Evaluating the impact of an insulin pump discontinuation action plan on patient or caregiver confidence and anxiety

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Abstract

Aims Insulin pump failure and adverse events are common and therefore anticipatory education is recommended. Research in other chronic diseases shows written action plans improve confidence and adherence during an acute deterioration. However, no similar data exists for patients with type one diabetes mellitus provided with anticipatory education via an insulin pump action plan. This study evaluates whether an insulin pump action plan improves patient and caregiver confidence in managing a potential pump failure without a subsequent increase in anxiety.

Methods Adults with type one diabetes mellitus and caregivers of children with type 1 diabetes on continuous subcutaneous insulin infusions across four New Zealand diabetes services participated. Participants completed a questionnaire examining pump-related adverse events and self-reported confidence and anxiety in managing pump failure. An insulin pump action plan and focused education by their diabetes team was provided, with a follow-up questionnaire at least 3 months later.

Results 174/270 pump patients participated initially, with a follow-up response rate of 84.5% (147/174). Despite prior provision, many could not recall having an insulin pump action plan at study commencement (101/174, 58%), and of these 92% stated they would have liked one. Patients had good levels of confidence in the reliability of their pump and infusion sets/sites (Likert scores of 4.4/5 and 3.95/5) which was not undermined by the insulin pump action plan. Confidence in managing a potential pump failure showed a small but significant increase (3.66/5 to 3.95/5, $p = 0.004$) present in both adults and parents, with anxiety also showing a small increase (2.16/5 to 2.38/5, $p = 0.012$).

Conclusion Patient recall of prior insulin pump action plan education is poor, with the vast majority of patients interested in further written anticipatory education regarding potential pump failure. The provision of an insulin pump action plan increases self-reported confidence in managing unexpected pump failure with a small associated increase in anxiety.

Keywords Action plan · Caregiver · CSII · Insulin pump · Malfunction · Management plan

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Abbreviations

AP	action plan
CSII	continuous subcutaneous insulin infusion
DKA	diabetic ketoacidosis
IPAP	insulin pump action plan
MDI	multiple daily injections
NZE	New Zealand European

Introduction

Following landmark studies such as the Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Interventions and Complications (EDIC) Trial

[1–4], intensive diabetes management has become the standard of care in both adults and children with type 1 diabetes. This evolution to intensive management has led to substantial improvements in insulin pump (continuous subcutaneous insulin infusion [CSII]) and related technology, which now play an increasing role in modern diabetes management [5, 6].

The theoretical advantage of CSII is to mimic physiological insulin release and allow flexibility in timing and amount of insulin depending on nutrition and physical activity [7]. The use of CSII is associated with a modest improvement in HbA1c of 0.2–0.5% [8, 9], a decreased risk of microvascular disease [10], and an improvement in quality of life with high patient satisfaction [7] compared to multiple daily injections (MDI). It also offers advantages in minimizing episodes of severe hypoglycaemia, nocturnal hypoglycaemia and frequency of diabetic ketoacidosis (DKA) [8, 11, 12].

However, CSII is also associated with adverse events, with early studies revealing cutaneous infections, ketoacidosis and hypoglycaemia [13]. As the technology has improved, this adverse event profile has changed; with the rate of hypoglycaemia decreasing, and hyperglycaemia and/or DKA now predominantly seen. Complication rates (mostly minor) have been reported to occur in 40% to 84% of patients/year [14–16] and include problems with the pump itself, set/site failures such as kinking or blockage, and infusion site/cutaneous issues such as lipohypertrophy and infection [14–18]. While most are minor, some adverse events can result in hospitalisation [14–17, 19].

In addition, in the event of complete pump failure, the average time to pump replacement is reported to be two to three days [14, 17]. Therefore, with all of the above reasons combined, it is imperative that patients receive anticipatory guidance on how to manage their diabetes and insulin requirements in the event of an unexpected pump or infusion site failure. However, no previous studies have been conducted examining whether this is occurring, nor the impact of this anticipatory education. Previous studies in children with other chronic illnesses such as asthma have demonstrated caregivers with written action plans feel more capable, confident and safe in the event of an exacerbation or deterioration [20–22]. They also have better symptom control, less acute care visits [23], and increased adherence to prescribed treatment and medical follow up [24]. This suggests that a similar written action plan may benefit patients and their families when using CSII. With this in mind, we implemented a written insulin pump action plan (IPAP) in both adults and children with type 1 diabetes on established CSII, and evaluated its impact on patient/family self-reported confidence and anxiety with regard to potential future unexpected insulin pump adverse events or discontinuation. The hypothesis being that a written IPAP will improve patient and caregiver confidence in managing an unanticipated pump failure without increasing associated anxiety.

