Early adopters' perceptions of a new diabetes medication system: A questionnaire survey

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Article points

1. Diabetes technology research often excludes patients that have psychological or physical barriers to treatment adherence.

2. Early adopters' perceptions of a new diabetes medication system identified that the system was associated with an alteration in participants' perceptions of insulin therapy, an increase in perceived perceptions of personal control, and an increase in adherence to insulin regimen.

Key words

– Adherence

– Insulin

– Technology

Authors

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Psychological and physical factors are barriers to insulin therapy adherence. Insulin delivery devices can help to overcome these barriers; however, research into their use often does not involve human participants, often being undertaken in a laboratory setting, and rarely includes those with impaired ability. Therefore, evidence of the benefits of particular insulin delivery design features for certain individuals within the diabetes population is lacking. The aim of this research, a cross-sectional questionnaire survey, was to identify early adopters' perceptions of a new diabetes medication system.

Psychological and physical factors affect insulin therapy adherence. Psychological insulin resistance (PIR) is the psychological opposition towards insulin use (Nathan et al, 2009). PIR represents complex beliefs about insulin therapy and can account for poor self efficacy regarding the skills required for therapy delivery, injection fears and a lack of accurate information (Polonsky et al, 2005; Brod et al, 2009). Key factors that contribute to PIR include the hassle of injecting oneself (Morris et al, 2005); fears that insulin will severely restrict one's life (Bogatean and Hancu, 2004); and social embarrassment (Peyrot et al, 2010; Broadbent et al, 2011; Peyrot and Rubin, 2011).

Physical factors affecting insulin adherence include cognitive decline, vision loss and impaired dexterity. Individuals with diabetes are twice as likely to develop dementia (Biessels et al, 2006; Strachan et al, 2011) and often forget to take their insulin (Training, Research and Education for Nurses on Diabetes UK [TREND-UK] and Institute of Diabetes for Older People [IDOP], 2013). Seventy-five percent of those who have had diabetes for 10 years or more will develop retinopathy (Public Health England [PHE], 2015), and they are twice as likely to need help

managing medication (McCann et al, 2012). Additionally, approximately 40% of people with diabetes experience polyneuropathy (Vinik et al 2003; Miralles-García et al, 2010), which causes a deterioration in manual skills and dexterity (Pfützner et al, 2011).

Insulin delivery devices can help to overcome both physical and psychological barriers to insulin therapy (Brod et al, 2009; Davies et al, 2013). However, although there is an increasing emphasis on harnessing the needs of users to guide device development and evaluation (National Patient Safety Agency [NPSA], 2010), outcome studies associated with insulin delivery devices often do not involve human participants (research is often undertaken in a laboratory setting) and studies rarely include those with disability (Rubin and Peyrot, 2004; Shelmet et al, 2004).

Evidence of the benefits of specific design features for certain individuals within the diabetes population is therefore lacking. It is particularly pertinent to evaluate insulin delivery devices in this population group as disability and health loss due to diabetes is increasing in the older population (Darbà et al, 2015). The aim of this study is to identify the perceptions of early adopters, people who start using a product or technology as soon as

it becomes available, of a new diabetes medication system.

The diabetes medication system

NeedleBay is developed by Diabetes Care Technology (DCT) Ltd and is a system for controlling and organising diabetes medication, which is available in the UK. It comprises a daily module (*Figure 1*) for dispensing and storing insulin needles. Insulin needles can be attached and removed safely from the insulin pen, and used needles can be emptied touch-free into a sharps bin. Modules are customised to hold two or more needles. A storage case enables needles to be prepared a week in advance. A clear plastic lid lets users see how many injections they have taken and this "proof of use" eliminates the risk of missing injections or double dosing.

Aim

To identify early adopters' perceptions of a new diabetes medication system using a cross-sectional questionnaire survey.

