How diabetes and insulin therapy affects the lives of people with type 1 diabetes

B Nafees, A Lloyd, T Kennedy-Martin, S Hynd*

Abstract

Background: Management of type 1 diabetes places a considerable burden upon patients in terms of frequent insulin injections and blood glucose monitoring.
Aims: Patients' fears and thoughts concerning diabetes and treatment were explored in two focus groups. The features of insulin therapy most likely to influence treatment preferences of type 1 patients were investigated. These features would then be used to inform a quantitative patient preference study using a discrete choice experiment.
Method: This qualitative study utilised two focus groups, guided by a detailed discussion script based upon clinician input and literature review. Six main topics related to diabetes and insulin therapy were discussed; impact on patient's lifestyle, hypoglycaemic events, predictability and ability to maintain blood glucose levels within recommended targets, injection devices, and negative effects of insulin therapies. In addition, the value people would place on improved insulin therapy measured in terms of their willingness to pay for new therapies, was discussed. Participants were recruited using a screener based upon clinician input. A total of 11 participants attended the two sessions. Transcripts were analysed using content analysis.
Results: Participants reported that all six areas were of significant importance in diabetes management. Diabetes and insulin therapy had a huge impact on lifestyle in terms of activity and diet. Fear and experience of hypoglycaemic events were reported as significant concerns. Participants described predicting variation in glucose levels as the key to better management. Participants were willing to pay from £0.70 to £5.00 a day for a better insulin therapy.
Conclusion: Diabetes and insulin therapy affects many areas of a patient's life. These data may help understand patients' motivations and treatment preferences, and shape future management and improve diabetic care.

Eur Diabetes Nursing 2006; 3(1): 92–97.

Key words

Diabetes; qualitative; patient treatment preferences

Introduction

Diabetes is a disease with a high prevalence; in 2003, approximately 48.4 million people in Europe had a diagnosis of diabetes.[1] It carries a substantial risk of complications if patients are unable to achieve good glycaemic control.[1,2] Insulin is the cornerstone of type 1 diabetes treatment and the benefits of intensive insulin in patients with type 1 diabetes have been demonstrated in large-scale clinical trials.[2] Paramount to the effective use of insulin, and glucose control, is patients' adherence to insulin regimens. This may be determined in part by patient preferences.[3,4]

Patient preferences for therapy are an important part of clinical guidelines for the management of type 1 diabetes in the UK. The National Institute for Health and Clinical Excellence (NICE) and the UK Department of Health have recognised the need to provide structured education programmes covering all aspects of self-care,[5] and the importance of incorporating patient preferences in developing care plans as detailed in the National Service Framework for diabetes.[6]

Authors

B Nafees, MSc, Research Associate, United BioSource Corporation, London, UK
A Lloyd, DPhil, Deputy Director, United BioSource Corporation, London, UK
T Kennedy-Martin, BA Hons, Msc, Novo Nordisk UK, Crawley, UK
S Hynd, BSc Hons, Research Nurse, University of Dundee/NHS Tayside, Dundee, Scotland, UK

***Correspondence to:**
Andrew Lloyd via e-mail to
Beenish Nafees:
beenish.nafees@unitedbiosource.com

Received: 10 April 2006
Accepted in revised form:
15 June 2006

There is a small body of qualitative evidence regarding patients' preference for insulin treatment. Patient self-reporting on the impact of illness and treatment on lifestyle offers insights into how to improve patients' management of disease and quality of life. This study was designed as a first step to understanding patient preferences through fostering open-ended discussion of different issues. Two focus groups (FG) were conducted to explore and understand more about the preferences of patients with type 1 diabetes regarding their insulin therapy. The study was also designed to assist the development of a quantitative patient preference study using the discrete choice experiment (DCE) methodology.[7]

To truly understand people's preferences we attempted to determine what they would be willing to give up in order to obtain improvements in their diabetes, and 'out of pocket cost' is one method to assessing this. Therefore, the focus groups were also designed to determine how much people would be willing to pay for treatment. This was an additional aim of the FG.

Method

Participants

All FG participants completed a clinical screener to ensure that they met study entry criteria after responding to a national newspaper advertisement. All participants had to be between 18 and 75 years of age, be a resident of the UK, have a diagnosis of type 1 diabetes from their doctor, inject insulin at least twice daily, and need to check their blood sugar level every day.

In total, 11 people (6 males and 5 females) were invited to attend the two FGs. One invitee failed to attend. All participants had brought their insulin with them (not at our request) and confirmed their diagnosis of type 1 diabetes by self-report. The mean age of participants was 41.6 years (±15.6 SD). The mean length of time during which participants had been injecting insulin was 7.9 years (±4.4 SD). Participants checked their blood sugar level on average of four times a day (±2.2 SD).

