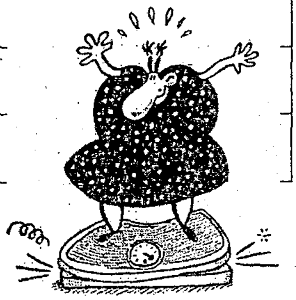
1	☐	No, my weight is fine
2	☐	No, but I should lose some weight
3	☐	No, because I need to put on weight
4	☐	Yes

9. Do you think your body is ...?

1	☐	Much too thin
2	☐	A bit too thin
3	☐	About the right size
4	☐	A bit too fat
5	☐	Much too fat

10. Have you gone on a **diet**, changed your **eating habits** or done **something else to control your weight** during the last 12 months?

0	☐	No, → go to question 12
1	☐	Yes, for a few days
2	☐	Yes, for a week
3	☐	Yes, for more than a week but less than a month
4	☐	Yes, for a month
5	☐	Yes, for more than a month but less than 6 months
6	☐	Yes, for 6 months or more



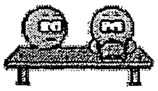
11. If you answered yes in question 10, which of the following things did you do **to control your weight** during the last 12 months? - Please tick one for each line.

		Yes	No
a	Exercise	☐	☐
b	Skip meals	☐	☐
c	Fasting (= go without eating for 24 hours or more)	☐	☐
d	Eat less sweets	☐	☐
e	Eat less fat	☐	☐
f	Drink less soft drinks	☐	☐
g	Eat less (= smaller amounts)	☐	☐
h	Eat more fruits and/or vegetables	☐	☐
i	Drink more water	☐	☐
j	Restrict my diet to 1 or more food groups (eat only fruit and vegetables, drink only, eat only bread and water ...)	☐	☐
k	Vomiting	☐	☐
l	Use diet pills or laxatives	☐	☐
m	Smoke more	☐	☐
n	Diet under supervision of a professional	☐	☐
o	Other, namely ________________________________		

12. How often did you miss insulin to control your weight?

☐	Never
☐	Once a month
☐	Once a week
☐	Every day

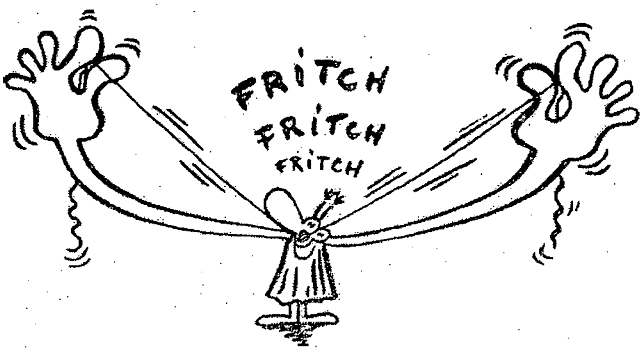
13. How often would you say you binge eat (eat excessively and uncontrolled)?



☐	Never
☐	Less than once a week
☐	Once a week
☐	More than once a week, less than once a day
☐	Once a day or more

14. How often do you brush your teeth?

☐	More than once a day
☐	Once a day
☐	At least once a week but not daily
☐	Less than once a week



15. At what age did you first do the following things?
If there is something you have not done, choose the 'never' category. Write on the line how old you were. 

1	Drink alcohol (more than a small amount)	Never ☐	I was _____ years old
2	Get drunk	Never ☐	I was _____ years old
3	Smoke a cigarette (more than a puff)	Never ☐	I was _____ years old

You're doing great! Already one third of the questions answered!

