Barriers to improving glycaemic control in CSII

Joan Everett, Anita Bowes, David Kerr

People with type 1 diabetes are encouraged to attain an HbA_{1c} level of <7.5% (<58 mmol/mol; NICE, 2009) to reduce the risk of developing long-term complications (Diabetes Control and Complications Trial Research Group, 1993). Continuous subcutaneous insulin infusion (CSII) has been used in Bournemouth since 1998, but the mean HbA_{1c} of users is 8% (64 mmol/mol). This article describes a study in which seventeen people with type 1 diabetes using CSII therapy participated in focus groups to determine the barriers to achieving better glycaemic control. Results showed these to be: expectations of increased hypoglycaemia; anticipated restrictions to lifestyle; mistrust of HbA_{1c} results; and the hard work associated with good glycaemic control. These barriers led participants to run their blood glucose levels higher than what they knew was expected from healthcare professionals. Although participants had settled with an HbA_{1c} level of 8%, they were eager to continue learning about getting the most out of their pump and agreed that learning seems to takes place in various ways.

Article points

1. Focus groups were conducted to determine why some people with type 1 diabetes using continuous subcutaneous insulin infusion (CSII) maintain their HbA_{1c} level above that generally advised by their healthcare professional (<7.5% [<58 mmol/mol]).
2. Discussions revealed that participants seemed happy to settle at an HbA_{1c} level of 8% (64 mmol/mol) because they feared they would lose some of the advantages of CSII and have more hypoglycaemia if they went lower.
3. This fear needs to be addressed early in the CSII pathway because avoidance strategies have already been learnt and new strategies are needed to change behaviour.

Key words

- CSII
- Glycaemic control
- Hypoglycaemia
- Pump therapy

Author details can be found at the end of the article.

People living with type 1 diabetes face a difficult task. They need to avoid long-term vascular complications by keeping their blood glucose levels as close to the normal range as possible (<7.5% [<58 mmol/mol]; NICE, 2009), while at the same time avoiding repeated hypoglycaemic episodes (Diabetes Control and Complications Trial Research Group, 1993).

Continuous subcutaneous insulin infusion (CSII, also known as insulin pump therapy) is associated with a lower risk of severe hypoglycaemia and improved glycaemic control compared with multiple daily insulin injections (Weissberg-Benchell et al, 2003). There is also evidence to suggest that CSII therapy use enhances quality of life, although this is not a consistent finding (Barnard and Skinner, 2007).

CSII therapy is recommended as a treatment option by NICE (2008), provided that the criteria are met. The guideline also recommends that CSII should only be continued if there is a sustained improvement in glycaemic control or a sustained decrease in the rate of hypoglycaemic episodes.

Insulin pump therapy was introduced at the authors' diabetes centre in Bournemouth in July 1998. Regular audit of pump users has shown that they have consistently achieved average HbA_{1c} levels of around 8% (64 mmol/mol) since the introduction of pump therapy.

Aim of the service improvement project

The aim of this project was to solve the clinical problem that prevents people with

type 1 diabetes treated with CSII therapy achieving the gold standard HbA_{1c} level of <7.5% (<58 mmol/mol).

Methods

People with diabetes at the Bournemouth Diabetes and Endocrine Centre regularly engage in service development projects aimed at improving the service. Eighty people with type 1 diabetes using CSII, with an HbA_{1c} level of >8% (>64 mmol/mol), were identified from the local register and sent a letter asking if they would be interested in participating in an informal group where insulin pump users could potentially find solutions to reducing their own HbA_{1c} level.

Twenty-one people accepted the invitation and agreed to attend at their chosen time and date. Of these 21 people, 17 participants attended (age [mean ± standard deviation] 44±13.3 years, duration of diabetes 28±11 years, HbA_{1c} 8.8±0.34% [73±3.7 mmol/mol] and using pump therapy for 3±2.5 years) one of four focus groups, each of which lasted approximately 1 hour.

A semi-structured interview schedule (*Box 1*) was designed, but each group was free to explore any issues that arose. The process of recording, transcribing and disseminating the results was explained before each focus group and verbal consent was obtained.

Analysis of results

Each focus group was recorded and transcribed, and the emerging themes identified. The authors compared and agreed the emerging themes, which were then sent to all participants to verify the accuracy of the transcripts and analysis.

Results

Expectations of CSII

Expectations of insulin pump therapy were a more flexible lifestyle, less experience of hypoglycaemia, improved HbA_{1c} level and more stable blood glucose levels. All participants said their expectations had been met, and in many areas exceeded, by gaining a new lease of life with less hassle in daily activities, and they could not now envisage their life without CSII therapy.