Subjects and methods

Paediatric and adult patients with type 1 diabetes using CSII were recruited from December 2014 to February 2016, from four diabetes services across New Zealand. Of the multiple sites, these included four of the six largest cities in New Zealand, and were university-affiliated. Three of the five hospitals operating from these services were tertiary centres (Auckland, Wellington and Dunedin) with both paediatric and adult endocrinologists present. Across these units at the time the study was conducted, CSII was the treatment method for 130 children (approximately 30% of total clinic population) and 140 adults (approximately 10% of total clinic population).

Study Inclusion criteria were children (<18 years) and adults (≥18 years) with confirmed type 1 diabetes on CSII for at least 12 weeks prior to study intervention. Patients were recruited from the clinic waiting rooms prior to routine clinic appointments or by direct approach by the investigators, with written consent gained prior to entry into the study.

All eligible patients were part of multidisciplinary teams composed of medical staff, diabetes nurse specialists/educators, dietitians, and psychology/social work services. All patients had undergone an appropriate CSII education program (“pump start”). Basic pump trouble-shooting and disconnection dosing plans were provided as part of this initial education, including emergency contacts for 24-h, 7 days-per-week medical phone support, and 24-h technical support provided by the relevant insulin pump manufacturer.

Patients (or their self-nominated caregivers, which included parents and guardians of the paediatric population, and a small number of partners of the adult population) who consented to the study were asked to complete a questionnaire in English by paper or online (via Survey Monkey TM, Palo Alto, CA, USA). Data were collected on self-reported anxiety and confidence in the reliability of the pump, the infusion set/sites, and their confidence in managing an unexpected pump failure using 5 point Likert scales (in a manner similar to previous asthma action plan research [22]). A response of 1 on the Likert Scale represented “not at all confident” or “not at all anxious”, a response of 3 was “neutral”, and a response of 5 represented “very confident” or “very anxious” respectively. Basic demographic information including name, age, gender, and ethnicity was collected from the questionnaire. Ethnicity was classified according to categories as per the New Zealand census, including if multiple ethnicities were selected, a patient was assigned to a single category following a hierarchical system of classification (prioritized ethnicity). Self-reported frequency of pump-related adverse events in the previous 12 months was also collected and has been published previously [16]. Further clinical data including date of diagnosis of type 1 diabetes, length of time using the insulin pump and socio-demographic data were collected from hospital

records. The most recent clinic HbA1c using Siemens DCA 2000 analyser was also collected.

The intervention involved a personalised written “Insulin Pump Action Plan” (Appendix Fig. 1). This comprised a wallet summary card and a single double-sided A5 page including insulin basal, bolus and total daily doses, carbohydrate ratios, insulin sensitivity factors, and essential phone numbers for team and company technical support. A flow chart for managing hyperglycaemia and ketosis in the event of a pump/set/site issue was also included. Each participant or caregiver received a short education session with a member of the Diabetes Team (either an Endocrinologist, Paediatrician or Diabetes Nurse Specialist) which explained the IPAP and ensured all needed consumables were prescribed (in event of temporary reversion to injection therapy). The education session involved explaining the purpose of the IPAP, a review of the patient and caregivers’ understanding of insulin requirements (both using CSII and MDI), insulin sensitivity factor and carbohydrate ratios, a review of how to manage hyperglycaemia and ketosis, and ensuring the patient had access to the supplies required to manage an unexpected pump failure. The patients then repeated the questionnaire at least 3 months after the implementation of the IPAP.

Statistical analyses

Appropriate summary statistics are provided for all variables of interest (means and standard deviations for normally distributed continuous variables, medians and 25th and 75th percentiles for non-normally distributed continuous variables, and counts and percentages for categorical variables). The paediatric and adult populations were compared in terms of their characteristics (except for age and duration since diagnosis as these naturally differ between these groups) using Mann–Whitney–Wilcoxon tests and Chi-squared/Fisher’s Exact tests, as appropriate. Likert scale data are presented as mean values and compared using Wilcoxon signed-rank tests in order to compare interval differences. Statistical analyses were performed using Stata (version 14.1; StataCorp, College Station, TX) and R statistical software version 3.4.0 using the lme4 library [25, 26], with two-sided (when available, otherwise one-sided) $p < 0.05$ considered statistically significant in all cases.

