

Title	Who gains clinical benefit from using insulin pump therapy? A qualitative study of the perceptions and views of health professionals involved in the REPOSE (Relative Effectiveness of Pumps over MDI and Structured Education) Trial
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Who gains clinical benefit from using insulin pump therapy? A qualitative study of the perceptions and views of health professionals involved in the REPOSE (Relative Effectiveness of Pumps over MDI and Structured Education) Trial

Running head: Staff views about who gains clinical benefit from insulin pump therapy

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Novelty Statement:

- This is the first study to explore staff views about the clinical benefits of Continuous Subcutaneous Insulin Infusion (CSII) and the kinds of individuals who should be recommended for this therapy.
- Alongside clinical criteria, staff described having recommended individuals for CSII based on their assessments of personal and psychological suitability.
- Staff's exposure to individuals on a trial where allocation to CSII was determined by a randomization process rather than their own judgment led them to reconsider who should be referred for CSII.
- To promote equitable access to CSII, staff attitudes and prejudicial assumptions may need to be identified and addressed.

Abstract

Aims: To explore health professionals' views about insulin pump therapy (Continuous Subcutaneous Insulin Infusion (CSII)) and the types of individuals they thought would gain greatest clinical benefit from using this treatment.

Methods: In-depth interviews with staff (n=18) who delivered the REPOSE (Relative Effectiveness of Pumps Over MDI and Structured Education) trial. Data were analysed thematically.

Results: Staff perceived insulin pumps as offering a better self-management tool to some individuals due to the drip feed of insulin, the ability to alter basal rates and other advanced features. However, staff also noted that, due to the diversity of features on offer, CSII is a more technically complex therapy to execute than multiple daily injections. For this reason, staff described how, alongside clinical criteria, they had tended to select individuals for CSII in routine clinical practice based on their perceptions about whether they possessed the personal and psychological attributes needed to make optimal use of pump technology. Staff also described how their assumptions about personal and psychological suitability had been challenged by working on the REPOSE trial and observing individuals make effective use of CSII who they would not have recommended for this type of therapy in routine clinical practice.

Conclusions: Our findings add to those studies which highlight the difficulties of using patient characteristics and variables to predict clinical success using CSII. To promote equitable access to CSII, attitudinal barriers and prejudicial assumptions amongst staff about who is able to make effective use of CSII may need to be addressed.

INTRODUCTION

Type 1 diabetes mellitus (Type 1DM) develops when the body's insulin-producing cells have been destroyed; hence, lifelong treatment with insulin is essential. Insulin is normally administered by means of multiple daily injections (MDI). This regimen comprises quick-acting insulin injected before eating (with doses adjusted to carbohydrate content) and long-acting basal insulin (normally injected once/twice daily) to control blood glucose between meals. While MDI can lead to improvements in glycaemic control [1-3], this therapeutic regimen cannot fully reproduce the physiological insulin profiles of individuals without diabetes due to limitations of insulin formulations and the site of insulin delivery. The inability of intermittent injection therapy to control blood glucose levels tightly without an attendant risk of hypoglycaemia may also result in individuals keeping their blood glucose at higher than clinically recommended levels [4]. Hence, insulin pumps (Continuous Subcutaneous Insulin Infusion (CSII)), which deliver insulin subcutaneously via a small plastic tube and cannula, are recommended in some cases. These devices infuse quick acting insulin at a slow rate over 24 hours, with patient activated boluses given to cover the carbohydrate content of meals/snacks. The pump also allows basal rates to be adjusted on an hourly and daily basis to accommodate situations such as the dawn phenomenon, sickness, physical activity and shift working [5]. Advanced features, such as dual and extended wave boluses, can be used to minimise post-prandial hypoglycaemia; for instance, after a fatty meal is consumed [4, 5].