The next questions ask you about physical activity

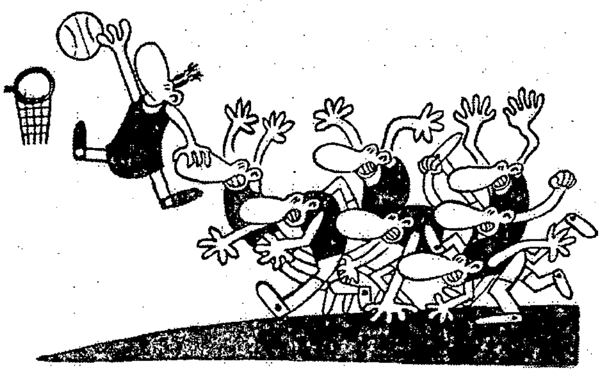
By physical activity we mean any activity that increases your heart rate and makes you get out of breath some of the time. Physical activity can be done in sports, school activities, playing with friends, or walking to school. Some examples of physical activity are running, brisk walking, rollerblading, biking, dancing, skateboarding, swimming, soccer, basketball, football and surfing.
For these next two questions, add up all the time you spend in physical activity each day.

16. In **the past 7 days**, on how many days were you physically active for a total of **at least 60 minutes per day**?

0 days	1	2	3	4	5	6	7 days
☐	☐	☐	☐	☐	☐	☐	☐

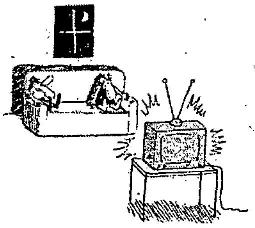
17. **Over a typical or usual week**, on how many days are you physically active for a total of **at least 60 minutes per day**?

0 days	1	2	3	4	5	6	7 days
☐	☐	☐	☐	☐	☐	☐	☐



18. About **how many hours a day** do you usually **watch television (including videos)** in your spare time?
Please tick **one box for weekdays** and **one box for weekend**

Weekdays		**Weekend**	
☐	None at all	☐	None at all
☐	About half an hour a day	☐	About half an hour a day
☐	About 1 hour a day	☐	About 1 hour a day
☐	About 2 hours a day	☐	About 2 hours a day
☐	About 3 hours a day	☐	About 3 hours a day
☐	About 4 hours a day	☐	About 4 hours a day
☐	About 5 hours a day	☐	About 5 hours a day
☐	About 6 hours a day	☐	About 6 hours a day
☐	About 7 or more hours a day	☐	About 7 or more hours a day



19. About **how many hours a day** do you usually spend doing **school homework out of school hours?**
Please tick **one box for weekdays** and **one box for weekend**

Weekdays		**Weekend**	
☐	None at all	☐	None at all
☐	About half an hour a day	☐	About half an hour a day
☐	About 1 hour a day	☐	About 1 hour a day
☐	About 2 hours a day	☐	About 2 hours a day
☐	About 3 hours a day	☐	About 3 hours a day
☐	About 4 hours a day	☐	About 4 hours a day
☐	About 5 hours a day	☐	About 5 hours a day
☐	About 6 hours a day	☐	About 6 hours a day
☐	About 7 or more hours a day	☐	About 7 or more hours a day

20. About **how many hours a day** do you usually **use a computer** (for playing games, e-mailing, chatting or surfing the internet) in your free time?
Please tick **one box for weekdays** and **one box for weekend**

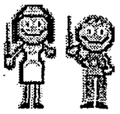
Weekdays		**Weekend**	
☐	None at all	☐	None at all
☐	About half an hour a day	☐	About half an hour a day
☐	About 1 hour a day	☐	About 1 hour a day
☐	About 2 hours a day	☐	About 2 hours a day
☐	About 3 hours a day	☐	About 3 hours a day
☐	About 4 hours a day	☐	About 4 hours a day
☐	About 5 hours a day	☐	About 5 hours a day
☐	About 6 hours a day	☐	About 6 hours a day
☐	About 7 or more hours a day	☐	About 7 or more hours a day

Now we would like to find out about your diabetes and how the people around you help you look after your diabetes.

There are no right or wrong answers, please just write what you think, feel or can remember.

21. Including today's clinic, how many times have you been to the hospital to see a member of the diabetes team in the last 6 months? Number of visits: ______.

22. As part of your Normal and Emergency-diabetes care how many times have you spoken to each of the following members of the diabetes-team during the last 6 months, including today's visit?