Box 1. Semi-structured questions for people with type 1 diabetes using insulin pump therapy, who had an HbA_{1c} level >8% (>64 mmol/mol).

1. What were your expectations when starting insulin pump therapy and have they been met?
2. What have been the advantages or disadvantages of pump therapy?
3. Do you know what HbA_{1c} level is recommended and why?
4. What was your HbA_{1c} level when you started pump therapy?
5. What HbA_{1c} level did you hope to achieve?
6. If you succeeded, what do you attribute your success to?
7. If you did not succeed, why do you think this was?
8. What are the barriers to achieving an HbA_{1c} level of 7% (53 mmol/mol)?
9. What could help you achieve an HbA_{1c} level of 7% (53 mmol/mol)?

Expected and realistic HbA_{1c} levels

Participants were asked to give their current HbA_{1c} level and the level they were aiming for.

All participants were able to give a fairly accurate description of what an HbA_{1c} blood test was and agreed that the ideal level expected of them was around 7% (53 mmol/mol). Some expressed the desire to have this level of HbA_{1c}, but in reality found it difficult to achieve. Most thought that 8% (64 mmol/mol) seemed to be the level that generally they were happy with and had settled at.

"My aspiration is getting between 6 and 7%, but as long as [it is] below 8% I am happy."

"I am happy around 8 – it suits me as a person and suits my lifestyle."

The main reasons for settling at this level were:

- Fear of hypoglycaemia.
- Not wanting to return to previous restrictions and the hard work involved in maintaining good control.
- A mistrust of HbA_{1c} as an accurate record of their overall control.

Fear of hypos and feeling safe

Several participants felt that if they achieved the expected target of 7% (53 mmol/mol) they would run the risk of more hypoglycaemia:

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2. Expectations of insulin pump therapy were a more flexible lifestyle, less experience of hypoglycaemia, improved HbA_{1c} level and more stable blood glucose levels.
3. Some people expressed the desire to have this level of HbA_{1c}, but in reality found it difficult to achieve. Most thought that 8% (64 mmol/mol) seemed to be the level that generally they were happy with and had settled at.

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1. Although all participants knew that normal blood glucose levels are between 4 and 7 mmol/L, some were not happy to run their levels between 4 and 6.5 mmol/L, although 7 mmol/L was acceptable to them.
2. Participants discussed the advantages of insulin pump therapy in terms of freedom, fewer restrictions and normality, but predicted that achieving good control would lead to compromise in these areas.
3. Participants also commented that the HbA_{1c} level result did not reflect their own experience, so they did not trust the result.
4. The overall opinion was that it was easier to reduce HbA_{1c} levels using pump therapy at the beginning, when the HbA_{1c} level was higher, but became more difficult as it reduced to around 8% (64 mmol/mol).

"Lowest result was when I had the most hypos I have ever had."

"…but to me, low HbA_{1c} means more hypos."

Sometimes comments such as this reflected participants' experiences of hypoglycaemia before starting pump therapy, but it was influencing their present behaviour in making an active decision to run their blood glucose level higher than was necessary to feel safe.

"'I like it [blood glucose] to be 7 to be safe."

The emotions expressed were of being scared and anxious. Two situations that came up several times were driving and working:

"This weekend I have been working on cherry pickers so I am always snacking to keep levels up."

'If I am riding my bike, my level must be 8 or 9 mmol/L."

One person expressed his anxiety about his daughter's safety:

"I reduce my insulin when I take my daughter out, just in case."

Although all participants knew that normal blood glucose levels are between 4 and 7 mmol/L, some were not happy to run their levels between 4 and 6.5 mmol/L, although 7 mmol/L was acceptable to them:

"Going down to 7 is a risk of hypos."

"I am happy at 7 but not below."

In these participants' minds, good control of diabetes was associated with more hypoglycaemia and they felt safe with a blood glucose level of 7 mmol/L.

Hard work

Many participants commented that hard work was required to achieve a good HbA_{1c} level:

"If it's high [HbA_{1c}], you can quickly get it down, but getting from 8 to 7 takes a long time; it's hard work and by the end you are fed up with it."

Restrictions

Participants discussed the advantages of insulin pump therapy in terms of freedom, fewer restrictions and normality, but predicted that achieving good control would lead to compromise in these areas:

"This HbA_{1c} thing – it can become a bit of a thing – you just want to get on and enjoy life."

"I cannot always be thinking about my diabetes."