In the UK, the clinical and other benefits of CSII have been the subject of appraisals by the National Institute for Health and Care Excellence (NICE). The most recent appraisal recommended that CSII be extended to adults with Type 1 DM who are at risk of disabling hypoglycaemia when attempting to achieve target HbA1c levels with MDI, as well as to those whose HbA1c levels have remained high (69mmol/mol [$\leq 8.5\%$]) despite a high level of care [6]. To date, these relatively broad recommendations have not resulted in a wide uptake in the UK, where only 6% of people with Type 1 DM currently use CSII [5]. This figure is lower than in some other European countries [5] and America where around 40% of people with Type 1 DM use insulin pumps, albeit in America this figure may be partly explained by high usage amongst children and adolescents [5, 7]. These global variations have raised questions about whether some policies and guidelines are depriving individuals

from the benefits of CSII [8]. At the same time, and due to the high costs of CSII, there have also been calls to restrict referrals to individuals who demonstrate the motivation and competence needed to use the technology effectively [6].

To inform guidance on the use of CSII, and to complement clinical research, there has been a growing interest in exploring the perspectives of those who use insulin pumps. To date, this work has overwhelmingly focused on adults and adolescents [9-14], including those who chose to discontinue CSII therapy [15], as well as parents who care for a child on CSII [16-18]. In contrast, the perspectives of health professionals remains an underexplored area, despite the crucial role these individuals play in advocating new treatments, educating and starting patients on CSII and providing on-going clinical support.

To address this imbalance, we report findings from a qualitative evaluation of the REPOSE (Relative Effectiveness of Pumps Over MDI and Structured Education) trial. This trial was conducted to determine whether CSII provides added benefit compared to optimised MDI therapy after individuals with Type 1 DM have received high-quality structured education [19]. The trial also included a wider population than would normally be considered for CSII under current NICE guidelines [19]. Full trial details are provided elsewhere [19] and information relevant to this paper is summarised in Figure 1. As part of the evaluation, we interviewed health professionals - diabetes specialist nurses (DSNs) and dietitians - who shared day-to-day responsibility for the trial, including recruitment, delivery of the structured and education, commencement of pump therapy and the collection of follow-up, clinical data for the trial. Key aims were to explore staff members' perceptions of, and views about, the potential benefits (if any) of CSII over MDI; and which kinds of individuals they thought would gain the most clinical benefit from using a pump, and why. The objectives were to aid interpretation of trial outcomes (forthcoming) and inform guidance for, and debates about, who should be referred for CSII therapy.

Figure 1 – about here

METHODS

Qualitative methods are recommended when little is known about the area of investigation as they allow findings to emerge from the data rather than testing predetermined hypotheses [20, 21]. In this study, interviews, informed by topic guides, were used to enable the discussion to stay relevant to the study aims, while allowing participants to share their own understandings of the issues under investigation and to raise issues they perceived as salient, including those unforeseen at the study's outset. The study entailed concurrent data collection and analysis in line with the principles of Grounded Theory research [22], enabling issues identified in the early interviews to inform areas explored in later ones.

Recruitment

Staff were recruited from seven of the eight REPOSE centres via written invitations accompanied by opt-in forms; the eighth site was not included as it was brought on board at the end of the trial and only recruited a small number of trial participants. All the staff approached agreed to take part. Recruitment and data collection continued until data saturation occurred; that is, no new findings or themes were identified in an analysis of new data collected. Three additional interviews were undertaken after data saturation was first observed to ensure it had occurred.

Data collection and analysis

Interviews were conducted between December 2012 and April 2013 by which time staff had gained experience of recruiting participants, delivering structured education courses and following up participants as part of the trial. The interviews were informed by a topic guide developed in light of literature reviews and revised in light of emergent findings (see above). Topics relevant to this paper are outlined in Figure 2. All staff chose to be interviewed at their workplace. Interviews averaged an hour, were digitally recorded (with consent), and transcribed in full.

Figure 2 – about here

Data were analysed thematically by JL, JK and DR who are experienced qualitative researchers, using the method of constant comparison [23]. After data collection had

concluded, each team member performed their own independent analyses, reading each participant's interview in full and repeatedly before cross-comparing all interviews to identify common issues and experiences. Team members wrote separate reports before meeting during and after data collection to discuss and reach agreement on key themes and develop a coding frame. The qualitative analysis software package NVivo9 (QSR International, Doncaster, Australia) was used to facilitate data coding and retrieval. Coded datasets were subjected to further, in-depth analyses to identify sub-themes and illustrative quotations.

The trial, including the interview study, was granted NHS ethics approval by the North-West Research Ethics Committee (Liverpool East), approval number 11/H1002/10. To protect participants' identities, identifiers are used below, with N referring to a diabetes specialist nurse and D to a dietitian.