Method
Questionnaire

The questionnaire comprised four sections. Section 1 collected demographic information (age, gender, diabetes type, manual dexterity, eyesight, and the frequency of insulin injections). Sections 2 and 3 asked participants about their experiences before and during use of the new technology. The primary outcome measure was whether participants either missed taking their insulin injection or took a double dose before or during use of the new technology. Secondary outcome measures included how often they experienced needle stick injuries; if they reused their injection needle; if they had difficulties storing used needles and attaching or removing their insulin pen from the needle; and whether respondents felt in control of their medication. Participants were also asked whether using the system had helped prevent an incorrect insulin dose being taken, and whether they believed the new technology to be an essential part of their insulin regimen (tertiary outcome measures). Six-point unipolar Likert scales and fixed choice "yes/no" answers were used to score each outcome.
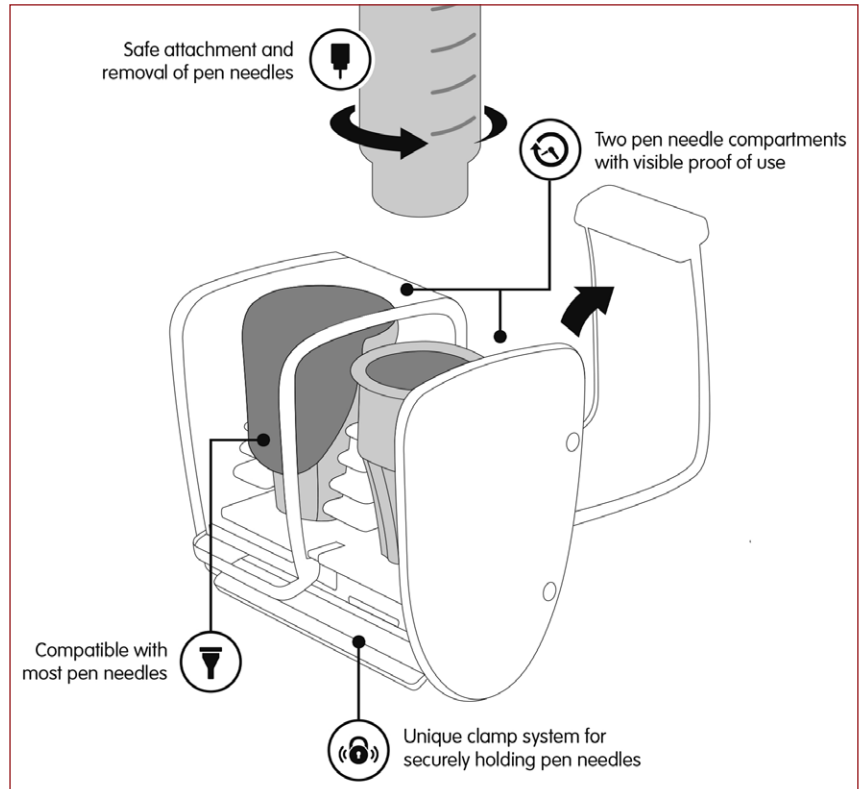

Figure 1. The diabetes medication system.

Section 4 asked participants to identify three main benefits of the system (tertiary outcome measures). Cognitive interviewing (Drennan, 2003) was undertaken with six users to validate sections 2 and 3 of the questionnaire and ensure that questions dealt with system features that were relevant for users. The questionnaire was piloted on 12 users. Only minor revisions were necessary.

Participants

All users of the new technology were contacted by DCT Ltd and invited to participate in the research. With users' permission, the contact details of those who expressed an interest, were passed to the research team. The median time from adoption of the new technology to conducting the survey was 6 months (minimum 6 months, maximum 35 months).

Data collection

All users who expressed an interest to take part were contacted by a researcher who provided information about the study, answered any queries

Box 1. Statistical methodology.

A McNemar hypothesis test for paired proportions was conducted on data collected in sections 2 and 3 and the effect measure expressed by odds ratios (logit method). Binary logistic regression was used to examine the relationship between: a) the introduction of the device and the odds of adhering to treatment schedule for each demographic group (age, gender, diabetes type, injection frequency, dexterity, poor eyesight); b) demographic group and the perceptions held by participants that proof of use helped prevent an incorrect insulin dose being taken and that the new technology was essential to their insulin medication regimen. For paired outcomes (before and after responses from the same respondent), a marginal binary logistic regression was used. Both the power study and the binary logistic regressions were conducted in SAS 9.4.

they had, and confirmed their willingness to participate, prior to conducting the questionnaire survey over the telephone. Data were collected between May 2015 and July 2015. Cardiff University Research Ethics Committee approval was obtained for the study.