Mistrust of HbA_{1c}

Participants also commented that the HbA_{1c} level result did not reflect their own experience, so they did not trust the result:

"If you get a week of highs followed by a week of lows, you get an average which does not reflect the real picture."

The topics that emerged from this discussion were therefore:

- Expectations of increased hypoglycaemia with good glycaemic control.
- The anticipated restrictions to lifestyle.
- Mistrust or irrelevance of HbA_{1c} results.
- The hard work with continued effort associated with good glycaemic control.

These barriers led half the participants to run their blood glucose levels higher than they knew was expected of them from healthcare professionals.

The overall opinion was that it was easier to reduce HbA_{1c} levels using pump therapy at the beginning, when the HbA_{1c} level was higher, but became more difficult as it reduced to around 8% (64 mmol/mol).

How learning takes place

Although participants had settled at an HbA_{1c} level of ≥8% (≥64 mmol/mol), they were eager to continue learning about how to get the most out of their pump, and agreed that learning seems to takes place in various ways.

Learning from experience

Experiential learning was evident in lots of areas and many situations were discussed

where self-management skills had been learned from previous experience:

"I find the multiwave useful and always use it for pasta."

"Temporary basal rates are marvellous – I use them for walking."

"I have started reducing basal rate if I am going hypo and it works really well."

Learning from others

An example of learning from others was demonstrated in one group, where one participant asked another:

"I want to know more about that pasta thing [using multiwave bolus]."

Many other examples of participants learning from each other were given:

"I was part of a group of 10 and it was really good to talk to each other and hear what others think and were doing; sometimes you think you are doing things wrong, but others are also doing it so it must be OK."

"In a group review clinic, someone would say something and I thought 'I never knew that'."

Learning from technology

Telehealth: Locally, the authors have been involved in developing a telehealth system (Axon TeleHealthCare) for use with CSII (Everett and Kerr, 2010). This system allows the individual to download, wirelessly, data from a glucose meter or insulin pump to their home computer in graphic form. Some people had been using this system and found it useful:

"I was part of Axon and it was useful because I was looking at it myself and making changes."

Sensors: A continuous glucose monitoring system can be used either to record, download and analyse data with the user after the event, or to display the data in real time. Both methods have been used at the Bournemouth clinic.

"I have been on a sensor, which I found most beneficial because you can see when the blood sugars are going up, when the insulin is kicking in and [the blood sugar is] going down."

Downloading data: All pumps have a download facility that shows the basal and bolus rates and lots of other information as graphs. This can be done either by the individual at home or during clinic visits.

"You can download info, make changes and see effect."

All participants learnt in a variety of ways, ranging from their own and other people's experiences, to learning from technology as well as from healthcare professionals.

"In real life …"

This phrase seemed to be used as a "but" in some areas, indicating that participants believed that the theory was good, but did not work in practical situations:

"Sounds good on paper **but** *in real life we don't want to be restricted in what we do."*

"I attended a seminar here where we used Rosemary Conley scales and I got excited about using them, **but** *it still hasn't brought the levels down."*

Throughout the discussions there was a theme of discrepancy between theory and practice and between healthcare professionals and participants' experiences (*Table 1*).

Discussion

This article looked at the reasons why some people with type 1 diabetes using CSII maintain their HbA_{1c} levels above what they know is advised by their healthcare professional. Participants in this study have settled at this level because they fear that if they reduce further they will lose some of the advantages of CSII therapy and experience more hypoglycaemia.

This fear needs to be addressed early in the CSII pathway because avoidance strategies

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2. All pumps have a download facility that shows the basal and bolus rates and lots of other information as graphs. This can be done either by the individual at home or during clinic visits.
3. All participants learnt in a variety of ways, ranging from their own and other people's experiences, to learning from technology as well as from healthcare professionals.
4. Throughout the discussions there was a theme of discrepancy between theory and practice and between healthcare professionals' and participants' experiences.

Table 1. Examples illustrating the theme of discrepancy between theory and practice and between healthcare professionals' and participants' experiences.