RESULTS

The final sample comprised 12 DSNs and six dietitians who had been working in diabetes care for 5-29 years and who comprised 72% (18/25) of the educators who worked in seven main trial sites. While some staff had considerable experience of working with insulin pumps, others did not and the latter received pump training prior to the trial commencing. All staff were trained educators who delivered the Dose Adjustment for Normal Eating (DAFNE) programme (see Table 1 for full details about the sample). Irrespective of their prior experiences of using insulin pumps, and their training and work role, all staff provided similar accounts of what they considered the potential benefits of CSII over MDI to be together with the kinds of individuals they thought would gain greatest clinical benefit from CSII. All staff, likewise, described how their opinions about individuals' suitability for CSII had been challenged and revised in light of working on the REPOSE trial and exposure to individuals using CSII who they would not have recommended for this therapy in routine clinical practice. Below, we explore these key findings in more detail before considering their implications.

Table 1 – about here

Perceived clinical benefits of insulin pump over MDI and pre-trial notions of pump candidacy

All staff emphasised that a MDI regimen, taught in conjunction with a DAFNE or similar educational approach, offered a very good toolkit for diabetes self-management and that most patients using MDI effectively neither needed nor would achieve additional clinical benefit from CSII :

“I think we can maximize most people on DAFNE and it’s wonderful, we really are DAFNE advocates and we’ve had a lot of improvements and reductions in hypos” (D4).

Hence, staff described how, in routine clinical practice, they would not usually refer people for CSII therapy until they had been given opportunity and support to optimize their glycaemic control using MDI:

“there are some people [using MDI] who probably still haven’t really optimised their control because they’re not really putting everything into practice. So they might have slipped a bit with their monitoring or keeping a diary and really reflecting on what their blood sugars are doing and making adjustments. And a lot of people just need some extra reminders and support with doing that rather than a pump.” (N10)

Clinical candidacy

In their accounts staff also suggested that, by virtue of the constant drip feed of insulin, the ability to adjust and manipulate basal rates and other advanced features on offer, pumps could potentially help some individuals achieve better and more fine-tuned control than would be possible using MDI:

“clearly some of those delivery features have to be more physiologically like, I mean it’s never going to be a pancreas, but some of those ways it can deliver insulin have the potential, for some people, to be very beneficial.” (N5)

Specifically, all staff highlighted the potential clinical benefits of CSII to individuals “whose background insulin cannot meet their changing insulin needs, particularly for the dawn phenomenon” (N9), those who “have severe hypos during the night and they’re on one unit of Levemir twice a day and you’re really not going to make too much difference with that” (D6), and “people who are extremely insulin sensitive, you know, even a half unit adjustment will make the difference between being profoundly hypo or really high” (N2). Relatedly, most staff also pointed to potential benefits for those “with really unpredictable lifestyles where things are constantly changing at the drop of a hat” (N11) and “sporty patients, long distance cyclists, hill climbers...they love the temporary basal feature because these guys are either eating constantly to stop having hypos, which is making them feel rotten, or they are just having so many hypos that they are feeling rotten.” (N1)

However, staff also emphasised that, to gain clinical benefit from a pump, people had to be able to use its features, otherwise, as D4 observed, “they will only use the pump as another method of injecting, so they’ll be just the same as the ordinary MDI patients” (D4). Hence, staff emphasised the importance of education, with some citing examples where, in routine clinical practice, they had encountered individuals who had:

“got a pump, and often they started abroad or in another centre and never received any training, and actually their control isn’t good... they’ve been sitting with one or two basals and they’ve made hardly any changes to those.” (D2)

Staff also suggested that, due to the variety of features on offer, such as those which allowed basal rates to be varied during the day, optimal use of CSII required more skill and effort than MDI:

“It’s a lot harder to use a pump and, although they’ve got the potential to make those really fine adjustments to basal rates, in practice, whether people are able to do [so] is another matter.”(N7)

Hence, staff, including N7 above, described having questioned whether some individuals had the aptitude and ability to make full and effective use of pump technology.