Materials

A literature review was undertaken to explore what work had previously investigated issues around how patients with diabetes perceive their disease and treatment. This review identified that there were relatively few studies relevant to our purpose. Some relevant research/information has emerged from the Diabetes Attitudes, Wishes, and Needs (DAWN) study, which is a large international cross-sectional survey of perceived barriers to care. This research has identified that diabetes-related distress occurs in around 40% of patients. This includes anxiety about finance, weight, risk of hypoglycaemic events, and other psychological problems. Hauber *et al*,[8] report a quantitative patient preference survey which revealed the importance of injections to patients. The authors report that participants were willing to risk negative health outcomes if they could reduce the number of injections they require. Rosal *et al*,[9] used qualitative methods to investigate the type of education programmes preferred by Hispanic patients with diabetes. Aristides *et al*,[10] report that people with type 2 diabetes were willing to pay €54.00 a month to reduce the number of night time hypoglycaemic episodes. Timing of insulin doses was also found to be important.

The review findings were used to guide the development of a FG discussion guide. The discussion guide was additionally reviewed and edited by two consultant diabetologists, a patient representative from a nationwide advocacy group, and several diabetes specialist nurses. The first section of the FG discussion guide was designed to encourage every participant to describe how diabetes and their insulin therapy affected them. The second section was designed to elicit specific information regarding participants' experience of:

- Hypoglycaemia, during the day and at night, including patients' fears
- Hyperglycaemia and related complications
- Predictability of fasting blood glucose levels and ability to maintain blood glucose levels within acceptable ranges
- Convenience and reliability of injection devices
- Treatment-related side-effects
- Weight gain
- Value, expressed as willingness to pay (out of pocket) for new, hypothetically improved therapies.

The FG guide was broad, and participants were encouraged to lead the discussion and highlight the areas of most importance to them. The two FGs were conducted by a trained facilitator (BN) and each lasted for approximately 90 minutes. Participants signed a consent form and were paid £25 for taking part.

Analysis

The FG discussions were recorded, transcribed verbatim and analysed using qualitative content analysis.[11–13] The transcript content was organised into six broad areas that partially reflected the FG discussion guide. It was felt that the FG discussion guide was quite prescriptive and designed to focus discussion into certain specific areas, therefore the authors felt that many forms of qualitative analysis were less appropriate because the discussion in the groups was quite constrained. Qualitative content analysis was undertaken in order to summarise the many areas of discussion. After several readings of the transcripts, the different broad areas/themes were agreed upon. Illustrative quotes and references relating to each area were extracted. Key words or words of potential interest were sought. Frequencies were obtained for words which were used to describe each theme/area. These were reviewed by an independent second researcher. The final summary was determined following several reviews of the text by the two researchers. As the discussion guide already included specific areas, the analysis was not used to derive themes spontaneously. Thus more sophisticated techniques of analysis were not used.

Results

The information relating to the six broad areas identified by the focus groups is summarised in Table 1. In discussing the issues the degree of consensus is indicated by the quantifiers 'some', meaning less than half the group, and 'most', meaning more than half the group.

The groups were interactive and the diverse backgrounds of

Area	Sub-area
Impact on patient's lifestyle	Diet Stress Activity
Hypoglycaemic events	Public reaction Loss of control
Predictability of, and ability to maintain, blood glucose levels within recommended targets	Causes of variation in blood glucose levels Anxiety Potential benefits of predictability
Injection devices	Syringes Pens Ideal features
Negative effects of insulin therapies	Weight gain Bruising/lumps Tingling feet/fingers Other long-term effects
Value of insulin therapies	Willingness to pay

Table 1. The broad areas and sub-areas that emerged from the focus group discussion regarding diabetes and treatment

participants allowed for a range of responses to be elicited. One participant had attended the Dose Adjustment for Normal Eating (DAFNE)[14] course; she highlighted its benefits and reported that it really changed the way she approached her self-care. The sessions also became supportive and educational for the participants as they all shared their individual experiences and learned from each other's experiences.

Impact on patients' lifestyle

All participants found that diabetes and its related therapy had changed their lifestyle but the extent of the impact varied. Lifestyle was affected in relation to stress, food and levels of physical activity. Diabetes and its management were reported to cause anxiety because of the need for blood glucose monitoring and control. Participants mentioned that their food intake changed and that there are restrictions on the types of food one can eat.

'I eat totally different foods now. I eat fresh food, cut down sugary foods.'