Subject	Healthcare professional	Participants' quotes reflecting the personal experience
Normal blood glucose levels	Between 4 and 7 mmol/L.	● "4.5 is too low for me." ● "When I drive I like it to be between 12 and 15 mmol/L." ● "If it was 5.5 I would need to eat straightaway." ● "I am comfortable with 7–9 mmol/L." ● "I don't like to go to bed with blood glucose below 10."
HbA_{1c}	Aim for 7% (53 mmol/mol).	● "I am happy at 8% [64 mmol/mol] because it suits my lifestyle." ● "I have had diabetes a long time so I should keep it at 8% [64 mmol/mol]." ● "I would like it just below 8% [64 mmol/mol]." ● "7% [53 mmol/mol] is best but 7–9% [53–75 mmol/mol] would do it, but aim for below 8% [64 mmol/mol]." ● "Going down to 7% [53 mmol/mol] means risk of hypos." ● "When I was 7.7% [61 mmol/mol] it did not reflect the real picture."
Illness management	Increase basal insulin rates by 30, 50 or 100% in times of illness.	● "I am happy to run 9–10 when unwell because I can function." ● "Will only use an increased basal rate after 1–2 weeks." ● "You increase 10%, then 20%, then up to 150%, then suddenly whatever is causing the high goes and you fall down the other side and go low." ● "Wait 2 or 3 weeks and try and ride it through or it does my head in with the ups and downs."
Corrections	Correct to target, usually 5–7 mmol/L.	● "Only give a correction if in double figures." ● "I would not correct if under 9." ● "If you give too many corrections, you go low." ● "I would not correct if blood sugar was 8–8.5."

have already been learnt and new strategies are needed to change behaviour.

The theme running throughout is that theory does not always work in practice, and managing illness is a case in point. Healthcare professionals diligently teach people how to increase basal insulin rates in illness according to blood glucose levels, which may mean increasing basal insulin rates by up to 100% to avoid diabetic ketoacidosis, but do not teach them how to reduce basal insulin rates afterwards to avoid blood glucose levels dropping too low too quickly. This may contribute to individuals with diabetes using CSII therapy not using increased basal insulin rates in future illness.

Another example of theory not working in practice can be seen in the use of corrections that would enable people with diabetes to keep to their target blood glucose levels – the more the corrections are used, the lower the HbA_{1c} level achieved (Kerr et al, 2008). All pumps now have a bolus calculator function which makes the calculations easier for individuals with diabetes. It also takes into consideration the active insulin on board, thereby avoiding over-correction.

In the UK, healthcare professionals have only been using CSII therapy for a relatively short period of time and are still learning about it themselves, so it is important that they listen to people with diabetes using CSII therapy to learn what happens in real life, and change their advice accordingly.

This focus group showed that participants learnt about CSII therapy by various means, and healthcare professionals need to make use of all these methods.

Implications for practice

- The window of opportunity to reduce HbA_{1c} appears to be in the first year of CSII therapy, so there needs to be regular education, intervention and follow-up during this time.
- Fear of hypoglycaemia needs to be addressed before starting CSII therapy, with support and strategies available during the first year.
- Healthcare professionals need to learn from people with diabetes using CSII what actually happens in practice so that they can make their advice more meaningful and practical.
- The use of technology should be encouraged.
- Healthcare professionals should use groups to provide support for individuals with diabetes using CSII and enable them to learn from each other at all opportunities.

Conclusion

These focus groups have given understanding and insight into the barriers that prevent people using CSII from achieving the desired HbA_{1c} level.

Fear of anticipated hypoglycaemia was found to be the biggest barrier and this will be addressed by increasing the group sessions for education and review during the first year of CSII therapy.

It is important that as healthcare professionals we listen carefully to people's experiences and adjust our advice accordingly. ■

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Barnard K, Skinner TC (2007) Qualitative study into quality of life issues surrounding insulin pump use in type 1 diabetes. *Practical Diabetes International* **24**: 143–8

Diabetes Control and Complications Trial Research Group (1993) The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin treated diabetes. *N Engl J Med* **329**: 977–86

Everett J, Kerr D (2010) Telehealth as adjunctive therapy in insulin pump treated patients: a pilot study. *Practical Diabetes International* **27**: 9–10

Kerr D, James J, Nicholls H (2008) Technologies as therapeutic devices. What do we expect from users of insulin pump therapy. *Infusystem International* **7**: 1–4

NICE (2008) *Continuous Subcutaneous Insulin Infusion for the Treatment of Diabetes Mellitus. NICE Technology Appraisal Guidance 151*. NICE, London. Available at: http://tinyurl.com/mfxlst (accessed 05.05.10)

NICE (2009) *Type 1 Diabetes: Diagnosis and Management of Type 1 Diabetes in Children, Young People and Adults in Primary and Secondary Care*. Update, June 2009. NICE, London. Available at: http://tinyurl.com/32yzwxo (accessed 05.05.10)

Weissberg-Benchell J, Antisdel-Lomaglio J, Seshadri R (2003) Insulin pump therapy: a meta-analysis. *Diabetes Care* **26**: 1079–87

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