	Don't know one	0	1	2-4	5 or more
Diabetes doctor	☐	☐	☐	☐	☐
Diabetes nurse/educator	☐	☐	☐	☐	☐
Dietician	☐	☐	☐	☐	☐
Social worker	☐	☐	☐	☐	☐
Psychologist/psychiatrist	☐	☐	☐	☐	☐

23. Do you have a diabetes dedicated (hot-line) phone-number to call 24 hours a day when you need help with your diabetes (for instance if you are sick)? ☎

Yes ☐ No ☐

About your long term sugar test, HbA_{1c} .

24a	Is your $HbA1_c$ measured every time you attend the outpatient clinic?		
	Yes	No	Don't know

24b Are you able to discuss the result on the day of the clinic or within one week?

Yes	No
☐	☐

24c What do you think the ideal result should be?				
Less than 7.0	Between 7.0 and 7.4	Between 7.5 and 8.0	Between 8.1 and 9.0	Don't know
☐	☐	☐	☐	☐
24d What result would you be happy with today?				
Less than 7.0	Between 7.0 and 7.4	Between 7.5 and 8.0	Between 8.1 and 9.0	More than 9.0
☐	☐	☐	☐	☐

25 ***I think*** *good diabetes sugar control is important for ...*

	not at all important	slightly important	fairly important	very important	extremely important
feeling in better health	☐	☐	☐	☐	☐
preventing long term complications	☐	☐	☐	☐	☐

The following questions will ask you about different aspects of your diabetes. It is important that you answer these as honest as possible. There are no right or wrong answers to any of these questions. Just say what you think, feel or remember.

		Never	Very seldom	Some-times	Often	All the time
26	How often are you teased because you have diabetes?	☐	☐	☐	☐	☐
27	How often do you find you eat something you shouldn't rather than tell someone that you have diabetes?	☐	☐	☐	☐	☐
28	How often do you hide from others the fact that you are having an insulin reaction?	☐	☐	☐	☐	☐
29	How often do you find your diabetes limiting your social relationships and friendships?	☐	☐	☐	☐	☐
30	How often does your diabetes keep you from cycling a bicycle or using a machine (for example a computer)?	☐	☐	☐	☐	☐
31	How often does your diabetes interfere with your exercising?	☐	☐	☐	☐	☐
32	How often do you find your diabetes interrupts your leisure-time activities?	☐	☐	☐	☐	☐
33	How often do you find your diabetes prevents you from participating in school activities (for example, being active in a school play, being on a sports team, being in a school band, etc.)?	☐	☐	☐	☐	☐
34	How often do you find that your parents are too protective of you?	☐	☐	☐	☐	☐
35	How often do you find that your parents worry too much about your diabetes?	☐	☐	☐	☐	☐
36	How often do you find that your parents act like diabetes is their disease, not yours?	☐	☐	☐	☐	☐
37	How often do you miss work, school, or household duties because of your diabetes?	☐	☐	☐	☐	☐

To be continued on next page.

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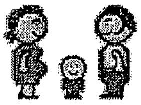
		Never	Very seldom	Some-times	Often	All the time
38	How often do you worry about whether you will get married?	☐	☐	☐	☐	☐
39	How often do you worry about whether you will have children?	☐	☐	☐	☐	☐
40	How often do you worry about whether you will not get a job you want?	☐	☐	☐	☐	☐
41	How often do you worry about whether you will pass out?	☐	☐	☐	☐	☐
42	How often do you worry about whether you will be able to complete your education?	☐	☐	☐	☐	☐
43	How often do you worry that your body looks different because of your diabetes?	☐	☐	☐	☐	☐
44	How often do you worry that you will get complications from your diabetes?	☐	☐	☐	☐	☐

For each of the following parts of your diabetes care, tick the box for the answer that best describes the way you handle things at home.

If you take responsibility or remind your parents to do things almost all the time, tick the ME box.

If you and your parent(s) share responsibility, tick the BOTH ME AND MY PARENTS box.

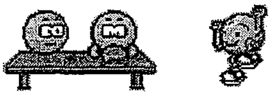
If your parent(s) take responsibility and/or remind you to do things almost all the time, tick the PARENT(S) box.