Personal/psychological candidacy

For the above reasons, staff reflected on how, alongside clinical criteria, they had tended to employ tacit and informal criteria when selecting individuals for CSII in routine clinical practice. This second set of criteria, as staff went on to describe, cohered around their perceptions about whether particular individuals had the right personal and psychological attributes to use a pump effectively. Specifically, staff indicated how they had not generally recommended CSII to those who they described as “troublesome and heart sink patients” (D1), even when such individuals had met the clinical criteria. This included those who “have always had poor control, poor compliance, you know, had some education around how to adjust their insulin, but have never achieved anything” (D1), and individuals who disliked putting effort into their diabetes management and, hence, who might expect a pump “to do all of the work” (N8). Staff also described having perceived people as poor candidates for a pump if they belonged to the “older generation” (D2) and/or were “not technical” (D3). Conversely, patients were seen as good candidates if, alongside demonstrating a clinical need, they were “more technically able, possibly that means younger” (N8); and, “more intelligent, you know, sort of educationally able to take on board all of the information needed to use the pump properly” (D3).

Lessons learned from taking part in the trial: revising pre-trial preconceptions

During the trial participant allocation to CSII was determined by a randomization process rather than being informed by staff’s own judgement about an individual’s personal and psychological suitability. As a consequence, as various staff members noted, they were exposed to people using CSII during the trial whom they would not have put forward for this kind of therapy in routine clinical practice:

“What I’ve also noticed, and this is a new thing for me, is that I’ve had patients that I thought previously I would never give a chance on a pump but, because the way the trial’s worked, we’ve given that person a chance.” (N1)

As N1, like others, went on describe, their participation in the trial, which had presented opportunities to observe participants engage with their pumps during the structured

education courses and when they attended follow up sessions, had forced them to take their “blinkers off” (N1) and “open our minds a bit more” as D1 put it. As N2 elaborated, this was by virtue of witnessing individuals “doing really, really well on pump therapy who we would have predicted would have really struggled, you know, ‘oh my god, no way!’” (N2). This included some elderly participants, as well as other individuals who staff had initially assumed would have struggled to assimilate and execute information relating to the use of the pump’s features:

“I have a lady, she’s 72, she came and her first comment to me bless her was, you know, ‘I can’t text. Can’t text.’ And she’s doing really well... So I I’ve stopped having preconceptions about who it will suit.” (N8).

“Some of them, we were worried that they didn’t have the capability to use the equipment to be honest, and they were worried as well. But I’ve found that when you actually sit down and show them it, work your way through it, actually they become more efficient. So in a way I don’t think there’s anyone who couldn’t do well on a pump.” (D4)

Relatedly, staff also described how working on the trial had forced them to question the criteria they had used to predict potential success, by virtue of observing some individuals who were highly educated or technologically savvy using their pump less effectively than others whom they had expected to struggle:

“Some of the ones who you are, you think are very good with the mechanics of the pump and everything, you think ‘oh they will pick it up very quick’, but, actually, it’s too quick, they go off and do all their own thing, whereas the ones who know, who I’m thinking ‘ooh, I don’t know if they’d manage the pump’ you know, that kind of way, in actual fact are perfect, because they do it by the book.” (D4)

As a consequence, staff described how they had revised their views about who should be referred for CSII in routine clinical practice:

“I’ve stopped having pre-conceptions about who it suits. They just have to be engaged and motivated... and we’d only know if we ask them, in terms of how much maybe their diabetes is debilitating them or affecting their daily routine to whether they really felt they needed something different to manage it.” (N8)

In some cases, as N8’s comment highlights, staff suggested that they now saw motivation as being a key criterion for success on CSII, and, hence, that motivational issues should be explored with individuals to help determine whether they should be referred for pump therapy. However, other staff noted observing individuals during the trial who had initially been unmotivated and uninterested in their diabetes, and for whom transitioning to CSII had acted as a tipping point for increased engagement with disease self-management:

“like this girl, we probably would have never have given her a chance to go on a pump, I don’t think anybody would ever have suggested that she went on a pump... She really was struggling, went through a phase of not caring about her diabetes, always put herself down, you know, she was thick, she couldn’t do anything. But actually she can and she’s done really well [on a pump]. She could see the flexibility really worked for her and actually was able to get better control... Really boosted her, really boosted her more and it gave her confidence to think ‘oh I can do this.’” (D1)