Participants expressed that their usual activities were very much dictated by their diabetes and related insulin treatment. Taking insulin regularly was reported to restrict daily activities and planning future activities such as holidays. Taking insulin can cause embarrassment and stress in public settings.

'I don't like staying anywhere. I get embarrassed.'

'…restricts you in going out and holidays.'

Participants found that they became accustomed to the changes required by diabetes and insulin therapy. Type 1 diabetes was felt to be a life-changing, all-consuming condition that affects all aspects of life.

'It's become a way of life. Diabetes is not so much of an issue any more because you get used to it. The first year is very hard. You are trying to get used to it, you have to inject so many times a day.'

'I would not recognise the person I was before I became diabetic. There has not been an aspect in my life that hasn't changed since I was diabetic.'

In addition, patients often felt that adequate information was not offered by doctors or nurses, which in turn led to poor management. Uncertainty and lack of information about insulin treatment led to anxiety and patients felt they had to self-manage their disease, which added to daily pressures.

'In the beginning, I wasn't calculating how much insulin I am taking in relation to what I eat, and then I worked out I was giving myself way too much insulin.'

'Specialists do not give you enough information. They do not have time.'

Hypoglycaemic events

Participants expressed immense concern regarding the possibility and the actual experience of hypoglycaemic events. They were described as 'scary' and they suggested that it is the fear of hypoglycaemic events as well as the events themselves that causes stress and anxiety, and this was related to the reactions of the public and feelings of 'loss of control'.

Experience of hypoglycaemic events varied widely in the groups. In our small sample, of those people who had discussed their fear of hypoglycaemic events, only about half of them had experienced serious, daytime hypoglycaemia. Despite this some of the participants still reported a fear of hypoglycaemia, especially nocturnal events, which were described as the biggest fear for patients.

'It is my greatest fear – hypo when you sleep. It could kill you.'

'…greatest fear for a diabetic…'

Several participants reported particular concerns surrounding experiencing a hypoglycaemic event in a public place or around strangers. The state of a hypoglycaemic event can be misunderstood by general public, leading to embarrassment.

'It can be embarrassing. People think you are seeking attention.'

'People in public places do not understand. They think you are drunk.'

There were some differences in participants' experiences. Some expressed uncertainty as to the cause of hypoglycaemic events. This added to pre-existing anxiety about the experience. However, some participants generally felt that hypoglycaemic events could be controlled or prevented by managing one's diet and treatment. One strategy that some participants reported was a willingness to let their glucose levels run too high in order to avoid hypoglycaemia.

'I would rather let the sugar level go too high to avoid hypos.'

Predictability and ability to maintain blood glucose within recommended targets

Participants discussed how variations in their blood glucose levels were troublesome. Variation in blood glucose levels was considered by many to be a 'big concern' and dictated patients' actions.

'Don't always know the cause of varying blood sugar levels.'

'Everything is geared towards staying in the range of normal sugar level.'

'Right now, I can't go on an unexpected journey, because it is stressful and it burns a lot of sugar.'

Some patients felt that variability in blood glucose levels could be explained in terms of activity or eating food, while others felt that variation could not always be explained. Participants reported that being better able to predict their blood glucose levels would reduce their anxiety and they would be 'able to relax more', and 'sleep better', be in better control of their lives, and would 'enjoy life more'.

Injection devices

All participants, except one, used injection devices or pens for their basal insulin injections. One person used a vial and syringe and described these as smaller and lighter than a pen, and simple because 'I can see what I am putting in'.

Participants described pens as 'convenient', 'less intrusive', and 'discreet'. However, participants also reported how they had experienced device failure and described design flaws, causing concern and anxiety. Small size, general convenience and discreetness for use in social situations were preferred by patients when describing ideal device characteristics. The ability to see the number of insulin units injected and time of last injection were also considered desirable features.

Negative effects of insulin therapy

There was some confusion between the side-effects of insulin therapy and the long-term complications of diabetes.

Weight gain was a significant concern, particularly among female participants. Participants reported that it 'lowers your confidence'. Some reported that they had gained up to 13 kg in weight, which they attributed to their diabetes and insulin therapy. Participants who experienced bruising or lumps (lipomas) due to injections expressed concern about how it affected their physical appearance.

'…makes you feel insecure, you cannot walk in [the beach] without a t-shirt.'

Patients often mistook microvascular problems for side-effects of insulin, and did not realise that long-term diabetic complications were caused by poor glycaemic control.

'Too much insulin in your body for too long can damage your nerves/arteries.

'It [insulin] affects your sex life. It's a major problem that is not acknowledged.'