Who remembers or decides what to do? 		Me	Both me and my parent(s)	Parent(s)
45	Telling friends about diabetes	☐	☐	☐
	Telling teachers about diabetes	☐	☐	☐
	Remembering to take insulin	☐	☐	☐
	Adjusting insulin according to results of blood sugar tests	☐	☐	☐
	Deciding what to eat at meals or snacks	☐	☐	☐
	Carrying some sugar in case of low blood sugar	☐	☐	☐
	Remembering when blood sugar should be tested	☐	☐	☐
	Noticing differences in health such as weight changes or signs of an infection	☐	☐	☐
	Rotating or moving around the injection sites	☐	☐	☐
	Noticing early signs of low blood sugar	☐	☐	☐

You're still doing great! Just a few more pages to go!

We would now like you to think what you do to control your diabetes

46. When your **blood glucose is high**, how often do you -

		Never	Sometimes	Frequently	Almost always
1	Eat less carbohydrate at next main meal/snack	☐	☐	☐	☐
2	Take more insulin	☐	☐	☐	☐
3	Do some exercise	☐	☐	☐	☐

47. How often do you adjust your insulin dose based on your blood sugar levels over the past few days?

☐	Never
☐	Sometimes
☐	Frequently
☐	Almost always

48. How often do you give extra doses of insulin, if you will eat or have eaten extra snacks?

☐	Never
☐	Sometimes
☐	Frequently
☐	Almost always

49. How often do you adjust your own insulin dose based on what you are going to eat at the next meal?

☐	Never
☐	Sometimes
☐	Frequently
☐	Almost always

50. If you have symptoms of a **hypo or low blood sugar**, how often do you -

		Never	Sometimes	Frequently	Almost always
A	Test your blood before eating	☐	☐	☐	☐
B	Just eat until you feel better	☐	☐	☐	☐
C	Eat some food, wait 5-10 min., then test blood to see if more food is needed	☐	☐	☐	☐

We would like you to tell us about your Father and Mother.

51.

Father 		**Mother** 	
Does your father have a job?		Does your mother have a job?	
☐	Yes	☐	Yes
☐	No	☐	No
☐	Don't know	☐	Don't know
☐	Don't have or don't see father	☐	Don't have or don't see mother

If NO, why does your father not have a job?		If NO, why does your mother not have a job?	
☐	He is sick, or retired or a student	☐	She is sick, or retired or a student
☐	He is looking for a job	☐	She is looking for a job
☐	He is looking after others, or is full-time in the home	☐	She is looking after others, or is full-time in the home
☐	I don't know	☐	I don't know

Finally, we would like you tell us how you are feeling

52. In the last 6 months: How often have you had the following ...?
Please tick one box for each line.

		About every day	More than once a week	About every week	About every month	Rarely or never
1	Headache	☐	☐	☐	☐	☐
2	Stomach-ache	☐	☐	☐	☐	☐
3	Back ache	☐	☐	☐	☐	☐
4	Feeling low	☐	☐	☐	☐	☐
5	Irritability or bad temper	☐	☐	☐	☐	☐
6	Feeling nervous	☐	☐	☐	☐	☐
7	Difficulties in getting to sleep	☐	☐	☐	☐	☐
8	Feeling dizzy	☐	☐	☐	☐	☐
9	Neck and shoulder pain	☐	☐	☐	☐	☐
10	Afraid	☐	☐	☐	☐	☐
11	Tired and exhausted	☐	☐	☐	☐	☐
12	Angry	☐	☐	☐	☐	☐

53. Would you say your health is ... ?

☐	Excellent
☐	Good
☐	Fair
☐	Poor

54.

Here is a picture of a ladder!!

The top of the ladder '10' is the best possible life for you and the bottom '0' is the worst possible life for you.

In general, where on the ladder do you feel you stand at the moment?

Tick the box next to the number that best describes where you stand

☐	10 **Best possible life**
☐	9
☐	8
☐	7
☐	6
☐	5
☐	4
☐	3
☐	2
☐	1
☐	0 **Worst possible life**

Thanks a lot for your help

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