Results

Responses were obtained from 174 of the 270 eligible participants, giving an initial response rate of 64.4%. The response

Table 1 Baseline patient demographics

	Adult (<i>n</i> = 83)	Child ^a (<i>n</i> = 91)	Total (<i>n</i> = 174)	<i>P</i> value
Age, years (mean (SD))	45.5 (15.2)	11.8 (4.1)	27.9 (20.1)	
Diabetes duration, years (mean (SD))	25.7 (14.3)	5.9 (3.3)		
Pump duration, months (median (25th, 75th percentile))	20.2 (14.0, 81.3)	18.5 (7.7, 37.6)		0.010 ^b
HbA1c (median (25th, 75th percentile)) mmol/mol	58 (62, 64)	61 (55, 68)		0.034 ^c
%	7.5 (7.8, 8.0)	7.7 (7.2, 8.4)		
Sex				
Female	52 (63)	42 (46)	94 (54)	
Male	31 (37)	49 (54)	80 (46)	0.029 ^d
Ethnicity				
NZE	80 (99)	83 (93)	163 (96)	
Maori	1 (1)	4 (5)	5 (3)	
Samoan	0 (0)	2 (2)	2 (1)	
Centre				
Auckland	24 (29)	0	24 (14)	
Wellington	0	9 (10)	9 (5)	
Tauranga	0	29 (32)	29 (17)	
Dunedin	59 (71)	53 (58)	112 (64)	
NZDep2006 ^e , <i>n</i> (%)				
Deciles 1–3	41 (49)	42 (46)		0.52 ^c
Deciles 4–7	34 (41)	35 (38)		
Deciles 8–10	8 (10)	14 (15)		
Pump Type				
Animas	68 (81.9)	78 (85.7)	146 (83.9)	0.59 ^d
Medtronic	13 (15.7)	9 (9.9)	22 (12.6)	
Roche	1 (1.2)	3 (3.3)	4 (2.3)	
Dana	1 (1.2)	1 (1.1)	2 (1.1)	
Set and Site				
Auto-inserting ^f	38 (46)	43 (48)	81 (47)	0.79 ^c
Self-inserting ^g	45 (54)	47 (52)	92 (53)	

All values are *n* (%) unless otherwise specified

^a Response from caregiver of child; ^b Mann–Whitney–Wilcoxon; ^c Chi squared; ^d Fisher’s Exact tests; ^e NZDep2006, New Zealand Deprivation Index – a marker of socioeconomic deprivation; ^f Auto-inserting – includes Inset II, Inset 30, ParadigmQuick-Set, Paradigm Silhouette, Accu-ChekFlexLink, Paradigm MIO; ^g Self-inserting – includes Rapid D link, Contact D, Comfort short

rates by centre were: Auckland adults: 34.3% (24/70); Dunedin adults: 84.3% (59/70); Wellington paediatrics: 20.0% (9/45); Tauranga paediatrics 96.7% (29/30); and Dunedin paediatrics: 96.4% (53/55). Basic patient demographics are shown in Table 1. The median duration between the implementation of the IPAP and the follow up survey was 100 days (range 85 - 331 days). The response rate for the follow up questionnaire after the IPAP was 84.5% overall (147/174) and varied between sites from 55.6% to 96.2%.

Although individualised written action plans were previously provided at the initiation of pump therapy, 101/174 (58%) of respondents did not recall having a prior IPAP. Comparing adult and paediatric populations, slightly more caregivers of children with type 1 diabetes (47/91, 51.6%) still had their original action plan from their “pump start” in place, whereas the majority of adults (51/83, 61.4%) did not recall receiving this education. Of those who could not recall having a prior IPAP, 91/98 (92%) stated they would like access to one.

As a reflection of support needed / provided, Table 2 shows the number of patients who had utilised telephone support over the prior 12 months (from 1st questionnaire date) either via the insulin pump manufacturers’ help line, or via the local hospital diabetes team. The number of patients were similar between the adult and paediatric groups, with 78/174 (44.8%) calling the insulin pump help line and 57/174 (32.8%) calling the local diabetes team for advice overall. The utilisation of support services following the institution of the IPAP decreased to approximately 19% of respondents (19.0% utilised the insulin pump manufacturers help line, and 18.4% utilised the hospital diabetes team), with similar rates in adult and paediatric populations. However this is over a shorter time period (median time period 100 days, range 85–331) than the initial questionnaire (12 months), so comparison of rates should be interpreted with caution.