“there’s that sort of psycho-social aspect of the pump where they really get more motivated with having this tool that can give them more flexibility.” (N1)

In light of their experiences, these staff concluded that insulin pumps should be made available to all patients who met clinical criteria, because, as N7 summed up:

“you simply can’t predict ... like I say you get a feel for something and you think ‘oh they’ll be fine’ and then they surprise you. And it works both ways ... so [how] are we ever going to know unless we give them all a chance?” (N7)

DISCUSSION

This is the first study to explore, in-depth, health professionals' perceptions of, and views about the kinds of individuals they thought would be most likely to gain clinical benefit from using an insulin pump. Staff described the pump as having the potential to provide some individuals with a better self-management tool than MDI, principally those meeting clinical criteria [6]. However, it was also noted that, due to the diversity of features on offer, CSII is a more complex regimen to execute than MDI. For this reason, staff emphasised the importance of providing comprehensive education and skills training to help ensure individuals use the technology to optimal effect. They also described how, alongside following clinical criteria, they had tended to use a second, more informal set of criteria when recommending or referring particular individuals for CSII therapy in their routine clinical practice. This second set of criteria cohered around staff members' assumptions about whether particular individuals possessed the personal, psychological and technological attributes needed to assimilate pump education and training and apply this to make optimal use of the technology. Staff also described how their preconceptions and assumptions had been challenged as a result of working on the REPOSE trial where a randomization process, rather than their own judgement, had determined who received CSII therapy, and observing individuals using insulin pumps in ways which they had not anticipated and predicted.

The difficulties staff encountered predicting which individuals would make active and effective use of CSII during the trial finds resonance in research undertaken directly with pump users. This includes an interview study by Garmo et al. [9] in which the authors highlighted the challenges of using individuals' own attitudes towards, and experiences of using, insulin pumps to determine which of their study participants (insulin pump users for ≥ 5 yrs) had been able to achieve optimal glycaemic control. Ritholtz et al., who also conducted qualitative research with veteran pump users, did find that individuals who had an active approach to their diabetes self-management tended to have better glycaemic control than those with a more passive approach [14]. However, Ritholtz et al. were unable to explain why some individuals had an 'active' and others a 'passive' approach [14]. Hence, these authors recommended that quantitative research be undertaken with people using CSII to identify and understand factors associated with active engagement [14]. To date,

only a limited number of quantitative studies have been conducted which have sought to explore factors influencing clinical outcomes using CSII, and these have shown both psychological and other variables to have limited predictive value [24, 25]. Similar issues and challenges have also been reported in work undertaken with people who use MDI. This includes a longitudinal questionnaire study conducted with people with Type 1 DM who attended DAFNE courses in the UK and which found that baseline demographic and psychosocial variables had minimal value in explaining improvements in HbA1c at 6 and 12-month follow-up [26].

There is growing impetus in diabetes care to identify predictors of clinical success; that is, the characteristics of individuals who, if given access to CSII (or another regimens), would be most likely to use it to optimal clinical effect [6]. While this kind of agenda is being promoted to help ensure individuals are matched to the most appropriate treatments [25], it is also being done because CSII is a much more expensive option than MDI [6, 27]. Hence, it has been recommended that CSII should only be made available to those individuals who demonstrate a motivation and ability to make full use of the technology [6]. However, a key point arising from this study, particularly when the findings are set alongside those of the studies described above [9, 14, 24, 26], is that identifying patient characteristics which can be used to predict clinical success using an insulin pump is not an easy or straightforward task. Although only preliminary conclusions can be drawn from staff members' own accounts, such a task which might be further complicated by the possibility that, in some cases at least, the pump might itself create the tipping point for an increased engagement in diabetes self-management [5].