Data analysis

The study was powered on the primary outcome defined by the question, "How often did you either miss taking an injection or mistakenly take

a double dose, before and after using the new technology?" The primary outcome was binary, coded as "never" or "not never" and paired, as each respondent provided a before and during use response. Pilot work provided input for the power study. At a nominal 5% significance level (a two-sided conditional McNemar test for paired proportions, assuming a reference proportion of 0.15 and a pairwise correlation of 0.2), a total sample size of 125 valid returns has 90% power to detect an effect size of at least 2.5 odds ratio units. There were 219 valid returns (i.e. 219 respondents replied to both sections 2 and 3). For full details of the statistical methodology see *Box 1*. Content analysis was used to analyse the free text comments in section 4.

Results

A total of 332 individuals were registered on the database, and 226 (68%) responded to the invitation to participate. The average age of participants was 57 years, and 62% were male, 62% had type 2 diabetes, and 38% had type 1 diabetes.

Outcome measures

Before the introduction of the new diabetes medication system, 31% of participants reported that they had never missed taking their insulin injection or had never mistakenly taken a double dose. Following the introduction of the system, 81% of participants had not missed a dose or taken a double dose (odds ratio [OR], 7.5; 95% confidence interval [CI], 4.9–11.3; *P*<0.001). This suggests a strong association between the introduction of the device and the odds of adhering to the treatment schedule. A summary of the results from the questionnaire for primary and secondary outcomes are reported in *Table 1*. All demographic groups responded similarly to the introduction of the new technology with regards to adherence to treatment schedule.

Following the introduction of the new technology, 176 participants (77.9%) reported that the system was essential to their insulin regimen. On a sliding scale of age, the younger the respondent, the higher the odds of believing that the new technology was essential: the OR for someone 5 years younger was 1.28 (95% CI, 1.2–2.26) and the odds for someone 10 years younger was 1.65 (95% CI, 1.2–2.26).

Table 1. Experiences before and during use of the new diabetes medication system (primary and secondary outcome measures).

Primary and secondary outcomes measures	Before* (%)	During use* (%)	*P* value	Odds ratio	95% confidence intervals	
I never miss taking my insulin injection or mistakenly take a double dose	31.0	80.8	<0.001	7.5	4.9	11.3
I never prick myself while attaching or removing the insulin pen from the needle	24.6	91.8	<0.001	8.7	6	12.6
I never reuse my insulin pen needle	56.8	90.5	<0.001	9	5.3	15.2
I never find it difficult to store used needles when out and about	37.9	96.3	<0.001	8.4	5.7	12.5
I never have difficulties attaching or removing my insulin pen from the pen needle	67.1	94.9	<0.001	5.9	3.5	10
I generally feel in control of my diabetes medication	81.7	99.1	<0.001	9	4.3	18.8

*% of participants before and during use of the diabetes medication system.

Someone with type 2 diabetes was nearly 3 times more likely to find the system essential than someone with type 1 diabetes (OR, 2.9; 95% CI, 1.4–6.0; P=0.0056). People who reported their eyesight as poor were also nearly three times more likely to find the system essential than someone who did not report their eyesight as poor (OR, 2.9; 95% CI, 1.1–7.9; P=0.0375).

Following the use of the new technology, 71% of respondents reported that proof of use of the pen needle had prevented them taking a duplicate dose of insulin. People with type 2 diabetes were 2.5 times more likely to report that the new technology had prevented them from taking an incorrect dose of insulin than some one with type 1 diabetes (95% CI, 1.4–4.5; P=0.0026).

The main benefits of the system as reported by participants were the prevention of an incorrect insulin dose being taken (24%), safety (i.e. fewer needle stick injuries; 20%) and ease of travel and transport (16.4%) and use (14%).

Discussion

Features of the diabetes medication system improved insulin treatment experience for a high number of users. There were fewer reported needle stick injuries, fewer difficulties attaching and removing the insulin pen from the needle, pen needles were reused less frequently and there were fewer needle storage problems. Reminder/proof of use, ease of use and convenience were reported benefits.

Delivery devices are extremely important to patients' perceptions of treatment utility and convenience (Niskanen et al, 2004). They can counter some of the factors that contribute to PIR (Korytkowski et al, 2003; Rubin and Peyrot, 2004), enhance convenience of insulin administration (Rubin and Peyrot, 2004), increase perceptions of personal control (Graff and McClanahan, 1998) and increase adherence (Peyrot et al, 2005). This diabetes medication system appears to have altered participants' perceptions of insulin treatment, increased perceived perception of personal control, and in turn, increased adherence to the insulin regimen.