Patients had good confidence in the reliability of their pump (Table 3) with adults giving a mean Likert Scale score of 4.35/5 and paediatric patients a score of 4.45/5. Overall (in both adults and caregivers of children

combined) there was a small but significant decrease in Likert Scale mean values from these high baseline values after the implementation of the IPAP (Table 3). Confidence in the reliability of infusion sets/sites was generally high for adults (3.91/5) and caregivers of children (3.99/5) at baseline and remained unaffected by the IPAP. Baseline confidence in managing CSII failure was similar between the adult and paediatric patients. Following implementation of the IPAP there was a significant increase in overall combined mean Likert scores (3.66/5 to 3.95/5, $p = 0.004$), particularly in parents (3.68/5 to 3.96/5, $p = 0.012$). Anxiety levels with regard to potential pump adverse events/discontinuation were generally low, but statistically rose from baseline following implementation of the IPAP (2.16/5 to 2.38, $p = 0.012$).

Discussion

This study is the first to investigate the addition of an individualised anticipatory IPAP for patients with diabetes using CSII. The main findings are that recall of prior IPAPs or prior anticipatory education is low, despite all patients having received this previously. In those who could not recall prior education, the vast majority wanted it. Confidence in managing a potential future pump failure was generally increased by providing an IPAP without changes in confidence in the reliability of the set/site infusion sets, but came at a cost of a small decrease in confidence in the reliability of the pump and a small increase in anxiety regarding future possible pump failure which, given its magnitude, was likely of little clinical significance.

Half of all patients do not recall having had a prior IPAP despite being provided with this at pump initiation (participant mean pumping duration of 18.5 to 20.2 months). In addition, of those who could not recall this prior education and plan, the vast majority (92%) wanted this education. This poor recollection may relate to the considerable volume of new information given at the time of a pump start, and suggests there is value in giving this written anticipatory guidance and repeat/updated education/IPAPs over time, and suggest in the first few months following commencement and then annually. Further support of this concept is the prior similar findings for asthma action plans (using similar methodology to this study) [20, 21, 24], the high rates of published pump adverse events [14, 16, 17], and the large proportion of participants in this study who required health care services and assistance with their pumps over the preceding year, with 44.8% contacting insulin pump manufacturers, and almost one third contacting their hospital diabetes team for assistance. An admission rate due to a pump adverse event in the previous 12 months in these participants was also previously reported at 9.8% [16]. Further, insulin requirements are dynamic,

Table 2 Telephone use of support service (in 12 month period prior to IPAP)

		Adult (n = 83)	Child ^a (n = 91)	Total (n = 174)
Pump company	No	44 (53.0)	50 (54.9)	94 (54.0)
	Yes	37 (44.6)	41 (45.1)	78 (44.8)
	Don't Know	2 (2.4)	0 (0.0)	1 (0.6)
Hospital diabetes team	No	49 (59.0)	59 (64.8)	108 (62.1)
	Yes	28 (33.7)	29 (31.9)	57 (32.8)
	Don't Know	6 (7.2)	3 (3.3)	9 (5.2)

All values are n (%)

^a Response from caregiver of child

Table 3 Patient/Caregiver self-reported confidence and anxiety relating to pump/infusion sets/sites

	Adult			Child ^a			Total		
	Before AP	After AP	p value	Before AP	After AP	p value	Before AP	After AP	p value
Confidence in reliability of pump	4.35	4.32	0.33	4.45	4.26	0.07	4.40	4.29	0.049
Confidence in reliability of sets/site	3.91	3.97	0.95	3.99	3.78	0.10	3.95	3.87	0.23
Confidence in managing pump failure	3.65	3.93	0.10	3.68	3.96	0.012	3.66	3.95	0.004
Anxiety ^b	2.17	2.37	0.09	2.15	2.38	0.07	2.16	2.38	0.012

5 point Likert Scale (1=“not at all confident or “not at all anxious”, 5 = “very confident” or “very anxious”)

^a Response from caregiver of child; ^b Anxiety related to potential adverse event/pump failure

especially in the paediatric population, which provides another reason for a repeat annual IPAP.

The findings of this study also emphasise that most patients and their families have a good level of confidence in the reliability of both the pump itself and the sets and sites available, and this is not undermined to an important degree by implementation of the IPAP. Patients and their families also have a moderate level of confidence in managing an unexpected total pump failure, with a small but significant enhancement following the implementation of the IPAP. This provides further evidence for the concept of an IPAP as part of pump-adverse event anticipatory guidance, as previously recommended in other studies [15, 16]. It is also a relatively cheap and simple tool to implement in the clinical setting. Although generally anxiety levels regarding a future unexpected pump malfunction were low, the implementation of the IPAP was associated with a statistically significant increase in anxiety, although the magnitude of this rise is of unlikely clinical importance. However, this study only reports on surrogate outcomes, as do the prior studies on asthma action plans (which are part of standard clinical practice). Whether or not this improved confidence and added knowledge translate into better clinical outcomes, and reduced hospitalisations for adults and children following a pump-related adverse event remains to be established, and given the numbers required in a study to show this, is unlikely to be conducted.