Value of insulin therapies

Participants were presented with the offer of a new, improved insulin therapy which avoided side-effects and asked what would make them willing to switch. Some participants were reluctant to switch to a hypothetically improved insulin therapy.

'You wouldn't know but the new therapy could cause side-effects. In my experience, if it is better, it will cause problems somewhere else.'

Avoiding injections was appealing to many people. Almost all participants said they would gladly swap to a hypothetical once-daily oral treatment.

Some participants said they that were not willing to pay anything for a new therapy and were opposed to the concept. Most participants were however willing to pay something for a better treatment.

'You would modify your lifestyle to pay for it, if it took away all symptoms of diabetes. I would make a balance.'

In monetary terms, of those participants willing to pay for improved insulin therapy the values ranged from £0.70 to £5.00 a day.

Other issues

Participants reported that they felt there was a lack of support and information from their doctor and nurses at their hospital/outpatient clinics, especially at the time of diagnosis.

'Specialists do not give you enough information. They do not have time.'

All participants expressed that they could benefit from learning more about insulin treatment. Participants felt that their needs and preferences for care were not recognised and thus not incorporated into their treatment plans.

Finally, participants stated the need to be 'in control' of their diabetes. A greater level of control would lead to greater confidence regarding the negative aspects of diabetes, e.g. fear of hypoglycaemic events.

'Don't let your diabetes control you, you control your diabetes.'

'You need to feel that you control the diabetes rather than it controls you.'

Discussion

This qualitative study provides some insight into the importance of different aspects of insulin therapy for patients with type 1 diabetes. These data can help our understanding of patients' motivations and preferences.

The information from the FGs indicated that diabetes and insulin therapies influence many areas of a patient's life. Fear of hypoglycaemia and actual hypoglycaemia both affected patients. Participants generally reported that hyperglycaemia was less of a concern to them than hypoglycaemia. They were happy for their blood glucose levels to go too high in order to avoid hypoglycaemia. This supports previous similar findings,[15,16] and has obvious implications for management and patient education.

There is very little primary research data regarding the importance of blood glucose variability for patients. Variability was a significant concern for some patients, making it considerably harder to keep their blood glucose levels under control. Novel basal insulin analogues are now available that have lower variability in action compared with traditional basal insulins.[17,18]

The discussion of side-effects of insulin therapy was mostly linked with discussion of complications. However, a few comments were made about the more serious long-term complications of diabetes. It is possible that people place much less importance on the long-term complications because it may be many years before they will be affected. There is considerable evidence to demonstrate that people would prefer to receive a benefit today rather than in the future.[19] In the present context patients with diabetes seem to have a strong preference for controlling the immediate risk of hypoglycaemia compared to the more long-term risks of hyperglycaemia.

This study provided information to support the development of a future patient preference survey using the DCE methodology.[7] The DCE survey presents pairs of hypothetical treatments which vary in terms of different attributes of therapy. This study will present hypothetical insulin therapies which vary in terms of specific attributes (e.g. convenience of use of insulin device, frequency of daytime hypoglycaemic events) to understand their value by asking participants to choose which they prefer. A multivariate statistical technique is employed to analyse preferences for various combinations of attributes. The qualitative data from the present study will help us to select the important attributes to value and also define suitable levels for each attribute.

There are several potential limitations to the present study. The decision to include only two FGs was slightly arbitrary and was partly determined by available resources. Recruiting patients from newspaper advertisements allowed us to capture a wide range of people. However, with this method we were unable to capture any clinical information such as severity of disease or HbA_{1c} levels. Furthermore, the group was a self-selecting population, and therefore may not represent a true sample of people with type 1 diabetes.

The discussion guide steered conversation to specific areas. This, however, meant that the FG discussion wasn't completely free-ranging, which makes it difficult to claim that any themes emerged spontaneously. This is one reason why we did not use more sophisticated qualitative analysis techniques, which are designed to extract themes and concepts and understand relationships between them. The discussion was semi-structured, but the advantage of this approach is that it allowed us to explore a range of specific areas. This use of a structured discussion guide was considered when interpreting the findings. We report what participants said in response to specific issues rather than claiming themes emerged from discussion.

The findings from the present study are in many ways consistent with the recent findings from the DAWN study.[4,20,21] This large international study highlights the psychological and social burden of diabetes. The authors of the DAWN study report how psychological problems experienced by diabetes patients influenced disease management by affecting adherence and self-care. The information from the present study, while not designed to inform care specifically, may have some useful messages for practitioners. Many people with type 1 diabetes clearly have a poor understanding of the importance of glycaemic control. Part of the solution to this may be more and better quality information and guidance from clinical staff and patient advocacy groups, which could lead to less anxiety and better adherence to treatment. Patient education has been shown to be an important part of disease management and is a valuable component to include in future education programmes.[22] These findings are important for future development of insulin therapies.