Alongside cost considerations, various commentators have raised concerns that, despite the existence of clinical guidelines to help ensure equitable access to CSII, barriers to access continue to exist [7, 8, 28]. In the UK, it has been noted that less than half the individuals with Type 1 DM who meet clinical criteria are currently accessing CSII, although this could be partly due to some individuals not wanting to use an insulin pump [5]. To help explain poor and inequitable access to CSII the existence of a "postcode lottery" has been highlighted [29]. In particular, it has been argued that organizational and resource-related barriers, such as lack of funding for the pump/consumables, lack of availability of

experienced teams to offer clinical support and the absence of clear referral pathways are leading to differential access to CSII therapy [5, 7, 28]. Hence, calls have been made for these barriers to be addressed through increased funding and staff provisioning [28]. What our findings suggest is that, alongside these structural/financial barriers, attitudinal barriers amongst staff may also exist which may further inhibit some individuals from accessing CSII. Hence, to promote equitable access, we would recommend that attitudinal barriers may need to be explored with staff involved in pump referrals, including any stereotypical assumptions they may have about the kinds of people who would be most likely to use an insulin pump effectively.

A key study strength is the use of a qualitative design which enabled identification of issues which were not anticipated at the study's outset, such as health professionals' use of formal (clinical) and informal (personal/psychological) criteria when recommending individuals for CSII. However, to avoid potential problems with recall bias, the study would have been strengthened through use of pre- as well as post-trial interviews. The study benefitted from being incorporated within the REPOSE trial because this resulted in staff being exposed to individuals using insulin pumps who they would not have recommended for CSII in routine clinical practice. However, the study's integration within the REPOSE trial also meant that staffs' exposure was to individuals who were willing to take part in a trial and be randomized and who had no (stated) preference for a pump over MDI; hence these individuals may have comprised unrepresentative patient groups. This study was only able to draw upon the perspectives of dietitians and DSNs. Hence, future research could be conducted with other health professionals involved in pump referrals, such as general practitioners and diabetes consultants. Given the large global variations in pump usage [5, 7, 8], future work undertaken with staff in different countries is also recommended. This could include comparison between countries with particularly high and low use of insulin pumps.

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Figure 1 – The REPOSE trial

REPOSE is a multi-centre, parallel group, cluster RCT, in which 321 adults with T1DM were recruited from eight UK secondary centres. Participants were allocated a space on a 5 day structured education course (DAFNE – Dose Adjustment for Normal Eating) and course groups were then randomly allocated in pairs to pump or MDI treatment. Inclusion criteria included: adults with T1DM for at least a year; willingness to undertake intensive insulin therapy; no stated preference for a pump or MDI; willingness to be randomized; and, a need for structured education to optimize blood glucose control. Participants were excluded from the trial if they had already completed a diabetes education course, used a pump in the past three years or if they had a strong need for pump therapy in the opinion of the investigator (e.g. recurrent disabling hypoglycaemia, elite athlete) p. After attending their pump or MDI courses, patients' clinical care was returned to their routine health care providers who were often the same people responsible for trial recruitment and delivery. Clinical data for the trial are being collected at 6, 12 and 24 months. Recruitment commenced in November 2011 and the trial is due to be completed in July 2015.

Figure 2 – Key areas explored in the interviews

- Previous experiences of working with patients with T1DM and with insulin pumps.
- Perceptions and understandings of insulin pump technology and the perceived benefits and drawbacks of using this technology as compared to MDI regimens.
- Perceptions and views prior to the trial about which kinds of patients would and would not gain clinical benefit from using an insulin pump, and why; (if relevant) how decisions about moving patients onto insulin pumps were made in routine clinical practice.
- Roles and responsibilities on the REPOSE trial; experiences of delivering education and patient care during the trial.
- Views about the randomization process; opinions and views about which patients did and did not benefit from randomization to insulin pump therapy, and why.
- (In light of emerging findings) how, in what ways, and why, routine clinical practice might change as a result of taking part in REPOSE; recommendations for future guidelines for pump therapy.

Table 1: Occupation and levels of experience in diabetes, DAFNE and pump therapy of 18 educators

Characteristic	N	Mean \pm SD & range
Occupation		
Nurse	12	
Dietitian	6	
Experience of working in diabetes care (years)		
Nurse		16.5 \pm 8.2 (6-29)
Dietitian		9.7 \pm 2.4 (5-12)
Experience of DAFNE (years)		
Nurse		8.2 \pm 5.0 (1-15)
Dietitian		7.8 \pm 2.5 (4-11)
Experience of pump therapy (years)		
Nurse		3.25 \pm 4.9 (0-15)
Dietitian		4.2 \pm 4.3 (2-10)