High numbers of participants reported their experience of insulin therapy to be improved following the use of the system. All demographic groups benefited similarly from the introduction

of the device with regards to adhering to the treatment schedule. Although the majority of the sample perceived the new technology to be essential, this was particularly so amongst younger participants, those with type 2 diabetes and those with poor eyesight. Similarly, although proof of use was reported by most of the sample to prevent an incorrect insulin dose from being taken, this was reported by higher numbers of participants with type 2 diabetes. Therefore, it could be suggested that certain features of the system were perceived as particularly useful by different sub-groups of the study population (including those with impaired ability).

Further research of the effect of the new diabetes system on adherence to insulin regimen is required. Such research should intentionally recruit people commonly represented in the diabetes population, including those with disability. Demographic factors should be analysed in relation to patient-reported outcome variables identified in this research. The system can then claim benefit for persons with specific impaired capability.

Implications for clinical practice

This new device provides a simple system whereby patients, healthcare professionals and carers, can monitor insulin administration, identify non-adherence issues, and so take appropriate action to help achieve better glycaemic control. Furthermore, evidence of improved insulin adherence provided by this and other new technology, could help to ensure more accurate titration of insulin doses when

Table 2. Reported benefits of the diabetes medication system.

Benefits	% of participants
Reminder/proof of use prevented an incorrect insulin dose being taken	24.1%
Safety (i.e. fewer needle stick injuries)	19.6%
Easy to transport and travel	16.4%
Safe storage of needles	15.6%
Ease of use	13.7%
Convenience	5.6%
Control of insulin regimen	3.2%
Simplified insulin regimen	1.8%
Number of responses	**100%**

"The described new system was associated with an alteration in participants' perceptions of insulin therapy, an increase in perceived perceptions of personal control and an increased insulin adherence."

needed, and better blood glucose control could assist in improving health outcomes.

Limitations

The self-reported data relied on patient recall and information, such as missed insulin dose, is likely to be estimated. The authors did not know prior treatment strategy or the time participants had been on insulin, which may have affected the patient-reported outcomes. Also, over a third of participants had type 1 diabetes, which is higher than the 10% national picture.

Conclusion

The described new system was associated with an alteration in participants' perceptions of insulin therapy, an increase in perceived perceptions of personal control and an increased insulin adherence. Given that four-fifths of NHS diabetes spending goes on treating the complications of diabetes (Diabetes UK, 2012), complications that could be reduced by insulin adherence, it is vital that insulin adherence is improved. Further effectiveness studies are required so that healthcare professionals can evaluate the use of the new technology for a full range of their patients. This is particularly important in the growing ageing population, in whom insulin dose is often intensified and more complex, and health loss increases. ∎

Author contribution

MC, JC and SB were responsible for the study conception and design, and questionnaire development. AL was responsible for the analysis and interpretation of the data. All authors participated in the drafting of this manuscript and have approved the final manuscript.

Biessels GJ, De Leeuw FE, Lindeboom J et al (2006) Increased cortical atrophy in patients with Alzheimer's disease and type 2 diabetes mellitus. *J Neurol Neurosurg Psychiatr* **77**: 304–7

Bogatean MP, Hancu N (2004) People with type 2 diabetes facing the reality of starting insulin therapy: factors involved in psychological insulin resistance. *Pract Diabetes Intern* **21**: 247–52

Broadbent E, Donkin L, Stroh JC (2011) Illness and treatment perceptions are associated with adherence to medications, diet, and exercise in diabetic patients. *Diabetes Care* **34**: 338–40

Brod M, Kongsø JH, Lessard S, Christensen TL (2009) Psychological insulin resistance: patient beliefs and implications for diabetes management. *Qual Life Res* **18**: 23–32

Darbà J, Kaskens L, Detournay B et al (2015) Disability-adjusted life years lost due to diabetes in France, Italy, Germany, Spain, and the United Kingdom: a burden of illness study. *Clinicoecon Outcomes Res* **7**: 163–71

Davies MJ, Gagliardino JJ, Gray LJ et al (2013) Real-world factors affecting adherence to insulin therapy in patients with type 1 or type 2 diabetes mellitus. *Diabet Med* **30**: 512–24