Fear of hypoglycaemic events remains to be a cause of concern. Future care should incorporate not only how to avoid the events but also to deal with the fear surrounding them. But any solution for better management of patients also has to come from the individual themselves, and changing the attitudes of people with diabetes remains one of the greatest challenges. We believe that a greater understanding of patient preferences regarding the management and treatment of diabetes is one step towards reaching this goal.

Conflict of interest statement:

United BioSource Corporation is an independent research organisation that conducts work on behalf of commercial organisations, publicly funded bodies and governments around the world.

The research described in this manuscript was undertaken on behalf of Novo Nordisk who provided the funding for the project. All focus group materials and analyses were undertaken by staff at United BioSource Corporation.

References

1. International Diabetes Federation (2005). http://www.eatlas.idf.org/Prevalence/All_diabetes/ [Accessed June 2006].
2. DCCT Research Group. The absence of a glycemic threshold for the development of long-term complications: the perspective of the Diabetes Control and Complications Trial. *Diabetes* 1996; **45:** 1289–1298.
3. Perros P, Deary IJ, Frier BM. Factors influencing preference of insulin regimen in people with type 1 (insulin-dependent) diabetes. *Diabetes Clin Res Pract* 1998; **39:** 23–29.
4. Peyrot M, Rubin R , Lauritzen T *et al.* Psychological problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabetes Med* 2005; **22:** 1379–1385.
5. National Institute of Health and Clinical Excellence (NICE). Diagnosis and management of type 1 diabetes in children, young people and adults. London, UK. http://www.nice.org.uk/page.aspx?o=213575. [Accessed February 2006]
6. Department of Health. *National Service Framework for Diabetes: Delivery Strategy.* London: DoH, 2002.
7. Ryan M, Farrar S. Eliciting preference for healthcare using conjoint analysis. *BMJ* 2000; **320:** 1530–1533.
8. Hauber AB, Johnson FR, Sauriol L, Lescrauwaet B. Risking health to avoid in injections – Preferences of Canadians with type 2 diabetes. *Diabetes Care* 2005; **28**(9): 2243–2245.
9. Rosal MC, Goins KV, Carbone ET, *et al.* Views and preferences of low-literate Hispanics regarding diabetes education: results of formative research. *Health Educ Behav* 2004; **31**(3): 388–405.
10. Aristides M, Weston AR, FitzGerald P, *et al.* Patient preference and willingness-to-pay for Humalog Mix25 relative to Humulin 30/70: a multi-country application of a discrete choice experiment. *Value in Health* 2004; **7**(4): 442–454.
11. Holsti OR. *Content Analysis for the Social Sciences.* Reading, MA: Addison-Wesley 1969.
12. Krippendorff, K. *Content Analysis. An Introduction to its Methodology.* The Sage CommText Series. London: Sage Publications Ltd, 1980.
13. Graneheim U, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004; **24:** 105–112.
14. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. *BMJ* 2002; **325:** 746–749.
15. Irvine AA, Cox D, Gonder-Frederick L. Fear of hypoglycemia: relationship to physical and psychological symptoms in patients with insulin-dependent diabetes mellitus. *Health Psychol* 1992; **11:** 135–138.
16. Shiu, ATY, Wong RYM. Fears and worries associated with hypoglycaemia and diabetes complications: perceptions and experience of Hong Kong Chinese clients. *J Adv Nurs* 2002; **39:** 155–163.
17. Chen JW, Christiansen JS, Lauritzen T. Limitations to subcutaneous insulin administration in type 1 diabetes. *Diabetes Obes Metabolism* 2003; **5:** 223–233.
18. Heise T, Nosek L, Biilmann Rønn B, *et al.* Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes* 2004; **53:** 1614–1620.
19. Cairns JA, van der Pol MM. The estimation of marginal time preference in a UK-wide sample (TEMPUS) project. *Health Technol Assess* 2000; **4**(1).
20. Peyrot M, Rubin RR, Lauritzen T *et al.* Patient and provider perceptions of care for diabetes: results of the cross-national DAWN study. *Diabetologia* 2006; **49**(2): 279–288.
21. Peyrot M, Rubin RR, Lauritzen T, *et al.* Resistance to insulin therapy among patients and providers. *Diabetes Care* 2005; **28:** 2673–2679.
22. Wikblad K, Leksell J, Smide B. 'I'm the Boss': testing the feasibility of an evidence-based patient education programme using problem-based learning. *Eur Diabetes Nursing* 2004; **1:** 13–17.