Strengths of this study are that it evaluates anticipatory written education for the first time, and includes a mixture of paediatric and adult patients in a multicentre design. There is a reasonable response rate (64.4%) to the original questionnaire, and a high response rate (84.5%) for the follow-up questionnaire which allows paired comparisons of the interval change in Likert Scales of confidence and anxiety levels. Although the questionnaires were not anonymised, they were completed in private rather than a face-to-face interview which may remove the bias associated with a “desire to please”. There are some limitations which may hinder the generalisability of results. As aspects of the study were conducted on a retrospective basis, recall

bias could confound results to some extent. The anxiety questions are also not based on validated anxiety tools, but specific to insulin pump failure. The IPAP was limited to literate patients who speak English. Also different centres throughout New Zealand and the world have different patient demographics, especially for ethnicity and literacy, and therefore our respondents may not be representative of the all those on CSII.

In conclusion, patients using insulin pumps have a poor recall of previous insulin pump discontinuation/adverse event education and adverse event/discontinuation action plans. Despite this, the vast majority of patients would like one. Due to patients’ and caregivers’ limited recollection of prior IPAPs, IPAPs and anticipatory education should be revisited regularly in clinical practice, perhaps yearly. When provided in the context of structured diabetes care, educational input and follow-up, an individualised IPAP can enhance confidence in managing an unexpected insulin pump discontinuation, without leading to a clinically important rise in adverse event related anxiety.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standard Ethical approval for this study was granted by the University of Otago Human Ethics Committee (H14/089).

Human and animal rights All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed consent Informed consent was obtained from all patients prior to their inclusion in the study.

Appendix

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Te Whare Wānanga o Ōtago
NEW ZEALAND

Patient name: _____

NHI: _____

DOB: _____

Pump Type: _____

Action plan date: _____

Insulin Pump Discontinuation Action Plan

For various reasons you may need to stop using your pump and switch back to injections. If this is required the following is a guide to assist with this process. This should be updated annually.

Consult your diabetes team (below) if you are not sure or having trouble adjusting the doses.

Technical support/pump troubleshooting can be provided by the appropriate 24 hour company support (below) and in many instances may resolve the issue.

The doses below are a starting point only and adjustments are then made according to monitoring, food intake, exercise etc. Extra monitoring is essential to guide these adjustments, including overnight monitoring initially.

If you/your child is unwell – consult your doctor, or call 111 in an emergency.

Temporary pump discontinuation injection dosing

Long acting insulin	<input style="width: 90%;" type="text"/>	Dose	<input style="width: 90%;" type="text"/>	Frequency	<input style="width: 90%;" type="text"/>
Novorapid / Humalog dosing					
	Breakfast	Lunch	Dinner		
Carb Ratios	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>		
ISF (CF)	<input style="width: 90%;" type="text"/>		<input style="width: 90%;" type="text"/>		
Pump TDD	<input style="width: 90%;" type="text"/>	units /day	Pump Total Basal	<input style="width: 90%;" type="text"/>	units/day

Essential phone numbers in event of pump discontinuation/problem

Animas 24 hour technical support	0508 634 103
Medtronic 24 hour technical support	0800 663 487
Paediatric Registrar Dunedin Hospital (after hours)	(03) 474 0999
Diabetes Nurse Specialist (work hours)	027 498 4519

Fig. 1 Written insulin pump action plan

Managing HYPERGLYCAEMIA while on a pump

When using pump therapy high blood sugars are serious – particularly if ketones are positive.

If the ketones are positive, immediate action is needed to prevent Diabetic ketoacidosis (DKA) from occurring. This may be the first sign that the pump or infusion set/site are no longer working. This is because there is no long acting insulin in your system. DKA is life threatening.

Check blood glucose and ketones after 1 hour to make sure the blood glucose and ketones are coming down.

Use caution when calculating "Insulin on Board" if correcting again within three hours and ketones are still present or have increased.

Version 3 / September 2014.

Developed by Paediatric Diabetes Team – Dunedin Public Hospital

Fig. 1 (continued)

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