Diabetes UK (2012) *NHS spending on diabetes 'to reach £16.9 billion by 2035'.* Diabetes UK, London. Available at: http://bit.ly/2gXYPBG (accessed 06.10.16)

Drennan J (2003) Cognitive interviews; verbal data in the development and pre-testing of questionnaires. *J Adv Nurs* **42**: 57–63

Graff MR, McClanahan MA (1998) Assessment by patients with diabetes mellitus of two insulin pen delivery systems versus a vial and syringe. *Clin Ther* **20**: 486–96

Korytkowski M, Bell D, Jacobsen C, Suwannasari R (2003) Multicenter, randomized, open-label, comparative, two-period crossover trial of preference, efficacy, and safety profiles of a prefilled, disposable pen and conventional vial/syringe for insulin injection in patients with type 1 or 2 diabetes mellitus. *Clin Ther* **25**: 2836–48

McCann RM, Jackson AJ, Stevenson M et al (2012) Help needed in medication self-management for people with visual impairment: case-control study. *Br J Gen Pract* **62**: e530–7

Miralles-García JM, de Pablos-Velasco P, Cabrerizo L et al (2010) Prevalence of distal diabetic polyneuropathy using quantitative sensory methods in a population with diabetes of more than 10 years' disease duration. *Endocrinol Nutr* **57**: 414–20

Morris JE, Povey RC, Street CG (2005) Experiences of people with type 2 diabetes who have changed from oral medication to self-administered insulin injections. *Practical Diabetes International* **22**: 239–43

Nathan DM, Buse JB, Davidson MB et al (2009) Medical management of hyper-glycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* **32**: 193–203

Niskanen l, Jensen LE, Råstam J et al (2004) Randomized, multinational, open-label, 2-period crossover comparison of biphasic insulin aspart 30 and biphasic insulin lispro 25 and pen devices in adult patients with type 2 diabetes mellitus. *Clin Ther* **26**: 532–40

NPSA (2010) *Design for patient safety: User testing in the development of medical devices.* NPSA, London

Peyrot M, Rubin RR (2011) Perceived medication benefits and their association with interest in using inhaled insulin in type 2 diabetes: a model of patients' cognitive framework. *Patient Prefer Adherence* **5**: 255–65

Peyrot M, Rubin RR, Lauritzen T et al (2005) Psychosocial problems and barriers to improved diabetes management: results of the cross-national Diabetes Attitudes, Wishes and Needs (DAWN) Study. *Diabet Med* **22**: 1379–85

Peyrot M, Rubin RR, Kruger DF, Luther BT (2010) Correlates of insulin injection omission. *Diabetes Care* **33**: 240–5

Pfützner J, Hellhammer J, Musholt P et al (2011) Evaluation of dexterity in insulin-treated patients with type 1 and type 2 diabetes mellitus. *J Diabetes Sci Technol* **5**: 158–65

Polonsky WH, Fisher L, Guzman S et al (2005) Psychological insulin resistance in patients with type 2 diabetes: the scope of the problem. *Diabetes Care* **28**: 2543–5

Public Health England (2015) *Diabetic eye screening programme.* Public Health England, London. Available at: https://www.gov.uk/topic/population-screening-programmes/diabetic-eye (accessed 15.10.15)

Rubin R, Peyrot M (2004) Quality of life, treatment satisfaction, and treatment preference associated with use of a pen device delivering a premixed 70/30 insulin aspart suspension (aspart protamine suspension/soluble aspart) versus alternative treatment strategies. *Diabetes Care* **27**: 2495–7

Shelmet J, Schwartz S, Cappleman J et al (2004) Preference and resource utilization in elderly patients: InnoLet versus vial/syringe. *Diabetes Res Clin Pract* **63**: 27–35

Strachan, MW, Reynolds RM, Marioni RE, Price JF (2011) Cognitive function, dementia and type 2 diabetes mellitus in the elderly. *Nat Rev Endocrinol* **7**: 108–14

TREND-UK, IDOP (2013) *Diabetes and dementia: Guidance on practical management 2013.* TREND-UK and IDOP, London

Vinik AI, Maser RE, Mitchell BD, Freeman R (2003) Diabetic autonomic neuropathy. *Diabetes Care* **26**: 1553–79